DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 414, 415, 423, 424, and 425

[CMS–1734–P]

RIN 0938–AU10

Medicare Program; CY 2021 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; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

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 requirements; Medicaid Promoting Interoperability Program requirements for Eligible Professionals; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; Medicare enrollment of Opioid Treatment Programs; payment for office/outpatient evaluation and management services; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a prescription drug plan or an MA–PD plan and Medicare Diabetes Prevention Program (MDPP) expanded model Emergency Policy.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 5, 2020. (See the **SUPPLEMENTARY INFORMATION** section of this proposed rule for a list of provisions open for comment.)

ADDRESSES: In commenting, please refer to file code CMS–1734–P.

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–1734–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–1734–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR 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 specialty-specific impacts of PFS proposals.

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

Emily Yoder, (410) 786–1804, Donta Henson, (410) 786–1947, and Patrick Sartini, (410) 786–9252, for issues related to telehealth and other services involving communications technology.

Liane Grayson, (410) 786–6583, for issues related to care management services and remote physiologic monitoring services.

Emily Yoder, (410) 786–1804, Christiane LaBonte, (410) 786–7237, Ann Marshall, (410) 786–3059, and Patrick Sartini, (410) 786–9252, for issues related to payment for office/outpatient evaluation and management visits.

Christiane LaBonte, (410) 786–7237, for issues related to teaching physician services.

Roberta Epps, (410) 786–4503, and Regina Walker-Wren, (410) 786–9160, for issues related to supervision of diagnostic tests.

Ann Marshall, (410) 786–3059, for issues related to incident to pharmacist services.

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

Sarah Leipnik, (410) 786–3933, for issues related to medical record documentation.

Lindsey Baldwin, (410) 786–1694 and Terry Simananda, (410) 786–8144, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Laura Ashbaugh, (410) 786–1113, for issues related to Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions.

Joseph Schultz, (410) 786–2656, for issues related to opioid treatment program provider enrollment regulation updates for institutional claim submissions.

Lisa Parker, (410) 786–4949, for issues related to RHCs and FQHCs, primary care management services, and the FQHC market basket.

Rachel Katonak, (410) 786–8564, for issues related to comprehensive screenings for seniors: Section 2002 of the Substance Use-Disorder Prevention that Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).

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 performance standard and quality reporting requirements.

Janae James, (410) 786–0801, or Elizabeth November, (410) 786–4518, or *SharedSavingsProgram@cms.hhs.gov,* for issues related to Shared Savings Program beneficiary assignment and repayment mechanism requirements.

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

Heather Hostetler, (410) 786–4515, for issues related to removal of selected national coverage determinations.

Joella Roland, (410) 786–7638, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan.

Edmund Kasaitis, (410) 786–0477, for issues related to Part B drug payment and Food Drug & Cosmetic Act section 505(b)(2) drug products.

Elizabeth Holland, (410) 786–1309, for issues related to updates to certified electronic health record technology due to the 21st Century Cures Act.

Julia Venanzi, (410) 786–1471, for issues related to the Hospital Inpatient Quality Reporting (IQR) Program

Irina Akelaitis, (410) 786–4602, for issues related to HCPCS Level II codes.

Amanda Rhee, (410) 786–3888, for the Medicare Diabetes Prevention Program (MDPP) expanded model emergency policy.

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

Brittany LaCouture, (410) 786–0481, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that website to view public comments.

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 *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.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 2021 PFS proposed rule, refer to item CMS–1734–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 makes 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. In addition, this proposed rule includes provisions related to other payment policy changes that are addressed in section III. of 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 2021 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 provisions regarding several other Medicare Part B payment policies.

Specifically, this proposed rule addresses:

- Practice Expense RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Telehealth and Other Services Involving Communications Technology (section II.D.)
- Care Management Services and Remote Physiologic Monitoring Services (section II.E.)
- Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the COVID–19 Pandemic (section II.F.)
- Scopes of Practice and Related Issues (section II.G.)
- Valuation of Specific Codes (section II.H.)
- Modifications related to Medicare Coverage for Opioid Use Disorder (OUD) Services Furnished by Opioid Treatment Programs (OTPs) (section II.I.)
- Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions, and a Comment Solicitation on Payment for Specimen Collection for Covid-19 Tests (section III.A.)
- Opioid Treatment Program Provider Enrollment Regulation Updates for Institutional Claim Submissions (section III.B.)
- Payment for Primary Care Management Services in RHCs and FQHCs (section III.C.)
- Changes to the Federally Qualified Health Center Prospective Payment System (FQHC PPS) for CY 2021: Proposed Rebasing and Revising of the FQHC Market Basket (section III.D.)
- Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention that Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (section III.E.)
- Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services (section III.H.)
- Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020 (section III.I.)
- Proposal to Remove Selected National Coverage Determinations (section III.J.)
- Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a prescription drug plan or an MA–PD plan (section III.K.)
- Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act (section III.L.)
- Updates to Certified Electronic Health Record Technology due to the 21st Century Cures Act Final Rule (section III.M.)
- Proposal to Establish New Code Categories (section III.N.)
- Medicare Diabetes Prevention Program (MDPP) expanded model Emergency Policy (section III.O.)
- CY 2021 Updates to the Quality Payment Program (section IV.)
- Planned 30-day Delayed Effective Date for the Final Rule (section V.)
- Collection of Information Requirements (section VI.)
- Response to Comments (section VII.)
- Regulatory Impact Analysis (section VIII.)

2. Summary of Costs and Benefits

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

3. Waiver of the 60-Day Delayed Effective Date for the Final Rule

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named ''SARS CoV 2'' and the disease it causes has been named ''Coronavirus disease 2019'' (abbreviated ''COVID–19'').

Due to the significant devotion of resources to the COVID–19 response, as discussed in section V. of the preamble of this proposed rule, we are hereby waiving the 60-day delay in the effective date of the final rule, and replacing it with a 30-day delay in the effective date of the final 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 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 by 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 '97) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA '97 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 '97 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.

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 VII. 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 2020 PFS final rule for a discussion of the last GPCI update (84 FR 62615 through 62623).

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS' 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 PE 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 titled ''CY 2021 PFS Proposed Rule PE/HR'' on the CMS website under downloads for the CY 2021 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

As noted above, we have established PE/HR values for various specialties without SMS or PPIS survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. On this note, stakeholders have raised concerns regarding the appropriate specialty crosswalk used for home PT/INR monitoring services. These services are currently classified under the independent diagnostic testing facilities specialty for PE/HR purposes, due to a lack of survey data for these services, and stakeholders have suggested to CMS that this specialty does not reflect the indirect costs associated with furnishing these services. Stakeholders have raised concerns that the practice pattern of PT/INR monitoring services are markedly different from that of the dominant parent specialty as most of the services are furnished remotely and require long-term relationship with beneficiaries similar to chronic therapy. Stakeholders also stated that this is a unique request due to the lack of home PT/INR monitoring supplier involvement in the last PPIS, and that payments for these services are derived from previously used supplemental survey data from the Association for Quality Imaging (AQI), blended with supplementary survey data from the American College of Radiology (ACR)—neither of which reflect indirect cost inputs for home PT/INR monitoring.

Therefore, we are soliciting comment from the public regarding the most accurate specialty crosswalk to use for indirect PE when it comes to home PT/INR monitoring services. We are seeking information on any additional costs associated with these services that are not reflected in our currently assigned PE/HR for independent diagnostic testing facilities, as well as which specialties would best capture these costs through the use of a crosswalk.

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.
- Then, 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 titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2021 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.

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 titled ''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 1.

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TABLE 1: 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

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- 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 2 details the manner in which the modifiers are applied.

TABLE 2: 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.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

We note that stakeholders including the RUC, specialty societies, and other commenters suggested a useful life of less than 1 year for several of the new equipment items for CY 2021, and as low as three months in one case. We have rarely, if ever, received requests for equipment useful life of less than one year in duration and note that these very short useful life durations are significantly lower than anything in our current equipment database, and if finalized would represent major outliers when compared to the rest of the equipment. Table 3 details the distribution of useful life durations of the equipment currently in our database:

TABLE 3: Equipment Life Durations

Useful Life Duration	Number of Equipment Codes	Percentage of Total
15 years or greater	37	5%
10-14 years	159	20%
6-9 years	210	27%
5 years	313	40%
3-4 years	54	7%
1-2 years	4	1%

As Table 3 demonstrates, the vast majority of equipment items have a useful life duration of 5 to 10 years, and only 4 out of the 777 equipment codes have a useful life duration of less than 3 years. We also note that due to the formula used to calculate the equipment cost per minute, decreasing the useful life of any equipment item from 5 years to 3 months has the same effect as increasing the price of the equipment 20 times over. In other words, decreasing the useful life from 5 years to 0.25 years has the same multiplicative effect as increasing the price of the equipment from $5,000 to 100,000 due to the formula listed above. Since we currently do not have any equipment items in our database with a useful life of less than one year, we are proposing a clarification on how to address these cases.

We disagree that assigning a useful life at these very short durations would be typical for new equipment, especially in light of the data provided by the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' reference. The equipment life durations listed in Table 3 were finalized over the last 15 years through the use of this reference material. We have concerns that assigning very low useful life durations to equipment items would fail to maintain relativity with other equipment on the PFS, effectively assigning a much higher price than other equipment items with more typical useful life durations. We believe that equipment items with very low useful life durations represent outlier cases that are not handled appropriately by the current equipment methodology and which we seek to clarify through this rulemaking. We also note that the equipment cost per minute formula was designed under the assumption that each equipment item would remain in use for a period of several years and depreciate over that span of time. Our current equipment formula is not designed to address cases in which equipment is replaced multiple times per year, and we believe that applying a multi-year depreciation in these situations would not be reflective of market pricing. We do not believe that items which are replaced on a monthly basis can be accurately priced using a formula which assumes they will be in use for years at a time, and that the use of such a formula would distort relativity with the overwhelming majority of equipment items which are in use for 5–10 years.

Therefore, we proposing to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. We believe that this is the most accurate way to incorporate these short equipment life durations within the framework of our current methodology. In the rare cases where items are replaced every few months, we believe that it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For example, we are proposing to establish the EECP compression equipment package (SD341) and the EECP electrical equipment package (SD342) as disposable supplies instead of equipment items as described in the Valuation of Specific Codes (section II.H. of this proposed rule) portion of the preamble. We expect these situations to occur only rarely, and we will evaluate them on an individual case-by-case basis. Our criteria will be based on whether or not the item in question could be more accurately classified as a disposable supply while maintaining overall relativity within our PE methodology. We welcome additional comments from stakeholders regarding the subject of useful life durations for new equipment items with unique useful life durations as described above and any additional suggestions on alternative ways to incorporate these items into our methodology or potential wider changes to the equipment cost per minute formula more broadly.

- *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 are not proposing a variable maintenance factor for equipment cost per minute pricing as we do not believe that we have sufficient information at present. 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). The Interest rates are listed in Table 4.

TABLE 4: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We are not proposing any changes to the equipment interest rates for CY 2021.

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 final 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 through 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 post service 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'' and ''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 a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard 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 and 59464).

Following the publication of the CY 2020 PFS proposed rule, a commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of the applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed that it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect that these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. For additional details, we direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584).

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 2021, 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 2021 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 noted 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. Based on the recommendations from the workgroup, we proposed to establish 23 new scope equipment codes. For the eight new scope equipment items where we received submitted invoices for pricing, we proposed to replace the existing scopes with the new scope equipment at the same amount of equipment time. This scope replacement involved approximately 100 HCPCS codes in total and was detailed in a table published in the CY 2020 proposed rule (84 FR 40495 through 40498). We noted that we did not receive pricing information along with the workgroup recommendations for the other 15 new scope equipment items. Therefore, although we proposed to establish new equipment codes for these scopes, we did not propose to replace existing scope equipment with the new equipment items as we did for the other eight new scope equipment items for CY 2020.

Following the publication of the CY 2020 PFS proposed rule, commenters provided additional information regarding pricing for the new scope equipment and their associated HCPCS codes. Based on this information provided by the commenters, we finalized a price for eight additional new scope equipment items and finalized the replacement of the existing scopes with the new scope equipment at the same amount of equipment time for approximately two dozen additional HCPCS codes (84 FR 62593 through 62595). Table 5 lists the CY 2020 finalized price for the new scope equipment codes:

TABLE 5: New Scope Equipment Codes

CMS Code	Scope Equipment Description	Finalized Price
ES070	rigid scope, cystoscopy	
ES071	rigid scope, channeled, hysteroscopy	$6,795.00
ES072	rigid scope, otoscopy	$2,333.98
ES073	rigid scope, nasal/sinus endoscopy	$3,004.75
ES074	rigid scope, proctosigmoidoscopy	
ES075	rigid scope, laryngoscopy	$3,966.08
ES076	rigid scope, colposcopy	$14,500.00
ES077	non-channeled flexible digital scope, hysteroscopy	
ES078	non-channeled flexible digital scope, nasopharyngoscopy	$21,923.43
ES079	non-channeled flexible digital scope, bronchoscopy	
ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
ES081	channeled flexible digital scope, cystoscopy	
ES082	channeled flexible digital scope, hysteroscopy	
ES083	channeled flexible digital scope, bronchoscopy	
ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
ES089	multi-channeled flexible digital scope, ileoscopy	$34,585.35
ES090	multi-channeled flexible digital scope, pouchoscopy	$17,360.00
ES091	ultrasound digital scope, endoscopic ultrasound	$0.00
ES092	non-video flexible scope, laryngoscopy	$5,105.97

We noted that although we updated the scope equipment pricing for CY 2020 such that the ES087 and ES089 scopes shared the same price with the ES088 scope, and the ES090 scope shared the same price with the ES085 scope, we did not mean to suggest that these scopes that shared pricing were identical with one another. We assigned the same price to these scopes because they replaced the same current scope equipment codes, and because we did not have individual pricing information for them. We remain open to the submission of additional invoices to establish individual pricing for these scopes, and we continue to welcome more data to help identify pricing for the remaining seven scope equipment codes that still lack invoices.

(5) Scope Proposals for CY 2021

We did not receive further recommendations from the Scope Equipment Reorganization Workgroup organized by the RUC following the publication of the CY 2020 final rule. However, we did receive invoices associated with the pricing of the scope video system (monitor, processor, digital capture, cart, printer, LED light) (ES031) equipment item as part of the review of the Esophagogastroduodenoscopy (EGD) with Biopsy and the Colonoscopy code families. We previously finalized a price of $36,306 for the ES031 equipment based on the sum of 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, $1,750 for the cart, $1,915 for the LED light, and $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.) We received 37 invoices associated with the components of the ES031 scope video system, which averaged out to prices of $21,988.89 for the processor, $16,175.87 for the digital capture device, $6,987.56 for the monitor, $7,922.80 for the printer, $4,945.45 for the cart, and $12,652.82 for the LED light. Based on the sum of these component prices, we are proposing to update the price the ES031 scope video system equipment to $70,673.38. We are not proposing to include an additional $1,000 to cover the expense of miscellaneous small equipment as the products listed on the component invoices indicated that cost of cables were already included in this significantly higher equipment pricing. We are soliciting additional comments from stakeholders regarding the pricing of the full ES031 scope equipment system as well as its components.

As part of our market-based supply and equipment pricing transition, we finalized a policy in CY 2019 to phase in any updated pricing established during the 4-year transition period for very commonly used supplies and equipment that are included in 100 or more codes, even if invoices are provided as part of the formal review of a code family (83 FR 59473 through 59475). Because the ES031 scope equipment system is utilized by more than 250 HCPCS codes, we are proposing to transition this pricing increase over the remaining two years of the pricing update, such that the CY 2021 equipment price will be $53,489.69 before moving to its destination price of $70,673.38 in CY 2022. We note that this transition policy also applies to the price of the suction machine (Gomco) (EQ235) equipment, which, although it is not a scope, is utilized by approximately 360 HCPCS codes, and therefore, is another example of this pricing transition policy. We are proposing to transition the EQ235 pricing increase over the remaining 2 years of the pricing update, such that the CY 2021 equipment price will be $1,981.66 before moving to its destination price of $ $3,195.85 in CY 2022. As we stated previously, this

policy is intended to minimize any potential disruptive effects during the pricing transition period due to the high number of services that make use of these very common supply and equipment items included in 100 or more HCPCS codes.

We also received invoices for the colonoscopy videoscope (ES033) and gastroscopy videoscopy (ES034) as part of the review of the Esophagogastroduodenoscopy (EGD) with Biopsy and the Colonoscopy code families. We finalized the replacement of both of these scope equipment items in the CY 2020 final rule (84 FR 62588 through 62590), replacing the colonoscopy videoscope (ES033) with the multi-channeled flexible digital scope, colonoscopy (ES086) equipment item and the gastroscopy videoscopy (ES034) with the multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD) (ES087) equipment item. In both cases, the submitted invoices were nearly identical to the finalized prices for the ES086 ($38,058.81) and ES087 ($34,585.35) equipment. We believe that these invoices reinforce the prices finalized through rulemaking last year, and therefore, we are not proposing to further update the prices of these scopes.

We remain open to further comments regarding the pricing of the remaining seven scope equipment codes that still lack invoices, as well as additional data regarding the pricing of the scope equipment codes that currently share the same price.

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

For CY 2021, we are proposing to address the following inconsistencies:

- Following the publication of the CY 2020 PFS final rule, stakeholders contacted CMS and clarified that CPT code 0466T (Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator) is always performed on an add-on basis and would never be used as a standalone code. Therefore, we are proposing to update the global period for CPT code 0466T to add-on status (ZZZ) to more accurately reflect the way in which this service is performed.

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 2021, we are proposing to update the price of one supply and four equipment items 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 2021 for these items instead of being phased in over 4 years. These supply and equipment items with updated prices associated with the formal review of a code family are listed in the valuation of specific codes section of the preamble under Table 27: CY 2021 Invoices Received for Existing Direct PE Inputs.

(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, enacted April 1, 2014) 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).
- The **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 we 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 6.

TABLE 6: Example of Direct PE Pricing Transition

Current Price	$100	
Final Price	$200	
Year 1 (CY 2019) Price	$125	1/4 difference between $100 and $200
Year 2 (CY 2020) Price	$150	1/3 difference between $125 and $200
Year 3 (CY 2021) Price	$175	1/2 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 timeframe 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 through 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 through 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 2021, we received invoice submissions for approximately a dozen supply and equipment codes from stakeholders as part of the third year of the market-based supply and equipment pricing update. The submitted invoices were used in many cases to supplement the pricing originally proposed for the CY 2019 PFS rule cycle. We 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 supply and equipment items listed in Table 7 of the CY 2021 PFS proposed rule.

We finalized a policy in CY 2019 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 6. For CY 2021, one half of the difference between the CY 2020 price and the final price will be implemented as per the previously finalized policy. Table 7 contains the list of proposed CY 2021 market-based supply and equipment pricing updates:

TABLE 7: Proposed CY 2021 Market-Based Supply and Equipment Pricing Updates

CMS CODE	Description	CMS 2020 Price	Prior CMS 2022 Price	Prior CMS 2021 Price	Updated CMS 2022 Price	Updated CMS 2021 Price
SA105	UroVysion test kit	$153.040	$129.280	$141.160	$187.490	$170.265
SD089	guidewire, hydrophilic	$39.435	$43.370	$41.403	$13.350	$26.393
SD136	vascular sheath	$36.650	$52.800	$44.725	$24.444	$30.547
SD155	catheter, RF endovenous occlusion	$637.500	$550.000	$593.750	$382.500	$510.000
EQ041	Vmax 22d and 62j (PFT equip, autobox, computer system)	$47,930.000	$47,930.000	$47,930.000	$47,406.540	$47,668.270
ER044	nuclide rod source set	$1,783.167	$2,171.333	$1,977.250	$2,081.167	$1,932.167

The proposed prices for the supply and equipment items listed in Table 7 were calculated based on averaging together the prices on the submitted invoices. In the case of the vascular sheath (SD136) and RF endovenous occlusion catheter (SD155) supplies, the proposed price was determined by removing the sheath or catheter from the eight submitted kit invoices and then averaging the resulting price together with the single standalone sheath/catheter invoice.

In addition to submitting invoices with information updating the price of

the ''Vmax 22d and 62j (PFT equip, autobox, computer system)'' (EQ041) equipment, stakeholders also clarified that the ''Vmax 229 (spirometry testing equip, computer system)'' (EQ040) and ''Vmax 29s (spirometry testing equip, computer system)'' (EQ043) equipment items have become obsolete and are no longer typically used in any HCPCS codes. Based on the information supplied by the stakeholders, we are proposing to remove the EQ040 and EQ043 equipment items, replacing them with the EQ041 equipment at the same number of minutes in the six HCPCS codes where they are utilized.

We are not proposing to update the price of additional supply and equipment items for which invoices were submitted following the publication of the CY 2020 PFS final rule. We are not proposing to update the price for the ''pipette, transfer 23ml'' (SL109), ''slide specimen mailer (1–5 microscope slides)'' (SL121), ''stain, hematoxylin'' (SL135), ''stain, eosin'' (SL201), and ''stain, PAP OG–6'' (SL491) supplies. In each case we received a single invoice for these five supplies detailing price increases ranging from 82 percent to 160 percent above the current pricing. These supplies are commonly used in cytopathology procedures and we disagree that the typical price for these supplies has more than doubled since being reviewed by the StrategyGen contractor two years ago for CY 2019.

We are also not proposing to update the price for the ''embedding mold'' (SL060) supply or the ''microscope, compound'' (EP060) equipment based on the same rationale. The submitted invoices represent pricing increases of 339 percent for the compound microscope and 7800 percent for the embedding mold and, based on the recent review of the pricing of these items by our contractor, we do not believe that the submitted invoices reflect typical market-based pricing. The same stakeholder also submitted an invoice to update the price of the surgical mask (SB033) supply by 617 percent over the current price. However, the invoice in question contains the price for a surgical mask with face shield, which is described by the SB034 supply code, not the SB033 supply code. Therefore, we are not proposing to update the price of the surgical mask (SB033) supply based on this invoice. Finally, we received an invoice for a ClosureFast Procedure Pack (CFP) but it was unclear what supply or equipment item this invoice was intended to update. As a result, we were unable to use this invoice to make a pricing proposal.

(2) Invoice Submission

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 2021 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

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. 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 will 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. Stakeholders are encouraged to submit invoices as part of their public comments or, if outside the public comment process, via email at *PE_Price_Input_Update@cms.hhs.gov.*

(3) Updated Supply Pricing for Venous and Arterial Stenting Services

Following the publication of the CY 2020 PFS final rule, stakeholders contacted CMS and presented additional information regarding supply pricing for certain venous and arterial stenting services. These stakeholders stated that the use of the ''stent, vascular, deployment system, Cordis SMART'' (SA103) supply was no longer typical in CPT codes 37238 (Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein) and 37239 (Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein). The stakeholders stated that a new venous stent system had become the typical standard of care for these services, and they supplied ten invoices for use in pricing this supply.

The stakeholders also requested additional information regarding the nature of the ''stent, balloon, implantable'' (SD299) supply included in CPT codes 37236 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery) and 37237 (Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery). The stakeholders specifically were unclear what the implantable stent balloon represented and sought guidance on whether pricing involved a stent, a balloon, or a combination of both.

In response to the additional information provided by the stakeholders, we are proposing to remove the SA103 supply item from CPT codes 37238 and 37239. We are proposing to replace it with a newly created ''venous stent system'' (SD340) supply at the same supply quantity. We are proposing a price of $1,750.00 for the venous stent system based on the median price of the ten invoices supplied by the stakeholders. We are proposing the use of the median price due to the presence of several invoices that appear to be outliers which are not reflective of market pricing for the venous stent system. With regards to the request for additional information regarding the nature of the ''stent, balloon, implantable'' (SD299) supply, the original invoice used to price this supply during the CY 2015 rule cycle listed an item named ''Renal and Biliary Stent System 7.0 mm x 15 mm x 135 cm''. We welcome additional information from stakeholders regarding the nature and pricing of this supply item.

(4) Myocardial PET Equipment Inputs

Following the publication of the CY 2020 PFS final rule, stakeholders contacted CMS and presented additional information regarding the direct PE inputs for several codes associated with Myocardial PET services. The stakeholders stated that the nuclide rod source set (ER044) equipment was inadvertently excluded

from the direct PE recommendations for CPT codes 78432 (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 (*e.g.,* myocardial viability);), 78459 (Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study;), 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)), and 78492 (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)), and requested that CMS add this equipment to the direct inputs for this group of CPT codes. The stakeholders also stated that the current useful life of 5 years for the ER044 equipment was incorrect as these sources are replaced every 9 months to 1 year. The stakeholders requested that CMS update the useful life of ER044 to 0.75 years. Finally, the stakeholders stated that the costs for the purchase of the Rubidium PET Generator (ER114) equipment are captured elsewhere through the billing of HCPCS supply code A9555, and the stakeholders recommended that we remove equipment item ER114 to avoid incorrect billing duplication.

We appreciate the additional information submitted by the stakeholders regarding the direct PE inputs for these Myocardial PET services. In response to this new information, we are proposing to update the price for the nuclide rod source set (ER044) equipment to $2,081.17 based on averaging together the price of the three submitted invoices after removing the shipping and delivery costs according to our standard pricing methodology. We are also proposing to add the ER044 equipment to CPT codes 78432, 78459, 78491, and 78492 as requested, assigning the same equipment time utilized by the ''PET Refurbished Imaging Cardiac Configuration'' (ER110) equipment in each service. We are proposing to update the useful life of the ER044 equipment to one year in accordance with our proposed policy to treat equipment useful life durations of less than 1 year as having a duration of one year. As we stated previously in section II.B we have concerns that assigning very low useful life durations of less than 1 year would fail to maintain relativity with other equipment on the PFS, and the equipment cost per minute formula was designed under the assumption that each equipment item would remain in use for a period of several years and depreciate over that span of time. We direct readers to the previous discussion regarding equipment cost per minute methodology earlier in section II.B. of this proposed rule. Finally, we are removing the ''PET Generator (Rubidium)'' (ER114) equipment from our database as requested by the stakeholders. We note that since the technical components for CPT codes 78432, 78459, 78491, and 78492 are all contractor-priced, there will be no change to the national pricing of these codes.

(5) 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 2021, we are proposing to continue with the fourth and final year of the transition of this adjustment to the standard process for allocating indirect PE.

e. Update on Technical Expert Panel Related to Practice Expense

The RAND Corporation is currently studying potential improvements to CMS' PE allocation methodology and the data that underlie it. As we noted earlier in this section, our current system for setting PE RVUs relies in part on data collected in the Physician Practice Information Survey (PPIS), which was administered by the AMA in CY 2007 and 2008.

RAND, in its first phase of research, available at *https://www.rand.org/pubs/research_reports/RR2166.html,* found that the PPIS data are outdated and may no longer reflect the resource allocation, staffing arrangements, and cost structures that describe practitioners' resource requirements in furnishing services to Medicare beneficiaries, and consequently may not accurately capture the indirect PE resources required to furnish services to Medicare FFS beneficiaries. For example, the PPIS preceded the widespread adoption of electronic health records, quality reporting programs, billing codes that promote team-based care, and hospital acquisition of physician practices. Notably, RAND found that practice ownership was strongly associated with indirect PE, with physician-owned practices requiring 190% higher indirect PE compared to facility-owned practices, suggesting a need to potentially update demographic information. Additionally, RAND found that aggregating Medicare provider specialties into broader categories resulted in small specialty-level impacts relative to the current system, suggesting that specialty-specific inputs may not be required to accurately reflect resource costs.

To follow up on these and other issues raised in the first phase of RAND's research, in the CY 2020 PFS, we announced that RAND was convening a technical expert panel (TEP) to obtain input from stakeholders including physicians, practice and health system managers, health care accountants, and health policy experts. The TEP occurred on January 10, 2020 and its report is available at *https://www.rand.org/pubs/working_papers/WR1334.html.* Topics discussed included identifying issues with the current system; changes in medicine that have affected PE; how PE inputs could be updated, including through a potential new survey instrument; how best to aggregate PE categories if there were to be new survey instrument; ways to maximize response rates in a potential new survey; and using existing data to inform PFS PE rates. In addition, RAND has issued the results of its subsequent phase of research, available at *www.rand.org/t/RR3248.* This report is also available as a public use file displayed on the CMS website under downloads for the CY 2021 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

Based on the results of the TEP and RAND's other ongoing research, we are interested in potentially refining the PE methodology and updating the data used to make payments under the PFS. We believe that potential refinements could improve payment accuracy and strengthen Medicare. Our goals are to balance obtaining the data as soon as practicable and in a way that would allow stakeholders and CMS to collectively examine many of the issues the TEP and RAND's research identified. We are thinking through several questions, including how to best incorporate market-based information, which could be similar to the market research that we recently conducted to update supply and equipment pricing used to determine direct PE inputs under the PFS payment methodology. For example, stakeholders have expressed an interest in updating the clinical labor data that we use for direct PE inputs based on current salaries and compensation for the health care workforce. We are soliciting comment regarding how we might update the clinical labor data. Historically, we have used data from the Bureau of Labor Statistics and are seeking comment to determine if this is the best data source or if there is an alternative. We are also interested in hosting a Town Hall meeting at a date to be determined to provide an open forum for discussion with stakeholders on our ongoing research to potentially update the PE methodology and the underlying inputs. Finally, we welcome feedback from all interested parties regarding RAND's report and we are not making any proposals based on this report at this time. Stakeholders are encouraged to submit feedback as part of their public comments or, if outside the public comment process, via email at *PE_Price_Input_Update@cms.hhs.gov.*

C. 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.H. of this proposed rule, Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association Resource-Based Relative Value Scale (RVS) Update Committee (RUC), Medicare Payment Advisory Commission (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 costs decline. 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 costs 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'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, 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 over 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 as 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). We have continued each year to consider and finalize a list of potentially misvalued codes that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2021 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 submissions nominating codes for review under the potentially misvalued code initiative, and several requests for review of practice expense related inputs prior to our February 10, 2020 deadline. We refer readers to section II.B. of this proposed rule, Determination of Practice Expense RVUs, for further discussion on the PE-related submissions. Our summary of the submissions reviewed under the potentially misvalued code initiative is discussed below.

We received multiple submissions requesting that CMS consider CPT code 22867 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level*) for nomination as potentially misvalued. In their request, the submitters suggested that the physician work assigned to this code significantly undervalues the procedure relative to the value of CPT code 63047 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar*). The submitters stated that the work performed during the surgical steps to perform a laminectomy for both procedures is generally similar except for the additional intensity and complexity involved in CPT code 22867 to implant the interspinous stabilization device. The submitters also requested that the malpractice RVUs assigned to this code be increased to better align with similar spine procedures, in terms of specialty level and service level risk factors, in addition to the intensity and complexity of the procedure. After considering the information provided by the submitter, which suggests that the current valuation for the service may not reflect the level of intensity inherent in furnishing the service relative to other similar services with inputs that exceed those for the nominated service we are proposing to nominate CPT code 22867 as potentially misvalued and welcome public comment on this code.

D. Telehealth and Other Services Involving Communications Technology

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

As discussed in this proposed 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.

a. Adding Services to the Medicare Telehealth Services List

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 Medicare telehealth services list 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 Medicare telehealth services list 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 Medicare telehealth services list. 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 Medicare telehealth services list. 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 Medicare telehealth services list, including the additions described later in this section, is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

For CY 2021, requests to add services to the Medicare telehealth services list must have been submitted and received by February 10, 2020. Each request to add a service to the Medicare telehealth services list 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 Medicare telehealth services list, 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 Medicare telehealth services list, including where to mail these requests, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

b. Requests To Add Services to the Medicare Telehealth Services List for CY 2021

Under our current policy, we add services to the Medicare telehealth services list on a Category 1 basis when we determine that they are similar to services on the existing Medicare telehealth services 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 Medicare telehealth services list that resemble those services already on the Medicare telehealth services list. We received several requests to add various services as Medicare telehealth services effective for CY 2021. We also conducted an internal review of potential services to add to the Medicare telehealth services list.

In response to the PHE for the COVID–19 pandemic, CMS undertook emergency rulemaking to add a number of services to the Medicare telehealth services list on an interim final basis. In the ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment period (IFC), (85 FR 19230, 19234 through 19241, March 31, 2020) (hereinafter referred to as the ''March 31st COVID–19 IFC''), on an interim final basis for the duration of the PHE for the COVID–19 pandemic, we also finalized the addition of a number of services to the Medicare telehealth services list on a Category 2 basis. The following is a list of those services:

- Emergency Department (ED) Visits, Levels 1–5 (CPT codes 99281–99285).
- Initial and Subsequent Observation and Observation Discharge Day Management (CPT codes 99217–99220; CPT codes 99224–99226; CPT codes 99234–99236).
- Initial hospital care and hospital discharge day management (CPT codes 99221–99223; CPT codes 99238–99239).
- Initial nursing facility visits, All levels (Low, Moderate, and High Complexity) and nursing facility discharge day management (CPT codes 99304–99306; CPT codes 99315–99316).
- Critical Care Services (CPT codes 99291–99292).
- Domiciliary, Rest Home, or Custodial Care services, New and Established patients (CPT codes 99327–99328; CPT codes 99334–99337).
- Home Visits, New and Established Patient, All levels (CPT codes 99341–99345; CPT codes 99347–99350).
- Inpatient Neonatal and Pediatric Critical Care, Initial and Subsequent (CPT codes 99468–99473; CPT codes 99475–99476).
- Initial and Continuing Intensive Care Services (CPT code 99477–994780).
- Assessment and Care Planning for Patients with Cognitive Impairment (CPT code 99483).
- Group Psychotherapy (CPT code 90853).
- End-Stage Renal Disease (ESRD) Services (CPT codes 90952, 90953, 90959, and 90962).
- Psychological and Neuropsychological Testing (CPT codes 96130–96133; CPT codes 96136–96139).
- Therapy Services, Physical and Occupational Therapy, All levels (CPT codes 97161–97168; CPT codes 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521–92524, 92507).
- Radiation Treatment Management Services (CPT codes 77427).

When we previously considered adding these services to the Medicare telehealth services list, either through a public request or through our own internal review, we considered whether these services met the Category 1 or Category 2 criteria. In many cases, we reviewed requests to add these services on a Category 1 basis, but did not receive or identify information that allowed us to review the services on a Category 2 basis. While we stated in the March 31st COVID–19 IFC that we did not believe the context of the PHE for the COVID–19 pandemic changes the assessment of these services as Category 1, we did reassess all of these services on a Category 2 basis in the context of the widespread presence of COVID–19 in the community. Given the exposure risks for beneficiaries, the health care work force, and the community at large, we stated that in-person interaction between professionals and patients poses an immediate potential risk that would not have been present when we previously reviewed these services. We were concerned that this new risk created a unique circumstance where health care professionals might have to choose between the best means to mitigate exposure risk for themselves and for their patients or seeking Medicare payment for the service. For example, certain persons, especially older adults who are particularly vulnerable to complications from this specific viral infection; those considered at risk because of underlying health conditions; and those known to be recently exposed or diagnosed, and therefore, likely to spread the virus to others, were often being directed by local public health officials to self-isolate as much as possible. At the same time, we noted that the risk to medical professionals treating patients is high and we considered it likely that medical professionals would try to treat patients as effectively as possible without exposing themselves or their patients unnecessarily. We explained that, in some cases, the use of telecommunication technology could mitigate the exposure risk; and in such cases, there is a clear clinical benefit of using such technology in furnishing the service. In other words, patients who should not be seen by a professional in-person due to the exposure risk were highly likely to be without access to clinically appropriate treatment or diagnostic options unless they have access to services furnished through interactive communication technology. Therefore, in the context of the PHE for the COVID–19 pandemic, we believed that all of the services we added met the Category 2 criteria to be added to the Medicare telehealth services list on the basis that there was a patient population that would otherwise not have access to clinically appropriate treatment. We noted that, as with other services on the Medicare telehealth services list, it may not be clinically appropriate or possible to use telecommunications technology to furnish these particular services to every person or in every circumstance. However, in the context of the PHE for the COVID–19 pandemic with specific regard to the exposure risks noted above, we recognized the clinical benefit of access to medically reasonable and necessary services furnished using telecommunications technology as opposed to the potential lack of access that could occur to mitigate the risk of disease exposure.

In addition to considering public requests and services identified through internal review for additions to the Medicare telehealth services list, we have also considered which of the services added to the Medicare

telehealth services list on an interim basis should remain on the Medicare telehealth services list permanently or on an interim basis after the end of the PHE. The following presents a discussion of these services and related proposals.

After reviewing the requests we received, the services we identified, and the services we added to the Medicare telehealth services list on an interim basis for the duration of the PHE, we identified the services we have listed in Table 8 as being sufficiently similar to services currently on the Medicare telehealth services list to be added on a Category 1 basis. Therefore, we are proposing to add the services in Table 8 to the Medicare telehealth services list on a Category 1 basis for CY 2021.

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TABLE 8: CY 2021 Proposed Additions to the Medicare Telehealth Services List on a Category 1 Basis

HCPCS Code	Long Descriptor
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 an evaluation and management visit)
90853	Group psychotherapy (other than of a multiple-family group)
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)
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)
99483	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (eg, basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for staging of dementia (eg, functional assessment staging test [FAST], clinical dementia rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (eg, home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (eg, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.
99334	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; 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. Typically, 15 minutes are spent with the patient and/or family or caregiver.
99335	Domiciliary or rest 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 with the patient and/or family or caregiver.
99347	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; 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. Typically, 15 minutes are spent face-to-face with the patient and/or family.
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.

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We believe the services described by the HCPCS codes in Table 8 are similar to services currently on the Medicare telehealth services list. The add-on codes to the office/outpatient E/M services are, by definition, part of the office/outpatient E/M services since they cannot be billed with any other codes. The Assessment of and Care Planning for Patients with Cognitive Impairment was defined as a service meant to be billed in specific clinical scenarios in lieu of a level 5 office/outpatient E/M visit. As such, these services fall within the Category 1 criteria because they are similar to the office visits that are already on the Medicare telehealth services list. As it describes group therapy, CPT code 90853 is similar to the other group therapy services currently on the Medicare telehealth services list.

While the patient's home cannot serve as an originating site (where the patient is located) for purposes of most Medicare telehealth services, the SUPPORT for Patients and Communities Act amended section 1834(m)(4)(C) of the Act and added a new paragraph at section 1834(m)(7) of the Act to remove geographic limitations and authorize the patient's home to serve as a telehealth originating site for purposes of treatment of a substance use disorder or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a substance use disorder diagnosis. These domiciliary/home visits contain the same elements and similar descriptors to the office/outpatient E/M visits, and therefore, we believe there is sufficient justification to add them to the Medicare telehealth services list on a Category 1 basis. Additionally, we believe that, due to the vulnerability of this particular patient population, who are receiving treatment for a diagnosed substance use disorder or co-occurring mental health disorder, we should maximize the availability of telehealth services for the treatment of substance use disorders and co-occurring mental health disorders. We note that, because the home is not generally a permissible telehealth originating site, these services could be billed when furnished as telehealth services only for treatment of a substance use disorder or co-occurring mental health disorder.

Finally, we received a request to add CPT code 96121 (*Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment,* [*e.g.,* acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)) on the basis that this is an add-on code to CPT code 96116 (*Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment,* [*e.g.,* acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour) which is currently on the Medicare telehealth services list. In the past we have added services to the Medicare telehealth services list that are add-on codes that describe a continuation or additional elements of services currently on the Medicare telehealth services list since the services would only be considered telehealth services when billed as an add-on to codes already on the Medicare telehealth services list (82 FR 53008). Therefore, we are proposing to add CPT code 96121 to the Medicare telehealth services list.

We also received a request to add services to the Medicare telehealth services list that do not meet our criteria for addition to the Medicare telehealth services list, as explained below. We are not proposing to add the services listed in Table 9 to the Medicare telehealth services list.

TABLE 9: Services Requested for Addition to the Medicare Telehealth Services List Not Proposed for Addition

Service Type	HCPCS	Long Descriptor
Medical Genetics	96040	Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family
	S0265	Genetic counseling, under physician supervision, each 15 minutes

We received a request to add Medical Genetics services to the Medicare telehealth services list. We note that CPT code 96040 is considered bundled into office/outpatient E/M visits, which are already on the Medicare telehealth services list. Therefore, we do not believe it is necessary to add CPT code 96040. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73096 through 73097), physicians and nonphysician practitioners who may independently bill Medicare for their services and who are counseling individuals would generally report office or other outpatient evaluation and management (E/M) CPT codes for office visits that involve significant counseling, including genetic counseling, and these office visit CPT codes are already on the Medicare telehealth services list. CPT code 96040 would only be reported by genetic counselors for genetic counseling services. Genetic counselors are not among the practitioners who can bill Medicare directly for their professional services, and they are also not practitioners who can furnish telehealth services as specified in section 1834(m)(4)(E) of the Act. As such, we do not believe that it would be necessary or appropriate to add CPT code 96040 to the Medicare telehealth services list.

HCPCS code S0265 is a Medication, Supplies, and Services code; and there is no separate payment under the PFS for this category of codes. Therefore, we are not proposing to add this service to the Medicare telehealth services list.

c. Proposed Temporary Addition of a Category 3 Basis for Adding to or Deleting Services From the Medicare Telehealth Services List

Recently enacted legislation to address the COVID–19 pandemic provided the Secretary with new authorities under section 1135(b)(8) of the Act, as added by section 102 of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116–123, March 6, 2020) and subsequently amended by section 6010 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020) and section 3703 of the

Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020)), to waive or modify Medicare telehealth payment requirements during the PHE for the COVID–19 pandemic. Due to the circumstances of the COVID–19 pandemic, particularly the need to maintain physical distance to avoid exposure to the virus, we anticipate that health care practitioners are developing new approaches to providing care using various forms of technology when they are not physically present with the patient. We have established several flexibilities to accommodate these changes in the delivery of care. Through waiver authority under section 1135(b)(8) of the Act, in response to the PHE for the COVID–19 pandemic, we have removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as the restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE for the COVID–19 pandemic. We also used waiver authority to allow certain telehealth services to be furnished via audio-only communication technology. In the March 31st COVID–19 IFC, we added to the Medicare telehealth services list on an interim basis the services identified at the beginning of this section. Through the May 1st COVID–19 IFC, on an interim basis, we removed the requirement that we undertake rulemaking to add or delete services on the Medicare telehealth services list so that we could consider the addition of services on a subregulatory basis as they were recommended by the public or identified internally. On a subregulatory basis, we simultaneously added several more additional services to the Medicare telehealth services list when we issued the May 1st COVID–19 IFC. At the conclusion of the PHE, these waivers and interim policies will expire, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act, and we will return to the policies established through the regular notice and comment rulemaking process, including the previously established Medicare telehealth services list. We believe that the experiences of clinicians who are furnishing telehealth services during the PHE will be useful to inform decisions about which of the services we added temporarily to the Medicare telehealth services list might be appropriate to add on a permanent basis. However, we also recognize that the annual PFS rulemaking schedule may not align perfectly with the expiration of the PHE, and that the clinicians providing services via telehealth during the PHE may not have the opportunity to conduct the kinds of review or develop the kind of evidence we usually consider when adding services to the Medicare telehealth services list on a permanent basis. In the event that the PHE ends prior to the end of calendar year 2021, stakeholders might not have the opportunity to use our current consideration process for telehealth services to request permanent additions to the Medicare telehealth services list prior to those services being removed from the Medicare telehealth services list. This is especially true for those services that might need to be considered on a Category 2 basis, which involves providing supporting documentation to illustrate the clinical benefit of such services. Recognizing the extent to which practice patterns are shifting as a result of the PHE from a model of care based on in-person services to one that relies on a combination of in-person services and virtual care, we believe that it would be disruptive to both clinical practice and beneficiary access to abruptly eliminate Medicare payment for these services when furnished via telehealth as soon as the PHE ends without first providing an opportunity to use information developed during the PHE to support requests for permanent changes to the Medicare telehealth services list.

As previously noted, in response to the PHE for the COVID–19 pandemic, we have added a broad range of services to the Medicare telehealth services list. Before eliminating the full range of these services from the Medicare telehealth services list and potentially jeopardizing beneficiary access to those services that have been clinically beneficial, based primarily on the timing of annual rulemaking, we believe it would be prudent to collect information from the public regarding which, where and how various telehealth services have been in use in various communities during the COVID–19 response. Feedback from patients and clinicians is essential to help CMS understand how the use of telehealth services may have contributed positively to, or negatively affected, the quality of care provided to beneficiaries during the PHE for the COVID–19 pandemic so that we can understand which services should be retained on the Medicare telehealth services list until we can give them full consideration under our established rulemaking process.

Therefore, we are proposing to create a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis. This new category would describe services that would be included on the Medicare telehealth services list on a temporary basis. We would include in this category the services that were added during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence available to consider the services as permanent additions under Category 1 or Category 2 criteria. Recognizing that the services we would add on a temporary basis under Category 3 would ultimately need to meet the criteria under categories 1 or 2 in order to be permanently added to the Medicare telehealth services list, and the potential for evidence development that could continue through the Category 3 temporary addition period, we considered each of the services we added on an interim final basis during the PHE. In developing the proposal to add specific services on a Category 3 basis, we conducted a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth outside the circumstances of the PHE and that we anticipate would be able to demonstrate that clinical benefit in such a way as to meet our Category 2 criteria in full. Any service added under the proposed Category 3 would remain on the Medicare telehealth services list through the calendar year in which the PHE ends. When assessing whether there was a potential likelihood of clinical benefit for a service such that it should be added to the Medicare telehealth services list on a Category 3 basis, we considered the following factors:

- Whether, outside of the circumstances of the PHE, there are increased concerns for patient safety if the service is furnished as a telehealth service.
- Whether, outside of the circumstances of the PHE, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.
- Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology.

We recognize that the circumstances of the PHE have provided clinicians with the opportunity to use telecommunications technology in health care delivery in a scope and manner far surpassing the telehealth services described under section 1834(m) of the Act, particularly as a

result of the removal of geographic and site of service restrictions, and the addition of many services to the Medicare telehealth services list. When adding services to the Medicare telehealth services list on an interim basis during the PHE, we reassessed services on a Category 2 basis in the context of the widespread presence of COVID–19 in the community. We recognized that healthcare access issues could arise due to the immediate potential exposure risks to patients and healthcare workers, and that the use of telecommunication technology could mitigate risk and facilitate clinically appropriate treatment. In the context of the PHE for the COVID–19 pandemic, we found that the added services met the Category 2 criteria on the basis that there is a patient population that would otherwise not have access to clinically appropriate care (85 FR 19234). While the interim addition of a broad swath of services to the Medicare telehealth services list is responsive to critical needs during the COVID–19 PHE, the impact of adding these services to the Medicare telehealth services list on a permanent basis is currently unknown. Specifically, although it is possible to assess the uptake among health care practitioners of the added telehealth services, the extent to which service delivery via telehealth demonstrates clinical benefit outside the conditions of the PHE is not known at this time. Adding services to the Medicare telehealth services list on a Category 3 basis will give the public the opportunity to gather data and generate requests to add certain services to the Medicare telehealth services list permanently, which would be adjudicated on a Category 1 or Category 2 basis during future PFS annual rulemaking, while maintaining access to telehealth services with potential likelihood of clinical benefit. We are also proposing that the Category 3 criteria and basis for considering additions to the Medicare telehealth services list would be temporary, to expire at the end of the calendar year in which the PHE expires.

We have identified a number of services that we believe, based on our clinical assessment, fit the Category 3 criteria enumerated above in that we did not identify significant concerns over patient safety, quality of care, or the ability of clinicians to provide all elements of the service remotely if these services were to remain on the Medicare telehealth services list for an additional period beyond the PHE. Therefore we are proposing to continue including these services on the Medicare telehealth services list through the calendar year in which the PHE ends. These services are listed in Table 10. We invite public comment on the services we identified for temporary addition to the Medicare telehealth services list through the Category 3 criteria—including whether some should not be considered as Category 3 temporary additions to the Medicare telehealth services list, or whether services currently not proposed as Category 3 additions to the Medicare telehealth services list should be considered as such. While our clinical assessment indicated that the services in Table 10 demonstrate potential likelihood of clinical benefit when furnished as telehealth services and, as such, the potential to meet the Category 1 or Category 2 criteria for permanent addition to the Medicare telehealth services list with the development of additional evidence, we are seeking information from the public that would supplement our clinical assessment and assist us in consideration of our proposals regarding the Category 3 addition of services, even though we recognize that formal analyses may not yet be available. The following are examples of the kinds of information we are seeking from the public to help inform our decisions about proposed additions under Category 3:

- By whom and for whom are the services being delivered via telehealth during the PHE;
- What practical safeguards are being employed to maintain safety and clinical effectiveness of services delivered via telehealth; and how are practices quickly and efficiently transitioning patients from telehealth to in-person care as needed;
- What specific health outcomes data are being or are capable of being gathered to demonstrate clinical benefit;
- How is technology being used to facilitate the acquisition of clinical information that would otherwise be obtained by a hands-on physical examination if the service was furnished in person. Certain services on the Medicare telehealth services list prior to the PHE, specifically the office/outpatient E/M code set, involve a physical exam. With the telehealth expansions during the PHE, clinicians may have had valuable experience providing other telehealth services to patients in higher acuity settings of care, such as an emergency department, that involve a hands-on physical examination when furnished in person.
- Whether patient outcomes are improved by the addition of one or more services to the Medicare telehealth services list, including whether inclusion on the Medicare telehealth services list increases access, safety, patient satisfaction, and overall quality of care;
- Whether furnishing this service or services via telecommunication technology promotes prudent use of resources;
- Whether the permanent addition of specific, individual services or categories of services to the Medicare telehealth services list supports quick responses to the spread of infectious disease or other emergent circumstances that may require widespread use of telehealth; and
- What is the impact on the health care workforce of the inclusion of one or more services or categories of services on the Medicare telehealth services list (for example, whether the health care workforce and its capabilities to provide care are expanded).

In addition, we note that CMS is committed to the following broad goals, and these weigh heavily in our decision-making around the addition, whether temporary or permanent, of a service or services to the Medicare telehealth services list. We request that commenters consider these goals in conjunction with their comments on our proposals for the treatment of the telehealth services we added on an interim basis during the PHE for the COVID–19 pandemic:

- Maintaining the capacity to enable rapid assessment of patterns of care, safety, and outcomes in the Medicare, Medicaid, CHIP and Marketplace populations;
- Establishing system safeguards to detect and avert unintended patient harms that result from policy adjustments;
- Ensuring high quality care is maintained;
- Demonstrating ongoing quality improvement efforts by Medicare participating providers, while maintaining access to necessary care;
- Establishing protections for vulnerable beneficiary populations (those with multiple chronic conditions, functional limitations, heart failure, COPD, diabetes, dementia), and sites of heightened vulnerability (such as nursing homes, rural communities) with high risk of adverse outcomes;
- Ensuring appropriate resource utilization and supporting cost efficiency;
- Supporting emergency preparedness and maintaining capacity to surge for potential coronavirus resurgence or other healthcare issues; and
- Considering timing and pace of policy corrections in light of local and

regional variations in systems of care and the impact of the COVID–19 pandemic.

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TABLE 10: Services Proposed for Temporary Addition to the Medicare Telehealth Services List

Service Type	HCPCS	Long Descriptor
Domiciliary, Rest Home, or Custodial Care services, Established patients	99336	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; 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 to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.
	99337	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to 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 moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.
Home Visits, Established Patient	99349	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; 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 moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.
	99350	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to 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 moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family.
Emergency Department Visits	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.
	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.
	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

Service Type	HCPCS	Long Descriptor
		severity.
Nursing facilities discharge day management	99315	Nursing facility discharge day management; 30 minutes or less
	99316	Nursing facility discharge day management; more than 30 minutes
Psychological and Neuropsychological Testing	96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
	96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)

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d. Comment Solicitation on Medicare Telehealth Services Added on an Interim Basis During the PHE for the COVID–19 Pandemic That CMS Is Not Proposing To Retain After the PHE Ends

In the March 31st COVID–19 IFC and the May 1st COVID–19 IFC, we finalized on an interim basis during the PHE for the COVID–19 pandemic the addition of a number of services to the Medicare telehealth services list. While a number of these services were previously requested and reviewed for addition by external stakeholders as part of our standard process for updating the Medicare telehealth services list, a few were identified through internal review. As discussed above, we conducted a clinical assessment of each of the services added to the Medicare telehealth services list to identify those for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth outside the circumstances of the PHE. In our clinical review of these services, we did not identify sufficient information to suggest there is a potential likelihood of clinical benefit for these services such that they could meet the Category 1 or Category 2 criteria outside the circumstances of the PHE. We specifically considered the potential for these services to be furnished, outside the circumstances of the PHE, without increased concerns for patient safety or jeopardizing quality of care; and furnished fully and effectively, including all elements of the service, by a remotely located clinician via two-way, audio/video telecommunications technology. Due to these concerns, we did not find a potential likelihood that the services could meet Category 2 criteria even with development of additional evidence. However, we are inviting public comment on whether any service added to the Medicare telehealth services list for the duration of the PHE for the COVID–19 pandemic should be added to the Medicare telehealth services list on a temporary, Category 3 basis, based on the criteria outlined above. We welcome additional information from commenters about these services, as outlined in our request for comment for services we are proposing to add to the Medicare telehealth services list on a Category 3 basis.

We are also seeking specific comment on the following considerations associated with particular services. Comments on these specific concerns will also inform our final decisions on whether these services should be added to the Medicare telehealth services list on a temporary, Category 3 basis:

- *Initial and final/discharge interactions (CPT codes 99234–99236 and 99238–99239):* We believe that the potential acuity of the patient described by these codes would require an in-person physical exam in order to fulfill the requirements of the service. We have concerns that without an in-person physical examination the need for the physician or health care provider to fully understand the health status of the person with whom they are establishing a clinical and therapeutic relationship would be compromised. We believe that the need for an in-person interaction would rise beyond any specific diagnosis, and serves as the foundation upon which any and all clinical decisions are based for these services. We are concerned that, without an in-person interaction, care planning that includes risk-benefit considerations and clinical decision-making will be less well-informed and create risk of patient harm.
- *Higher level emergency department visits (CPT codes 99284–99285):* We are concerned that the full scope of service elements of these codes cannot be met via two-way, audio/video telecommunications technology as higher levels are indicated by patient characteristics, clinical complexity, urgency for care, and require complex decision-making. We also believe, due to the acuity of the patient described by these codes, that an in-person physical examination is necessary to fulfill the service requirements.
- *Hospital, Intensive Care Unit, Emergency care, Observation stays (CPT*

codes CPT 99217–99220; 99221–99226; 99484–99485, 99468–99472, 99475–99476, and 99477–99480): These codes describe visits that are furnished to patients who are ill enough to require hospital evaluation and care. We believe that the codes describe an evaluation for these potentially high acuity patients that is comprehensive and includes an in-person physical examination. Our view that in-person care is necessary to fulfill the requirements of the code is driven by the need for the physician or health provider to fully understand the health status of the person with whom they are establishing a clinical and therapeutic relationship. We believe that the need for an in-person interaction would rise above any specific diagnosis, and serves as the foundation upon which any and all clinical decisions are based for these services. We are concerned that, without an in-person interaction, care planning that includes risk-benefit considerations and clinical decision-making will be less well-informed and create risk of patient harm.

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TABLE 11: Telehealth Services for the PHE That Are Not CY 2021 Medicare Telehealth Proposals

Service Type	HCPCS	Long Descriptor
Radiation Treatment Management Services	77427	Radiation treatment management, 5 treatments
End-Stage Renal Disease (ESRD) Services	90952	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month
	90953	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
	90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
	90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month
Psychological and Neuropsychological Testing	96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes
	96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
	96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes
	96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
Therapy Services, Physical and Occupational Therapy, All levels	92521	Evaluation of speech fluency (eg, stuttering, cluttering)
	92522	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria);
	92523	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)
	92524	Behavioral and qualitative analysis of voice and resonance
	92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
	97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
	97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate

Service Type	HCPCS	Long Descriptor
		complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.
	97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.
	97165	Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1-3 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (eg, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97166	Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3-5 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.
	97167	Occupational therapy evaluation, high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 5 or more performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient

Service Type	HCPCS	Long Descriptor
		and/or family.
	97168	Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
	97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
	97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
	97535	Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
	97750	Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes
	97755	Assistive technology assessment (eg, to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes
	97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes
	97761	Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes
Hospital, ICU, Emergency care, Observation stays	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.])
	99218	Initial observation care, per day, for the evaluation and management of a patient which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or 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 problem(s) requiring admission to outpatient hospital "observation status" are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99219	Initial observation care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive 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 problem(s) requiring admission to outpatient hospital "observation status" are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99220	Initial observation care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or

Service Type	HCPCS	Long Descriptor
		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 problem(s) requiring admission to outpatient hospital "observation status" are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99221	Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or 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 problem(s) requiring admission are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99222	Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive 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 problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99223	Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: 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 problem(s) requiring admission are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99224	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: Problem focused interval history; Problem focused examination; Medical decision making that is straightforward or 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 patient is stable, recovering, or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99225	Subsequent observation care, per day, for the evaluation and management of a 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 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 patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99226	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; 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 patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.
Higher Level Emergency	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

Service Type	HCPCS	Long Descriptor
Department Visits		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.
	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.
Initial and final observation and discharge day management visits	99234	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or 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) requiring admission are of low severity. Typically, 40 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99235	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive 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) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99236	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: 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) requiring admission are of high severity. Typically, 55 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99238	Hospital discharge day management; 30 minutes or less
	99239	Hospital discharge day management; more than 30 minutes
Inpatient Neonatal and Pediatric Critical Care	99468	Initial inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger
	99469	Subsequent inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger
	99471	Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age
	99472	Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age
	99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration
	99475	Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age

Service Type	HCPCS	Long Descriptor
	99476	Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age
Initial and Continuing Intensive Care Services	99477	Initial hospital care, per day, for the evaluation and management of the neonate, 28 days of age or younger, who requires intensive observation, frequent interventions, and other intensive care services
	99478	Subsequent intensive care, per day, for the evaluation and management of the recovering very low birth weight infant (present body weight less than 1500 grams)
	99479	Subsequent intensive care, per day, for the evaluation and management of the recovering low birth weight infant (present body weight of 1500-2500 grams)
	99480	Subsequent intensive care, per day, for the evaluation and management of the recovering infant (present body weight of 2501-5000 grams)
Critical Care Services	99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes
	99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)

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With regard to the physical therapy, occupational therapy, and speech-language pathology services in Table Creceived a number of requests that we add therapy services to the Medicare telehealth services list. In the CY 2018 PFS final rule, we noted that section 1834(m)(4)(E) of the Act specifies the types of practitioners who may furnish and bill for Medicare telehealth services as those practitioners under section 1842(b)(18)(C) of the Act. Physical therapists (PTs), occupational therapists (OTs) and speech-language pathologists (SLPs) are not among the practitioners identified in section 1842(b)(18)(C) of the Act. We stated in the CY 2017 PFS final rule (81 FR 80198) that because these services are predominantly furnished by PTs, OTs, and SLPs, we did not believe it would be appropriate to add them to the Medicare telehealth services list at this time. In a subsequent request to consider adding these services for 2018, the original requester suggested that we might propose these services to be added to the Medicare telehealth services list so that payment can be made for them when furnished via telehealth by physicians or practitioners who can serve as distant site practitioners. We stated that since the majority of the codes are furnished over 90 percent of the time by therapy professionals who are not included on the statutory list of eligible distant site practitioners, we believed that adding therapy services to the Medicare telehealth services list could result in confusion about who is authorized to furnish and bill for these services when furnished via telehealth. While we continue to believe this is generally the case, and we are not proposing to add these services permanently to the Medicare telehealth services list, we are seeking comment on whether these services should be added to the Medicare telehealth services list so that, in instances when a practitioner who is eligible to bill for telehealth services furnishes these services via telehealth, they could bill and receive payment for them. We are also seeking comment on whether all aspects of these services can be fully and effectively furnished via two-way, audio/video telecommunications technology. We also note that given our clarification regarding telehealth services furnished incident to the professional services of a physician or practitioner (85 FR 27562), if these services were added to the Medicare telehealth services list, they could be furnished by a therapist and billed by a physician or practitioner who can furnish and bill for telehealth services provided that all of the ''incident to'' requirements are met.

With regard to the critical care services listed in Table 11, we have received a number of requests in prior years to add these services to the Medicare telehealth services list. In response to one such request, we finalized creation of two HCPCS G codes, G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth*) and G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth*), to describe the work associated with furnishing consultation services via Medicare telehealth to critically ill patients in the CY 2017 PFS final rule. We stated that CPT guidance makes clear that a variety of other services are bundled into the payment rates for critical care, including gastric intubations and vascular access procedures, among others. While we continue to believe that the full range of care for critically ill patients cannot be performed via two-way, audio/video telecommunications technology for the reasons articulated above, we are seeking comment on whether current coding (either through the CPT codes describing in-person critical care or the HCPCS G codes describing critical care consults furnished via telehealth) does not reflect additional models of critical care delivery, specifically, models of care delivery that utilize a combination of remote monitoring and clinical staff at the location of the beneficiary to allow, when an onsite practitioner is not available, for a practitioner at a distant site to monitor vital signs and direct in-person care as needed.

We are seeking comment on the definition, potential coding and valuation for this kind of remote service. We are also seeking comment on the following concerns:

- How to distinguish the technical component of the remote monitoring portion of the service from the diagnosis-related group (DRG) payment already being provided to the hospital.
- How to provide payment only for monitoring and interventions furnished to Medicare beneficiaries when the remote intensivist is monitoring multiple patients, some of which may not be Medicare beneficiaries.
- How this service intersects with both the critical care consult G codes and the in-person critical care services.

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TABLE 12: Summary of CY 2021 Proposals for Addition of Services to the Medicare Telehealth Services List

Type of Service	Specific Services and CPT Codes
1. Services we are proposing for permanent addition to the Medicare telehealth services list	• Group Psychotherapy (CPT code 90853) • Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT codes 99334-99335) • Home Visits, Established Patient (CPT codes 99347- 99348) • Cognitive Assessment and Care Planning Services (CPT code 99483) • Visit Complexity Inherent to Certain Office/Outpatient E/Ms (HCPCS code GPC1X) • Prolonged Services (CPT code 99XXX) • Psychological and Neuropsychological Testing (CPT code 96121)
2. Services we are proposing as Category 3, temporary additions to the Medicare telehealth services list.	• Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT codes 99336-99337) • Home Visits, Established Patient (CPT codes 99349-99350) • Emergency Department Visits, Levels 1-3 (CPT codes 99281-99283) • Nursing facilities discharge day management (CPT codes 99315-99316) • Psychological and Neuropsychological Testing (CPT codes 96130- 96133)
3. Services we are not proposing to add to the Medicare telehealth services list but are seeking comment on whether they should be added on either a Category 3 basis or permanently.	• Initial nursing facility visits, all levels (Low, Moderate, and High Complexity) (CPT 99304-99306) • Psychological and Neuropsychological Testing (CPT codes 96136-96139) • Therapy Services, Physical and Occupational Therapy, All levels (CPT 97161- 97168; CPT 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521- 92524, 92507) • Initial hospital care and hospital discharge day management (CPT 99221-99223; CPT 99238- 99239) • Inpatient Neonatal and Pediatric Critical Care, Initial and Subsequent (CPT 99468- 99472; CPT 99475- 99476) • Initial and Continuing Neonatal Intensive Care Services (CPT 99477-99480) • Critical Care Services (CPT 99291-99292) • End-Stage Renal Disease Monthly Capitation Payment codes (CPT 90952, 90953, 90956, 90959, and 90962) • Radiation Treatment Management Services (CPT 77427) • Emergency Department Visits, Levels 4-5 (CPT 99284-99285) • Domiciliary, Rest Home, or Custodial Care services, New (CPT 99324-99328) • Home Visits, New Patient, all levels (CPT 99341- 99345) • Initial and Subsequent Observation and Observation Discharge Day Management (CPT 99217- 99220; CPT 99224- 99226; CPT 99234-99236)

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2. Technical Refinement to the Medicare Telehealth Services List To Reflect Current Coding

For CY 2020, 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; reassessment*), 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*)). However, we inadvertently neglected to make the corresponding update to reflect these coding changes on the Medicare telehealth services list in CY 2020 PFS rulemaking. Therefore, we are proposing to delete CPT codes 96150–96155 from the Medicare telehealth services list and replace them with the following successor codes: CPT code 96156 (*Health behavior assessment, including reassessment (i.e., health-focused clinical interview,*

behavioral observations, clinical decision making)); CPT code 96158 (*Health behavior intervention, individual, face-to-face; initial 30 minutes*); CPT code 96159 (*Health behavior intervention, individual, face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*); CPT code 96164 (*Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes*); CPT code 96165 (*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 96167 (*Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes*); CPT code 96168 (*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 96170 (*Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes*); and CPT code 96171 (*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 also proposing to amend our regulations to stipulate that when new codes are issued to replace codes that describe the same clinical services that are currently on the Medicare telehealth services list, we will consider those new codes to be successor codes to those that are on the Medicare telehealth services list, and will update the Medicare telehealth services list accordingly. At § 410.78(f), we are proposing to revise the final sentence of the paragraph to read: CMS maintains on the CMS website the Medicare telehealth services list under this section, including the current HCPCS codes that describe the services.

3. Furnishing Telehealth Visits in Inpatient and Nursing Facility Settings, and Critical Care Consultations

The long term care facility regulations at § 483.30(c) require that residents of SNFs receive an initial visit from a physician, and periodic personal visits subsequently by either a physician or other nonphysician practitioner (NPP). In the CY 2010 PFS final rule with comment period (74 FR 61762) we stated that these regulations ensure that at least a minimal degree of personal contact between a physician or a qualified NPP and a resident is maintained, both at the point of admission to the facility and periodically during the course of the resident's stay. In that rule we stated that we believe that these federally-mandated visits should be conducted in-person, and not as Medicare telehealth services. We therefore revised § 410.78 to restrict physicians and practitioners from using telehealth to furnish the physician visits required under § 483.30(c).

During the PHE for the COVID–19 pandemic, we waived the requirement in 42 CFR 483.30 for physicians and nonphysician practitioners to personally perform required visits for nursing home residents, and allowed visits to be conducted via telehealth (*https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf*).

We are seeking public comment on whether it would be appropriate to maintain this flexibility on a permanent basis outside of the PHE for the COVID–19 pandemic. We invite public comment on whether the in-person visit requirement is necessary, or whether two-way, audio/video telecommunications technology would be sufficient in instances when, due to continued exposure risk, workforce capacity, or other factors, the clinician determines an in-person visit is not necessary.

We have also received requests to revise our frequency limitations for telehealth subsequent inpatient and nursing facility visits. Currently, we limit the provision of subsequent inpatient visits via Medicare telehealth to once every 3 days and subsequent nursing facility visits to once every 30 days. We received a request to remove the frequency limitation on the subsequent inpatient services and a separate request to revise the subsequent nursing facility visits to once every 3 days, rather than 30 days.

As we stated in the CY 2019 PFS final rule, we believed the potential acuity of illness of hospital inpatients is greater than that of patients who are likely to receive services that were on the Medicare telehealth services list at that time. We also stated that it would be appropriate to permit some subsequent hospital care services to be furnished through telehealth to ensure that hospitalized patients have frequent encounters with their admitting practitioner. In addition, we expressed our belief that the majority of these visits should be furnished in person to facilitate the comprehensive, coordinated, and personal care that medically volatile, acutely ill patients require on an ongoing basis. Because of our concerns regarding the potential acuity of illness of hospital inpatients, we finalized the addition of CPT codes 99231–99233 to the Medicare telehealth services list, but limited the provision of these subsequent hospital care services through telehealth to once every 3 days. We continue to believe that admitting practitioners should continue to make appropriate in-person visits to all patients who need such care during their hospitalization. Our concerns with, and position on, the provision of subsequent hospital care services via telehealth have not changed (83 FR 59493). Therefore, we are not proposing to modify our current policy.

In the CY 2018 PFS final rule, we reiterated that we believed it would be appropriate to permit some subsequent nursing facility (NF) care services to be furnished through telehealth to ensure that complex nursing facility patients have frequent encounters with their admitting practitioner, but because of our concerns regarding the potential acuity and complexity of NF inpatients, we limited the provision of subsequent NF care services furnished through telehealth to once every 30 days. We also stated that we continued to have concerns regarding more routine use of telehealth given the potential acuity and complexity of NF inpatients, and therefore, we were not proposing to remove the frequency limitation for subsequent NF care services (83 FR 59494). We have received comments from stakeholders who stated that the once every 30-day frequency limitation for subsequent NF visits furnished via Medicare telehealth limits access to care for Medicare beneficiaries in the NF setting. Stakeholders stated that the use of Medicare telehealth is crucial to maintaining a continuum of care in this setting and that CMS should leave it up to clinicians to decide how frequently a visit may be furnished as a Medicare telehealth service rather than in person depending on the needs of specific patients. We are persuaded by the comments from these stakeholders, and therefore, are proposing to revise the frequency limitation from one visit every 30 days to one visit every 3 days. We believe this interval strikes the right balance between requiring in-person visits and allowing flexibility to furnish services via telehealth when clinically appropriate to do so. We are also seeking comment on whether frequency limitations broadly are burdensome and limit access to necessary care when services are available only through telehealth, and how best to ensure that patients are receiving necessary in-person care.

4. Proposed Technical Amendment To Remove References to Specific Technology

The final sentence of our regulation at § 410.78(a)(3) prohibits the use of telephones, facsimile machines, and electronic mail systems for purposes of furnishing Medicare telehealth services. In the March 31st COVID–19 IFC, we added a new § 410.78(a)(3)(i) (and reserved § 410.78(a)(3)(ii) for later use) to provide for an exception that removes application of that sentence during the PHE for the COVID–19 pandemic. We added the new section on an interim final basis because we believe that the first sentence of § 410.78(a)(3) adequately describes the technology requirements for an interactive telecommunication system that may be used to furnish a Medicare telehealth service. That sentence defines interactive telecommunication system as ''multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication.'' We were also concerned that the reference to ''telephones'' in the second sentence of the regulation as impermissible technology could cause confusion in instances where an otherwise eligible device, such as a smart phone, may also be used as a telephone. Because these concerns are not situation- or time-limited to the PHE for COVID–19, we are proposing to remove the second sentence of the regulation at § 410.78(a)(3) which specifies that ''[t]elephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.'' As we are proposing to adopt this change on a permanent basis, we are also proposing to delete the subparagraphs at § 410.78(a)(3)(i) and 410.78(a)(3)(ii). We believe these amendments to our regulations would remove outdated references to specific types of technology and provide a clearer statement of our policy.

5. Communication Technology-Based Services (CTBS)

In the CY 2019 PFS final rule, we finalized separate payment for a number of services that could be furnished via telecommunications technology, but that are not considered Medicare telehealth services. Specifically, we 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*), and 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*). We finalized maintenance of these codes as part of the set of codes that is only reportable by those practitioners that can furnish E/M services. We stated that we believed this was appropriate since the service describes a check-in directly with the billing practitioner to assess whether an office visit is needed. However, we did note that similar check-ins provided by nurses and other clinical staff can be important aspects of coordinated patient care (83 FR 59486).

In the CY 2020 PFS final rule, we finalized separate payment for HCPCS codes G2061 (*Qualified nonphysician healthcare professional online assessment and management, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*), G2062 (*Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*), and G2063 (*Qualified nonphysician qualified healthcare professional assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*). In that rule, we stated that these codes may be billed by nonphysician practitioners (NPPs) consistent with the definition of their respective benefit category, although we did not provide specific examples (84 FR 62796).

We have received a number of questions regarding which benefit categories HCPCS codes G2061 through G2063 fall under. In the March 31st COVID–19 IFC (85 FR 19244–19245) we established on an interim basis for the duration of the PHE for the COVID–19 pandemic that these services could be billed for example, by licensed clinical social workers and clinical psychologists, as well as PTs, OTs, and SLPs who bill Medicare directly for their services when the service furnished falls within the scope of these practitioner's benefit categories. We are proposing to adopt that policy on a permanent basis. We note that this is not an exhaustive list and we are seeking comment on other benefit categories into which these services fall.

We are also proposing to allow billing of other CTBS by certain nonphysician practitioners, consistent with the scope of these practitioners' benefit categories through the creation of two additional HCPCS G codes that can be billed by practitioners who cannot independently bill for E/M services:

- G20X0 (*Remote assessment 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 service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.*)
- G20X2 (*Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot 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 a service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*).

We are proposing to value these services identically to HCPCS codes G2010 and G2012, respectively. We acknowledge that it has been agency policy, in general, to differentially value similar services that are performed by practitioners who can and cannot, respectively, bill independently for E/M services, with higher values for the service performed by practitioners who can independently bill E/M services. However, given the relatively low values for HCPCS codes G2010 and G2012, we do not think that there is a significant differential in resource costs to warrant different values, but are seeking comment on whether we should value these services differentially, including potentially increasing the valuation of HCPCS codes G2010 and G2012.

Further, to facilitate billing of the CTBS by therapists, we are proposing to designate HCPCS codes G20X0, G20X2, G2061, G2062, and G2063 as ''sometimes therapy'' services. When billed by a private practice PT, OT, or SLP, the codes would need to include the corresponding GO, GP, or GN therapy modifier to signify that the CTB are furnished as therapy services furnished under an OT, PT, or SLP plan of care.

We also note that in section II.K. of this proposed rule we are proposing for CY 2021 to replace the eVisit G codes with corresponding CPT codes, and that this policy would also apply to those codes.

For all of these CTBS, we are also making clear that the consent from the patient to receive these services can be documented by auxiliary staff under general supervision, as well as by the billing practitioner. While we continue to believe that beneficiary consent is necessary so that the beneficiary is notified of cost sharing when receiving these services, we do not believe that the timing or manner in which beneficiary consent is acquired should interfere with the provision of one of these services. We are retaining the requirement that, in instances when the brief communication technology-based service originates from a related E/M service (including one furnished as a telehealth service) provided within the previous 7 days by the same physician or other qualified health care professional, this service would be considered bundled into that previous E/M service and would not be separately billable.

6. Comment Solicitation on Continuation of Payment for Audio-Only Visits

In the March 31st COVID–19 IFC, we established separate payment for audio-only telephone evaluation and management (E/M) services (85 FR 19264 through 19266). The telephone E/M services are CPT codes 99441 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian 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*); 99442 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian 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; 11–20 minutes of medical discussion*); and 99443 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian 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; 21–30 minutes of medical discussion*). We noted that, although these services were previously considered non-covered under the PFS, in the context of the PHE and with the goal of reducing exposure risks associated with the COVID–19 pandemic, especially in the case that two-way, audio and video technology is not available to furnish a Medicare telehealth service, we believed there are circumstances where prolonged, audio-only communication between the practitioner and the patient could be clinically appropriate, yet not fully replace a face-to-face visit. For example, an established patient who was experiencing an exacerbation of their condition could have a 25-minute phone conversation with their physician during which the physician determines that an adjustment to the patient's medication would alleviate their symptoms. The use of CPT code 99443 in this situation prevents a similar in-person service as the evaluation of the patient's symptoms and determination to adjust medication could be conducted without patient and the practitioner being in the same location. We stated our belief that these telephone E/M codes, with their established description and valuation, were the best way to recognize the relative resource costs of these kinds of services and make payment for them under the PFS. For these codes, we initially finalized on an interim basis during the PHE for the COVID–19 pandemic, work relative value units (RVUs) as recommended by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC), as discussed in the CY 2008 PFS final rule with comment period (72 FR 66371), of 0.25 for CPT code 99441, 0.50 for CPT code 99442, and 0.75 for CPT code 99443. We also finalized the RUC-recommended direct practice expense (PE) inputs which consist of 3 minutes of post-service Registered Nurse/Licensed Practical Nurse/Medical Technical Assistant clinical labor time for each code.

In the May 1st COVID–19 IFC, we noted that in the time since we established these payment amounts, stakeholders had informed us that use of audio-only services was more prevalent than we had previously considered, especially because many beneficiaries were not utilizing video-enabled communication technology from their homes. In other words, there were many cases where practitioners would under ordinary circumstances utilize telehealth or in-person visits to evaluate and manage patients' medical concerns, but were instead using audio-only interactions to manage more complex care (85 FR 27589 through 27590). While we had previously acknowledged the likelihood that, under the circumstances of the PHE, more time would be spent interacting with the patient via audio-only technology, we stated that the intensity of furnishing an audio-only visit to a beneficiary during the unique circumstances of the COVID–19 pandemic was not accurately captured by the valuation of these services we established in the March 31st COVID–19 IFC. This would be particularly true to the extent that these audio-only services are actually serving as a substitute for office/outpatient Medicare telehealth visits for beneficiaries not using video-enabled telecommunications technology contrary to the situation we anticipated when establishing payment for them in the March 31st COVID–19 IFC. We stated that, given our understanding that these audio-only services were being furnished primarily as a replacement for care that would otherwise be reported as an in-person or telehealth visit using the office/outpatient E/M codes, we established new RVUs for the telephone E/M services based on crosswalks to the most analogous office/outpatient E/M codes, based on the time requirements for the telephone codes and the times assumed for valuation for purposes of the office/outpatient E/M codes. Specifically, we crosswalked CPT codes 99212, 99213, and 99214 to CPT codes 99441, 99442, and 99443, respectively. We therefore finalized, on an interim basis and for the duration of the COVID–19 PHE, the following work RVUs: 0.48 for CPT code 99441; 0.97 for CPT code 99442; and 1.50 for CPT code 99443. We also finalized the direct PE inputs associated with CPT code 99212 for CPT code 99441, the direct PE inputs associated with CPT code 99213 for CPT code 99442, and the direct PE inputs associated with CPT code 99214 for CPT code 99443. We did not finalize increased payment rates for CPT codes 98966–98968 as these codes describe services furnished by practitioners who cannot independently bill for E/M services and so these telephone assessment and management services, by definition, are not being furnished in lieu of an office/outpatient E/M service. We noted that to the extent that these extended phone services are taking

place instead of office/outpatient E/M visits (either in-person or via telehealth), the direct crosswalk of RVUs also better maintains overall budget neutrality and relativity under the PFS. We stated that we believed that the resources required to furnish these services during the PHE for the COVID–19 pandemic are better captured by the RVUs associated with the level 2–4 established patient office/outpatient E/M visits. Additionally, we stated that, given our understanding that these audio-only services were being furnished as substitutes for office/outpatient E/M services, we recognized that they should be considered as telehealth services, and added them to the Medicare telehealth services list for the duration of the PHE. For these audio-only E/M services, we separately issued a waiver under section 1135(b)(8) of the Act, as amended by section 3703 of the CARES Act, of the requirements under section 1834(m) of the Act and our regulation at § 410.78 that Medicare telehealth services must be furnished using video technology.

We are not proposing to continue to recognize these codes for payment under the PFS after conclusion of the PHE for the COVID–19 pandemic because, outside of the circumstances of the PHE, we are not able to waive the requirement that telehealth services be furnished using an interactive telecommunications system that includes two-way, audio/video communication technology. However, we recognize that the need for audio-only interaction could remain as beneficiaries continue to try to avoid sources of potential infection, such as a doctor's office; and in that circumstance, a longer phone conversation may be needed to determine if an in-person visit is necessary than what is described by the virtual check-in. We are seeking comment on whether CMS should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value. We are seeking input from the public on the appropriate duration interval for such services and the resources in both work and PE that would be associated with furnishing them. We are also seeking comment on whether separate payment for such telephone-only services should be a provisional policy to remain in effect until a year or some other period after the end of the PHE or if it should be PFS payment policy permanently.

7. Comment Solicitation on Coding and Payment for Virtual Services

The health care community uses the term ''telehealth'' broadly to refer to medical services furnished via communications technology. Under current PFS payment rules, Medicare routinely pays for many of these kinds of services. This includes some kinds of remote patient monitoring (either as separate services or as parts of bundled services), interpretations of diagnostic tests when furnished remotely and, under conditions specified in section 1834(m) of the Act, services that would otherwise be furnished in person but are instead furnished via real-time, interactive communication technology. Over the past several years, we have also established several PFS policies to make separate payment for non-face-to-face services included as part of ongoing care management. Although all of the kinds of services stated above might be called ''telehealth'' by patients, other payers and health care providers, we have generally used the term ''Medicare telehealth services'' to refer to the subset of services defined in section 1834(m) of the Act. Section 1834(m) of the Act defines Medicare telehealth services and specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real time telecommunication technology.

We believe that the provisions in section 1834(m) of the Act apply particularly to the kinds of professional services explicitly enumerated in the statutory provisions, like professional consultations, office visits, and office psychiatry services. Generally, the services we have added to the Medicare telehealth services list are similar to these kinds of services. As has long been the case, certain other kinds of services that are furnished remotely using communications technology are not considered ''Medicare telehealth services'' and are not subject to the restrictions articulated in section 1834(m) of the Act. This is true for services that were routinely paid separately prior to the enactment of the provisions in section 1834(m) of the Act and do not usually include patient interaction (such as remote interpretation of diagnostic imaging tests), and for services that were not discretely defined or separately paid for at the time of enactment and that do include patient interaction (such as chronic care management services).

In recent years, we have begun making separate payment for a number of services that use telecommunications technology but are not considered Medicare telehealth services. These CTB services include, for example, certain kinds of remote patient monitoring (either as separate services or as parts of bundled services), a virtual check-in, and a remote asynchronous service. These services are different than the kinds of services specified in section 1834(m) of the Act, in that they are not the kind of services that are ordinarily furnished in person but are routinely furnished using a telecommunications system.

In the past, we have received requests to add certain services, such as chronic care management or remote physiologic monitoring to the Medicare telehealth services list. However, as these services fall outside the scope of services addressed, and the enumerated list of services included in section 1834(m) of the Act, they are not considered telehealth services and, therefore, are not subject to the same restrictions. We are seeking comment on whether there are additional services that fall outside the scope of telehealth services under section 1834(m) of the Act where it would be helpful for us to clarify that the services are inherently non-face-to-face, so do not need to be on the Medicare telehealth services list in order to be billed and paid when furnished using telecommunications technology rather than in person with the patient present. We are also seeking comment on physicians' services that use evolving technologies to improve patient care that may not be fully recognized by current PFS coding and payment, including, for example, additional or more specific coding for care management services. Finally, we are broadly seeking comment on any impediments that contribute to healthcare provider burden and that may result in practitioners being reluctant to bill for CTBS. We appreciate the ongoing engagement and additional information from stakeholders as we work to improve coding and payment for these services that utilize telecommunications technology.

8. Proposed Clarification of Existing PFS Policies for Telehealth Services

In response to the waiver of statutory requirements and the relaxation of regulatory requirements for telehealth during the PHE for the COVID–19 pandemic, we received a number of requests to clarify existing PFS policy for telehealth. For example, we received questions as to whether Medicare allows incident-to billing for telehealth services, particularly for practitioners such as counselors who are supervised

by a physician in private practice. We note that there are no Medicare regulations that explicitly prohibit eligible distant site practitioners from billing for telehealth services provided incident to their services. However, we also note that our existing definition of direct supervision requires on-site presence of the billing clinician when the service is provided. That requirement could make it difficult for a billing clinician to provide the direct supervision of services provided via telehealth incident to their professional services by auxiliary personnel. Under our proposed amendment to the definition of direct supervision to permit virtual presence, we acknowledge that billing practitioners could more easily meet the direct supervision requirements for telehealth services provided incident to their services. Consequently, we believe that services provided incident to the professional services of an eligible distant site physician or practitioner could be reported when they meet direct supervision requirements at both the originating and distant site through the virtual presence of the billing physician or practitioner. Therefore, we are proposing to clarify that services that may be billed incident-to may be provided via telehealth incident to a physicians' service and under the direct supervision of the billing professional. This is consistent with a policy clarification that we made through the May 1st COVID–19 IFC (85 FR 27562).

We have also received questions as to whether services should be reported as telehealth services when the individual physician or practitioner furnishing the service is in the same location as the beneficiary; for example, if the physician or practitioner furnishing the service is in the same institutional setting but is utilizing telecommunications technology to furnish the service due to exposure risks. We are clarifying, as we did in the May 1st COVID–19 IFC (85 FR 27562) that if audio/video technology is used in furnishing a service when the beneficiary and the practitioner are in the same institutional or office setting, then the practitioner should bill for the service furnished as if it was furnished in person, and the service would not be subject to any of the telehealth requirements under section 1834(m) of the Act or § 410.78 of our regulations.

9. Direct Supervision by Interactive Telecommunications Technology

Many services for which payment is made under the PFS can be furnished under a level of physician or NPP supervision rather than being performed directly by the billing practitioner. In many cases, the supervision requirements necessitate the presence of the physician or NPP in a particular location, usually in the same location as the beneficiary when the service is provided. For example, as described at § 410.26, services furnished by auxiliary personnel incident to a physician's or NPP's professional service usually require the direct supervision of the physician or NPP. In addition to these ''incident to'' services, there are a number of diagnostic services under the PFS that also must be furnished under direct supervision. As currently defined in §§ 410.26 and 410.32(b)(3)(ii), direct supervision means that the physician or NPP must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. Direct supervision does not require the physician or NPP to be present in the room when the service or procedure is performed.

For the duration of the PHE for the COVID–19 pandemic, for purposes of limiting exposure to COVID–19, we adopted an interim final policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology (85 FR 19245). We recognized that in some cases, the physical proximity of the physician or practitioner might present additional infection exposure risk to the patient and/or practitioner. In the context of the PHE for the COVID–19 pandemic, given the risks of exposure, the immediate risk of foregone medical care, the increased demand for healthcare professionals, and the widespread use of telecommunications technology, we believed that individual practitioners were in the best position to make decisions about how to meet the requirement to provide appropriate direct supervision based on their clinical judgment in particular circumstances.

We are proposing to extend this policy until the later of the end of the calendar year in which the PHE ends or December 31, 2021, to recognize the different and unique circumstances faced by individual communities that may continue after the PHE ends, and provide time to solicit public input on circumstances where the flexibility to use interactive audio/video real-time communications technology to provide virtual direct supervision could still be needed and appropriate. The extension of this flexibility would allow time for clinicians to make adjustments and for us to obtain public input on services and circumstances for which this policy might be appropriate on a permanent basis. We note that if we finalize this proposal and the PHE ends before the CY 2021 PFS final rule takes effect, the interim policy adopted during the PHE to allow direct supervision using real-time, interactive audio and video technology would no longer be in effect during the period between expiration of the PHE and the date the final policy takes effect.

Given our continued interaction with practitioners during the PHE and our growing understanding of how services may be furnished remotely and safely, we now have a better understanding of how, in some cases, depending upon the unique circumstances of individual patients and billing practitioners or physicians, telecommunications technology could safely allow the practitioner or physician's immediate availability to furnish assistance and direction without necessarily requiring the supervising practitioner's or physician's physical presence in the location where the service is being furnished. In such cases, the use of real-time, audio and video telecommunications technology may allow the supervising practitioner or physician to observe the beneficiary and the auxiliary staff performing the service or be engaged (Direct supervision does not require the physician or NPP to be present in the room when the service or procedure is performed) to provide assistance and direction of the service through virtual means, and without the supervising practitioner or physician being physically present.

Consequently, we are proposing to revise § 410.32(b)(3)(ii) to allow direct supervision to be provided using real-time, interactive audio and video technology through the later of the end of the calendar year in which the PHE ends or December 31, 2021. Specifically, we propose to continue our current rule that ''Direct supervision'' in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician (or other supervising practitioner) must be present in the room when the procedure is performed. We propose to add that, until the later of the end of the calendar year in which the PHE ends or December 31, 2021, the presence of the physician (or other practitioner) may include virtual presence through audio/video real-time communications technology (excluding audio-only) subject to the clinical judgement of the

supervising physician or (other supervising practitioner). In response to questions received since we issued our interim policy for the PHE, we are clarifying that, to the extent our policy allows direct supervision through virtual presence using audio/video real-time communications technology, the requirement could be met by the supervising physician (or other practitioner) being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure.

While flexibility to provide direct supervision through audio/video real-time communications technology was adopted to be responsive to critical needs during the PHE to ensure beneficiary access to care, reduce exposure risk and to increase the capacity of practitioners and physicians to respond to COVID–19, we are concerned that direct supervision through virtual presence may not be sufficient to support PFS payment on a permanent basis, beyond the PHE, due to issues of patient safety. For instance, in complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures, a patient's clinical status can quickly change and we believe it is necessary for such services to be furnished or supervised in person to allow for rapid on-site decision-making in the event of an adverse clinical situation. For example, there could be a case in which a practitioner or physician uses audio/video interactive communications to virtually supervise a nurse performing a post-op evaluation following surgery for hip fracture, and the nurse might note that the patient is uncooperative. In this scenario, had a full exam been performed directly by the practitioner or physician, or under the in-person supervision of a practitioner or physician who was physically or immediately available in the clinic to provide the necessary direction, the physician or practitioner would have recognized that the patient exhibited signs of crystal-mediated acute arthritis, and that the patient's lack of cooperation was likely due to hypoactive delirium. Instead, the supervising practitioner or physician may not have been able to identify this clinical issue as a result of being available only via audio/video interactive communications technology. In this case, the presence of the supervising practitioner or physician through audio/video interactive communications technology would have been insufficient. There also may be certain patient populations that require greater clinical attentiveness and skill than the supervising practitioner or physician could provide via audio/video interactive communications technology. For example, patients with cognitive impairment or dementia, or patients with communication disabilities, may require the experience and skill of a physically present supervising practitioner or physician to recognize needs such as the need for specialized testing. It may not be possible for a supervising practitioner or physician to recognize or meet these clinical needs while being present for the service only through audio/video interactive communications technology. Moreover, the virtual connection between the individual performing the service and the supervising practitioner or physician could be disrupted, making it challenging for the supervising practitioner or physician to remain immediately available to provide assistance and direction to the physically present clinical staff or auxiliary personnel to furnish appropriate care to the patient.

We are seeking information from commenters as to whether there should be any additional ''guardrails'' or limitations to ensure patient safety/clinical appropriateness, beyond typical clinical standards, as well as restrictions to prevent fraud or inappropriate use if we were to finalize a policy to permit direct supervision through audio/video interactive communications technology, with consideration of relevant patient safety, clinical appropriateness criteria or other restrictions, on a temporary basis through the later of the end of the calendar year in which the PHE ends or December 31, 2021, or consider it beyond the time specified. We are also seeking information on what risks this policy might introduce to beneficiaries as they receive care from practitioners that would supervise care virtually in this way. Further we are seeking comment on potential concerns around induced utilization and fraud, waste, and abuse and how those concerns might be addressed. We also invite commenters to provide data and information about their implementation experience with direct supervision using virtual presence during the PHE, and are interested in comments on the degree of aging and disability competency training that is required for effective use of audio/video real-time communications technology.

10. Comment Solicitation on PFS Payment for Specimen Collection for COVID–19 Tests

When physicians and other practitioners collect specimens for clinical diagnostic laboratory tests as part of their professional services, Medicare generally makes payment for the services under the PFS, though often that payment is bundled into the payment rate for other services, including office and outpatient visits. Typically, collection of a specimen via nasal swab or other method during the provision of a service might be reported as part of (bundled with) an office/outpatient E/M visit (CPT codes 99201 through 99205, 99211 through 99215). In visits where a patient has a face-to-face interaction with a billing professional with whom they have an established relationship, these services are generally reported with a level 2 through a level 5 visit (CPT codes 99212 through 99215). In cases where the specimen is collected during a visit where the face-to-face interaction only involves clinical staff of the billing professional with whom the patient has an established relationship, these services are generally reported using CPT code 99211.

In the May 1st COVID–19 IFC (85 FR 27604–27605), we finalized on an interim basis that physicians and NPPs may use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID–19 testing, if the billing practitioner does not also furnish a higher level E/M service to the patient on the same day. We are considering whether to extend or make permanent the policy to allow physicians and NPPs to use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID–19 testing, and are soliciting public comments on whether we should continue this policy for a period of time, or permanently, after the COVID–19 PHE ends.

E. Care Management Services and Remote Physiologic Monitoring Services

1. Background

In recent years, we have updated PFS policies to improve payment for care management and 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 describe services that involve direct patient

contact (for some services, in-person) or do not involve direct patient contact; represent a single encounter, monthly service, or both; are timed services; address specific conditions; and represent the work of the billing practitioner, auxiliary personnel (specifically, clinical staff), or both (*see* Table 13). In this proposed rule for CY 2021, we continue our work to improve payment for care management services through proposed code refinements related to remote physiologic monitoring (RPM), transitional care management (TCM), and psychiatric collaborative care model (CoCM) services.

TABLE 13: Summary of 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, 2020, 2021) (CPT codes 99487, 99489, 99490, 99491, HCPCS code G2058 (99XXX proposed 2021 replacement)	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, HCPCS code GCOL1 proposed for 2021)	Management of behavioral health conditions(s), timed, per month
Cognitive Impairment Assessment and Care Planning (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)	Prolonged non-face-to-face E/M work related to a face-to-face visit (other than office/outpatient visits beginning in 2021), timed
Prolonged Office/Outpatient E/M Visit (adopted for 2021) (CPT code 99XXX)	Prolonged face-to-face and/or non-face to face E/M work related to an office/outpatient E/M visit, timed
Remote Physiologic Monitoring Treatment Management Services (RPM) (adopted in 2020) (CPT codes 99457, 99458)	Development and management of a plan of treatment based upon patient physiologic data
Interprofessional Consultation (adopted in 2019) (CPT codes 99446, 99447, 99448, 99449, 99451, 99452)	Inter-practitioner consultation
Principal Care Management (adopted in 2020) (HCPCS codes G2064, G2065)	Management of a single, high risk disease

2. Digitally Stored Data Services/Remote Physiologic Monitoring/Treatment Management Services (RPM)

RPM involves the collection and analysis of patient physiologic data that are used to develop and manage a treatment plan related to a chronic and/or acute health illness or condition. In recent years, we have finalized payment for seven CPT codes in the RPM code family. Five of the seven codes have been the focus of frequent questions from stakeholders.

In response to proposals in the CY 2019 PFS proposed rule (83 FR 35771) and the CY 2020 PFS proposed rule (84 FR 40555 through 40556), stakeholders requested that we clarify how we interpret aspects of the RPM code descriptors for CPT codes 99453, 99454, 99091, and 99457. Commenters asked us, for example, to identify who can furnish RPM services, what kinds of medical devices can be used to collect data, how data should be collected, and how ''interactive communication'' is defined. We stated in the CY 2020 PFS final rule (84 FR 62697) that we would provide guidance in the future about the codes. For CY 2021, we are clarifying how we read CPT code descriptors and instructions associated with CPT codes 99453, 99454, 99091, and 99457 (and the add-on code, CPT code 99458) and their use to describe remote monitoring of physiologic parameters of a patient's health.

The RPM process begins with two practice expense (PE) only codes, CPT codes 99453 and 99454, finalized in the CY 2019 PFS final rule (83 FR 39574 through 39576). As PE only codes they are valued to include clinical staff time, supplies, and equipment, including the medical device for the typical case of remote monitoring. 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*) is

valued to reflect clinical staff time that includes instructing a patient and/or caregiver about using one or more medical devices. CPT code 99454 (*Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*) is valued to include the medical device or devices supplied to the patient and the programming of the medical device for repeated monitoring. We reviewed the PE inputs for CPT code 99454 for purposes of this proposal, and are clarifying that the medical device or devices that are supplied to the patient and used to collect physiologic data are considered equipment and as such are direct PE inputs for the code.

Review of CPT prefatory language (CPT® 2020 Professional Codebook (hereafter, CPT Codebook), p. 42) provides additional information about the two PE only codes. For example, the CPT prefatory language indicates that monitoring must occur over at least 16 days of a 30-day period in order for CPT codes 99453 and 99454 to be billed. Additionally, these two codes are not to be reported for a patient more than once during a 30-day period. This language suggests that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected. We also note that CPT 99453 can be billed only once per episode of care where an episode of care is defined as ''beginning when the remote physiologic monitoring service is initiated and ends with attainment of targeted treatment goals'' (CPT Codebook, p. 42).

Other stakeholder inquiries about CPT codes 99453 and 99454 focus upon the kinds of medical devices that can be used to collect the patient's physiologic data. Prefatory language in the CPT Codebook states that ''the device must be a medical device as defined by the FDA.'' CPT simply specifies that the device must meet the FDA's definition of a medical device as described in section 201(h) of the Federal, Food, Drug and Cosmetic Act (FFDCA). We have found no language in the CPT Codebook indicating that a medical device must be FDA cleared as some stakeholders have suggested although such clearance may be appropriate. Nor have we found information that suggests a medical device must be prescribed by a physician, although this could be possible depending upon the medical device. Beyond acknowledging the CPT specification that the medical device supplied for CPT code 99454 must meet the FDA definition of a medical device, we are clarifying that the medical device should digitally (that is, automatically) upload patient physiologic data (that is, data are not patient self-recorded and/or self-reported). We note also that use of the medical device or devices that digitally collect and transmit a patient's physiologic data must, as usual for most Medicare covered services, be reasonable and necessary for the diagnosis or treatment of the patient's illness or injury or to improve the functioning of a malformed body member. Further, the device must be used to collect and transmit reliable and valid physiologic data that allow understanding of a patient's health status to develop and manage a plan of treatment.

The CPT Codebook lists the RPM codes under the main heading Evaluation and Management (E/M). We are clarifying that as E/M codes, CPT codes 99453, 99454, 99091, 99457, and 99458, can be ordered and billed only by physicians or nonphysician practitioners (NPPs) who are eligible to bill Medicare for E/M services.

Although we initially described RPM services in the CY 2019 PFS final rule (83 FR 35771) as services furnished to patients with chronic conditions, we are also clarifying that practitioners may furnish these services to remotely collect and analyze physiologic data from patients with acute conditions, as well as from patients with chronic conditions.

After the 30-day data collection period for CPT codes 99453 and 99454, the physiologic data that are collected and transmitted are analyzed and interpreted by the physician or practitioner as described by CPT code 99091, a code that includes only professional work, that is, there are no direct PE inputs. We finalized payment for CPT code 99091 (*Collection and interpretation of physiologic data 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 requiring a minimum of 30 minutes of time, each 30 days*) in the CY 2018 PFS final rule (82 FR 59473). The valuation for CPT code 99091 includes a total time of 40 minutes of physician or nonphysician practitioner work broken down as follows: 5 minutes of preservice work (for example, chart review); 30 minutes of intra-service work (for example, data analysis and interpretation, report based upon the physiologic data, as well as a possible phone call to the patient); and 5 minutes of post-service work (that is, chart documentation). We note that stakeholders have expressed confusion about the specification in the code descriptor for CPT code 99091 that the service is furnished by a ''physician or other qualified health care professional, qualified by education, training, licensure/regulation.'' The phrase ''physician or other qualified healthcare professional'' is defined by CPT as, ''an individual who is qualified by education, training, licensure/regulation (when applicable) and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service. These professionals are distinct from ''clinical staff . . . [which refers to] a person who works under the supervision of a physician or other qualified healthcare professional and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specified professional service but does not individually report that professional service.'' [1] Accordingly, when referring to a particular service described by a CPT code for Medicare purposes, a physician or other qualified healthcare professional is an individual whose scope of practice and Medicare benefit category includes the service and who is authorized to independently bill Medicare for the service. See our previous discussion of this in the CY 2016 PFS final rule at 80 FR 70957. Medicare also covers and makes payment for certain services performed by auxiliary personnel (which includes clinical staff) ''incident to'' the professional services of the billing practitioner. Our regulation at § 410.26(a) defines auxiliary personnel (a term that includes clinical staff) and delineates the conditions for payment for ''incident to'' services.

After analyzing and interpreting a patient's remotely collected physiologic data, the next step in the process of RPM is the development of a treatment plan that is informed by the analysis and interpretation of the patient's data. It is at this point that the physician or nonphysician practitioner develops a treatment plan with the patient and/or caregiver (that is, patient-centered care) and then manages the plan until the targeted goals of the treatment plan are attained, which signals the end of the episode of care. CPT code 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar*

[1] CPT Codebook, p.xiii.

month requiring interactive communication with the patient/caregiver during the month; first 20 minutes) and its add-on code, CPT code 99458 (*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*) describe the treatment and management services associated with RPM. Medicare stakeholders have requested that we clarify aspects of these two codes. The two most frequently asked questions include, ''Who can furnish the services described by CPT codes 99457 and 99458?'' and ''What does it mean to have an 'interactive communication' with a patient?''

We addressed who can furnish CPT codes 99457 and 99458 in the CY 2020 PFS final rule (84 FR 62697 through 62698) when we designated both codes as care management services. We explained that, like other care management services, CPT codes 99457 and 99458 can be furnished by clinical staff under the general supervision of the physician or NPP. We note that RPM services are not considered to be diagnostic tests; that is, they cannot be furnished and billed by an Independent Diagnostic Testing Facility on the order of a physician or NPP.

The services described by CPT codes 99457 and 99458 are services that are typically furnished remotely using communications technologies that allow ''interactive communication,'' which we read as real-time interaction, between a patient and the physician, nonphysician practitioner, or clinical staff who provide the services. Stakeholders have requested that we define ''interactive communication'' as used in the code descriptors for CPT codes 99457 and 99458. We see this remote, non-face-to-face exchange as being similar to the exchange that occurs in providing services described by HCPCS code G2012, *Brief Communication Technology Based Service,* which we finalized in the CY 2019 final rule (83 FR 59483 through 59486). Thus, we are clarifying that ''interactive communication'' for purposes of CPT codes 99457 and 99458 involves, at a minimum, a real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission. As indicated in the code descriptor for CPT code 99457, the interactive communication must total at least 20 minutes of interactive time with the patient over the course of a calendar month for CPT code 99457 to be reported. Each additional 20 minutes of interactive communication between the patient and the physician/nonphysician practitioner/clinical staff is reported using CPT code 99458. The CPT Codebook states that unless there are code- or code-range specific instructions, parenthetical instructions, or code descriptors to the contrary, time is considered to be the ''face-to-face'' time with the patient or patient's caregiver/medical decision-maker. See the CPT Codebook, page xvii, as well as pages 10, 13, and 16 for more information about measuring time. Where, as here, the services are not typically furnished in person with the patient, we interpret time in the code descriptor to mean the time spent in direct, real-time interactive communication with the patient.

Lastly, we are proposing to establish as permanent policy two of the changes we made on an interim basis to the requirements for furnishing RPM services in response to the PHE for the COVID–19 pandemic. (See 85 FR 19264 and 85 FR 27605 through 27606 for the interim modifications and clarifications to RPM services in response to the PHE for the COVID–19 pandemic).

Our goals during the PHE for the COVID–19 pandemic have been to reduce exposure risks to the Novel Coronavirus for practitioners and patients while also increasing access to health care services. We eliminated as many obstacles as possible to allow timely delivery of reasonable and necessary health care. We wanted patients to be able to access services quickly and without barriers. With the goals of reducing exposure and increasing access to services, we finalized that RPM services could be furnished to new patients, as well as established patients. We also finalized on an interim basis for the duration of the PHE for the COVID–19 pandemic policies to allow consent to be obtained at the time services are furnished, and by individuals providing RPM services under contract with the billing physician or practitioner; and to allow RPM codes to be billed for a minimum of 2 days of data collection over a 30-day period, rather than the required 16 days of data collection over a 30-day period as provided in the CPT code descriptors.

For CY 2021, we are proposing on a permanent basis to allow consent to be obtained at the time that RPM services are furnished. Because the CPT code descriptors do not specify that clinical staff must perform RPM services, we are also proposing to allow auxiliary personnel (which includes other individuals who are not clinical staff but are employees, or leased or contracted employees) to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.

When the PHE for the COVID–19 pandemic ends, we again will require that RPM services must be furnished only to an established patient. We believe that a physician or practitioner who has an established relationship with a patient would likely have had an opportunity to provide a new patient E/M service. During the new patient E/M service, the physician or practitioner would have collected relevant patient history and conducted a physical exam, as appropriate. As a result, the physician or practitioner would possess information needed to understand the current medical status and needs of the patient prior to ordering RPM services to collect and analyze the patient's physiologic data and to develop a treatment plan. Additionally, and in keeping with the CPT prefatory language for CPT codes 99453 and 99454, when the PHE for the COVID–19 pandemic ends, we will once again require that 16 days of data be collected within 30 days to meet the requirements to bill CPT codes 99453 and 99454.

Finally, in response to the May 19, 2020 Executive Order 13924, ''Regulatory Relief To Support Economic Recovery,'' (85 FR 31353 through 31356), we are seeking comment from the medical community and other members of the public on whether the current RPM coding accurately and adequately describes the full range of clinical scenarios where RPM services may be of benefit to patients. For example, CPT codes 99453 and 99454 currently require use of a medical device (as defined by the FDA) that digitally collects and transmits 16 or more days of data every 30 days in order for the codes to be billed. However, some patients may not require remote monitoring for 16 or more days in a 30-day period. For some patients, continuous short-term monitoring might be more appropriate. For example, a post-surgical patient who is recovering at home might benefit from remote monitoring of his or her body temperature as a means of assessing infection and managing medications or dosage. In some situations, monitoring several times throughout a day, over a period of 10 days, may be reasonable and necessary. Sixteen or more days might be unnecessary. We are asking for information that would help us to understand whether it would be beneficial to consider establishing

coding and payment rules that would allow practitioners to bill and be paid for RPM services with shorter monitoring periods. Specifically, we are interested in understanding whether one or more codes that describe a shorter duration, for example, 8 or more days of remote monitoring within 30 days, might be useful. We welcome comments including any additional information that the medical community and other members of the public believe may provide further clarification on how RPM services are used in clinical practice, and how they might be coded, billed and valued under the Medicare PFS.

3. Transitional Care Management (TCM)

Payment for TCM CPT codes 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 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*) was finalized in the CY 2013 PFS final rule (77 FR 68979 through 68993). At that time, we identified a list of 57 HCPCS codes (see 77 FR 68990 for the original guidance) that we stated could not be billed concurrently with TCM services because of potential duplication of services.

For CY 2020, recognizing that use of TCM services was low when compared to the number of Medicare beneficiaries with eligible discharges and that increased utilization of medically necessary TCM services could improve patient outcomes, one of our proposals included modifying our prior rule that prohibited the billing of TCM services with many other services that we had viewed as duplicative (77 FR 68990). In the CY 2020 PFS final rule (84 FR 40549 through 40550), we finalized a policy to allow concurrent billing of TCM services, when reasonable and necessary, with 16 actively priced (that is, not bundled or non-covered) codes during the 30-day period covered by TCM services. We stated at the time that we would continue to refine our billing policies for TCM through future notice and comment rulemaking.

We are proposing now for CY 2021 to remove 14 additional actively priced (not bundled or non-covered) HCPCS codes from the list of remaining HCPCS codes that cannot be billed concurrently with TCM. We believe that no overlap exists that would warrant preventing concurrent reporting between TCM and the services of these 14 codes. We are also proposing to allow the new Chronic Care Management code HCPCS code G2058 to be billed concurrently with TCM when reasonable and necessary. We note that the minutes counted for TCM services cannot also be counted towards other services. See Table 14 for the list of 15 codes that we are proposing could be billed concurrently with TCM services when reasonable and necessary. We welcome comment on our proposal to allow these additional services to billed concurrently with the TCM service.

TABLE 14: 15 Additional Codes That Could Be Billed Concurrently with TCM

Code Family	CPT Code	Descriptor
End Stage Renal Disease Services (for ages less than 2 months through 20+ years)	90951	ESRD related services with 4 or more face-to-face visits per month; for patients <2 months of age
	90954	ESRD related services with 4 or more face-to-face visits per month; for patients 2-11 years
	90955	ESRD related services with 2-3 face-to-face visits per month; for patients 2-11 years
	90956	ESRD related services with 1 face-to-face visit per month; for patients 2-11 years
	90957	ESRD related services with 4 or more face-to-face visits per month; for patients 12-19 years
	90958	ESRD related services with 2-3 face-to-face visits per month; for patients 12-19 years
	90959	ESRD related services with 1 face-to-face visit per month; for patients 12-19 years
	90963	ESRD related services for home dialysis per full month; for patients <2 years of age
	90964	ESRD related services for home dialysis per full month; for patients 2-11 years
	90965	ESRD related services for home dialysis per full month; for patients 12-19 years
	90966	ESRD related services for home dialysis per full month; for patients 20 years and older
	90967	ESRD related services for dialysis less than a full month of service; per day; for patients <2 years of age
	90968	ESRD related services for dialysis less than a full month of service; per day; for patients 2-11 years
	90969	ESRD related services for dialysis less than a full month of service; per day; for patients 12-19 years
Complex Chronic Care Management Services	G2058	Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month

4. Psychiatric Collaborative Care Model (CoCM) Services (HCPCS Code GCOL1)

In the CY 2017 PFS final rule (81 FR 80230), we established G-codes used to bill for monthly services furnished using the Psychiatric Collaborative Care Model (CoCM), an evidence-based approach to behavioral health integration that enhances ''usual'' primary care by adding care management support and regular psychiatric inter-specialty consultation. These G-codes were replaced by CPT codes 99492–99494, which we established for payment under the PFS in the CY 2018 PFS final rule (82 FR 53077).

Stakeholders have requested additional coding to capture shorter increments of time spent, for example, when a patient is seen for services, but is then hospitalized or referred for specialized care, and the number of minutes required to bill for services using the current coding is not met. To accurately account for these resources costs, we are proposing to establish a G-code to describe 30 minutes of behavioral health care manager time. Since this code would describe one half of the time described by the existing code that describes subsequent months of CoCM services, we are proposing to price this code based on one half the work and direct PE inputs for 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 practitioners;
- 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.

Therefore, the proposed work RVU for the new proposed code is 0.77. We are proposing that this code could be used for either the initial month or subsequent months. We note that the existing CPT time rules for the CoCM services would apply. The proposed code is:

- GCOL1: Initial or subsequent psychiatric collaborative care management, first 30 minutes in a 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.

We are proposing that the required elements listed for CPT code 99493 would also be required elements for billing HCPCS cod GCOL1. Additionally, we propose that CPT time rules would apply, consistent with the guidance in the CPT codebook for CPT codes 99492–99494.

In the CY 2017 PFS final rule (81 FR 80235), we finalized that CCM and BHI services could be billed during the same month for the same beneficiary if all the requirements to bill each service are separately met. We are also proposing that HCPCS code GCOL1 could be billed during the same month as CCM and TCM services, provided that all requirements to report each service are met and time and effort are not counted more than once. We note that the patient consent requirement would apply to each service independently.

In the CY 2017 PFS final rule (81 FR 80235), we finalized that the psychiatric CoCM services may be furnished under general supervision because we do not believe it is clinically necessary that the professionals on the team who provide services other than the treating practitioner (namely, the behavioral health care manager and the psychiatric consultant) must have the billing practitioner immediately available to them at all times, as would be required under a higher level of supervision. Therefore, consistent with the other codes in this code family (CPT codes 99492–99494), we propose to add HCPCS code GCOL1 to the list of designated care management services for which we allow general supervision.

We welcome comments on the proposal to create this new code, as well as the proposed valuation.

F. Refinements to Values for Certain Services To Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability During the COVID–19 Pandemic

1. Background

a. Evaluation and Management (E/M) Visits Overview

Physicians and other practitioners who are paid under the PFS bill for common office visits for evaluation and management (E/M) visits using 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 historically have included three key components within their code descriptors: History of present illness (history), physical examination (exam), and medical decision-making (MDM).[2]

Currently, there are five levels of office/outpatient E/M visits. There are five codes representing each level for new patients (CPT codes 99201 through 99205), and five codes representing each level for established patients (CPT codes 99211 through 99215). CPT code 99211 (Level 1 established patient) is the only code in the office/outpatient E/M visit code set that describes a visit that may be performed by the billing practitioner or by clinical staff under supervision, and that has no specified history, exam or MDM (see Table 15).

In total, E/M visits billed using these CPT codes comprise approximately 40 percent of allowed charges for PFS services; and office/outpatient E/M visits, in particular, comprise approximately 20 percent of allowed charges for PFS services. Within the E/M visits 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 charges for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests. Generally, these practitioners include primary care practitioners and certain other 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,

[2] 2019 CPT Codebook, Evaluation and Management, pages 6 through 13.

tend to bill more E/M visits on the same day as they bill minor procedures.

b. Overview of Policies Finalized in CY 2020 for CY 2021

In the CY 2020 PFS final rule (84 FR 62844 through 62860), for the office/outpatient E/M visit code set (CPT codes 99201 through 99215), we finalized a policy to generally adopt the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA's CPT Editorial Panel (see *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management*) and will be effective January 1, 2021. Under this new CPT coding framework, history and exam will no longer be used to select the level of code for office/outpatient E/M visits. Instead, an office/outpatient E/M visit will 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 will no longer apply, and the history and exam components will only be performed when, and to the extent, reasonable and necessary, and clinically appropriate.

As indicated in Table 15, the changes will include deletion of CPT code 99201 (*Level 1 office/outpatient visit, new patient*), which the CPT Editorial Panel decided to eliminate because CPT codes 99201 and 99202 are both straightforward MDM and currently largely differentiated by history and exam elements. Table 15 provides an overview of how the level 1 and level 2 office/outpatient E/M visits are currently structured, demonstrating this current overlap.

TABLE 15: Overview of Levels 1 and 2 Office/Outpatient E/M Visits, CY 2020

CPT Code	Service Overview
CPT code 99201 (level 1 new patient)	• Problem-focused history and exam • Straightforward medical decision-making • Typically 10 minutes face-to-face, presenting problem(s) usually self-limited or minor
CPT code 99202 (level 2 new patient)	• Expanded problem-focused history and exam • Straightforward medical decision-making • Typically 20 minutes face-to-face, presenting problem(s) usually of low to moderate severity
CPT code 99211 (level 1 established patient)	• Evaluation and management that may not require the presence of a physician or other qualified healthcare professional • Typically 5 minutes are spent performing or supervising these services, presenting problem(s) usually minimal
CPT code 99212 (level 2 established patient)	• Problem-focused history and exam • Straightforward medical decision-making • Typically 10 minutes face-to-face, presenting problem(s) usually self-limited or minor

For levels 2 through 5 office/outpatient E/M visits, selection of the code level to report will be based on either the level of MDM (as redefined in the new AMA/CPT guidance framework, also available on the AMA website at *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management* 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). We continue to believe these policies will further our ongoing effort to reduce administrative burden, improve payment accuracy, and update the office/outpatient E/M visit code set to better reflect the current practice of medicine.

Regarding prolonged visits, we finalized separate payment for a new prolonged visit add-on CPT code (CPT code 99XXX), and discontinued the use of CPT codes 99358 and 99359 (*prolonged E/M visit without direct patient contact*) to report prolonged time associated with office/outpatient E/M visits. We refer readers to the CY 2020 PFS final rule for a detailed discussion of this policy (84 FR 62849 through 62850).

Also we finalized separate payment for HCPCS code GPC1X, to provide payment for 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.

The AMA RUC resurveyed and revalued the revised office/outpatient E/M visit code set, concurrent with the CPT Editorial Panel redefining the services and associated interpretive guidance, and provided us with its recommendations. In the CY 2020 PFS final rule, we also addressed and responded to the AMA RUC recommendations. We finalized new values for CPT codes 99202 through 99215, and assigned RVUs to the new office/outpatient E/M prolonged visit CPT code 99XXX, as well as the new HCPCS code GPC1X. These valuations were finalized with an effective date of January 1, 2021. In Table 16, we provide a summary of the codes and work RVUs finalized in the CY 2020 PFS final rule for CY 2021.

TABLE 16: Summary of Codes and Work RVUs Finalized in the CY 2020 PFS Final Rule for CY 2021

HCPCS Code	Current Total Time (mins)	Current Work RVU	CY 2021 Total Time (mins)	CY 2021 Work RVU
99201	17	0.48	N/A	N/A
99202	22	0.93	22	0.93
99203	29	1.42	40	1.6
99204	45	2.43	60	2.6
99205	67	3.17	85	3.5
99211	7	0.18	7	0.18
99212	16	0.48	18	0.7
99213	23	0.97	30	1.3
99214	40	1.5	49	1.92
99215	55	2.11	70	2.8
99XXX	N/A	N/A	15	0.61
GPC1X	N/A	N/A	11	0.33

c. Continuing Stakeholder Feedback

Since issuing the CY 2020 PFS final rule, we have continued to engage with the stakeholder community on the issues addressed in this section of our proposed rule. In the CY 2020 PFS final rule (84 FR 62859 through 62860), we discussed public comments we received in response to our request for comment about whether it would be appropriate to revalue certain services, other than the global surgical codes which we addressed separately, for which the values are closely tied to the values of the office/outpatient E/M visit codes in order to improve payment accuracy and maintain relativity within the PFS. We responded that we would consider the commenters' recommendations for future rulemaking. Since publication of the CY 2020 PFS final rule, we have received additional feedback from stakeholders, in the form of written requests and in-person meetings, indicating that certain other services on which we did not seek comment in the CY 2020 PFS proposed rule, but which are similar to the office/outpatient E/M visits, have values that were established relative to values for the office/outpatient E/M visits or contain office/outpatient E/M visits as constituent parts of the bundled services included in the code for the service. We address many of these requests in the following section, and are seeking comment on whether there are additional, similarly situated services for which we should consider similar adjustment or revaluation through future rulemaking. We have also received questions about the definition and utilization assumptions for the HCPCS add on code GPC1X.

2. Proposals for CY 2021

a. Time Values for Levels 2–5 Office/Outpatient E/M Visit Codes

In the CY 2020 PFS proposed rule (84 FR 62568), we sought comment on the times associated with the office/outpatient E/M visits as recommended by the AMA RUC. When surveying these services for purposes of valuation, the AMA RUC requested that survey respondents consider the total time spent on the day of the visit, as well as any pre- and post-service time occurring within a timeframe of 3 days prior to the visit and 7 days after, respectively. In developing its recommendations to us, the AMA 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 approach used by the AMA RUC to develop recommendations sometimes resulted in two conflicting sets of times: The component times as surveyed and the total time as surveyed. In the CY 2020 PFS final rule, we finalized adoption of the RUC-recommended times as explained below, but stated that we would continue to consider whether this issue has implications for the PFS broadly. When we establish pre-, intra-, and post-service times for a service under the PFS, these times always sum to the total time. We believe it would be illogical for component times not to sum to the total, and this idea is reflected in our ratesetting system which requires component times to sum to the total time. Commenters on the CY 2020 PFS proposed rule (84 FR 62849) stated that we should adopt the times as recommended by the RUC, and did not provide any additional details on the times they believed we should use when the total time is not the sum of the component times. Table 17 illustrates the AMA RUC surveyed times for each service period and the surveyed total time. It also shows the actual total time calculated as the sum of the component times.

TABLE 17: 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

Given the lack of clarity provided by commenters on the CY 2020 PFS proposed rule about why the sum of minutes in the components would differ from the total minutes, and our view and systems requirement that total time must equal the mathematical total of component times, we are proposing beginning for CY 2021 to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215.

b. Revaluing Services That Are Analogous to Office/Outpatient E/M Visits

In the CY 2020 PFS proposed rule, we recognized that 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. We specifically identified transitional care management (TCM) services (CPT codes 99495, 99496); cognitive impairment assessment and care planning (CPT code 99483); certain end-stage renal disease (ESRD) services (CPT codes 90951 through 90970); and the annual wellness visit (AWV) and initial preventive physical exam (IPPE) (HCPCS codes G0402, G0438, G0439). Many of these services were valued via a building block methodology and have office/outpatient E/M visits explicitly built into their definition or valuation. We stated that we may consider adjusting the RVUs for these services in future rulemaking, and we sought public input on such a policy. We noted that, unlike the global surgical codes, some of these services always include an office/outpatient E/M visit(s) furnished by the reporting practitioner as part of the service, and therefore, it may be appropriate to adjust their valuations commensurate with any changes made to the values for office/outpatient E/M visits. Some of these services do not actually include an E/M visit, but 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. Overall, we believe that the magnitude of the changes to the values of the office/outpatient E/M visit codes and the associated redefinitions of the codes themselves are significant enough to warrant an assessment of the accuracy of the values of services containing, or closely analogous to, office/outpatient E/M visits. These proposals take into account input from the public and our own internal review.

We received public comments in support of revaluing certain services relative to the new office/outpatient E/M visit values. There was particular support for revaluing the ESRD monthly capitation payment (MCP) services, TCM services, cognitive impairment assessment and care planning services, and the emergency department (ED) visits. Based on input provided since publication of the CY 2020 PFS final rule by the American College of Obstetricians and Gynecologists (ACOG), we have also considered the maternity surgical packages which, unlike other global surgery services, were valued using a methodology, described in more detail below, that allowed the valuation of the composite parts of the package to sum to the total value. Additionally, unlike the 10- and 90-day global surgical services codes (referred to in this section as 10- and 90-day globals), we have never expressed concerns as to the accuracy of the values of the maternity packages, and these services were not part of the policy we adopted to transition all 10- and 90-day globals to 0-day globals (79 FR 67591), though that policy was overridden by statutory amendments before it took effect.

(1) End-Stage Renal Disease Monthly Capitation Payment Services

In the CY 2004 PFS final rule with comment period (68 FR 63216), we established new Level II HCPCS G codes for ESRD services and established MCP rates for them as specified under section 1881(b)(3)(A)(ii) of the Act. For ESRD center-based patients, payment for the G codes varied based on the age of the beneficiary and the number of face-to-face visits furnished each month (for example, 1 visit, 2–3 visits and 4 or more visits). We believed that many physicians would provide 4 or more visits to center-based ESRD patients, and a small proportion would provide 2–3 visits or only one visit per month. Under the MCP methodology, to receive the highest payment, a physician would have to furnish at least 4 ESRD-related visits per month. In contrast, payment for home dialysis MCP services only varied by the age of beneficiary. Although we did not initially specify a frequency of required visits for home dialysis MCP services, we stated that we expect physicians to provide clinically appropriate care to manage the home dialysis patient.

The CPT Editorial Panel created new CPT codes to replace the G codes for monthly ESRD-related services, and we finalized the new codes for use under the PFS in CY 2009 (73 FR 69898). The codes created were CPT codes 90951 through 90962 for monthly ESRD-related services with a specified number of visits; CPT codes 90963 through 90966 for monthly ESRD-related services for home dialysis patients; and CPT codes 90967 through 90970 for home dialysis patients with less than a full month of services. The latter set of codes are billed per encounter and valued to be 1/30 of the value of CPT codes 90965 and 90966.

In response to our comment solicitation in the CY 2020 PFS final rule and interim final rule regarding

whether to adjust the values of the ESRD MCP codes to reflect the increased values of the office/outpatient E/M visit codes, we received a number of supportive comments, particularly from specialty societies representing nephrologists. These commenters pointed out that the MCP bundled payments for all ESRD-related care for a month were constructed using a building block methodology and a number of office/outpatient E/M visits were component parts of those bundles; and that the specified number of visits in the code descriptor must be furnished in order to bill for the service. Commenters also noted that although the values of office/outpatient E/M visit codes have been increased once since the creation of the MCP G codes and once after adoption of the MCP CPT codes, the valuation of the ESRD MCP codes was never adjusted to account for increases to the office/outpatient E/M visit codes. In Table 18, we provide a summary of the visits bundled into each ESRD MCP service.

TABLE 18: Number and Level of Office/Outpatient E/M Visits Bundled into the ESRD MCP Services

HCPCS	Short Descriptor	Bundled Office/Outpatient visit(s)
90951	Esrd serv 4 visits p mo <2yr	13x 99214
90954	Esrd serv 4 vsts p mo 2-11	Crosswalked to CPT code 99471
90955	Esrd srv 2-3 vsts p mo 2-11	1x 99215
		2x 99214
90956	Esrd srv 1 visit p mo 2-11	1x 99215
90957	Esrd srv 4 vsts p mo 12-19	1x 99215
		3x 99214
		3x 99213
90958	Esrd srv 2-3 vsts p mo 12-19	1x 99215
		2x 99214
90959	Esrd serv 1 vst p mo 12-19	1x 99215
90960	Esrd srv 4 visits p mo 20+	1x 99213
		3x 99214
90961	Esrd srv 2-3 vsts p mo 20+	3x 99214
90962	Esrd serv 1 visit p mo 20+	1x 99214
90963	Esrd home pt serv p mo <2yrs	1x 99215
		2x 99214
90964	Esrd home pt serv p mo 2-11	1x 99215
		1x 99214
90965	Esrd home pt serv p mo 12-19	1x 99215
		1x 99214
90966	Esrd home pt serv p mo 20+	3x 99214
90968	Esrd svc pr day pt 2-11	RVU of 90964/30
90969	Esrd svc pr day pt 12-19	RVU of 90965/30
90970	Esrd svc pr day pt 20+	RVU of 90966/30

In the past, we have not updated the valuation of this code set to reflect updates to the valuation of the office/outpatient E/M visit code set and so over time, the values of the ESRD MCP codes have become out of step with valuation of their constituent visits. We believe there is sufficient reason to revalue these services to take into account the changes in valuation for the office/outpatient E/M visits. These services were initially valued using a building block methodology which summed the value of the individual service from its components, and for some of the codes in this code set, a specified number of visits must be furnished in order to bill for the respective ESRD MCP code because they are included in the code descriptor.

Therefore, we believe that the ESRD MCP codes should be updated to more accurately account for the associated office/outpatient E/M visits. We are proposing to increase the work, physician time, and PE inputs in the form of clinical staff time of the ESRD MCP codes based on the marginal difference between the 2020 and 2021 office/outpatient E/M visit work, physician time, and PE inputs built into each code, as summarized in Tables 19 and 20. By improving payment accuracy for the ESRD MCP codes, we would also be supporting broader efforts at advancing kidney health.[3] We believe the majority of the visits included in the ESRD MCP bundles are being furnished, but are seeking comment on whether there are instances where the number and level of visits being furnished are not consistent with the number and level of visits built into the valuation of the code.

[3] HHS Launches President Trump's 'Advancing American Kidney Health' Initiative: *https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html.*

3. TCM Services (CPT Codes 99495 and 99496)

The goal of TCM services is to improve the health outcomes of patients recently discharged from inpatient and certain outpatient facility stays. We began making separate payment for TCM services in CY 2013. At that time, CPT code 99495 (*Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic)*

with the patient and/or caregiver with 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) was valued to include one, level 4 established patient office/outpatient visit, while CPT code 99496 (*Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver with 2 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*) was valued to include one, level 5 established patient office/outpatient visit (77 FR 68991). In the CY 2020 PFS final rule (84 FR 62687), we finalized the RUC-recommended work and direct PE inputs for the TCM codes which resulted in small RVU increases for both codes.

Because both TCM codes include a required face-to-face E/M visit (either a level 4 or 5 office/outpatient E/M visit), we are proposing to increase the work RVUs associated with the TCM codes commensurate with the new valuations for the level 4 (CPT code 99214) and level 5 (CPT code 99215) office/outpatient E/M visits for established patients. Please see Tables 19 and 20 for long descriptors, as well as current and proposed work RVUs, physician time, and clinical staff time, for the TCM codes.

4. Maternity Services

In the CY 2002 PFS final rule with comment period (66 FR 55393), we finalized separate payment for maternity care services. The maternity packages are unlike other services for which payment is made under the PFS in that they are the only global codes that provide a single payment for almost 12 months of services, including visits, surgical services, and imaging (among other services); and were valued using a building-block methodology as opposed to the magnitude estimation method that is commonly used to value the 10- and 90-day global services. There are 17 CPT codes that are used for billing delivery, antepartum, and postpartum maternity care services, and these codes are all designated with a unique global period indicator ''MMM.''

For CY 2021, the AMA RUC made a recommendation to revalue these services, along with their recommendations to revalue the 10- and 90-day global surgical packages, to account for increases in the values of office/outpatient E/M visits. In the CY 2020 PFS final rule, we decided not to make changes to the valuation of 10- and 90-day global surgical packages to reflect changes made to values for the office/outpatient E/M visit codes while we continue to collect and analyze the data on the number and level of office/outpatient E/M visits that are actually being performed as part of these services.

The 10- and 90-day global surgical packages are commonly valued using a methodology known as magnitude estimation. Magnitude estimation refers to a methodology for valuing work that identifies 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. Since its inception, the AMA RUC has worked under the prevailing assumption that magnitude estimation is the standard for valuation of all physicians' services, including those with global surgical packages. Consequently, the work values associated with expected typical E/M visits within a code's global period are not necessarily added to the physician work value for the code to determine the final work RVU. The postoperative visits in the 10- or 90-day global surgical code periods are often valued with reference to RVUs for separately-billed E/M visits, but the bundled post-operative visit RVUs do not directly contribute a certain number of RVUs to the valuation of the procedures. However, the MMM codes are unique in both the length of the global period and the methodology under which they were valued. When CMS established values for the maternity packages, we based them on RUC recommendations developed by the relevant specialty societies using the building block methodology. When it is used for a CPT code representing a bundle of services, the building block methodology components are the CPT codes that make up the bundled code and the inputs associated with those codes. Therefore, when the maternity packages were valued, the work (and other inputs) associated with the office/outpatient E/M visits in each package were explicitly accounted for.

In addition, unlike the global surgical codes, we have reason to believe the visits included in the maternity codes are actually furnished given the evidence-based standards and professional guidelines for obstetrical care. For example, The *Guidelines for Perinatal Care* state that ''a woman with an uncomplicated first pregnancy is examined every 4 weeks for the first 28 weeks of gestation, every 2 weeks until 36 weeks of gestation, and weekly thereafter.'' [4] For this reason, we excluded the maternity codes from our recent global surgery data collection.

Given the valuation methodology and expectations for office/outpatient E/M visits in the maternity package codes, and the revaluation recommendation developed by the AMA RUC, we believe that the maternity packages should be updated to more accurately reflect the values of the office/outpatient E/M visits included in the packages. We believe that, due to the use of the building block valuation methodology rather than magnitude estimation, and the likelihood that the bundled visits are actually being furnished, the valuations recommended to us by the AMA RUC more accurately reflect the resource costs associated with furnishing these services. In the past, the work, physician time, and PE for these services have not been revalued to reflect changes to the office/outpatient E/M visits that are included as part of the package and therefore, the valuation of the MMM surgical packages have become misaligned with the valuation of their constituent office visits.

When revaluing the maternity packages, the AMA RUC used a methodology similar to what we used when revaluing the ESRD MCP codes and TCM by adding in the marginal differences in work, physician time, and practice expense (PE) in the form of clinical staff time between the current and 2021 E/M values. We believe that this method accurately accounts for the increase in valuation relative to the office/outpatient E/M visits, and therefore, we are proposing to increase the work RVUs, physician time, and PE inputs in the form of clinical staff time associated with the maternity packages by accepting the revaluation recommendation from the AMA RUC as detailed in Tables 19 and 20.

We would also note that, in addition to appropriately reflecting changes to values of the office and outpatient E/M visits, increases made to the valuation of the maternity package codes would be consistent with our broader focus on improving maternal health and birth outcomes. The proposed changes would account for additional resources involved with additional work that is needed on the part of practitioners to improve care for this patient population, such as risk identification and ensuring appropriate interventions and referrals.[5]

[4] Kilpatrick SJ, Papile L, and Macones GA, eds. AAP Committee on Fetus and Newborn and ACOG Committee on Obstetric Practice. Guidelines for Perinatal Care. Eighth Edition. 2017. Page 150.

[5] *https://www.hhs.gov/blog/2020/01/29/achieving-better-health-mothers-and-babies.html; https://www.cms.gov/About-CMS/Agency-*

5. Assessment and Care Planning for Patients With Cognitive Impairment (CPT Code 99483)

In CY 2017, we established payment for HCPCS code G0505 (*Assessment and care planning for patients with cognitive impairment*) to provide payment for cognitive impairment assessment and care planning, believing that the CPT Editorial Panel was developing new coding for that service. In response to the CY 2017 PFS proposed rule, the AMA RUC submitted recommended values for this code, which we adopted in the CY 2017 PFS final rule. In CY 2018, the CPT Editorial Panel created CPT code 99483 for reporting of this service and in CY 2018, CMS adopted CPT code 99483 (deleting HCPCS code G0505) without changing the service valuation. Based on input from commenters and the AMA RUC, the valuation of this service reflected the complexity involved in assessment and care planning for patients with cognitive impairment by including resource costs that are greater than the highest valued office/outpatient E/M visit (CPT code 99205, new patient level 5 visit) (81 FR 80352). Specifically, the service includes a cognition-focused evaluation including a pertinent history and examination, and medical decision making of moderate or high complexity, in addition to many functional and other assessments specific to cognitive status. With the revaluation we finalized in the CY 2020 PFS final rule for CPT code 99205 effective beginning in CY 2021, the current work RVU for CPT code 99483 would have a lower work RVU than a new patient level 5 office/outpatient E/M visit, which would create a rank order anomaly between the two codes that, given the way the code was valued, we do not believe would be appropriate. Rather, because CPT code 99483 was valued in relation to a level 5 office/outpatient E/M visit, we believe that an adjustment to the work, physician time, and PE for this service to reflect the marginal difference between the value of the level 5 new patient office/outpatient E/M visit in CY 2020 and CY 2021 would be appropriate to maintain payment accuracy. Therefore, we are proposing to adjust the work, time, and PE in the form of clinical staff time for CPT code 99483 as shown in Tables 19 and 20.

6. Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness (AWV) Visits

In the CY 2011 PFS final rule with comment period, we finalized separate payment for HCPCS codes G0438 (*Annual wellness visit; includes a personalized prevention plan of service (pps), initial visit*) and G0439 (*Annual wellness visit, includes a personalized prevention plan of service (pps), subsequent visit*). These services were valued via a direct crosswalk to the work, time, and direct PE inputs associated with CPT codes 99204 and 99214, respectively. In that same rule, we stated that the HCPCS code G0402 (*Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment)* was also valued based on a direct crosswalk to the work, time, and direct PE inputs for CPT code 99204 (75 FR 73408–73411).

Because these codes are valued using direct crosswalks to office/outpatient E/M visits, and based on the principles articulated above, we believe that to maintain payment accuracy for the IPPE and the AWV, their values should be adjusted to reflect the changes in value for CPT codes 99204 and 99214. Therefore, we are proposing to revise the work, physician time, and direct PE inputs for these codes as shown in Tables 19 and 20.

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Information/OMH/equity-initiatives/rural-health/21-Maternal-Health-Forum-Improving-Maternal-Health-for-Our-Communities.pdf; https://innovation.cms.gov/innovation-models/maternal-opioid-misuse-model.

TABLE 19: CY 2020 Work RVUs and CY 2021 Proposed Work RVUs

HCPCS Code	Long Descriptor	CY 2020 Work RVUs	Proposed CY 2021 Work RVUs
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care	32.16	36.58
59410	Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care	18.01	18.34
59425	Antepartum care only; 4-6 visits	6.31	7.80
59426	Antepartum care only; 7 or more visits	11.16	14.3
59430	Postpartum care only (separate procedure)	2.47	3.22
59510	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care	35.64	40.39
59515	Cesarean delivery only; including postpartum care	21.47	22.13
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery	33.87	38.29
59614	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care	19.73	20.06
59618	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery	36.16	40.91
59622	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care	22.00	22.66
90951	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	18.46	23.92
90954	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	15.98	21.44
90955	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	8.79	10.32
90956	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	5.95	6.64
90957	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	12.52	15.46
90958	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified	8.34	9.87

HCPCS Code	Long Descriptor	CY 2020 Work RVUs	Proposed CY 2021 Work RVUs
	health care professional per month		
90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	5.50	6.19
90960	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	5.18	6.77
90961	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	4.26	5.52
90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month	3.15	3.57
90963	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	10.56	12.09
90964	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	9.14	10.25
90965	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	8.69	9.80
90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older	4.26	8.04
90968	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age	0.30	0.34
90969	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age	0.29	0.33
90970	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older	0.14	0.27
99483	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (eg, basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for staging of dementia (eg, functional assessment staging test [FAST], clinical dementia rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (eg, home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or	3.44	3.80

HCPCS Code	Long Descriptor	CY 2020 Work RVUs	Proposed CY 2021 Work RVUs
	revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (eg, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.		
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.	1.70	1.88
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.	1.53	2.05
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	2.36	
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	3.10	3.74

HCPCS Code	Long Descriptor	CY 2020 Work RVUs	Proposed CY 2021 Work RVUs
	period; face-to-face visit within 7 calendar days of discharge		
G0402	Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment	2.43	2.60
G0438	Annual wellness visit; includes a personalized prevention plan of service (pps), initial visit	2.43	2.60
G0439	Annual wellness visit, includes a personalized prevention plan of service (pps), subsequent visit	1.50	1.92

TABLE 20: Comparison of Physician Time, and Clinical Staff Time (Non-facility and Facility) for HCPCS Codes, CY 2020 Final Values vs. CY 2021 Proposed Values

HCPCS	Phys. Time (Minutes) – CY 2020 Final	Phys. Time (Minutes) – CY 2021 Proposed	NF Clinical Staff Time (Minutes) - CY2020 Final	NF Clinical Staff Time (Minutes) – CY 2021 Proposed	Fac. Clinical Staff Time (Minutes) – CY 2020 Final	Fac. Clinical Staff Time (Minutes) – CY 2021 Proposed
59400	739.5	753.5	N/A	N/A	551.0	551.0
59410	398.5	327.5	N/A	N/A	42.0	42.0
59425	137.0	180.0	206.0	198.0	-	-
59426	252.0	330.0	386.0	378.0	-	-
59430	63.0	77.0	89.0	87.0	-	-
59510	817.5	818.5	N/A	N/A	587.0	587.0
59515	476.5	392.5	N/A	N/A	78.0	78.0
59610	739.5	753.5	N/A	N/A	551.0	551.0
59614	398.5	327.5	N/A	N/A	42.0	42.0
59618	792.5	793.5	N/A	N/A	587.0	587.0
59622	451.5	367.5	N/A	N/A	78.0	78.0
90791	90.0	90.0	-	-	-	-
90792	90.0	90.0	-	-	-	-
90832	45.0	45.0	-	-	-	-
90834	60.0	60.0	-	-	-	-
90837	75.0	75.0	-	-	-	-
90951	274.0	365.0	60.0	34.0	60.0	60.0
90954	240.0	240.0	60.0	-	60.0	60.0
90955	198.0	227.0	60.0	55.0	60.0	60.0
90956	148.0	163.0	60.0	59.0	60.0	60.0
90957	253.0	310.0	60.0	53.0	60.0	60.0
90958	183.0	212.0	60.0	55.0	60.0	60.0
90959	133.0	148.0	60.0	59.0	60.0	60.0
90960	128.0	156.0	60.0	54.0	60.0	60.0
90961	113.0	134.0	60.0	54.0	60.0	60.0
90962	63.0	70.0	60.0	58.0	60.0	60.0
90963	258.0	287.0	60.0	55.0	60.0	60.0
90964	233.0	255.0	60.0	57.0	60.0	60.0
90965	218.0	240.0	60.0	57.0	60.0	60.0
90966	75.0	96.0	60.0	54.0	60.0	60.0
90968	7.8	8.5	2.0	1.9	2.0	2.0
90969	7.3	8.0	2.0	1.9	2.0	2.0
90970	2.5	3.2	2.0	1.8	2.0	2.0
92521	110.0	110.0	-	-	N/A	N/A
92522	85.0	85.0	-	-	N/A	N/A
92523	157.0	157.0	-	-	N/A	N/A
92524	75.0	75.0	-	-	N/A	N/A
97161	55.0	55.0	41.0	41.0	N/A	N/A
97162	55.0	55.0	41.0	41.0	N/A	N/A
97163	55.0	55.0	41.0	41.0	N/A	N/A
97164	35.0	35.0	34.0	34.0	N/A	N/A
97165	65.0	65.0	32.0	32.0	N/A	N/A
97166	65.0	65.0	32.0	32.0	N/A	N/A
97167	65.0	65.0	32.0	32.0	N/A	N/A
97168	45.0	45.0	26.0	26.0	N/A	N/A

HCPCS	Phys. Time (Minutes) – CY 2020 Final	Phys. Time (Minutes) – CY 2021 Proposed	NF Clinical Staff Time (Minutes) - CY2020 Final	NF Clinical Staff Time (Minutes) – CY 2021 Proposed	Fac. Clinical Staff Time (Minutes) – CY 2020 Final	Fac. Clinical Staff Time (Minutes) – CY 2021 Proposed
99201	17.0	N/A	26.0	N/A	-	-
99202	22.0	20.0	39.0	34.0	-	-
99203	29.0	35.0	51.0	43.0	-	-
99204	45.0	60.0	62.0	54.0	-	-
99205	67.0	88.0	71.0	67.0	-	-
99211	7.0	7.0	19.0	17.0	-	-
99212	16.0	16.0	28.0	28.0	-	-
99213	23.0	30.0	36.0	36.0	-	-
99214	40.0	47.0	53.0	51.0	-	-
99215	55.0	70.0	63.0	62.0	-	-
99283	30.0	30.0	N/A	N/A	-	-
99284	40.0	40.0	N/A	N/A	-	-
99285	55.0	55.0	N/A	N/A	-	-
99483	85.0	85.0	92.0	92.0	-	-
99492	40.0	40.0	85.0	85.0	-	-
99493	36.0	36.0	60.0	60.0	-	-
99495	47.0	54.0	107.0	105.0	-	-
99496	60.0	75.0	145.0	144.0	-	-
G0402	0.2	45.0	62.0	54.0	-	-
G0438	0.2	45.0	62.0	54.0	-	-
G0439	0.4	1.9	40.0	0.4	51.0	40.0

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7. Emergency Department Visits

The ED visit codes have been revalued under the PFS three times- in 1997, 2007, and most recently in 2018 as part of the misvalued code initiative for CY 2020 rulemaking. Each subsequent revaluation was done in part to maintain relativity with the office/outpatient E/M visit codes. Specifically, when these services were revalued in prior rulemaking, the principle was that levels 1 through 3 of the ED visits should have the same value as the level 1 through 3 new patient office/outpatient E/M visits and that the levels 4 and 5 ED visits should be valued higher than the levels 4 and 5 new patient office/outpatient E/M visits to reflect higher typical intensity in the ED setting. In the CY 2018 PFS final rule, we finalized a proposal to nominate the level 1 through level 5 ED visit codes (CPT codes 99281–99285, see Table 21 for long descriptors) as potentially misvalued based on information suggesting that the work RVUs for ED visits may not appropriately reflect the full resources involved in furnishing these services. Specifically, stakeholders expressed concerns that the work RVUs for these services have been undervalued given the increased acuity of the patient population and the heterogeneity of the sites, such as freestanding and off-campus EDs, where ED visits are furnished (82 FR 53018). The AMA RUC surveyed and reviewed five of these codes for the April 2018 RUC meeting and provided a recommendation to CMS for consideration in CY 2020 rulemaking. In the CY 2020 PFS final rule, we finalized 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 did not finalize, any direct PE inputs for the codes in this family. The AMA RUC submitted these recommended values to CMS prior to the submission of the RUC-recommended revaluation of the office/outpatient E/M visit code family.

In response to our comment solicitation in CY 2020 PFS rulemaking regarding whether certain services should be revalued to maintain relativity with office/outpatient E/M visits, the American College of Emergency Physicians submitted a public comment stating that relativity between the ED visits and office/outpatient E/M visits should be maintained, and provided CMS with a specific recommendation for CPT codes 99283–99285. The association believed we should continue to preserve the same relationship between the ED and office/outpatient E/M visit code sets that was established in prior years and would have likely been maintained had the office/outpatient E/M visits been revalued prior to the ED visits. They have also submitted a subsequent letter to this effect. We agree with the society, particularly since the justification provided by the AMA RUC recommendations we accepted for the CY 2020 revaluation was, in part, to maintain relativity with the office/outpatient E/M visits, and that relativity would be disrupted if they were to remain unadjusted. The proposed values are consistent with the principle that the levels 1–3 ED visits should remain the same as the levels 1–3 new patient office visits but the levels 4–5 ED visits should have a higher value than the corresponding office visits, due to the complexity of the patients requiring that level of emergency care. Therefore, we are proposing the values recommended by ACEP as shown in Table 21.

8. Therapy Evaluations

There are a number of services paid under the PFS that are similar in many respects to the office/outpatient E/M visit code set, but do not specifically include, were not valued to include, and were not necessarily valued relative to,

office/outpatient E/M visits. These codes inherently include work associated with assessment and work associated with management, similar to the work included in the office/outpatient E/M visits, which involve time spent face-to-face assessing and treating the patient. These services include therapy evaluation services and psychiatric diagnostic evaluation services. The practitioners who furnish these services are prohibited by CMS from billing E/M services due to the limitations of their Medicare benefit categories. As such, the CPT Editorial Panel has created specific coding to describe the services furnished by these practitioners. Although these services are billed using specific, distinct codes relating to therapy evaluations and psychiatric diagnostic evaluations, we believe that a significant portion of the overall work in the codes is for assessment and management of patients, as it is for the office/outpatient E/M visit codes.

Therefore, we are proposing to adjust the work RVUs for these services based on a broad-based estimate of the overall change in the work associated with assessment and management to mirror the overall increase in the work of the office/outpatient E/M visits. We calculated this adjustment based on a volume-weighted average of the increases to the office/outpatient E/M visit work RVUs from CY 2020 to CY 2021. Details on this calculation are available as a public use file on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.* We are proposing to apply that percentage increase, which we estimate to be approximately 28 percent, to the work RVUs for the therapy evaluation and psychiatric diagnostic evaluation services codes. We believe that it is important to the relativity of the PFS to revalue these services to reflect the overall increase in value associated with spending time assessing and managing patients, as reflected in the changes to work values for the office/outpatient E/M visits, particularly in recognition of the value of the clinicians' time which is spent treating a growing number of patients with greater needs and multiple medical conditions. We recognize that this is not the methodology typically used to value services under the PFS and are seeking comment on potential alternative methodologies or specific values for these services, particularly about whether commenters believe it would be better to develop values using comparator codes from the office/outpatient E/M visit code set, and if so, why.

9. Behavioral Healthcare Services

The psychotherapy code set is divided into psychotherapy that can be furnished as a standalone service and psychotherapy furnished in conjunction with an office/outpatient E/M visit. The standalone psychotherapy services are CPT codes 90832, 90834, and 90837 (See Table 21 for long descriptors). The CPT codes describing psychotherapy furnished in conjunction with an office/outpatient E/M visit are CPT codes 90833 (*Psychotherapy, 30 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)*), 90836 (*Psychotherapy, 45 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)*) and 90838 (*Psychotherapy, 60 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)*). As the values for the office/outpatient E/M visits are increasing, there will necessarily be an increase in the overall value for psychotherapy furnished in conjunction with office/outpatient E/M visits. We believe that it is important, both in terms of supporting access to behavioral health services through appropriate payment and maintaining relativity within this code family, to increase the values for the standalone psychotherapy services to reflect changes to the value of the office/outpatient E/M visits which are most commonly furnished with the add-on psychotherapy services with equivalent times. For example, under the finalized revaluation of the office/outpatient E/M visits, the proportional work value of the standalone psychotherapy CPT code 90834 (*Psytx w pt 45 minutes*) would decrease relative to the combined work RVUs for CPT code 99214 (*Level 4 Office/outpatient visit est*) when billed with CPT code 90836 (*Psytx w pt w e/m 45 min*). The current combined 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. With the revaluation of the office/outpatient E/M visits beginning for CY 2021, the combined work RVU for CPT codes 99214 and 90836 would be 3.82 (1.90 + 1.92), while the current work RVU for 90834 would remain at 2.0, resulting in a change to relativity between these services.

To maintain the current relativity, which we believe to be appropriate based on the proportionate difference between these services, we are proposing to increase the work RVU for CPT code 90834 from 2.00 to 2.25 based on the marginal increase in work value for CPT code 99214 from CY 2020 to CY 2021. Similarly, for CPT code 90832, which describes 30 minutes of psychotherapy, we are proposing to increase its work RVU based on the increase to CPT code 99213, which is most commonly billed with the 30 minutes of psychotherapy add-on, CPT code 90833. For CPT code 90837, which describes 60 minutes of psychotherapy, we propose to increase the work RVU based on the proportional increase to CPT codes 99214 and 90838, which is the office/outpatient E/M visit code most frequently billed with the 60 minutes of psychotherapy add-on. Table 21 provides a summary of the current and proposed RVUs for these services.

TABLE 21: Current and Proposed Work RVUS for ED Visits, Therapy, and Psychotherapy Services

HCPCS Code	Long Descriptor	Current Work RVU	Proposed Work RVU
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.	1.42	1.60
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.	2.60	2.74
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	4.00
90791	Psychiatric diagnostic evaluation	3.00	3.84
90792	Psychiatric diagnostic evaluation with medical services	3.25	4.16
90832	Psychotherapy, 30 minutes with patient	1.50	1.70
90834	Psychotherapy, 45 minutes with patient	2.00	2.24
90837	Psychotherapy, 60 minutes with patient	3.00	3.31
97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97163	Physical therapy evaluation: high complexity, requiring these components: A	1.2	1.54

HCPCS Code	Long Descriptor	Current Work RVU	Proposed Work RVU
	history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.		
97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.	0.75	0.96
97165	Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1-3 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (eg, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97166	Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3-5 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97167	Occupational therapy evaluation, high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 5 or more performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification	1.2	1.54

HCPCS Code	Long Descriptor	Current Work RVU	Proposed Work RVU
	of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.		
97168	Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.	0.75	0.96
92521	Evaluation of speech fluency (eg, stuttering, cluttering)	1.75	2.24
92522	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria);	1.5	1.92
92523	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)	3	3.84
92524	Behavioral and qualitative analysis of voice and resonance	1.5	1.92

10. Ophthalmological Services

We received a request to revalue the following ophthalmological services which we are not proposing to revalue:

- CPT code 92002: *Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program; intermediate, new patient.*
- CPT code 92004: *Ophthalmological services: medical examination and evaluation with initiation of diagnostic and treatment program; comprehensive, new patient, 1 or more visits.*
- CPT code 92012: *Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient.*
- CPT code 92014: *Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits.*

We are not proposing to revalue these services because they are not sufficiently analogous or connected to the office/outpatient E/M visit codes. While these ophthalmological services have historically been valued relative to office/outpatient E/M visits, they have not been reviewed by the RUC since 2007. Two of these ophthalmological services can include more than one visit, and the number of visits included in the package is uncertain and therefore are not so closely tied to office and outpatient E/M services which describe a single visit. In addition, starting in 2021, the office/outpatient E/M visit codes will be substantially redefined to allow time or medical decision-making for code level selection, concepts that do not apply in these ophthalmological visits which rely on criteria specific to evaluation, examination, specified technical procedures, and treatment of ocular conditions for purposes of level selection.[6] The number of levels within the two code sets differs, and the number of levels has changed for office/outpatient E/M visits. Given the revised code set and framework for level selection for office/outpatient E/M visits, the level of office/outpatient E/M visits to which the ophthalmological visits might be analogous is no longer clear. We are also aware that ophthalmologists report office/outpatient E/M visits as well these ophthalmologic-specific evaluation codes. The relationship between the two separate code sets and the reason for relying on both of them is unclear.

In addition, the four ophthalmological evaluation codes are reported with modifier -25 (significant, separately identifiable E/M service by the same physician on the same day of the procedure or other service) approximately 4 to 14 percent of the time (depending on the code in question). Similarly, ED visits are reported with modifier -25 approximately 4 to 12 percent of the time (depending on the code in question). In contrast, the office/outpatient E/M visit codes are reported with modifier -25 approximately 18 to 35 percent of the time (depending on the code in question). We are in the process of analyzing these data further to assess how often the accompanying service is a minor procedure rather than a visit. We believe that visit/evaluation codes furnished the same day as a minor procedure are not closely analogous to stand-alone office/outpatient E/M visits, and therefore should not be revalued commensurate with the increase to stand-alone office/outpatient E/M visits for 2021. As we discussed in prior PFS rules, we continue to believe that separately identifiable visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing office/outpatient E/M visits to warrant different payment (see, for example, the CY 2019 PFS final rule, 83 FR 59639)). As we continue our analysis, we are seeking public comment on whether visits/evaluations that are furnished frequently with same-day procedures should be revalued commensurate with increases to the office/outpatient E/M visits, or whether they are substantially different enough to warrant independent valuation. We note that the stand-alone psychotherapy services would be revalued to maintain relativity with the psychotherapy services that can be performed in conjunction with an E/M visit. Standalone psychotherapy services cannot be billed with office/outpatient E/M visits while ophthalmological visits can, as well as with a separate procedure.

[6] CPT Codebook pp. 656–7.

c. Comment Solicitation on the Definition of HCPCS Code GPC1X

Although we believe that the RUC-recommended values for the revised office/outpatient E/M visit codes will more accurately reflect the resources involved in furnishing a typical office/outpatient E/M visit, we continue to believe that the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits. Therefore, in the CY 2020 PFS final rule (84 FR 62856), we finalized the HCPCS add-on code GPC1X which describes the ''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 condition.'' We stated that we were not restricting billing based on specialty, but that we did assume that certain specialties furnished these types of visits more than others.

Since the publication of the CY 2020 PFS final rule, some specialty societies have stated that our definition of this service, as articulated in the code descriptor and the associated preamble discussion, is unclear. For example, some stakeholders have suggested that HCPCS add-on code GPC1X, as currently described, could be applicable for every office/outpatient E/M visit. They have also expressed concerns regarding our utilization assumptions, since we assumed that specialties that predominantly furnish the kind of care described by the code would bill it with every visit. Therefore, we are soliciting from the public comments providing additional, more specific information regarding what aspects of the definition of HCPCS add-on code GPC1X are unclear, how we might address those concerns, and how we might refine our utilization assumptions for the code.

We continue to believe that the time, intensity, and PE involved in furnishing services to patients on an ongoing basis that result in a comprehensive, longitudinal, and continuous relationship with the patient and involves delivery of team-based care that is accessible, coordinated with other practitioners and providers, and integrated with the broader health care landscape, are not adequately described by the revised office/outpatient E/M visit code set. We believe the inclusion of HCPCS add-on code GPC1X appropriately recognizes the resources involved when practitioners furnish services that are best-suited to patients' ongoing care needs and potentially evolving illness. We also believe the work reflected in HCPCS add-on code GPC1X is inherently distinct from existing coding that describes preventive and care management services. For example, the AWV describes and pays for a static annual health assessment rather than the time, intensity, and PE involved in furnishing services to patients on an ongoing basis. Similarly, TCM service codes are focused on care management for 30 days following a discharge rather than the time, intensity, and PE involved in furnishing services to patients on an ongoing basis. Chronic care management and principal care management service codes are limited to patients with chronic condition(s). Under chronic care management codes, patients have two or more chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, whereas principal care management services are for patients who have a single high-risk disease of sufficient severity to place the patient at risk of hospitalization or have been the cause of recent hospitalization. In contrast, we believe HCPCS add-on code GPC1X reflects the time, intensity, and PE when practitioners furnish services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single-high risk disease) and to address the majority of patients' health care needs with consistency and continuity over longer periods of time. For example, in the context of primary care, HCPCS add-on code GPC1X could recognize the resources inherent in holistic, patient-centered care that integrates the treatment of illness or injury, management of acute and chronic health conditions, and coordination of specialty care in a collaborative relationship with the clinical care team. In the context of specialty care, HCPCS add-on code GPC1X could recognize the resources inherent in engaging the patient in a continuous and active collaborative plan of care related to an identified health condition the management of which requires the direction of a clinician with specialized clinical knowledge, skill and experience. Such collaborative care includes patient education, expectations and responsibilities, shared decision-making around therapeutic goals, and shared commitments to achieve those goals. In both examples, HCPCS add-on code GPC1X reflects the time, intensity, and PE associated with providing services that result in care that is personalized to the patient. Finally, we believe that the HCPCS add-on code GPC1X could bolster the efforts of practitioners in rural communities, including NPPs, to deliver the comprehensive and longitudinal care that HCPCS add-on code GPC1X describes.

d. Prolonged Office/Outpatient E/M Visits (CPT Code 99XXX)

We reviewed our final policy for 2021 regarding the reporting of prolonged office/outpatient E/M visits finalized in the CY 2020 PFS final rule (84 FR 62848 through 62850). To report these visits beginning in 2021, we finalized 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 additional 15 minutes (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services)).* CPT code 99XXX is only reported when time is used to select the visit level, and only time of the physician or qualified healthcare professional is counted. In the CY 2020 PFS final rule, we stated that our interpretation of revised CPT prefatory language and reporting instructions would mean that CPT code 99XXX could be reported when the physician's (or NPP's) time is used for code level selection and the time for a level 5 office/outpatient E/M visit (the floor of the level 5 time range) is exceeded by 15 minutes or more on the date of service (84 FR 62848 through 62849). The intent of the CPT Editorial Panel was unclear because of the use of the terms ''total time'' and ''usual service'' in the CPT code descriptor (''*requiring total time with or without direct patient contact beyond the usual service.*'') The term ''total time'' is unclear because office/outpatient E/M visits now represent a range of time, and ''total'' time could be interpreted as including prolonged time. Further, the term, ''usual service'' is undefined. There is no longer a typical time in the code descriptor that could be used as point of reference for when the ''usual time'' is exceeded for all practitioners, and there would be variation (as well as potential double counting of time) if applied at the individual practitioner level.

Having reviewed the policy we finalized last year, we believe that allowing reporting of CPT code 99XXX

after the minimum time for the level 5 visit is exceeded by at least 15 minutes would result in double counting time. As a specific example, the time range for CPT code 99215 is 40–54 minutes. If the reporting practitioner spent 55 minutes of time, 14 of those minutes are included in the services described by CPT code 99215. Therefore, only 1 minute should be counted towards the additional 15 minutes needed to report CPT code 99XXX and prolonged services should not be reportable as we finalized last year (see Table 33 of the CY 2020 PFS final rule (84 FR 62849)). Therefore, we are proposing that when the time of the reporting physician or NPP is used to select office/outpatient E/M visit level, CPT code 99XXX could be reported when the maximum time for the level 5 office/outpatient E/M visit is exceeded by at least 15 minutes on the date of service. In Tables 22 and 23, we provide examples.

TABLE 22: Proposed Prolonged Office/Outpatient E/M Visit Reporting - New Patient

CPT Code(s)	Total Time Required for Reporting*
99205	60-74 minutes
99205 x 1 and 99XXX x 1	89-103 minutes
99205 x 1 and 99XXX x 2	104-118 minutes
99205 x 1 and 99XXX x 3 or more for each additional 15 minutes.	119 or more

*Total time is the sum of all time, including prolonged time, spent by the reporting practitioner on the date of service of the visit.

TABLE 23: Proposed Prolonged Office/Outpatient E/M Visit Reporting – Established Patient

CPT Code(s)	Total Time Required for Reporting*
99215	40-54 minutes
99215 x 1 and 99XXX x 1	69-83 minutes
99215 x 1 and 99XXX x 2	84- 98 minutes
99215 x 1 and 99XXX x 3 or more for each additional 15 minutes.	99 or more

*Total time is the sum of all time, including prolonged time, spent by the reporting practitioner on the date of service of the visit.

G. Scope of Practice and Related Issues

We are proposing several policies consistent with the President's Executive Order 13890 on ''Protecting and Improving Medicare for Our Nation's Seniors'' to modify supervision and other requirements of the Medicare program that limit healthcare professionals from practicing at the top of their license (84 FR 53573, October 8, 2019, Executive Order #13890). In December 2019, we requested feedback in response to part of this Executive Order seeking the public's help in identifying additional Medicare regulations which contain more restrictive supervision requirements than existing state scope of practice laws, or which limit health professionals from practicing at the top of their license (the request for feedback is available at *https://www.cms.gov/files/document/request-information-reducing-scope-practice-burden.pdf*). Through review of the feedback we received, we identified the policies in this section to address in the PFS proposed rule. We believe that physicians, NPPs, and other professionals should be able to furnish services to Medicare beneficiaries in accordance with their scope of practice and state licensure, including education and training, to the extent permitted under the Medicare statute, as long as it is not likely to result in fraud, waste or abuse. These proposed policies may also help ensure an adequate number of clinicians, in addition to physicians are able to furnish critical services including primary care services in areas where there is a shortage of physicians.[7] Some of the proposals may also help alleviate the opioid crisis.

We note that the responses to our request for feedback on the topics in this section did not indicate the number of states that have more flexible scope of practice rules than our federal regulations, or whether facilities (such as hospitals or nursing facilities) have relevant policies that limit the ability of the impacted professionals to perform certain services. For example, if Medicare payment policy provided for payment of diagnostic tests supervised by NPPs, there may still be facility- or state-specific policies in place that limit NPPs' ability to supervise some or all diagnostic tests, and those limitations would inform the potential impact of changing our policy. While our proposed flexibility may increase the capacity and availability of practitioners who can supervise diagnostic tests, which would alleviate some of the demand on physicians as the only source to perform this particular function, we have not located information indicating the degree to which NPP scope of practice includes supervision of auxiliary staff, especially for the subset of services that are diagnostic tests. There is a wide range of diagnostic tests, from a simple strep throat swab to more sophisticated and/or invasive tests such as x-rays and cardiology procedures. We would need to understand the scope of practice for many types of auxiliary staff (some of whom are not licensed) who could potentially provide these tests under the supervision of an NPP, including RNs, LPNs, medical assistants, radiologic technicians, and many others. To the extent practice patterns change, there

[7] Zhang et al. Physician workforce in the United States of America: forecasting nationwide shortages. *Human Resources for Health* (2020); 18:8. Published online February 6, 2020 and available online at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7006215/*.

could be induced utilization that would increase costs, but this might be offset by reduced payment rates because direct payment to NPPs is at a lower rate than payment to physicians. Therefore, in this proposed rule, we are also seeking information about the number and names of states that have licensure or scope of practice laws in place, as well as any facility-specific policies, that would impact the ability of clinicians to exercise the flexibilities we are proposing, to help us assess the potential impact of, or challenges for, our proposed changes. Information about specific services (service-level information) would be especially helpful. We are seeking public comment on whether applicable state laws, scope of practice, and facility policies would permit practitioners to exercise the proposed flexibilities if CMS were to adopt the policies proposed in this section, and to what extent practitioners would be permitted to exercise these proposed flexibilities, such as for all diagnostic tests or only a subset.

1. Teaching Physician and Resident Moonlighting Policies

a. Background

In the March 31st COVID–19 IFC (85 FR 19258 through 19261) and the May 1st COVID–19 IFC (85 FR 27550 through 27629), we implemented several policies on an interim final basis related to PFS payment for the services of teaching physicians involving residents and resident moonlighting regulations. The comment periods for both the March 31st COVID–19 IFC (85 FR 19230) and the May 1st COVID–19 IFC (85 FR 27550) have closed. Therefore, we plan to address the IFC comments for issues in which we have proposals in this proposed rule when we publish the PFS final rule. We are considering whether these policies should be extended on a temporary basis (that is, if the PHE ends in 2021, these policies could be extended to December 31, 2021 to allow for a transition period before reverting to status quo policy) or be made permanent, and are soliciting public comments on whether these policies should continue once the PHE ends. We believe public comment will assist us in identifying appropriate policy continuation decisions that we would consider finalizing in the CY 2021 PFS final rule.

For teaching physicians, section 1842(b)(7)(A)(i)(I) of the Act specifies that in the case of physicians' services furnished to a patient in a hospital with a teaching program, the Secretary shall not provide payment for such services unless the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought.

Regulations regarding PFS payment for teaching physician services and services of moonlighting residents are codified in 42 CFR part 415. In general, under § 415.170, payment is made under the PFS for services furnished in a teaching hospital setting if the services are personally furnished by a physician who is not a resident, or the services are furnished by a resident in the presence of a teaching physician, with exceptions as specified in subsequent regulatory provisions in part 415. Under § 415.172, if a resident participates in a service furnished in a teaching setting, PFS payment is made only if the teaching physician is present during the key portion of any service or procedure for which payment is sought. The regulation at § 415.180 states that, for the interpretation of diagnostic radiology and other diagnostic tests, PFS payment is made if the interpretation is performed or reviewed by a physician other than a resident. Under § 415.184, PFS payment is made for psychiatric services furnished under an approved graduate medical education (GME) program if the requirements of §§ 415.170 and 415.172 are met, except that the requirement for the presence of the teaching physician during psychiatric services in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device.

b. Supervision of Residents in Teaching Settings Through Audio/Video Real-Time Communications Technology

In both the March 31st COVID–19 IFC (85 FR 19258 through 19261) and the May 1st COVID–19 IFC (85 FR 27550 through 27629), we adopted a policy on an interim basis during the COVID–19 PHE that, under § 415.172, the requirement for the presence of a teaching physician during the key portion of the service furnished with the involvement of a resident can be met using audio/video real-time communications technology. In other words, the teaching physician must be present, either in person or virtually through audio/video real-time communications technology, during the key portion of the service. This policy generally requires real-time observation (not mere availability) by the teaching physician through audio and video technology, and does not include audio-only technology (for example, telephone without video). For the primary care exception under § 415.174(c), we adopted a policy on an interim final basis for the duration of the COVID–19 PHE to allow the teaching physician to direct the care furnished by the resident, and to review the services furnished by the resident during or immediately after the visit, remotely using audio/video real-time communications technology.

Under § 415.180, we adopted a policy on an interim basis for the duration of the COVID–19 PHE to allow PFS payment to be made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through audio/video real-time communications technology. A physician other than the resident must still review the resident's interpretation. Under § 415.184, we adopted a policy on an interim basis during the COVID–19 PHE that the requirement for the presence of the teaching physician during the psychiatric service in which a resident is involved may be met by the teaching physician's direct supervision using audio/video real-time communications technology.

We are considering whether the flexibilities described above that we implemented on an interim basis during PHE under §§ 415.172, 415.174, 415.180, and 415.184 should be extended on a temporary basis (that is, if the PHE ends in 2021, these policies could be extended to December 31, 2021 to allow for a transition period before reverting to status quo policy) or be made permanent, and are soliciting public comments on whether these policies should continue once the PHE ends. We believe public comment will assist us in identifying appropriate policy continuation decisions that we would consider finalizing in the CY 2021 PFS final rule. In addition, we are proposing to make a technical edit to the regulation text at § 415.184 to eliminate the term ''direct supervision'' to conform with the language in sections §§ 415.172, 415.174, and 415.180 regarding the presence of the teaching physician via audio/video real-time communications technology.

While we believe it was appropriate to permit teaching physicians to be involved in services furnished with residents through audio/video real-time communications technology to respond to critical needs during the PHE to reduce exposure risk and to increase the capacity of teaching settings to respond to COVID–19, we are concerned that continuing to permit teaching physicians to be involved through their virtual presence may not be sufficient to warrant PFS payment to the teaching

physician on a temporary or permanent basis. Absent the circumstances of the PHE, the physical, in-person presence of the teaching physician may be necessary to provide oversight to ensure that care furnished to Medicare beneficiaries is medically reasonable and necessary, and to ensure that the teaching physician renders sufficient personal services to exercise full, personal control of the key portion of the case.

We also have some concerns about patient safety when the teaching physician is only virtually present. For example, in the March 31st COVID–19 IFC, we excluded the surgical, high risk, interventional, endoscopic, or other complex procedures identified under § 415.172(a)(1), and anesthesia services under § 415.178 from the policy to allow the teaching physician to be present using audio-video real-time communications technology because we believe the requirement for the physical, in-person presence of the teaching physician for either the entire procedure or the key portion of the service with immediate availability throughout the procedure, as applicable, is necessary for patient safety given the risks associated with these services. In complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures, a patient's clinical status can quickly change. To permit payment under the PFS for these teaching physician services, we believe the services must be furnished with a certain level of personal oversight and involvement of the teaching physician who has the experience and judgment that is necessary for rapid on-site decision-making during these procedures.

There may be circumstances in which virtual presence of the teaching physician, considered in light of the potential risks to patient safety and absent exposure risk concerns due to COVID–19, does not demonstrate sufficient personal involvement in the service to the patient to warrant payment to the teaching physician under the PFS. For example, a resident could evaluate a patient for change in mental status following surgery for hip fracture, perform a physical exam and report it as unrevealing, and note that the patient is uncooperative with a full exam. If a full exam had been performed by the teaching physician or with the physical presence of the teaching physician (or with the teaching physician immediately available in the clinic to provide the necessary direction, under the primary care exception) to render personal and identifiable physicians' services to the patient, the exam would likely have revealed crystal-mediated acute arthritis, and that the patient's lack of cooperation was due to hypoactive delirium. However, the teaching physician may not have been able to identify this concern through the use of audio/video interactive communications technology. In this case, the presence of the teaching physician through audio/video interactive communications technology might have been insufficient to allow the teaching physician to render personal and identifiable physicians' services to exercise full, personal control over the key portion of the encounter.

There also may be certain patient populations that require greater clinical attentiveness and skill than the teaching physician could provide via audio/video interactive communications technology. For example, patients with cognitive impairment or dementia may require the experience and skill to recognize a need for specialized testing, and patients with communication disabilities may require more experience and skill to recognize specialized needs. It may not be possible for the teaching physician to meet these clinical needs and exercise full, personal control while being present for the key portion of the service through audio/video interactive communications technology. Moreover, the virtual connection between the teaching physician and the resident who is with the patient could be disrupted (as with any virtual supervision scenario), rendering it impossible for the teaching physician to provide necessary direction for the resident to furnish appropriate care to the patient, thus foreclosing the ability of the teaching physician to exercise full, personal control over the key portion of the services, and potentially putting the patient's safety at risk.

While we have significant concerns about extending our interim policy to permit virtual presence of the teaching physician, whether on a temporary or permanent basis, we believe public comment would be helpful as we further consider the status of this policy. For example, because COVID–19 may continue to persist in some communities after the expiration of the PHE, we are considering extending our policy to permit the teaching physician to be present through audio/video interactive communications technology on a temporary basis until the end of the calendar year in which the PHE ends. The presence of COVID–19 may result in a need for some teaching settings to continue to limit exposure risks, especially for high risk patients isolated for their own protection or in cases where the teaching physician has been exposed to the virus and must be under quarantine. If the teaching physician is under quarantine, termination of the policy to permit virtual presence of the teaching physician could unintentionally limit the number of licensed practitioners available to furnish services to Medicare patients in some communities, and could have the unintended consequence of limiting access to services for Medicare patients. Some communities may experience a resurgence of COVID–19, and extending our policy until the end of the calendar year in which the PHE ends to permit PFS payment when the teaching physician is present through audio/video real-time communications technology could temporarily help teaching settings remain prepared with surge capacity.

Based on the clinical experience gained during the PHE, we might identify circumstances or procedures for which the teaching physician can routinely render sufficient personal and identifiable services to the patient to exercise full, personal control over the management of the key portion of the case when the services are furnished by a resident with the teaching physician present through audio/video real-time communications technology. For example, under ordinary circumstances for the primary care exception at § 415.174, we permit PFS payment to the teaching physician when a resident furnishes office/outpatient evaluation and management (E/M) visit codes of lower and mid-level complexity and annual wellness visits without the presence of a teaching physician (these codes are discussed in section II.F. of this proposed rule). Additionally, the teaching physician may be able to provide sufficient involvement for simple procedures such as CPT code 36410 (*Venipuncture, age 3 years or older, necessitating the skill of a physician or other qualified health care professional (separate procedure), for diagnostic or therapeutic purposes (not to be used for routine venipuncture)* or CPT code 51701 (*Insertion of non-indwelling bladder catheter (e.g., straight catheterization for residual urine)*. For such circumstances and procedures, it may be appropriate to continue the virtual presence policy on a temporary or permanent basis.

We note that having the virtual presence policy in place temporarily or permanently would not preclude teaching physicians from providing a greater degree of involvement in services furnished with residents, and teaching physicians would still have discretion to determine whether, and if

so, when it is appropriate to be present virtually rather than in person depending on the services being furnished and the experience of the particular residents involved. We seek comment to help us understand how the option to provide for teaching physician presence using audio/video real-time communications technology would support patient safety for all patients and particularly for at-risk patients (for example, patients who are aged and/or who have a disability); ensure burden reduction without creating risks to patient care or increasing fraud; avoid duplicative payment between the PFS and the IPPS for GME programs; and support emergency preparedness. We also invite commenters to provide data and other information on their experiences implementing this policy during the PHE.

c. Virtual Teaching Physician Presence During Medicare Telehealth Services

In the March 31st COVID–19 IFC (85 FR 19260), we adopted a policy on an interim basis to allow Medicare to make payment under the PFS for teaching physician services when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using audio/video real-time communications technology. We are considering whether this policy should be extended on a temporary basis (that is, if the PHE ends in 2021, this policy could be extended to December 31, 2021 to allow for a transition period before reverting to status quo policy) or be made permanent, and are soliciting public comments on whether this policy should continue once the PHE ends. We believe public comment will assist us in identifying appropriate policy continuation decisions that we would consider finalizing in the CY 2021 PFS final rule. Outside the circumstances of the PHE, under the requirements at section 1834(m) of the Act that discuss payment for telehealth services, the patient would be located at a telehealth originating site, and the teaching physician would be furnishing the service as the distant site practitioner with the involvement of the resident.

While teaching physician presence through audio/video real-time communications technology when a resident furnishes Medicare telehealth services was responsive to critical needs during the PHE to reduce exposure risk and to increase the capacity of teaching settings to respond to COVID–19, we are concerned that the policy to permit virtual presence of the teaching physician may not allow for sufficient personal and identifiable physicians' services to exercise full, personal control over the services such that PFS payment to the teaching physician would be appropriate outside the circumstances of the PHE on a temporary or permanent basis. We are concerned that if the resident was furnishing the service at the distant site and the teaching physician was at a third site and present with the resident through audio/video real-time communications technology, the teaching physician may not be able to render sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the service to warrant separate payment on the PFS.

Absent the need to reduce exposure risk to COVID–19 during the PHE, we also have some concerns about patient safety when the teaching physician is present only virtually during a telehealth service furnished by a resident. For example, the virtual connection between the teaching physician and the resident who is with the patient could be disrupted (as with any virtual supervision scenario), rendering it impossible for the teaching physician to provide necessary direction for the resident to furnish appropriate care to the patient, thus foreclosing the ability of the teaching physician to exercise full, personal control over the key portion of the service, and potentially putting the patient's safety at risk.

However, because COVID–19 may continue to persist in some communities and some communities may experience a resurgence of COVID–19 after the expiration of the PHE, we are seeking comment about whether it would be appropriate to extend this policy on a temporary basis until the end of the calendar year in which the PHE ends. The presence of COVID–19 may result in a need to continue to limit exposure risks. In cases where the teaching physician has been exposed to the virus and is under quarantine, termination of the policy to permit virtual presence of the teaching physician could unintentionally limit the number of licensed practitioners available to furnish services to Medicare patients in some communities, and could have the unintended consequence of limiting access for Medicare patients. Finally, based on experience gained during the PHE, we might identify circumstances for which the teaching physician can routinely render sufficient personal and identifiable services to the patient to exercise full, personal control over the management of the key portion of the case while providing virtual presence during Medicare telehealth services furnished by a resident on a permanent basis. For example, under ordinary circumstances for the primary care exception at § 415.174, we permit PFS payment to the teaching physician when a resident furnishes office/outpatient E/M visit codes of lower and mid-level complexity and annual wellness visits without the presence of a teaching physician (these codes are discussed in section II.F. of this proposed rule). For such services, it may be appropriate to continue the virtual presence policy on a temporary or permanent basis. We seek comment to help us understand how the option to allow teaching physician presence using audio/video real-time communications technology could support patient safety for all patients and particularly for at-risk patients (for example, patients who are aged and/or who have a disability), ensure burden reduction without creating risks to patient care or increasing fraud, avoid duplicative payment between the PFS and the IPPS for GME programs, and support emergency preparedness. We also invite commenters to provide data and other information on their experiences implementing this policy during the PHE.

d. Resident Moonlighting in the Inpatient Setting

Under certain conditions, the services of a licensed resident physician who is ''moonlighting'' are considered to be furnished by the individual in their capacity as a physician, rather than as a resident in an approved GME program. As specified in the regulation at § 415.208, except during the PHE, as defined in the regulation at § 400.200, the services of residents to inpatients of hospitals in which the residents have their approved GME program are not considered separately billable as physicians' services and instead are payable under §§ 413.75 through 413.83 regarding direct GME payments, whether or not the services are related to the approved GME training program. When a resident furnishes services that are not related to their approved GME programs in an outpatient department or emergency department of a hospital in which they have their training program, those services can be billed separately as physicians' services and payable under the PFS if they meet the criteria described in our regulation at § 415.208(b)(2) (i) through (iii). In addition, under § 415.208(c), services of a licensed resident furnished outside the scope of an approved GME program when moonlighting in a hospital or other setting that does not participate in

the approved GME program are payable under the PFS when the resident is fully licensed to practice in the state where the services are furnished, and the resident's time spent in patient care activities in that setting is not counted for the purpose of Medicare direct GME payments.

In the March 31st COVID–19 IFC, we amended our regulation at § 415.208 to state that, during the PHE for COVID–19, the services of residents that are not related to their approved GME programs and are furnished to inpatients of a hospital in which they have their training program are separately billable physicians' services for which payment can be made under the PFS provided that the services are identifiable physicians' services and meet the conditions for payment of physicians' services to beneficiaries in providers in § 415.102(a), the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the state in which the services are performed, and the services can be separately identified from those services that are required as part of the approved GME program.

We are considering whether this flexibility that we implemented on an interim basis should be extended on a temporary basis (that is, if the PHE ends in 2021, these policies could be extended to December 31, 2021 to allow for a transition period before reverting to status quo policy) or be made permanent, and are soliciting public comments on whether this policy should continue once the PHE ends. We are concerned that there may be risks to program integrity in allowing residents to furnish separately billable physicians' services to inpatients in the teaching hospitals where they are training when the services are outside the scope of their approved GME program. For example, there could be a risk of duplicate Medicare payment for the resident's services under the IPPS for GME and the PFS if the physicians' services furnished by residents were not adequately separately identified from those services that are required as part of the GME program. However, because COVID–19 may continue to persist in some communities or some communities may experience a resurgence of COVID–19 after the expiration of the PHE, it may be appropriate for us to extend this policy on a temporary basis to meet the needs of teaching hospitals to ensure that there are as many qualified practitioners available as possible. We believe public comment will assist us in identifying appropriate policy continuation decisions that we would consider finalizing in the CY 2021 PFS final rule. We also invite commenters to provide data and other information on their experiences implementing this policy during the PHE.

e. Primary Care Exception Policies

The regulation at § 415.174 sets forth an exception to the conditions for PFS payment for services furnished in teaching settings in the case of certain E/M services furnished in certain centers. Under the so-called ''primary care exception,'' Medicare makes PFS payment in certain teaching hospital primary care centers for certain services of lower and mid-level complexity furnished by a resident without the physical presence of a teaching physician. Section 415.174(a)(3) requires that the teaching physician must not direct the care of more than four residents at a time, and must direct the care from such proximity as to constitute immediate availability (that is, provide direct supervision) and must review with each resident during or immediately after each visit, the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies. Section 415.174(a)(3) also requires that the teaching physician must have no other responsibilities at the time, assume management responsibility for the beneficiaries seen by the residents, and ensure that the services furnished are appropriate.

As provided in the regulation at § 415.174(a), the codes of lower and mid-level complexity that can be furnished under the primary care exception are specified in section 100 of chapter 12 of the Medicare Claims Processing Manual (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf*). They are the following:

- CPT code 99201 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; 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. Typically, 10 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99202 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; 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 of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99203 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed 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 moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family*);
- 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. Typically, 5 minutes are spent performing or supervising these services*);
- CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; 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. Typically, 10 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and 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, 15 minutes are spent face-to-face with the patient and/or family);

• HCPCS code G0402 (*Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment*);

• HCPCS code G0438 (*Annual wellness visit; includes a personalized prevention plan of service (PPS), initial visit*); and

• HCPCS code G0439 (*Annual wellness visit, includes a personalized prevention plan of service (PPS), subsequent visit*).

In the March 31st COVID–19 IFC, we amended § 415.174 of our regulations to allow, during the PHE for COVID–19, all levels of office/outpatient E/M visits to be furnished by the resident and billed by the teaching physician under the primary care exception. In the May 1st COVID–19 IFC (85 FR 27550 through 27629), we further expanded the list of services included in the primary care exception during the PHE for COVID–19. We also allowed PFS payment to the teaching physician for services furnished by residents via telehealth under the primary care exception if the services were also on the list of Medicare telehealth services.

We are considering whether these policies should be extended on a temporary basis (that is, if the PHE ends in 2021, these policies could be extended to December 31, 2021 to allow for a transition period before reverting to status quo policy) or be made permanent, and are soliciting public comments on whether these policies should continue once the PHE ends. We believe public comment will assist us in identifying appropriate policy continuation decisions that we would consider finalizing in the CY 2021 PFS final rule. We are also considering whether specific services added under the primary care exception should be extended temporarily or made permanent and are soliciting public comment on whether these services should continue as part of the primary care exception once the PHE ends. These services are the following:

• CPT code 99204 *(Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; 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 to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family);*

• CPT code 99205 *(Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; 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 moderate to high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family);*

• CPT code 99214 *(Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; 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 to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family);*

• CPT code 99215 *(Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; 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 moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family);*

• 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*);

• 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*);

• CPT code 99421 (*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 99422 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes*);

• CPT code 99423 (*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*);

• CPT code 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes*);

• CPT 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*); and

• 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*).

Expanding the array of services for which Medicare may make PFS payment to the teaching physician when furnished by a resident under the primary care exception was responsive to critical needs during the PHE for patients who may be quarantined at home or who may need to be isolated for purposes of minimizing exposure risk based on presumed or confirmed COVID–19 infection. Because COVID–19 may continue to persist in some communities or some communities may experience a resurgence of COVID–19

after the expiration of the PHE, it may be appropriate for us to extend all of these services on a temporary basis (that is, until the end of the calendar year in which the PHE ends).

However, we are concerned that it may be inappropriate to extend all of these services on a temporary basis or add them to the primary care exception permanently. The intent of the primary care exception as described in § 415.174 is that E/M visits of lower and mid-level complexity furnished by residents are simple enough for a teaching physician to be able to direct and manage the care of up to four residents at any given time and direct the care from such proximity as to constitute immediate availability. While CPT code 99421 and HCPCS code G2012 may be simple services, others such as levels 4 and 5 office/outpatient E/M visits (CPT codes 99204 through 99205 and CPT codes 99214 through 99215) and transitional care management codes (CPT codes 99495 through 99496) require medical decision making that is of at least moderate complexity. We are concerned that the teaching physician may not be able to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower and mid-level complexity. We are also concerned that when the teaching physician is directing the care of a patient that requires moderate or higher medical decision making, the ability to be immediately available to other residents could be compromised, potentially putting patients at risk. Thus, we are considering whether, upon expiration of the PHE, we should extend on a temporary basis some or all of the services we added to the primary care exception list during the PHE and are soliciting public comments on whether these services should continue as part of the primary care exception after the PHE ends. We also invite commenters to provide data and other information on their experiences implementing this policy during the PHE.

We are also considering whether our interim final policy that PFS payment could be made to the teaching physician when residents furnish telehealth services under the primary care exception should be extended on a temporary basis or be made permanent, and are soliciting public comments on whether this policy should continue once the PHE ends. In these cases, outside the circumstances of the PHE, the patient would be at the originating site and the resident furnishing the care, along with the teaching physician billing for it, would be located at the primary care center as the distant site practitioner. If we were to temporarily extend or add permanently to the primary care exception services such as e-visits or communication technology-based services, it may also make sense to permit PFS payment to the teaching physician when the resident furnishes an office/outpatient E/M visit via telehealth, on the basis that the patient is not physically in the clinic and that these services all involve the use of virtual technology (for example, patient portals for e-visits, telecommunications technology for the office/outpatient E/M visit) to facilitate care delivery. If we were to remove the services that we added to the primary care exception on an interim basis, we could separately consider continuing to permit PFS payment to the teaching physician when the resident furnishes an office/outpatient E/M visit via telehealth because the teaching physician would be immediately available in the distant site clinic with the resident to direct and manage the care.

f. Conclusion

In summary, we remind stakeholders that during the PHE we implemented these policies on an interim basis to support our goals of ensuring beneficiary access to necessary services and maintenance of sufficient workforce capacity through flexibilities afforded to providers to safely furnish services to patients. While we anticipate reverting to our previous teaching physician policy that was in place prior to the PHE for the reasons discussed above, we are considering whether the teaching physician and resident moonlighting policies that we implemented on an interim basis should be extended on a temporary basis (that is, if the PHE ends in 2021, these policies could be extended to December 31, 2021 to allow for a transition period before reverting to status quo policy) or be made permanent policy for CY 2021. We are soliciting public comments on whether these policies should be continued, and if so, whether they should be made permanent, or temporarily extended and the appropriate scope of the extension. As discussed above, we are concerned that the teaching physician may not be able to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower and mid-level complexity. We are also concerned that when the teaching physician is directing the care of a patient that requires moderate or higher medical decision making, the ability to be immediately available to other residents could be compromised, potentially putting patients at risk. We will also consider under which scenarios our policies for moonlighting or virtual presence as discussed above, should apply, if any. As discussed for our moonlighting policy, we are concerned that there may be risks to program integrity in allowing residents to furnish separately billable physicians' services to inpatients in the teaching hospitals where they are training when the services are outside the scope of their approved GME program. For example, there could be a risk of duplicate Medicare payment for the resident's services under the IPPS for GME and the PFS if the physicians' services furnished by residents were not adequately separately identified from those services that are required as part of the GME program. Under our discussion of virtual presence, we highlighted concerns about how continuing to permit teaching physicians to be involved through their virtual presence may not be sufficient to warrant PFS payment to the teaching physician on a temporary or permanent basis. Absent the circumstances of the PHE, the physical, in-person presence of the teaching physician may be necessary to provide oversight to ensure that care furnished to Medicare beneficiaries is medically reasonable and necessary, and to ensure that the teaching physician renders sufficient personal services to exercise full, personal control of the key portion of the case. We also discussed concerns about patient safety when the teaching physician is only virtually present.

We believe public comment, especially those that focus on the variables we identify above regarding the specific services included on the primary exception list, clinical scenarios under which residents could moonlight or furnish certain types of services under the supervision of a teaching physician via virtual presence, will assist us in identifying the appropriate policy continuation decisions after the end of the PHE, which we will consider finalizing in the CY 2021 PFS final rule. As part of our review of public comments, we will weigh and make decisions based on the potential benefits and risks associated with the potential temporary or permanent continuation, in whole or in part, of these policies. The benefits of continuation may include limiting COVID–19 exposure risk for practitioners and patients, increasing workforce capacity of teaching settings

to respond to continuing effects following the PHE as practitioners may be asked to assist with the response, and increasing access so that we do not unintentionally limit the number of licensed practitioners available to furnish services to Medicare beneficiaries, which could have the unintended consequence of limiting access to services paid under the PFS. The risks may include the potential for duplicative payment with Medicare Part A reimbursement for graduate medical education training programs, the potential for increases to cost-sharing for Medicare beneficiaries that could result from additional Part B claims for services furnished by the teaching physician with the involvement of residents, and potential risks to patient safety.

2. Supervision of Diagnostic Tests by Certain NPPs

In response to Executive Order #13890 discussed above, we sought assistance from stakeholders in identifying Medicare regulations that contain more restrictive supervision requirements than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license. In response to our request for feedback discussed above, physician assistants (PAs) and nurse practitioners (NPs) recommended regulatory changes that would allow them to supervise the performance of diagnostic tests because they are currently authorized to do so under their state scope of practice rules in many states. In the May 1st COVID–19 IFC (85 FR 27550 through 27629), we established on an interim basis during the COVID–19 PHE, a policy to permit these and certain other NPPs to supervise diagnostic tests. We now propose to make those changes permanent by making modifications to the regulations at § 410.32. We are planning to address comments we receive on our proposals included in this proposed rule and comments received on the May 1st COVID–19 IFC (85 FR 27550 through 27629) simultaneously in the final rule since the comment period for the May 1, 2020 COVID–19 IFC (85 FR 27550 through 27629) recently closed on July 7, 2020.

Prior to the COVID–19 PHE, under § 410.32(a)(2), physicians, NPs, CNSs, PAs, certified nurse-midwives (CNMs), clinical psychologists (CPs), and clinical social workers (CSWs) who are treating a beneficiary for a specific medical problem may order diagnostic tests when they use the results of the tests in the management of the beneficiary's specific medical problem. However, generally only physicians were permitted to supervise diagnostic tests. The regulation at § 410.32(b)(1) provided as a basic general rule that all diagnostic tests paid under the PFS must be furnished under an appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Section 410.32(b)(2) then provided for certain exceptions to which this basic rule did not apply. For instance, under § 410.32(b)(2)(v), the requirement that diagnostic tests must be furnished under the appropriate level of supervision by a physician did not apply for tests performed by an NP or CNS authorized under applicable state law to furnish the test. (We note that, as for all services furnished by a NP or CNS, they would have to be furnished working in collaboration with a physician as provided in regulations at §§ 410.75 and 410.76, respectively). Similarly, under the regulation at § 410.32(b)(2)(vii), the requirement that diagnostic tests must be furnished under the appropriate level of supervision by a physician did not apply for tests performed by a CNM authorized under applicable state law to furnish the test. This exception is in place because the Medicare statute does not include any physician supervision requirement for CNM services. Thus, while NPs, CNSs, PAs, and CNMs were permitted to furnish diagnostic tests to the extent they were authorized under state law and their scope of practice to do so, the regulations at § 410.32 did not address whether these practitioners could supervise others who furnished diagnostic tests.

In light of stakeholder feedback to CMS on identifying additional Medicare regulations that contain more restrictive supervision requirements than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license, effective January 1, 2021, we are proposing to amend the basic rule under the regulation at § 410.32(b)(1) to allow NPs, CNSs, PAs or CNMs to supervise diagnostic tests on a permanent basis as allowed by state law and scope of practice. These NPPs have separately enumerated benefit categories under Medicare law that permit them to furnish services that would be physician's services if furnished by a physician, and are authorized to receive payment under Medicare Part B for the professional services they furnish either directly or ''incident to'' their own professional services, to the extent authorized under state law and scope of practice.

We are proposing to amend the regulation at § 410.32(b)(2)(iii)(B) on a permanent basis to specify that supervision of diagnostic psychological and neuropsychological testing services can be done by NPs, CNS's, PAs or CNMs to the extent that they are authorized to perform the tests under applicable State law and scope of practice, in addition to physicians and CPs who are currently authorized to supervise these tests. We are also proposing to amend on a permanent basis, the regulation at § 410.32 to add paragraph (b)(2)(ix) to specify that diagnostic tests performed by a PA in accordance with their scope of practice and State law do not require the specified level of supervision assigned to individual tests, because the relationship of PAs with physicians under § 410.74 would continue to apply. We are also proposing to make permanent the removal of the parenthetical, previously made as part of the May 1, 2020 COVID–19 IFC (85 FR 27550 through 27629), at § 410.32(b)(3) that required a general level of physician supervision for diagnostic tests performed by a PA.

3. Pharmacists Providing Services Incident to Physicians' Services

Stakeholders have asked us to clarify that pharmacists can provide services incident to the professional services of a physician or other NPP just as other clinical staff may do. These stakeholders have asked us, in particular, about pharmacists who provide medication management services. Medication management is covered under both Medicare Part B and Part D. We are reiterating the clarification we provided in the May 1st COVID–19 IFC (85 FR 27550 through 27629), that pharmacists fall within the regulatory definition of auxiliary personnel under our regulations at § 410.26. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or NPP and in accordance with the pharmacist's state scope of practice and applicable state law.

We note that when a pharmacist provides services that are paid under the Part D benefit, the services are not also reportable or paid for under Part B. In addition to circumstances where medication management is offered as part of the Part D benefit, Part B payment is also not available for services included in the Medicare Part D dispensing fees, such as a pharmacist's time in checking the computer for information about an individual's coverage, measurement or

mixing of the covered Part D drug, filling the container, physically providing or delivering the completed prescription to the Part D enrollee. Similarly, performing required quality assurance activities consistent with § 423.153(c)(2), such as screening for potential drug therapy problems due to therapeutic duplication, age/gender-related contraindications, potential over-utilization and under-utilization, drug-drug interactions, incorrect drug dosage or duration of drug therapy, drug-allergy contraindications, and clinical abuse/misuse are considered part of dispensing fees under Part D and are not separately reportable services under Part B. Additionally, services and supplies paid under the incident to benefit must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness (§ 410.26). We also note that our manual provisions specify that ''incident to'' services must be of a type that are medically appropriate to provide in the office setting; and that where a physician supervises auxiliary personnel to assist him or her in rendering services to patients and includes the charges for their services in his or her own bills, the services of such personnel are considered incident to the physicians' service if there is a physicians' service rendered to which the services of such personnel are an incidental part and there is direct supervision by the physician (section 60.1 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100–02) available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf*).

Although it is fully consistent with current CMS policy for pharmacists to provide services incident to the services of the billing physician or NPP, we believe this clarification may encourage pharmacists to work with physicians and NPPs in new ways where pharmacists are working at the top of their training, licensure and scope of practice. It may free up the time of physicians and NPPs for other work and increase access to medication management services, for individuals with chronic conditions and other conditions. As an example, we found that this clarification was helpful in recently addressing in the May 1st COVID–19 IFC (85 FR 27550 through 27629), the ability of pharmacies to enroll as laboratories and work with physicians in the assessment of clinical information, specimen collection and reporting results of COVID–19 clinical diagnostic laboratory tests.

4. Provision of Maintenance Therapy by Therapy Assistants

In response to our request for feedback on scope of practice (noted above), consistent with Executive Order #13890, respondents requested that we allow physical therapist assistants (PTAs) and occupational therapy assistants (OTAs) to furnish maintenance therapy services associated with a maintenance program. The respondents said that our Part B therapy policy is not consistent with policies for these services when provided to patients in the skilled nursing facility (SNF) and home health (HH) settings paid under Part A. Other respondents told us that because the therapist is responsible for a patient's care over an episode, that this should include assigning responsibilities for maintenance therapy to an assistant when it is clinically appropriate. Some respondents stated that permitting PTAs and OTAs to furnish maintenance therapy services would give Medicare patients greater access to care and permit therapists and therapy providers more flexibility for resource utilization.

After considering respondents' concerns about the incongruity between our Part B and Part A maintenance therapy policy, and to provide flexibility to increase the availability of needed health care services during the COVID–19 PHE, we amended our policy on an interim final basis in the May 1st COVID–19 IFC (85 FR 27550 through 27629) to allow the physical therapist (PT) or occupational therapist (OT) who established the maintenance program to assign the duties to a PTA or OTA, as clinically appropriate, to perform maintenance therapy services.

We explained that making this change could free-up the PT or OT to furnish other services, particularly those related to the COVID–19 PHE that require a therapist's assessment and evaluation skills, and including the CTBS, that is, e-visits, virtual visits, remote evaluations, and phone evaluations—that were added as ''sometimes therapy'' services in the March 31st COVID–19 IFC for PTs, OTs and speech-language pathologists (SLPs). We stated explicitly that the maintenance therapy services furnished by therapist-supervised OTAs and PTAs will be paid in the same manner as those we already pay for as rehabilitative therapy services, and referred the reader to regulatory payment conditions for Part B outpatient occupational and physical therapy services (§§ 410.59 and 410.60, respectively) that require, as a basic rule, that the services be provided by an individual meeting qualifications in 42 CFR part 484 for an OT or PT, or an appropriately supervised OTA or PTA.

In this proposed rule, we are proposing to make permanent our Part B policy for maintenance therapy services effective January 1, 2021 in order to create greater conformity in payment policy for maintenance therapy services that are furnished and paid under Part B with those in SNF and HH settings under Part A. If adopted, our policy would dovetail with our amended policy set forth in the May 1st COVID–19 IFC (85 FR 27550 through 27629) that grants PTs and OTs the discretion to delegate maintenance therapy services to the PTAs and OTAs, as clinically appropriate, for the duration of the PHE. If the PHE is ended prior to January 1, 2021, the therapist would need to personally furnish the maintenance therapy services until the proposed policy change takes effect. We plan to address comments from the May 1st COVID–19 IFC in conjunction with the comments from this proposed rule in the final rule, given the comment period has only just closed on that IFC.

Our policy for maintenance therapy services is explained in section 220.2 of chapter 15 of the Medicare Benefit Policy Manual (see *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf*) in cases where rehabilitative services, requiring the improvement in the patient's functional status, are no longer or were not previously covered. This manual section explains that skilled therapy services related to a reasonable and necessary maintenance program are available for the establishment or design of the maintenance program and the delivery of the maintenance program, that is, maintenance therapy, when it needs to be carried out as maintenance therapy services. Maintenance programs that can be carried out by the patient alone or with the assistance of caregivers, are not covered. Sections 230.1 and 230.2 of chapter 15 of the Medicare Benefit Policy Manual specify that a PTA or OTA may not provide skilled maintenance program services.

In considering our proposal, we reviewed regulatory requirements for conditions of payment for outpatient occupational therapy, physical therapy, and speech-language pathology services at §§ 410.59, 410.60 and 410.62; the regulation for therapy treatment plans at § 410.61, and the regulations specifying treatment plan certification and recertification requirements at § 424.24 for Part B occupational therapy, physical therapy, and speech-language

pathology services, in addition to the above mentioned manual provisions.

Given that we already make payment for rehabilitative services requiring improvement in the patient's functional status when they are furnished by PTAs and OTAs at the discretion of the supervising therapist treating the patient in accordance with the therapist-established plan of care, we believe that it would be appropriate for the therapist to use that same judgement in deciding whether to delegate to the PTA or OTA the performance of maintenance therapy services under the associated plan of care. We believe that there is little difference between the rehabilitative therapy services furnished to improve a patient's functional status and those for maintenance therapy services other than the goals set by the therapist in the therapy plan that are aimed to maintain, slow or prevent further decline of a patient's condition. We do not believe that the therapist-only maintenance therapy requirement is needed in the case of outpatient physical or occupational therapy services, and instead believe that it would be appropriate for an OT or PT to be permitted to use their professional judgement to assign the performance of maintenance therapy services to an OTA or PTA when it is clinically appropriate to do so.

As such, we propose to allow, on a permanent basis, therapists to delegate performance of maintenance therapy services to an OTA or PTA for outpatient occupational and physical therapy services in Part B settings beginning January 1, 2021. This proposal would better align our Part B policy with that in SNFs and HH paid under Part A where maintenance therapy services may be performed by a therapist or a therapy assistant. Since our regulations at §§ 410.59, 410.60, 410.61, 410.62 and 424.24, do not now distinguish between rehabilitative and maintenance therapy services, we are not proposing to amend them. Instead, we propose to revise sections 220.2, 230.1 and 230.2 of chapter 15 of the Medicare Benefit Policy Manual to clarify that PTs and OTs no longer need to personally perform maintenance therapy services and to specifically remove the prohibitions on PTAs and OTAs from furnishing such services. Therefore, we believe our proposal to allow PTs and OTs to delegate maintenance therapy services to their supervised assistants is in keeping with Executive Order #13890 and appeals by respondents to our request for feedback on scope of practice that followed, rather than the alternative option of maintaining the pre-COVID–19 policy of requiring PTs and OTs to personally furnish them, after the COVID–19 PHE is ended.

We note that therapists and therapy providers should consult the CQ and CO modifier policies to consider whether these modifiers should be applied to claims for services furnished in whole or in part by PTAs and OTAs which will, beginning January 1, 2022, be paid at 85 percent of the amount that would otherwise apply for the service, as required by section 1834(v) of the Act which was added by section 53107 of the Bipartisan Budget Act of 2018. See the CY 2020 PFS rulemaking for policies related to the application of CQ and CO modifiers and the associated regulatory requirements (84 FR 40558 through 40564 (proposed rule) and 84 FR 62702 through 60708 (final rule)).

5. Medical Record Documentation

As we established in the CY 2020 PFS final rule (84 FR 62681 through 62684), and similarly expressed in the May 1st COVID–19 IFC (85 FR 27556 through 27557), any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. We note that although there are currently no documentation requirements that would impact payment for PTs, OTs, or SLPs when documentation is added to the medical record by persons other than the therapist, we are responding in this proposed rule to stakeholder requests for clarification. Specifically, we are clarifying that the broad policy principle that allows billing clinicians to review and verify documentation added to the medical record for their services by other members of the medical team also applies to therapists. This will help ensure that therapists are able to spend more time furnishing therapy services, including pain management therapies to patients that may minimize the use of opioids and other medications, rather than spending time documenting in the medical record. We emphasize that, while any member of the medical team may enter information into the medical record, only the reporting clinician may review and verify notes made in the record by others for the services the reporting clinician furnishes and bills. We also emphasize that information entered into the medical record should document that the furnished services are reasonable and necessary.

H. 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.C. 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 re-proposed 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 proposed 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 includes 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.

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 valuation considered for specific codes. Table 24 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, 2020. The proposed work RVUs, work time and other payment information for all CY 2021 payable codes are available on the CMS website under downloads for the CY 2021 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 25 details our 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 refinements that would be common across codes. 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 25 result in changes under the $0.35 threshold and are unlikely to result in a change to the RVUs.

We also note that the direct PE inputs for CY 2021 are displayed in the CY 2021 direct PE input files, available on the CMS website under the downloads for the CY 2021 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 CY 2021 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 2021 we received invoices for several new supply and equipment items. Tables 27 and 28 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 27 and 28 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 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 2021 are available on the CMS website under downloads for the CY 2021 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 2021

(1) Fine Needle Aspiration (CPT Codes 10021, 10004, 10005, 10006, 10007, 10008, 10009, 10010, 10011, and 10012)

In June 2017, the CPT Editorial Panel deleted CPT code 10022, revised CPT code 10021, and created nine new codes to describe fine needle aspiration procedures with and without imaging guidance. These ten codes were surveyed and reviewed for the October 2017 and January 2018 RUC meetings. In the CY 2019 final rule, we finalized the RUC-recommended work RVU for seven of the ten codes in the family, while finalizing a lower work RVU for CPT codes 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*), 10009 (*Fine needle aspiration biopsy, including CT guidance; first lesion*), and 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*). For a full discussion of this review, we refer readers to the CY 2019 PFS final rule (83 FR 59517 through 59521).

Following the publication of the CY 2019 final rule, RUC staff stated that CMS erroneously double-counted the utilization for new codes that had image guidance bundled. We disagreed that this constituted a technical error and communicated to the RUC in conversations following the publication of the rule that the surveying specialties could instead nominate the affected codes from these families as being potentially misvalued. At the January 2020 RUC meeting, the RUC reaffirmed its CY 2019 recommendations for physician work and direct practice expense (PE) for the ten codes in the Fine Needle Aspiration code family.

In discussing this group of codes, we would like to clarify again that we disagree with the RUC and do not believe that utilization was erroneously double-counted for this code family. We publish our proposed utilization crosswalk each year as a public use file available on the CMS website; the current such file is available under downloads for the CY 2021 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* During the CY 2019 rule cycle, we proposed the utilization crosswalk for the Fine Needle Aspiration family as it was recommended to CMS by the RUC, and we did not receive any comments on this subject until after the valuation of these codes had been finalized. We proposed and finalized the utilization crosswalk for this code family as recommended by the RUC without receiving any comments from the RUC or other stakeholders. If the RUC or other stakeholders believed that what CMS had proposed was incorrect or misunderstood what the RUC had recommended, there was an opportunity to comment during the 60 days following the publication of the proposed rule. We disagree that the utilization crosswalk was erroneous, and we did not make a technical correction following the publication of the CY 2019 final rule for this reason.

We also disagree with the RUC that the utilization crosswalk was ''the

principle reason CMS rejected the RUC recommendations'' for the codes in the Fine Needle Aspiration family, as stated in the RUC's CY 2021 recommendations for this code family. As we stated in the CY 2019 proposed rule and restated in the CY 2019 final rule, our refinements to the work RVUs of CPT codes 10021, 10005, and 10009 were primarily based on changes in surveyed work time and the relationship between the codes in the family. For example, this was our rationale for refining the work RVU of CPT code 10021 from the RUC-recommended value of 1.20 to the finalized value of 1.03: In reviewing CPT code 10021, we noted that the recommended intraservice time is decreasing from 17 minutes to 15 minutes (12 percent reduction), and the recommended total time is decreasing from 48 minutes to 33 minutes (32 percent reduction); however, the RUC-recommended work RVU is only decreasing from 1.27 to 1.20, which is a reduction of just over 5 percent. In the case of CPT code 10021, we believed that it was more accurate to propose a work RVU of 1.03 based on a crosswalk to CPT code 36440 to account for these decreases in the surveyed work time (83 FR 59518). We note that this primary rationale for refining the work RVU did not mention the utilization crosswalk at all.

When we communicated to the RUC following the publication of the CY 2019 final rule that the codes in the Fine Needle Aspiration family could be nominated as potentially misvalued, we indicated that we were open to receiving new information about the valuation of these codes. In reaffirming its recommendations from CY 2019, however, the RUC has not provided any new information that was not already presented for the previous CMS review of these codes. Therefore, we are not proposing any changes to the codes in the Fine Needle Aspiration family, as the reaffirmed CY 2021 RUC recommendations are identical to the CY 2019 RUC recommendations that already went through notice and comment rulemaking. We welcome the submission of new information regarding these services that was not part of the previous CY 2019 review of the code family.

(2) Tissue Expander Other Than Breast (CPT Code 11960)

This service was included in a larger group of similarly related codes that were recommended for review for the October 2019 RUC meeting. The RUC recommended to re-review this code at a more granular level for the January 2020 RUC meeting.

We disagree with the RUC-recommended work RVU of 12.40 for CPT code 11960 (tissue expander other than breast). We are proposing to maintain the current work RVU of 11.49 supported by a reference code, CPT code 45560 (repair of rectocele (separate procedure)), which has a work RVU of 11.50. CPT code 45560 shares the same intraservice time of 90 minutes with CPT code 11960 and has a slightly higher total time of 367 minutes. The recommended total time for CPT code 11960 decreased from 444 minutes to 357 minutes, with a slight increase in intraservice time of 78 minutes to 90 minutes. We believe the similar work RVU of the reference CPT code 45560, as well as the reduction in total time, supports maintaining the current work RVU of 11.49 for CPT code 11960. We are proposing the RUC-recommended direct PE inputs for CPT code 11960 without refinements.

(3) Breast Implant-Expander Placement (CPT Codes 11970, 19325, 19340, 19342, and 19357)

These services were included in a larger group of 22 breast reconstruction and similarly related codes that were recommend for survey for the October 2019 RUC meeting. At the October 2019 RUC meeting, these codes were recommended for a more granular review for the January 2020 RUC meeting.

We disagree with the RUC-recommended work RVU of 8.01 for CPT code 11970 (*replacement of tissue expander with permanent implant*). We are proposing a work RVU of 7.49 supported by a reference code CPT code 35701 (*exploration not followed by surgical repair, artery; neck (e.g., carotid, subclavian)*), which has a work RVU of 7.50. CPT code 35701 shares the same intraservice time of 60 minutes with CPT code 11970 and has a slightly higher total time of 229 minutes as compared to 216 minutes. In addition, during our review of CPT code 11970, we noted that the recommended intraservice time is decreasing from 78 minutes to 60 minutes and the recommended total time of 231 minutes is decreasing to 216 minutes. We also note that our proposed work RVU of 7.49 for CPT code 11970 is equal to the total time ratio amount, which is the current total time compared to the RUC-recommended total time. We are proposing the RUC-recommended direct PE inputs for CPT code 11970.

We disagree with the RUC-recommended work RVU of 8.64 for CPT code 19325 (breast augmentation with implant). Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 11970 and 19325 is equivalent to the RUC-recommended interval of 0.63 RVUs. Therefore, we are proposing a work RVU of 8.12 for CPT code 19325, based on the recommended interval of 0.63 additional RVUs above our proposed work RVU of 7.49 for CPT code 11970. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We are also supporting our proposed work RVU of 8.12 based on a reference code, CPT code 25652 (open treatment of ulnar styloid fracture). CPT code 25652 shares the same intraservice time of 60 minutes and the same total time of 225 minutes with a lower work RVU of 8.06. In addition, during our review of CPT code 19325, we noted that the total time has decreased from 244 minutes to 225 minutes and the intraservice time has decreased from 90 minutes to 60 minutes. We are proposing the RUC-recommended direct PE inputs for CPT code 19325.

We disagree with the RUC-recommended work RVU of 11.00 for CPT code 19340 (*insertion of breast implant on same day of mastectomy (i.e. immediate)*). Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 19325 and 19340 is equivalent to the RUC-recommended interval of 2.36 RVUs. Therefore, we are proposing a work RVU of 10.48 for CPT code 19340, based on the recommended interval of 2.36 additional RVUs above our proposed work RVU of 8.12 for CPT code 19325. We are also supporting our proposed work RVU of 10.48 based on a reference code, CPT code 47562 (*laparoscopy, surgical; cholecystectomy*). CPT code 47562 shares the same intraservice time of 80 minutes and only a slightly lower total time of 251 minutes with a similar work RVU of 10.47. In addition, during our review of CPT code 19340, we noted that the total time has decreased from 366 minutes to 261 minutes and the intraservice time has decreased from 120 minutes to 80 minutes. We are proposing the RUC-recommended direct PE inputs for CPT code 19340.

We disagree with the RUC-recommended work RVU of 11.00 for CPT code 19342 (*insertion or replacement of breast implant on different day from mastectomy*). Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work

between CPT codes 19325 and 19342 is equivalent to the RUC-recommended interval of 2.36 RVUs. Therefore, we are proposing a work RVU of 10.48 for CPT code 19342, based on the recommended interval of 2.36 additional RVUs above our proposed work RVU of 8.12 for CPT code 19325. We also note that the RUC-recommended work RVU of 11.00 is equal to the RUC-recommended work RVU for CPT code 19340 because they have stated that both services involve an identical amount of physician work and similar times. We are also supporting our proposed work RVU of 10.48 based on a reference code, CPT code 47562 *(laparoscopy, surgical; cholecystectomy*). CPT code 47562 shares the same intraservice time of 80 minutes and only a slightly lower total time of 251 minutes with a similar work RVU of 10.47. The total time for CPT code 19342 has decreased from 320 minutes to 252 minutes and the intraservice time has decreased from 115 minutes to 80 minutes. We are proposing the RUC-recommended direct PE inputs for CPT code 19342.

We disagree with the RUC-recommended work RVU of 15.36 for CPT code 19357 (*tissue expander placement in breast reconstruction, including subsequent expansion*). Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 11970 and 19357 is equivalent to the RUC-recommended interval of 7.35 RVUs. Therefore, we are proposing a work RVU of 14.84 for CPT code 19357, based on the recommended interval of 7.35 additional RVUs above our proposed work RVU of 7.49 for CPT code 11970. We are also supporting our proposed work RVU of 14.84 based on a reference code, CPT code 37605 (*ligation; internal or common carotid artery*). CPT code 37605 shares the same intraservice time of 90 minutes and only a slightly lower total time of 342 minutes with a lower work RVU of 14.28. In addition, during our review of CPT code 19357, we noted that the total time has decreased from 468 minutes to 344 minutes and the intraservice time has decreased from 110 minutes to 90 minutes. We are proposing the RUC-recommended direct PE inputs for CPT code 19357.

(4) Breast Implant-Expander Removal (CPT Codes 11971, 19328, and 19330)

These services were included in a group of codes that were recommended for survey for the October 2019 RUC meeting as part of a large group of 22 breast reconstruction and similarly related services. At the October 2019 RUC meeting, they agreed that a 22 code family was too expansive. They recommended these codes be re-reviewed as part of a smaller and more granular code family for the January 2020 RUC meeting.

We disagree with the RUC-recommended work RVU of 7.02 for CPT code 11971 (*removal of tissue expander w/out insertion of implant*). Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 11970 and 11971 is equivalent to the RUC recommended interval of 0.99 RVUs. Therefore, we are proposing a work RVU of 6.50 for CPT code 11971, based on the recommended interval of 0.99 RVUs below our proposed work RVU of 7.49 for CPT code 11970. We note that as stated previously, we believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within families of similarly revised codes. We are also supporting our proposed work RVU of 6.50 based on a reference code, CPT code 25671 (*percutaneous skeletal fixation of distal radioulnar dislocation*). CPT code 25671 shares the same intraservice time of 45 minutes and a slightly less total time of 210 minutes with a very similar work RVU of 6.46. In addition, during our review of CPT code 11971, we noted that the total time has decreased from 303 minutes to 215 minutes and the intraservice time has decreased from 90 to 45 minutes. We are proposing the RUC-recommended direct PE inputs for CPT code 11971.

We disagree with the RUC-recommended work RVU of 7.44 for CPT code 19328 (*removal of intact breast implant*). Although we disagree with the RUC-recommended work RVU, we propose increasing the current work RVU from 6.48 to 6.92 to account for the increases in total and intraservice time. We also concur that the relative difference in work between CPT codes 11971 and 19328 is equivalent to the RUC recommended interval of 0.42 RVUs. Therefore, we are proposing a work RVU of 6.92 for CPT code 19328, based on the recommended interval of 0.42 additional RVUs above our proposed work RVU of 6.50 for CPT code 11970. We are also supporting our proposed work RVU of 6.92 based on a reference code, CPT code 28289 (*Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant*). CPT code 28289 shares the same intraservice time of 45 minutes and a slightly higher total time of 210 minutes with a very similar work RVU of 6.90. The total time for CPT code 19328 has increased from 173 minutes to 199 minutes and the intraservice time has increased from 38 to 45 minutes. We are proposing the RUC-recommended direct PE inputs for CPT code 19328.

We are proposing the RUC-recommended work RVU of 9.00 for CPT code 19330 (*removal of ruptured breast implant, including implant contents*). The survey total time for CPT code 19330 has increased from 218 minutes to 229 minutes and the intraservice time has increased from 62 minutes to 75 minutes. We are also proposing the RUC-recommended direct PE inputs for this code without refinements.

(5) Modified Radical Mastectomy (CPT Code 19307)

The RUC recommended that CPT code 19307 (*Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle*) be surveyed for the January 2020 RUC meeting for site of service anomaly. The Relativity Assessment Workgroup identified services performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital E/M services within the global period and with 2018 Medicare utilization over 5,000. The RUC recommended lowering the work RVU to 17.99 which is the survey 25th percentile.

We are proposing the RUC-recommended work RVUs of 17.99 for CPT code 19307. We are also proposing the RUC-recommended direct PE inputs for this code.

(6) Breast Lift-Reduction (CPT Codes 19316 and 19318)

These services were included in a larger code group of similarly related services that were recommended for review for the October 2019 RUC meeting. CPT code 19316 (*mastopexy*) and CPT code 19318 (*Breast reduction*) were then recommended for a more granular review for the January 2020 RUC meeting.

We are proposing the RUC-recommended work RVU of 11.09 for CPT code 19316 (*mastopexy*) and 16.03 for CPT code 19318 (*Breast reduction*). We are proposing the RUC-recommended direct PE inputs for this code family without refinements.

(7) Secondary Breast Mound Procedure (CPT Codes 19370, 19371, and 19380)

These services were included in a large group of breast reconstruction codes that were recommended to be surveyed for the October 2019 RUC meeting. At the October 2019 RUC meeting, the RUC concurred with the

more granular code families but recommended these codes be re-surveyed for the January 2020 RUC meeting.

We disagree with the RUC-recommended work RVU of 10.0 for CPT code 19370 (*Revision of peri-implant capsule, breast, including capsulorrhaphy, and/or partial capsulectomy*). We are proposing to maintain the current work RVU of 9.17 based on a supporting reference code, CPT code 28299 (*Correction, hallux valgus (bunionectomy*), with sesamoidectomy, when performed; with double osteotomy, any method), which has a work RVU of 9.29. CPT code 28299 shares a similar intraservice time of 75 minutes with CPT code 19370 and has a slightly higher total time of 256 minutes. In addition, we noted during our review of CPT code 19370 that the recommended total time has increased minimally from 253 minutes to 255 minutes, with a slight decrease in intraservice time of 82 minutes to 78 minutes. We believe the similar work RVU of the supporting CPT code 28299, as well as the minimal changes in physician work time for CPT code 19370, supports maintaining the current work RVU of 9.17. We are proposing the RUC-recommended direct PE inputs for CPT code 19370 without refinements.

We disagree with the RUC-recommended work RVU of 10.81 for CPT code 19371 (*Peri-implant capsulectomy, breast, complete, including removal of all intra-capsular contents*). Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 19370 and 19371 is equivalent to the RUC recommended interval of 0.81 RVUs. Therefore, we are proposing a work RVU of 9.98 for CPT code 19371, based on the recommended interval of 0.81 additional RVUs above our proposed work RVU of 9.17 for CPT code 19370. We note that as stated previously, we believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We are also supporting our proposed work RVU of 9.98 based on a reference code, CPT code 25628 (*Open treatment of carpal scaphoid (navicular) fracture, includes internal fixation, when performed*). CPT code 25628 shares the same intraservice time of 90 minutes and a slightly higher total time of 277 minutes with a work RVU of 9.67. In addition, during our review of CPT code 19371, we noted that the total time for CPT code 19371 has decreased from 306 minutes to 261 minutes and the intraservice time has decreased from 117 to 90 minutes. We are proposing the RUC-recommended direct PE inputs for CPT code 19371.

We disagree with the RUC-recommended work RVU of 12.00 for CPT code 19380 (Revision of reconstructed breast (*eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)*). Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 19371 and 19380 is equivalent to the RUC recommended interval of 1.19 RVUs. Therefore, we are proposing a work RVU of 11.17 for CPT code 19380, based on the recommended interval of 1.19 additional RVUs above our proposed work RVU of 9.98 for CPT code 19371. We are also supporting our proposed work RVU of 11.17 based on a reference code, CPT code 64569 (*Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generato*). CPT code 64569 shares the same intraservice time of 120 minutes and only a slightly higher total time of 312 minutes with a work RVU of 11.0. The total time increased from 277 minutes to 307 minutes and the intraservice time has increased from 89 minutes to 120 minutes. We are proposing the RUC-recommended direct PE inputs for CPT code 19380.

(8) Hip-Knee Arthroplasty (CPT Codes 27130 and 27447)

CPT codes 27130 (*Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft*) and 27447 (*Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)*) were identified as potentially misvalued codes under the CMS high expenditure procedural code screen in the CY 2014 final rule with comment period (78 FR 74334). These codes were reviewed by the AMA RUC who provided recommendations for work RVUs and physician time for these services for CY 2014. We agreed with the RUC recommendation to value CPT code 27130 and CPT code 27447 equally and thus established the same CY 2014 interim final work RVUs for these two procedures (78 FR 74334). This change resulted in a 1.12 work RVU increase for the visits in the global period. We added the additional work to the AMA RUC-recommended work RVU of 19.60 for CPT codes 27130 and 27447, resulting in an interim final work RVU of 20.72 for both services.

In the CY 2015 final rule with comment period (79 FR 67632), we discussed how in the CY 2014 final rule with comment period, we sought public comment regarding the appropriate work RVUs for these services and the most appropriate reconciliation for the conflicting information regarding time values for these services as presented to us by the physician community. We did not find the rationales provided for modifying the interim final work values established in CY 2014 compelling, and thus we finalized the CY 2014 interim final values for these procedures based upon the best data we had available and to preserve appropriate relativity with other codes.

In the CY 2019 final rule (83 FR 59500 through 595303), CPT code 27130 and CPT code 27447 were added to the list of potentially misvalued codes. A stakeholder submitted information requesting that CMS nominate these codes as potentially misvalued. The stakeholder stated that there were substantial overestimates in pre-service and post-service time including follow-up inpatient and outpatient visits that do not take place included in the valuation of the service. As a result the codes were resurveyed for the October 2019 RUC meeting.

We are proposing the RUC-recommended work RVU of 19.60 for CPT code 27130 and the RUC-recommended work RVU of 19.60 for CPT code 27447. We are also proposing the RUC-recommended direct PE inputs for both codes. Additionally, we are seeking comment from the medical community on how to consider and/or include pre-optimization time (pre-service work and/or activities to improve surgical outcomes) going forward. We are also interested in stakeholders' thoughts on what codes could be used to capture these pre-optimization activities that could be billed in conjunction with the services discussed previously. Overall, we are interested in continuing our ongoing dialog with stakeholders about how CMS might pay more accurately for improved clinical outcomes that may result from increased efficiency in furnishing care through activities, such as pre-optimization and are appreciative of information provided by the medical community. We invite the medical community to continue to engage with CMS on this and other topics.

(9) Toe Amputation (CPT Codes 28820 and 28825)

These services were identified by the RUC Relativity Assessment Workgroup through a site of service anomaly screen based on the review of 3 years of data (2015, 2016 and 2017) for services with utilization over 10,000 in which a service is typically performed in the inpatient hospital setting, yet only a half discharge day management identified by CPT code 99238 is included. Prior to conducting the RUC survey, the specialty societies recommended that it would be appropriate for these services to have their global period changed from 090-day to 000-day so the site of service is less of a contributing factor to the codes' valuation. These codes were surveyed as a 000-day global service, and we are proposing them as 000-day global services.

We disagree with the RUC-recommended work RVU of 4.10 for CPT code 28820 (*Amputation, toe; metatarsophalangeal joint*). We believe that it would be more accurate to propose a work RVU of 3.51, and we are supporting this value with a crosswalk to CPT code 33958 (*Extracorporeal membrane oxygenation (ECMO)/ extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed*)), which has a work RVU of 3.51, to account for the decrease in the surveyed work time. We do not believe the RUC-recommended reduction in work RVU from the current value of 5.82 is commensurate with the RUC-recommended 102-minute reduction in total time. We believe that a further reduction in work RVUs is warranted given the significant reduction in RUC-recommended physician time.

We disagree with the RUC-recommended work RVU of 4.00 for CPT code 28825 (*Amputation, toe; interphalangeal joint*). We are proposing a work RVU of 3.41 based on the RUC-recommended increment relationship between this code and CPT 28820 (a difference of -0.10), which we apply to our proposed value for the latter code. We do not believe the RUC-recommended reduction in work RVU from the current value of 5.37 is commensurate with the RUC-recommended 97-minute reduction in total time. We believe that a further reduction in work RVUs is warranted given the significance of RUC-recommended reduction in physician time.

For the direct PE inputs, we are proposing to refine the pre-service clinical labor times to conform to the 000-day global period standards for both codes in the family for CPT codes 28820 and 28825. We are also proposing to refine the clinical labor times for the ''Provide education/obtain consent'' (CA011) and the ''Prepare room, equipment and supplies'' (CA013) activities to conform to our established standard time of 2 minutes each in the non-facility setting for CPT codes 28820 and 28825. We are also proposing to refine the equipment time to conform to these changes in the clinical labor time for both codes.

(10) Shoulder Debridement (CPT Codes 29822 and 29823)

In September 2019, the CPT Editorial Panel approved revision of CPT code 29822 (*Arthroscopy, shoulder, surgical; debridement, limited, 1 or 2 discrete structures (eg, humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies]*]) and CPT code 29823 (*Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures (eg, humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies]*]) to clarify limited and extensive debridement by specifying the number of discrete structures debrided and providing examples of the structures.

We are proposing the RUC-recommended work RVU of 7.03 for CPT code 29822 and 7.98 for CPT code 29823 without refinement.

For the direct PE inputs, we are proposing the RUC recommendations CPT codes 29822 and 29823 without refinement.

(11) Absorbable Nasal Implant Repair (CPT Codes 30XX0)

In September 2019, the CPT Editorial Panel approved the addition of CPT code 30XX0 (*Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)) to report repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)*).

We are proposing the RUC-recommended value of 2.80 work RVUs without refinement for CPT code 30XX0.

For the direct PE inputs, were also proposing the RUC-recommended values without refinement.

(12) Lung Biopsy-CT Guidance Bundle (CPT Code 324X0)

CPT codes 32405 (*Biopsy, lung or mediastinum, percutaneous needle*) and 77012 (*Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation*) were identified by the AMA through a screen of code pairs that are reported on the same day, same patient and same NPI number at or more than 75 percent of the time. The CPT Editorial Panel deleted CPT code 32405 and replaced it with 324X0 (*Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed*).

We are not proposing the RUC-recommended work RVU of 4.00, which is the survey median, because we believe this value somewhat overstates the increase in intensity. Although we do not imply that the decrease in time, when considering the aggregate time values for CPT codes 32405 and 77012, 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 the work RVU. Intraservice and total time ratios using the aggregate time values of current CPT codes 32405 and 77012 suggest a significantly lower work RVU; however, we do not believe a decrease from the current aggregate value of 32405 and 77012 is warranted. We believe there is some overlap in physician work and time for the two current services, and that the recommended increase to 4.00 does not appropriately recognize this overlap. Therefore, we are proposing a work RVU of 3.18, which is the sum of the work RVUs of the two base codes.

We are proposing the RUC-recommended direct PE inputs without refinement.

(13) Atrial Septostomy (CPT Codes 33XX0, 33XX1, 33XX2)

Septostomy procedures are performed on extremely small newborns and neonates with severe forms of congenital heart disease and are lifesaving/temporizing procedures that do not provide definitive therapy to these critically ill patients. These procedures are not typical of the Medicare population and are of low volume. CPT code 92992 (*Atrial septectomy or septostomy; transvenous*

method, balloon (eg, Rashkind type) (includes cardiac catheterization)) and CPT code 92993 (*Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)*), are carrier-priced codes. These services were not formally designated as potentially misvalued in the CY 2019 PFS final rule (83 FR 59500), but we did make mention that the RUC had signaled their intention to review these two codes. Both services were referred to the CPT Editorial Panel by the specialty societies who indicated that CPT code 92992 may not have included related imaging guidance, and also commented that CPT code 92993 was antiquated and rarely performed, so both CPT codes were deleted and are now being replaced with the following proposed CPT codes.

CPT code 33XX0 (*Transcatheter atrial septostomy (TAS) for congenital cardiac anomalies to create effective atrial flow, including all imaging guidance by the proceduralist, when performed, any method (eg, Rashkind, Sang-Park, balloon, cutting balloon, blade)*), is one of three codes intending to replace the two deleted Septostomy codes. For CPT code 33XX0, the RUC recommends an RVU only crosswalk to CPT code 33340 (*Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation*), which has a work RVU of 14.00. The RUC recommends 20 minutes of preservice evaluation time, 15 minutes of preservice positioning time, 15 minutes preservice scrub/dress/wait time, 55 minutes intraservice time and 45 minutes immediate postservice time, for 150 minutes total time. We are proposing the RUC recommended work RVU of 14.00 and physician times without refinement.

CPT code 33XX1 (*Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); initial intracardiac shunt*) is another proposed new procedure currently performed on neonate infants to children with severe forms of congenital heart disease, by having a stent implanted inside of an infant's beating heart (and not within a blood vessel). This stent replaces the methods in the old atrial septostomy codes utilizing the balloon and blade method. The RUC recommends 25 minutes preservice evaluation time, 15 minutes preservice positioning time, 15 minutes preservice scrub/dress/wait time, 92 minutes intraservice time and 60 minutes immediate postservice time, for 207 minutes total time. The RUC recommends 20.00 work RVUs for CPT code 33XX1. We are proposing the RUC recommended work RVUs and their recommended physician times.

CPT code 33XX2, (*Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); each additional intracardiac shunt location (List separately in addition to code for primary procedure)*), is the add-on code to the proposed new procedure CPT code 33XX1, for 60 minutes of physician intraservice time. The RUC recommends a work RVU of 10.50 for CPT code 33XX2. This value for the add-on code, in comparison to the recommended work value of 20.00 RVUs with 92 minutes/intraservice time and 207 minutes of total time for CPT code 33XX1 appears to be unsupportable given the 60 minutes of additional physician intraservice time. We are instead proposing a work RVU of 8.00 for add-on CPT code 33XX2, which is the 25th percentile value from the survey and of similar valuation from reference CPT code 93592 (*Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)*).

This family of CPT codes are facility-only services and have no direct PE inputs.

(14) Percutaneous Ventricular Assist Device Insertion (CPT Codes 339X1, 33990, 33991, 33992, 339X2, and 33993)

In May 2019, the CPT Editorial Panel approved the revision of four codes to clarify the insertion and removal of right and left heart percutaneous ventricular assist devices (PVAD), and the addition of two codes to report insertion of PVAD venous access and removal of right heart PVAD. These codes were surveyed with 000-day global periods and reviewed at the October 2019 RUC meeting.

We are proposing the RUC-recommended work RVUs for all six codes in the family. We are proposing a work RVU of 6.75 for CPT code 33990 (*Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only*), a work RVU of 6.75 for CPT code 339X1 (*Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only*), a work RVU of 8.84 for CPT code 33991 (*Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture*), a work RVU of 3.55 for CPT code 33992 (*Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), separate and distinct session from insertion*), a work RVU of 3.00 for CPT code 339X2 (*Removal of percutaneous right heart ventricular assist device, venous cannula, separate and distinct session from insertion*), and a work RVU of 3.10 for CPT code 33993 (*Repositioning of percutaneous right or left heart ventricular assist device, with imaging guidance, at separate and distinct session from insertion*).

Stakeholders contacted CMS regarding the valuation of the codes in this family following the arrival of the RUC recommendations. They stated that the RUC recommendations did not accurately reflect the work time of these procedures, which they stated to be increasing due to the adoption of new technology. The stakeholders requested that CMS propose to maintain the current work RVUs for the codes in this family and to crosswalk the work RVU of the new codes to existing codes.

We disagree with the stakeholders and are proposing the RUC-recommended work RVUs for each code in this family as noted previously. We note that in this case where the surveyed work times for the existing codes are decreasing and the utilization of CPT code 33990 is increasing significantly (quadrupling in the last 5 years), we have reason to believe that practitioners are becoming more efficient at performing the procedure, which, under the resource-based nature of the RVU system, lends support for proposing the RUC's recommended work RVUs. Although the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. We disagree

with the stakeholders that the incorporation of this new technology would necessarily be grounds for maintaining the current work RVU, as improvements in technology are commonplace across many different services and are not specific to this procedure. As detailed earlier, we also have reason to believe that the improved technology has led to greater efficiencies in the procedure which, under the resource-based nature of the RVU system, lends further support for proposing a lower work RVU for the existing CPT codes.

The RUC did not recommend and we are not proposing any direct PE inputs for this facility only code family. We are proposing a 000-day global period for all six codes as surveyed by the RUC.

(15) Esophagogastroduodenoscopy (EGD) With Biopsy (CPT Code 43239)

In the CY 2019 PFS final rule (83 FR 59500), CPT code 43239 (*Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple*) was publicly nominated for review under the potentially misvalued code initiative. As requested, the specialty societies conducted a survey for the April 2019 RUC meeting. The RUC survey results showed that the current work RVU of 2.39, which is below the survey 25th percentile work RVU of 2.50, accurately reflects the physician work for CPT code 43239.

We are proposing to maintain the current work RVU of 2.39 as recommended by the RUC. We are proposing the RUC-recommended direct PE inputs for CPT code 43239 without refinement.

(16) Colonoscopy (CPT Code 45385)

In the CY 2019 final rule (83 FR 59500), CPT code 45385 (*Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique*) was publicly nominated for review under the potentially misvalued code initiative. As requested, the specialty societies conducted a survey for the April 2019 RUC meeting. The RUC survey results showed that the current work RVU of 4.57, which is slightly above the survey 25th percentile work RVU of 4.50, accurately reflects the physician work for CPT code 45385.

We are proposing to maintain the current work RVU of 4.57 as recommended by the RUC. We are proposing the RUC-recommended direct PE inputs for CPT code 45385 without refinement.

(17) Transrectal High Intensity Focused US Prostate Ablation (CPT Codes 558XX)

In May 2019, the CPT Editorial Panel established a new code to report ablation of malignant prostate tissue with high intensity focused ultrasound (HIFU), including ultrasound guidance. For CPT code 558XX, we are not proposing the RUC recommendation to use the survey median work RVU of 20.00 to value this service because we believe total time ratios to the two key reference codes, CPT codes 55840 (*Prostatectomy, retropubic radical, with or without nerve sparing*) and 55873 (*Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)*) indicate that this value is somewhat overstated and does not accurately reflect the physician time, and because an analysis of all 090-global period codes with similar time values indicates that this service is overvalued. We are proposing a work RVU of 17.73 based on a crosswalk to CPT code 69930 (*Cochlear device implantation, with or without mastoidectomy*) which has similar total time and identical intraservice time values and is more consistent with other codes of similar time. We are proposing the RUC-recommended PE inputs without refinement.

(18) Computer-Aided Mapping of Cervix Uteri (CPT Code 57XX0)

In September 2019, the addition of CPT code 57XX0 (*Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect (List separately in addition to code for primary procedure)*) was approved by the CPT Editorial Panel to report computer-aided mapping of cervix uteri during colposcopy. The RUC recommended the survey median work RVU of 0.81 for this service. We are proposing the RUC-recommended value of 0.81 for CPT code 57XX0. We are also proposing the RUC-recommended direct PE inputs for this code.

We are seeking comment on a new medical supply indicated on the PE spreadsheet submitted by the RUC. A ''computer aided spectral imaging system (colposcopy) disposal speculum'' was noted in the RUC PE meeting materials. This name suggests it is digital. However, on the actual invoice submitted, the supply item in question was listed as a ''disposable medium speculum'' with no mention of a spectral imaging system or a digital component. We researched this speculum and could not find any evidence that it has a digital component. Therefore, we are proposing to change the name of this new supply item to ''disposable speculum, medium'' (SD337) to reflect the actual product on the invoice submitted. We are seeking clarification as to what aspect of the speculum is digital or if a cheaper, non-digital speculum would suffice. We note for example that the vaginal specula (SD118) supply has a CY 2021 price of $1.12 and we were able to find disposable medium specula readily available online for a price of roughly $1.00. We are proposing the new SD337 supply at the $5.80 price as listed on the invoice submitted in the RUC materials and are seeking comment as to why other disposable speculums at a lower price would not be typical for this procedure.

(19) Colpopexy (CPT Codes 57282 and 57283)

The CPT codes 57282 (*Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)*) and 57283 (*Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)*) were identified by the RUC Relativity Assessment Workgroup as services performed less than 50 percent of the time in the inpatient setting yet include inpatient hospital E/M services within the global period and the 2018 Medicare utilization is over 5,000. This code family was surveyed and reviewed for the January 2020 RUC meeting. For CY 2021, the RUC recommended a work RVU of 13.48 for CPT code 57282, and a work RVU of 13.51 for CPT code 57283.

We disagree with the RUC-recommended work RVUs for the CPT code family of 57282 and 57283. We are proposing a work RVU of 11.63 for CPT code 57282, and are also proposing to maintain the current work RVU of 11.66 for CPT code 57283. For CPT code 57283, we based our disagreement on the total time ratio between the current time of 349 minutes and the recommended time established by the survey of 231 minutes. This ratio equals 66 percent, and 66 percent of the current work RVU of 11.66 for CPT code 57283 equals a work RVU of 7.70. When we reviewed CPT code 57283, we found that the recommended work RVU was higher than other codes with similar time values. This is supported by the reference CPT codes we compared to CPT code 57283 with 90 minutes of intraservice time; reference CPT code 19350 (*Nipple/areola reconstruction*) has a work RVU of 9.11 with 229 minutes of total time, and reference CPT

code 47563 (*Laparoscopy, surgical; cholecystectomy with cholangiography*) which has a work RVU of 11.47 with 238 minutes of total time. 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 reflected in decreases to work RVUs. The recommendation from the RUC acknowledged that the time had decreased for CPT code 57283, and also noted that there has been an increase in intensity due to a change in technique and knowledge necessary to perform the service. In the case of CPT code 57283, we believe it would be more accurate to propose maintaining the current work RVU of 11.66 instead of the RUC-recommended work RVU of 13.51 to account for these decreases in the surveyed work time while still accounting for the increase in intensity. We also note that the intensity of CPT code 57283 would nearly double by maintaining the proposed work RVU of 11.66, due to the significant decreases in surveyed work time, which we believe supports the RUC's contention that the intensity of this code has increased over time.

For CPT code 57282, we disagree with the RUC-recommended RVU of 13.48. We note that the significant decrease in total time for code 57282 suggests an RVU lower than 13.48. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 57282 and 57283 is equivalent to the RUC-recommended interval of 0.03 RVUs. We believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Therefore, we are proposing a work RVU of 11.63 for CPT code 57282, based on the RUC recommended interval of 0.03 RVUs below our proposed work RVU of 11.66 for CPT code 57283.

We are proposing the RUC-recommended direct PE inputs for the CPT code family of 57282 and 57283 without refinement.

(20) Laparoscopic Colpopexy (CPT Code 57425)

The CPT code 57425 (*Laparoscopy, surgical, colpopexy (suspension of vaginal apex)*) was identified by the RUC Relativity Assessment Workgroup as a service performed less than 50 percent of the time in the inpatient setting yet includes inpatient hospital E/M services within the global period and the 2018 Medicare utilization is over 5,000. This service was surveyed and reviewed for the January 2020 RUC meeting.

We disagree with the RUC-recommended work RVU of 18.02 for CPT code 57425 and propose to maintain the current RVU of 17.03 based on the total time ratio between the current time of 404 minutes and the recommended time established by the survey of 351 minutes. This is supported by the reference CPT codes we compared to CPT code 57425 with the same intraservice time; reference CPT code 26587 (*Reconstruction of polydactylous digit, soft tissue and bone*) which has a work RVU of 14.50, and reference CPT code 20696 (*Application of multiplane (pins or wires in more than 1 plane), unilateral, external fixation with stereotactic computer-assisted adjustment (e.g., spatial frame), including imaging; initial and subsequent alignment(s), assessment(s), and computation(s) of adjustment schedule(s)*) which has a work RVU of 17.56. Both CPT codes 26587 and 20696 have 180 minutes of intraservice time, which is equal to the 180 minutes of intraservice time in the RUC recommendation for CPT code 57425, and over 400 minutes of total time. The total time for CPT code 57425 decreased from 404 to 351 minutes and the RUC did not appear to take this into account. Therefore, we are proposing to maintain the current work RVU of 17.03.

We are proposing the RUC-recommended direct PE inputs for CPT code 57425 without refinement.

(21) Intravitreal Injection (CPT Code 67028)

CPT code 67028 (*Intravitreal injection of a pharmacologic agent*) was identified via the RUC's Relativity Assessment Workgroup as a code where the original valuation was based on a crosswalk code that had since been revalued. The RUC recommended that CPT code 67028 should be surveyed for the April 2019 RUC meeting. We are proposing the RUC-recommended work RVU of 1.44 for CPT code 67028.

For the direct PE inputs, we are proposing to refine the clinical labor time for the ''Clean room/equipment by clinical staff'' (CA024) activity from the RUC-recommended 5 minutes to 3 minutes for CPT code 67028, because 3 minutes is the standard time for this clinical labor activity code, and we disagree that there would typically be a need for 2 additional minutes for cleaning, sterilizing, and re-packaging a reusable eyelid speculum in a sterile package to prepare for its next case. Additionally, 3 minutes is the standard time for cleaning the room *and* cleaning the equipment; although we agree that these cleaning tasks would take place, we do not believe that the removal of the same day E/M visit would result in the need for 2 additional minutes of cleaning time. We note that we are proposing to maintain the current time for this clinical labor activity, which was previously finalized in the CY 2011 PFS final rule at the standard value of 3 minutes (75 FR 73353). We are also proposing to refine the equipment times to match the change in clinical labor time.

(22) Dilation of Eustachian Tube (CPT Codes 697XX and 697X1)

In September 2019, the CPT Editorial Panel created two new codes CPT code 697XX (*Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral*) and CPT code 697X1(*Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral)*) to describe the dilation of the eustachian tube via surgical nasopharyngoscopy, unilateral and bilateral. We are proposing the RUC-recommended work RVUs of 3.00 and 4.27 for CPT codes 697XX and 697X1, respectively. For the direct PE inputs, we are proposing the RUC-recommended values without refinement.

(23) X-Ray of Eye (CPT Code 70030)

CPT code 70030 (*Radiologic examination, eye, for detection of foreign body*) was identified through an updated screen of CMS/Other source codes with Medicare utilization over 20,000. We are proposing the RUC-recommended work RVU of 0.18 for this service. We are proposing the RUC-recommended direct PE inputs without refinement.

(24) CT Head-Brain (CPT Codes 70450, 70460, and 70470)

In the CY 2019 PFS final rule (83 FR 59500 through 59503), a stakeholder nominated CPT code 70450 (*Computed tomography, head or brain; without contrast material*) as potentially misvalued, citing GAO and MedPAC reports that suggest that work RVUs are overstated for procedures such as these, and the specialty society surveyed family codes 70460 (Computed tomography, head or brain; with contrast material(s)) and 70470 (Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections). We are proposing the RUC

recommendation to maintain the current work RVUs of 0.85, 1.13, and 1.27 for CPT codes 70450, 70460, and 70470, respectively. For CPT code 70450, we note that the surveyed times are nearly identical to the current times for these services, and we believe that the RUC's reference to CPT code 70486 (*Computed tomography, maxillofacial area; without contrast material*), which has similar physician time and the same work RVU, is appropriate. For CPT code 70460, we note that the surveyed times are nearly identical to the current times for these services, and we believe that the RUC's reference to CPT code 70487 (*Computed tomography, maxillofacial area; with contrast material(s)*), which has similar physician time and the same work RVU is appropriate. Similarly, for CPT code 70470, we note that the surveyed times are nearly identical to the current times for these services, and we believe that the RUC's reference to CPT code 70488 (*Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections*)), which has similar physician time and the same work RVU, is appropriate. We also note that these codes are relatively consistently valued compared to other codes with similar time values and a global period of XXX. We are proposing the RUC-recommended direct PE inputs without refinement.

(25) Screening CT of Thorax (CPT Codes 71250, 71260, 71270, and 712X0)

In October 2018, AMA staff identified the CMS/Other Source codes with 2017 Medicare utilization over 30,000. HCPCS code G0297 (*Low dose ct scan (ldct) for lung cancer screening*) was identified. In January 2019, the RUC recommended to refer to CPT Editorial Panel to establish a permanent code for this procedure. In May 2019, the CPT Editorial Panel revised three codes and added one code to distinguish diagnostic computed tomography, thorax from computed tomography, thorax, low dose for lung cancer screening.

For CPT code 71250 (*Computed tomography, thorax; without contrast material*), we are not proposing the RUC recommendation to maintain the current work RVU of 1.16 as we believe this does not accurately reflect the reduction in physician work time, and because an analysis of all XXX-global period codes with similar time values indicates that this service is overvalued. We are instead recommending to propose a work RVU of 1.08 based on the ratio of current to RUC-recommended intraservice time. As support for this value, we note that it falls slightly below CPT code 76391 (*Magnetic resonance (eg, vibration) elastography*), which has a work RVU of 1.10 and also has higher physician time values.

Similarly, for CPT code 71260 (*Computed tomography, thorax; with contrast material(s)*), we are not proposing the RUC recommendation to maintain the current work RVU of 1.24 as we believe this does not accurately reflect the reduction in physician time, and we are instead proposing a work RVU of 1.16 based the ratio of current to RUC-recommended intraservice time. Although we disagree with the RUC-recommended work RVU, we concur that the relative difference between CPT codes 71250 and 71260 is equivalent to the RUC-recommended interval of 0.08 RVUs. As stated previously, we believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We note that that the proposed work RVU of 1.16 maintains the RUC-recommended interval of 0.08 additional RVUs above our proposed work RVU of 1.08 for CPT code 71250.

For CPT code 71270 (*Computed tomography, thorax; without contrast material, followed by contrast material(s) and further sections)*), we are not proposing the RUC recommendation to maintain the current work RVU of 1.38 as we believe this does not accurately reflect the reduction in physician time, and we are instead proposing a work RVU of 1.25 with a crosswalk to 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*) and we support this value by noting that it is slightly higher than values suggested by the ratio of current to RUC-recommended intraservice time For CPT code 712X0 (*Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)*), we are not proposing the RUC-recommended work RVU of 1.16, and we are instead proposing a work RVU of 1.08 so that the value of this code is consistent with that of CPT code 71250 as current code G0297 is valued based on the value of CPT code 71250, and to maintain the relative relationship among these codes. In the CY 2016 PFS final rule (80 FR 70974) we finalized that CPT code G0297 should be identically valued to CPT code 71250.

We are proposing the RUC-recommended direct PE inputs without refinement for CPT codes 71250, 71260, and 71270. For the direct PE inputs for CPT code 712X0, we are proposing 2 minutes for the clinical labor activity CA011: ''Provide education/obtain consent'' rather than the RUC-recommended 3 minutes to be consistent with other non-contrast screening codes, and we are proposing 4 minutes for the clinical labor activity CA038 ''Coordinate post-procedure services'' rather than the RUC-recommended 6 minutes to be consistent with other screening services, and because we do not see any compelling evidence that this service has changed significantly since G0297 was implemented for CY 2015 to warrant the recommended 2 additional minutes.

(26) X-Ray Bile Ducts (CPT Codes 74300, 74328, 74329, and 74330)

CPT codes 74300 (*Cholangiography and/or pancreatography; intraoperative, radiological supervision and interpretation*) and 74328 (*Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation*) were identified through a screen of CMS/Other Source codes with 2017 Medicare utilization over 30,000. CPT codes 74329 (*Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation*) and 74330 (*Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation*) were included as part of the same code family and the family was surveyed. The codes describe x-rays of the liver, pancreas, and bile ducts. They are performed in facilities and have no direct PE inputs.

We disagree with the RUC-recommended work RVU of 0.32 for CPT code 74300. We are proposing a work RVU of 0.27 based on a crosswalk to CPT code 74021 (*Radiologic examination, abdomen; 3 or more views*), one of the reference services from the RUC survey and that has an intraservice time of 4 minutes, nearly identical to the RUC's recommendation of 5 minutes of intraservice time for CPT code 74300. Our proposal is supported by CPT code 93922 (*Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries*) with a work RVU of 0.25 and an intraservice time of 5 minutes and a total time of 10 minutes. These times are nearly identical to the RUC's recommended

intraservice of 5 minutes and total time of 10 minutes for CPT code 74300.

We are proposing the RUC-recommended work RVU of 0.47 for CPT code 74328 (*Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation*), with an intraservice time of 10 minutes and a total time of 20 minutes.

We disagree with the RUC's recommended work RVU of 0.50 for CPT code 74329 (*Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation*). We are proposing a crosswalk to CPT code 74328 at a work RVU of 0.47 because the intraservice and total times for both codes are identical and we believe the work involved in the biliary ductal and pancreatic ductal systems is similar.

We disagree with the RUC's recommended work RVU of 0.70 for CPT code 74330 (*Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation*) and we are proposing a work RVU of 0.56 based on our proposal of the RUC's recommendation for CPT code 74328 to create internal consistency within the code family, based on our time ratio methodology and further supported by a reference to CPT code 93228 (*External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional*) with nearly identical and total time values to CPT code 74330.

The RUC did not recommend and we are not proposing any direct PE inputs for these codes.

(27) Venography (CPT Codes 75820 and 75822)

The review of CPT code 75820 (*Venography, extremity, unilateral, radiological supervision and interpretation*) was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 20,000 claims in a year. CPT code 75820 currently has a work RVU of 0.70 with 14 minutes of total time. This service involves the supervision and interpretation of a contrast injection and imaging of either the upper or lower extremity. For CPT code 75820, the RUC recommends 12 minutes preservice time, 20 minutes intraservice time, 10 minutes postservice time and 42 minutes of total time. The specialty societies' survey at the 25th percentile yielded a 1.05 work RVU, and it is the RUC's recommended work value. We are proposing the RUC recommended value for CPT code 75820.

CPT code 75822 (*Venography, extremity, bilateral, radiological supervision and interpretation*) is reviewed as part of the family of codes included with CPT code 75820. CPT code 75822 has a current 1.06 work RVU and 21 minutes of total time. The RUC recommends 15 minutes preservice time, 30 minutes intraservice time, 12 minutes postservice time and 57 minutes of total time, and the survey's 25th percentile work RVU of 1.48. The service is similar to CPT 75820, except that this CPT code is bilateral, involving the supervision and interpretation of a contrast injection and imaging of both of either the upper or lower extremities. The RUC recommends 1.48 work RVU and 57 minutes of total time for CPT code 75822. We are proposing these RUC recommended values for CPT code 75822.

(28) Introduction of Catheter or Stent (CPT Code 75984)

The RUC recommended reviewing CPT code 75984 (*Change of percutaneous tube or drainage catheter with contrast monitoring (e.g., genitourinary system, abscess) radiological supervision and interpretation*) after more utilization data was available, which resulted in this service being surveyed and reviewed for the April 2019 RUC meeting. We are proposing the work RVU of 0.83 as recommended by the RUC. We are proposing the RUC-recommended direct PE inputs for CPT code 75984 without refinement.

(29) Medical Physics Dose Evaluation (CPT Code 7615X)

The CPT Editorial Panel created CPT code 7615X (*Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report*), which is a new PE-only code. Because of the high amount of clinical staff time and the fact that there are not analogous services, the PE Subcommittee requested that the specialty societies conduct a PE survey. In addition, they stated that the service is stand-alone, meaning that the medical physicist works independently from a physician and there are no elements of the PE that are informed by time from a physician work survey. Following the meeting, the specialty societies developed a PE survey which was reviewed and approved by the Research Subcommittee. We are proposing the RUC-recommended direct PE inputs for CPT code 7615X without refinement.

(30) Ophthalmic Ultrasound Anterior Segment (CPT Code 76513)

CPT code 76513 (*Ophthalmic ultrasound, diagnostic; anterior segment ultrasound, immersion (water bath) B-scan or high resolution biomicroscopy*) was identified by the RUC due to volume growth, attributed to improved equipment. The CPT Editorial Panel has since revised this code to clarify that it is either unilateral or bilateral (it was previously unilateral). It was then surveyed. The code describes a test for glaucoma and is performed on the same day as an office/outpatient evaluation and management (O/O E/M) visit. The CPT and RUC removed CPT code 76513 from its former code family, creating a family of 1 service.

In reviewing this code, we noted that the recommended total time is decreasing from 19 minutes to 15 minutes (21 percent) while the RUC-recommended work RVU is decreasing from 0.66 to 0.60 (9 percent). 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 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 76513, we believe that it would be more accurate to propose a work RVU of 0.53 based on a crosswalk to CPT code 74230 (*Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (eg, barium) study*) with identical intraservice and total times.

For the direct PE inputs, we are proposing to make two refinements to the clinical labor times of CPT code 76513. We are proposing a reduction of 1 minute for the clinical labor task CA009: ''Greet patient, provide gowning, ensure appropriate medical records are available'' because the EHR information should already be linked from the preceding O/O E/M visit and the entry of information would be redundant and paid under indirect PE. We are also proposing a reduction of 1 minute for the clinical labor task CA011: ''Provide education/obtain consent'' to be consistent with the time for this

clinical labor task for the services in CPT code 76513's former code family.

(31) Radiation Treatment Delivery (CPT Code 77401)

CPT code 77401 (*Radiation treatment delivery, superficial and/or ortho voltage, per day*) was identified by the RUC Relativity Assessment Workgroup through a screen of high-volume growth, for services with 2017 Medicare utilization of 10,000 or more that has increased by at least 100 percent from 2012 through 2017. In January 2019, the RUC recommended to refer to this service to the CPT Editorial Panel to better define the set of services associated with delivery of superficial radiation therapy (SRT).

We are proposing the following direct PE refinements: A reduction of 2 minutes for the clinical labor task CA024: ''Clean room/equipment by clinical staff,'' to the standard 3 minutes, and we are not proposing to include the new equipment item ER119 ''Lead Room,'' as we do not have enough information on what this equipment item contains, and we are requesting more information to allow us to determine if it is more accurately priced as direct or indirect PE. CPT code 77401 is a PE only code and we are proposing to maintain the current work RVU of 0.00.

(32) Proton Beam Treatment Delivery (CPT Codes 77520, 77522, 77523, and 77525)

In April 2018, the RUC's Relativity Assessment Workgroup (RAW) identified CPT code 77522 (*Proton treatment delivery; simple, with compensation) and CPT code 77523 (Proton treatment delivery; intermediate*) as contractor-priced Category I CPT codes with 2017 estimated Medicare utilization over 10,000 services. Although the RAW agreed with the specialty society that this family of codes should remain contractor priced, the RUC determined that these services should be surveyed for PE. CPT codes 77520 (*Proton treatment delivery; simple, without compensation*) and 77525 (*Proton treatment delivery; complex*) were added to the family and the group was surveyed for PE for the April 2019 RUC meeting.

We encountered significant difficulties in reviewing the recommended direct PE inputs for the codes in the Proton Beam Treatment Delivery family. These difficulties were largely associated with determining a price for the two new equipment items in the code family, the Proton Treatment Vault (ER115) and the Proton Treatment Delivery System (ER116). These equipment items had extraordinarily high prices of $19,001,914 and $30,400,000 respectively on the invoices submitted with the code family. By way of comparison, the highest equipment price currently existing in our database for CY 2021 is the ''SRS system, Linac'' (ER082) equipment item at $4,233,825. We have concerns that establishing equipment pricing for the proton treatment vault and delivery system at a rate that is so much higher than anything else in our equipment database could distort relativity.

We also have concerns about the information provided on the submitted invoices used for the pricing of these two new equipment items. The invoices for both the Proton Treatment Vault and the Proton Treatment Delivery System contained building construction costs such as asphalt paving, masonry and carpentry expenses, drywall packaging, and the installation of electrical systems. We understand that these proton treatment equipment items are extremely capital-intensive and require the construction of custom-built offices to house the equipment. However, the expenses associated with constructing new office facilities fall outside of our direct PE methodology, and would be more accurately classified as a form of building maintenance or office rent under indirect PE. We do not agree that construction costs should be included as a form of direct PE because they are not individually allocable to a particular patient for a particular service. Although we agree that the provider does need to bear the costs associated with the storage of this equipment, this is a form of indirect PE under our methodology. We do not believe that it would serve the interests of relativity to include these building construction costs for the proton treatment equipment as a type of direct PE expense.

As a result, we are proposing to maintain contractor pricing for CPT codes 77520, 77522, 77523, and 77525 instead of proposing active pricing for these services. We believe that maintaining contractor pricing will allow the limited providers of these very expensive services to adapt more quickly to shifts in the market-based costs associated with the proton treatment equipment. The RUC similarly expressed concern in its recommendations about the extremely high cost of this equipment, agreed that these services were extremely hard to value, and noted the difficulties that had taken place in surveying the family of codes. The recommendations from the RUC also noted that proton treatment is a rapidly changing technology and the change in the treatment equipment often requires extensive modification to the vault. We believe that these frequent changes can be more accurately captured through contractor pricing as opposed to the need to update the pricing of the proton treatment equipment on an annual basis.

If we were to propose active pricing for the codes in this family, we believe that we would need to remove the building construction costs from the Proton Treatment Vault and the Proton Treatment Delivery System as forms of indirect PE, which would substantially lower their overall equipment prices. We would also refine the equipment times to the standard formula for highly technical equipment, which would result in 3 minutes less time for each equipment item (such as 14 minutes for all three equipment items in CPT code 77522).

(33) Immunization Administration (CPT Codes 90460, 90461, 90471, 90472, 90473, and 90474 and HCPCS codes G0008, G0009, and G0010)

Especially in the context of the current Public Health Emergency (PHE) related to the COVID–19 pandemic, it is evident that consistent beneficiary access to vaccinations is vital to public health. Many stakeholders have raised concerns regarding the reductions in payment rates for vaccine administration services over the past several years. The codes that describe these services have generally been valued based on a direct crosswalk to CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular). Because we proposed and finalized reductions in valuation for that code for CY 2018 and because the reductions in overall valuation have been subject to the multi-year phase-in of significant reductions in RVUs, the payment rate for the vaccine administration codes has been concurrently reduced.

In the CY 2020 PFS final rule, we acknowledged that it is in the public interest to ensure appropriate resource cost are reflected in the valuation of the immunization administration services that are used to deliver vaccines and noted that we planned to review the valuations for these services in future rulemaking. For CY 2020, we maintained the CY 2019 national payment amount for immunization administration services described by HCPCS codes G0008 (*Administration of influenza virus vaccine*), G0009 (*Administration of pneumococcal*

vaccine), and G0010 (*Administration of hepatitis b vaccine*) in the interim.

The RUC has recently re-submitted recommendations from 2009 regarding the appropriate valuation for the broader range of vaccine administration services, including CPT codes 90460 (*Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered*), 90471 (*Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid))*, and 90473 (*Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid))*. In its recommendation, the RUC noted that the current RVUs assigned are directly crosswalked from CPT code 96372 (like the vaccine administration G-codes had been) and the resulting payment rates are substantially lower than current Centers for Disease Control and Prevention (CDC) regional maximum charges. The RUC also pointed out that that appropriate payment for immunization administration that reflects resource cost is critical in maintaining high immunization rates in the United States, as well as having the capacity to respond quickly to vaccinate against preventable disease outbreaks.

We agree with the RUC's assertions regarding the importance of appropriate resource based valuations for vaccine administration services. We also recognize that the importance of these services is increased in the context of the current PHE related to the COVID–19 pandemic, especially should there be a vaccine for this particular disease.

We reviewed and considered the 2009 RUC-recommended direct PE inputs for CPT codes 90460–90474 (as well as the related G-codes) in place of the existing policy based on a crosswalk to CPT code 96372. However, the RUC-recommended direct PE inputs from 2009 would result in significant decreases in valuation for these 6 CPT codes even compared to the current crosswalk. At this time, we do not believe that either the existing crosswalk or the RUC recommendations from over a decade ago reflect the relative resource costs associated with these services. Without updated information to use in developing rates specific to these codes based on direct PE inputs, and in consideration of the import of these services for Medicare beneficiaries, as well as the public health concerns raised by commenters, we believe that it would be most appropriate to value these services using a crosswalk methodology that better reflects the relative resources involved in furnishing all of these services.

Therefore, we are proposing to crosswalk the valuation of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000 (*Introduction of needle or intracatheter, vein*). CPT code 36000 is a service with a nearly identical work RVU (0.18 as compared to 0.17 for CPT codes 90460, 90471, and 90473) and a similar clinical vignette. We believe that the additional clinical labor, supply, and equipment resources associated with the furnishing of CPT code 36000 more accurately capture the costs associated with these immunization codes. We also note that this crosswalk will result in payment rates for vaccine administration services at approximately the same CY 2017 rates that were paid prior to the revaluation of CPT code 96372, which had previously served as the basis of the crosswalk. We believe that the proposed crosswalk is the most accurate valuation of these services and will also serve to ensure the appropriate relative resources involved in furnishing all of these services is reflected in the payment for these critical immunization and vaccination services in the context of the health needs of Medicare beneficiaries.

Regarding the add-on codes associated with these services, CPT codes 90461 (*Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered*), 90472 (*Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid)*), and 90474 (*Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid)*), we note that the previous valuation methodology set their RVUs at approximately half of the valuation for the associated base codes, described above. Absent additional information, we are proposing to maintain that approach by valuing the three add-on codes at half of the RVUs of the aforementioned crosswalk to CPT code 36000.

Finally, we are proposing this valuation to apply to all of these existing vaccine administration codes, using the valuation of CPT code 90471 for base codes and CPT code 90472 for add-on codes. Should a vaccine for COVID–19 or other infectious disease become available during CY 2021, we would anticipate applying the same approach to valuing the administration of such vaccines, regardless of whether separate coding for such services would need to be introduced.

(34) Liver Elastography (CPT Code 91200)

CPT code 91200 (*Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report*) was targeted for review through the RUC's new technology/new services screen. The RUC reviewed 3 years of available Medicare claims data (2016, 2017 and 2018) and surveyed the code for the January 2020 meeting.

We are proposing the RUC-recommended work RVU of 0.21. We are also proposing the RUC-recommended direct PE inputs for CPT code 91200 without refinement.

(35) Remote Retinal Imaging (CPT Codes 92227, 92228, and 9225X)

The AMA CPT Editorial Panel revised CPT code 92227 (*Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral*) and CPT code 92228 (*Imaging of retina for detection or monitoring of disease; with remote physician or qualified health professional review and report, unilateral or bilateral*) that are reported for the treatment of diabetic retinopathy. Two practice sites are involved in these services: The acquiring site (for example, a primary care practice) and the reading site (for example, the ophthalmology practice). Both codes can be used to report diagnostic and monitoring services and the distinction is in whom provides the service: Physician (CPT code 92228) or clinical staff only (CPT code 92227). Thus, only CPT code 92228 includes work, accounting for the physician at the reading site. For both CPT codes 92227 and 92228, direct PE pays for the clinical staff at both sites.

The AMA CPT Editorial Panel also created CPT code 9225X (*Imaging of retina for detection or monitoring of disease; with point-of-care automated analysis with diagnostic report; unilateral or bilateral*) for point-of-care automated analysis that uses innovative artificial intelligence technology to perform the interpretation of the eye exam, without requiring that an ophthalmologist interpret the results. CPT code 9225X can be used at a primary care practice site and the artificial intelligence technology

interprets the test instead of a remotely located ophthalmologist. Because no physician is involved, this service is PE only. We are considering CPT code 9225X to be a diagnostic service under the PFS and are creating separate payment for it.

For CPT code 92228, we are proposing the RUC's recommended work RVU of 0.32. CPT codes 92227 and 9225X are PE only codes, and we are proposing a work RVU of 0.00 for both codes.

For both CPT codes 92227 and 92228, we are proposing the AMA RUC's recommended direct PE inputs. We are proposing two refinements to the direct PE inputs for CPT code 9225X. We are proposing a reduction of 1 minute for the clinical labor task CA009, ''Greet patient, provide gowning, ensure appropriate medical records are available,'' to be consistent with the amount of clinical labor for this task in CPT codes 92228 and 92227. We are also not proposing the RUC's recommendation of a $25 analysis fee for remote imaging because we consider this a service fee that constitutes a form of indirect PE and that this cost is appropriately captured via the indirect PE methodology as opposed to being included as a separate direct PE input. We do not believe that the analysis fee would be allocated to the use of an individual patient for an individual service, and can be better understood as an indirect cost similar to other administrative expenses.

(36) Auditory Evoked Potentials (CPT Codes 92584, 92X51, 92X52, 92X53, and 92X54)

CPT codes 92585 (*Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive*) and 92586 (*Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; limited*) were identified through a RAW requested screen of CMS/Other Source codes with 2017 Medicare utilization over 30,000. Since these codes were last valued, audiologists, the primary reporter of these services, can now report Medicare services independently. As a result, the audiologist work for these services is moving from PE to work.

To better describe tests of auditory function, the CPT created CPT code 92584 (*Electrocochleography*) and replaced CPT codes 92585 and 92586 with four new services. We are proposing the RUC-recommended work RVUs of 1.00 for CPT code 92584, 1.00 for CPT code 92X52 (*Auditory evoked potentials; for hearing status determination, broadband stimuli, with interpretation and report*), 1.50 for CPT code 92X53 (*Auditory evoked potentials; for threshold estimation at multiple frequencies, with interpretation and report*), and 1.05 for CPT code 92X54 (*Auditory evoked potentials; neurodiagnostic, with interpretation and report*). CPT code 92X51 (*Auditory evoked potentials; screening of auditory potential with broadband stimuli, automated analysis*) is a screening service and is not payable by Medicare. Therefore, we are not proposing a valuation for this code; however, we will display the RUC-recommended work RVU of 0.25.

We are proposing the RUC-recommended direct PE inputs for this code family without refinement.

(37) Vestibular Evoked Myogenic Potential Testing (CPT Codes 925X1, 925X2, and 925X3)

In response to a 2017 RAW request, AMA staff compiled a list of CMS/Other codes with Medicare Utilization of 30,000 or more. CPT code 92585 (*Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive*) was identified as one of the codes. In 2018, the AMA/RUC referred CPT code 92585 and its family member CPT code 92586 (*Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; limited*) to the February 2019 CPT Editorial Panel meeting to clarify code descriptors and define the terms ''limited'' and ''comprehensive'' auditory evoked potentials.

During the discussion of CPT codes 92585 and 92586 at the February 2019 CPT Editorial Panel meeting, specialty societies introduced a new procedure, Vestibular Evoked Myogenic Potential (VEMP), and suggested new coding. As a result, the CPT Editorial Panel created 3 new codes: CPT code 925X1 (*Vestibular evoked myogenic potential testing, with interpretation and report; cervical (cVEMP)*); CPT code 925X2 (*Vestibular evoked myogenic potential testing, with interpretation and report; ocular (oVEMP)*); and CPT code 925X3 (*Vestibular evoked myogenic potential testing, with interpretation and report; cervical and ocular*). The RUC reviewed the three codes at its April 2019 meeting.

We are proposing the RUC-recommended work RVU of 0.80 for CPT codes 925X1 and 925X2. For CPT code 925X3, we are proposing the RUC-recommended work RVU of 1.20. We also are proposing the RUC-recommended direct PE inputs without refinement for these three VEMP codes.

(38) Complete Electrocardiogram (CPT Codes 93000, 93005, and 93010)

In the CY 2019 PFS final rule (83 FR 59452), CPT code 93000 was nominated for review under the potentially misvalued code initiative. The RUC reviewed these services at the April 2019 meeting where the specialty societies explained that the family of electrocardiogram (ECG) codes were relatively unique in that CPT code 93000 (*Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report*) is the global service which is billed in the hospital setting, CPT 93005 (*Electrocardiogram, routine ECG with at least 12 leads; tracing only, without interpretation and report*) is the technical component and CPT 93010 is the professional component.

We are proposing the RUC-recommended work RVU of 0.17, which is the current value for both codes, for CPT codes 93000 and 93010. CPT code 93005 is a PE only technical component code, and we are proposing to maintain the current work RVU of 0.00.

For the direct PE inputs, we are also proposing the RUC-recommended values without refinement.

(39) External Extended ECG Monitoring (CPT Codes 93224, 93225, 93226, 93227, 93XX0, 93XX1, 93XX2, 93XX3, 93XX4, 93XX5, 93XX6, and 93XX7)

In September 2019, the CPT Editorial Panel replaced four Category III codes with 8 new Category I codes to report external electrocardiographic (ECG) recording by continuous rhythm recording and storage for periods longer than 48 hours. The existing Holter monitor codes (CPT codes 93224 through 93227) that include up to 48 hours of continuous recording were also reviewed as part of this family of services at the January 2020 RUC meeting.

We are proposing the RUC-recommended work RVU for all 12 codes in the family. We are proposing a work RVU of 0.39 for CPT codes 93224 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional*) and 93227 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional*); a work RVU of 0.50 for CPT codes 93XX0 (*External electrocardiographic recording for more than 48 hours up to 7 days by*

continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation) and 93XX3 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation*); and a work RVU of 0.55 for CPT codes 93XX4 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*) and 93XX7 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation*).

The other six codes in the family are technical component codes that do not have a work RVU; we are proposing a work RVU of 0.00 for CPT codes 93225 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)*), 93226 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report*), 93XX1 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), 93XX2 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report*), 93XX5 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), and 93XX6 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report*).

For the direct PE inputs, we are proposing to refine the clinical labor time for the ''Perform procedure/service—NOT directly related to physician work time'' (CA021) activity for CPT codes 93XX0, 93XX2, 93XX4, and 93XX6. We are proposing to reduce the clinical labor time by 5 minutes for each code as the description of the tasks taking place in the recommended materials includes activities that are considered to be indirect PE under our methodology. The recommended materials stated that ''incoming patch deliveries are sorted and distributed to work queues. The return box is opened, diary book removed, top housing is removed using a custom tool to expose USB connection, and device is plugged in to extract serial number and diagnostic logs.'' These unboxing and filing activities are classified as administrative expenses under our PE methodology, and therefore, do not constitute clinical labor as a direct expense. We are proposing to remove 5 minutes from the clinical labor to reflect these activities which are indirect as opposed to direct costs. We are also proposing to refine the equipment time for the desktop computer (ED021) to reflect these changes in the clinical labor time.

We noted an inconsistency in the RUC-recommended direct PE inputs for CPT codes 93XX0 and 93XX4. Both of these codes are the ''global component'' for their respective group of codes, such that the direct costs for CPT codes 93XX1–93XX3 must sum up to the direct cost of CPT code 93XX0 and the direct costs for CPT codes 93XX5 through 93XX7 must sum up to the direct cost of CPT code 93XX4. However, CPT codes 93XX0 and 93XX4 each contained 2 pairs of non-sterile gloves (SB022) whereas their constituent technical component codes (93XX1 and 93XX5 respectively) only contained a single pair of non-sterile gloves. Therefore, we are proposing to refine the quantity of the non-sterile gloves down to 1 pair for CPT codes 93XX0 and 93XX4 to correct this inconsistency. We also considered increasing the quantity of the gloves to 2 as in CPT codes 93224 through 93227. However, we believe that only 1 pair of gloves would typically be needed to attach the ECGs, as the patient does not return to have the ECGs removed in CPT codes 93XX0 through 93XX7 as opposed to CPT codes 93224 through 93227 where the patient does return for ECG removal.

We are proposing the RUC-recommended equipment time of 1474 minutes for the Holter monitor (EQ127) equipment included in CPT codes 93224 and 93226, based on an equipment time of 34 minutes during the procedure along with 1440 minutes (24 hours) of equipment time thereafter. We note that an external stakeholder wrote to request that the number of minutes of equipment time for the Holter monitor be increased from 1440 minutes (24 hours) to 2160 minutes (36 hours) to reflect the average length of equipment time. The stakeholder wrote that the 24-hour and 48-hour test were each performed approximately 50 percent of the time and stated that the most accurate number of equipment minutes would be the average time. The RUC disagreed with the stakeholder's request in its review because it concluded that there was insufficient evidence to warrant a change from the current 24 hours of equipment time; the RUC-recommended equipment time for the Holter monitor was based on the typical rather than the average service. We are proposing the RUC-recommended equipment time of 1474 minutes because our PE methodology is indeed based on the typical case, specifically what would be typical and reasonable and necessary for the procedure in question. Although we appreciate the feedback from the stakeholder, our previously finalized PE methodology establishes pricing based on the typical case. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

The recommendations for this family of codes contain one new supply item, the ''extended external ECG patch, medical magnetic tape recorder'' (SD339). We did not receive a traditional invoice to establish a price for this supply item, instead receiving pricing information from two sources: A weighted median of claims data with the cost of the other direct PE inputs removed, and a top-down approach calculating the cost of the supply per service based on summing the total costs of the provider and dividing by the total number of tests furnished. The former methodology yielded a supply price of approximately $440 while the latter methodology produced an estimated supply price of $416.85. Stakeholders also submitted a series of invoices from the clinical study marketplace with a price of $595. Although we are appreciative of the data provided by the stakeholder, we require an invoice representative of commercial market pricing to establish a national price for a new supply or equipment item. Although we are aware of the unusual circumstances surrounding the ''extended external ECG patch, medical magnetic tape recorder'' in terms of how it uploads data to the provider, we cannot establish supply pricing based on an analysis of claims data and in absence of a representative invoice.

Therefore, we are proposing to employ a crosswalk to an existing supply for use as a proxy price until we have an invoice to use for the ''extended external ECG patch, medical magnetic tape recorder'' item. We are proposing to use the ''kit, percutaneous neuro test stimulation'' (SA022) supply as our proxy item at a price of $413.24.

Although this kit is not clinically similar to the extended external ECG patch, we believe that it is the closest match from a pricing perspective to employ as a proxy until we are able to arrive at an invoice that is representative of commercial market pricing. We welcome the submission of invoices or other additional information for use in pricing the ''extended external ECG patch, medical magnetic tape recorder'' supply.

(40) Complete Transthoracic Echocardiography (TTE) With Doppler (CPT Code 93306)

In the CY 2019 PFS final rule (83 FR 59500), a submitter nominated CPT code 93306 (*Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography*) as potentially misvalued, citing GAO, MedPAC, and Urban Institute reports that suggest the work RVUs are overstated. Although the code was most recently surveyed in 2016, the specialty societies and the RUC stated that there has been a change in the technique and technology used to perform the procedure, so they resurveyed the code. The RUC recommended decreasing the work RVU from 1.50 to 1.46 and we are proposing this value.

Although we are proposing the RUC's recommended direct PE inputs without refinement we note that the RUC's recommendation included both 25 mL and 50 mL of ultrasound transmission gel. We are proposing a supply quantity of 25 mL and seeking clarification on the correct amount.

(41) Pacing Heart Stimulation (CPT Code 93623)

Review of CPT code 93623 (*Programmed stimulation and pacing after intravenous drug infusion (List separately in addition to code for primary procedure)*), was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 30,000 claims in a year. This service is to create an arrhythmia by an intravenous drug infusion and it is an add-on code with 60 minutes of total time and a current work RVU of 2.85.

The RUC recommends the 25th percentile survey value of 2.04 work RVUs and 20 minutes of intraservice time.

The revision of CPT code 93623 physician's time adjusting from the current 60 minutes to 20 minutes is a significant change. 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 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 93623, we believe that it would be more accurate to propose a work RVU of 0.98 based on CPT code 76810 (*Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; each additional gestation (list separately in addition to code for primary procedure)*) with 20 minutes of intraservice time. We are proposing a work RVU of 0.98 with 20 minutes of intraservice time for CPT code 93623.

This CPT code is a facility-only service and has no direct PE inputs.

(42) Intracardiac Echocardiography (ECG) (CPT Code 93662)

The review of CPT code 93662 (*Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure*), was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 10,000 claims in a year that had an increase in volume by 100 percent between the 2012 to 2017. This procedure has since changed from its last review, in its reduced use of fluoroscopy, now replaced with ultrasound that create arrhythmia mapping systems with intracardiac echo images processed to produce 3-dimensional electroanatomical maps. The physician can now visualize better and have more accurate details for more effective catheter ablation for a wide range of arrhythmias. CPT code 93662 currently has a work RVU of 2.80 with 5 minutes of preservice evaluation time, 55 minutes of intraservice time, 10 minutes of immediate postservice time, and 70 minutes of total time.

The survey resulted in a median intraservice time of 25 minutes, a significant shift from the current intraservice time of 55 minutes. The RUC recommends a work RVU of 2.53 and 25 minutes of intraservice time for add-on CPT code 93662. 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 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. CPT code 92979 (*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (ivus) or optical coherence tomography (oct) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (list separately in addition to code for primary procedure)*), with 1.44 work RVUs and 25 minutes of intraservice time, is a good equivalent comparator code in light of the significant physician time reduction from 55 minutes. A similarly proportioned reduction of physician intraservice time from the current 55 minutes to the surveyed 25 minutes, if applied to the current work RVU would result in a value much lower than our reference CPT code 92979's work RVU, so we are proposing a work RVU of 1.44 and 25 minutes of intraservice time for add-on CPT code 93662.

This CPT code is a facility only service and has no direct PE inputs.

(43) Ventricular Assist Device (VAD) Interrogation (CPT Code 93750)

The review of CPT code 93750, (*Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow and volume status, septum status, recovery), with programming, if performed, and report*) was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 10,000 claims in a year and had had an increased in volume by 100 percent between the 2012 to 2017. CPT code 93750 currently has a work RVU of 0.92 with 30 minutes of intraservice time.

For physician times, the societies' survey for CPT code 93750 yielded 6 minutes preservice time, 10 minutes intraservice time, 7 minutes immediate post-service time, and 23 minutes of total time. The 25th percentile surveyed work RVU was 0.96. The RUC compared the survey code to CPT code 78598 (*Quantitative differential pulmonary perfusion and ventilation (eg, aerosol or gas), including imaging when performed*) (0.85 work RVU and 5 minutes of preservice time, 10 minutes of intraservice time, 9 minutes of immediate postservice time, and total time of 24 minutes). The RUC

recommends crosswalking the work RVU of 0.85 from CPT code 78598 to 93750.

CPT code 93289 (*Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements*), with 0.75 work RVUs and 5 minutes of preservice time, 10 minutes of intraservice time, 8.5 minutes of immediate postservice time, and total time of 23.5 minutes, we believe is a more precise comparator code. CPT code 93289's intraservice times, pre and post times, and total times are almost identical to CPT code 93750's survey times, so we are proposing a work RVU of 0.75 and 23 minutes of total time for CPT code 93750.

The PE Subcommittee corrected the equipment times based on the formulas as provided by CMS. In addition, the PE Subcommittee changed the clinical staff type for direct labor item ID CA013 Prepare Room, Equipment and Supplies, from an RN to the RN/LPN/MTA blend and the direct equipment item ID EQ168 light, exam was removed from CPT code 93750. We are proposing to accept the RUC-recommended direct PE inputs.

(44) Spirometry (CPT Codes 94010 and 94060)

CPT code 94010 (*spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation*) and CPT code 94060 (*Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator administration*) were identified as part of a Relativity Assessment Workgroup (RAW) review of action plans on the status of services that were RUC referrals to develop CPT Assistant articles. These codes were recommended to be surveyed.

We are proposing the RUC-recommended work RVU of 0.17 for CPT code 94010 (*spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation*) and the RUC-recommended work RVU of 0.22 for CPT code 94060 (*Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator administration*). We are proposing the RUC-recommended direct PE inputs for this code family without refinements.

(45) Exercise Test for Bronchospasm (CPT Codes 946X0, 94617, 94618, and 94621)

In 2018, the CPT Editorial Panel created CPT code 94617 (*Exercise test for bronchospasm, including pre- and post-spirometry, electrocardiographic recording(s), and pulse oximetry*), and CPT code 94618 (*Pulmonary stress testing (eg, 6-minute walk test), including measurement of heart rate, oximetry, and oxygen titration, when performed*) from the now deleted CPT code 94620 (*Pulmonary stress testing; simple (eg, 6-minute walk test, prolonged exercise test for bronchospasm with pre- and post-spirometry and oximetry)*), and revised CPT code 94621 (*Cardiopulmonary exercise testing, including measurements of minute ventilation, co2 production, o2 uptake, and electrocardiographic recordings*) to better describe the specialty's pulmonary exercise test. Shortly after the creation and revision of these codes, the specialty society became aware of some providers performing CPT code 94617 without ECG monitoring, so to more accurately account for this work without the ECG monitoring, The CPT Editorial Panel proposed to establish CPT code 946X0 with the descriptor, (*Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; without electrocardiographic recording(s)*). For the October 2019 RUC meeting, the specialty societies surveyed CPT code 946X0, and included a request to reaffirm the values of the rest of the codes in the code family.

For CPT code 946X0, the surveyed physician time yielded 5 minutes of preservice time, 9 minutes of intraservice time, followed by 10 minutes of immediate post-service time, for a total time of 24 minutes. This distribution of physician times is of course very similar to the times for CPT code 94617, total time of 26 minutes, except without the task of including an electrocardiographic recording. The RUC recommends the survey's median work RVU of 0.49 for CPT code 946X0.

We are proposing the RUC's recommendation of a work RVU of 0.49 and a total physician time of 24 minutes for CPT code 946X0.

This CPT family of codes that includes CPT code 946X0, are CPT codes 94617, 94618, and 94621 and there are no changes to their physician service times, no change to their descriptors, nor their work RVUs, and remain as they currently are. The specialty societies reaffirmed these current valuations and we propose to accept them without change.

We are proposing the RUC-recommended PE changes without refinement.

(46) Evaluation of Wheezing (CPT Codes 94640, 94667, 94668, and 94669)

At the April 2019 RUC meeting, four PE only CPT codes from the Evaluation of Wheezing code family were reviewed. The codes included CPT codes 94640 (*Pressurized or nonpressurized inhalation treatment for acute airway obstruction for therapeutic purposes and/or for diagnostic purposes such as sputum induction with an aerosol generator, nebulizer, metered dose inhaler or intermittent positive pressure breathing (IPPB) device*), 94667 (*Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; initial demonstration and/or evaluation*), 94668 (*Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lunch function; subsequent*), and 94669 (*Mechanical chest wall oscillation to facilitate lung function, per session*).

We are proposing the RUC-recommended direct PE inputs for the four PE only codes. The RUC did not recommend work RVUs and we are proposing to maintain the current work RVU of 0.00 for all four codes.

(47) Exhaled Nitric Oxide Measurement (CPT Code 95012)

In January 2019, the RAW reviewed services with 2017 Medicare utilization of 10,000 or more that had increased by at least 100 percent from 2012 through 2017. The RUC recommended that CPT code 95012 (*Nitric oxide expired gas determination*) be surveyed for the April 2019 meeting. We are proposing the direct PE inputs for CPT code 95012 without refinement. CPT code 95012 is a PE-only code with no work RVU, and we are proposing to maintain the current work RVU of 0.00.

(48) Acupuncture Services (CPT Codes 97810, 97811, 97813, and 97814)

The CPT Editorial Panel created two new codes and two new add-on codes in 2004 to describe the appropriate time or additional time and levels of service that can be performed using acupuncture and electroacupuncture, acupuncture therapy with electrical stimulation. These codes were designated as noncovered services since Medicare did not reimburse for acupuncture services at the time. In January 2020, we issued a decision memo stating that Medicare will cover acupuncture for chronic low back pain

under section 1862(a)(1)(A) of the Act (CAG–00452N). This was reflected in the April 2020 PFS Quarterly Update which changed CPT codes 97810 through 97814 to active payment status (CMS Change Request 11661). Because we had never conducted a review of these four acupuncture codes, the CY 2020 payment rate consisted of the work RVUs recommended by the RUC in 2004.

For CY 2021, we are proposing to establish work RVUs for these four acupuncture codes based on a pair of crosswalks to two recently reviewed codes in the Dry Needling family. We are proposing a work RVU of 0.48 for CPT codes 97810 (*Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient*) and 97813 (*Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient*) based on a crosswalk to CPT code 20561 (*Needle insertion(s) without injection(s); 3 or more muscles*). We are proposing a work RVU of 0.32 for CPT codes 97811 (*Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)*) and 97814 (*Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)*) based on a crosswalk to CPT code 20560 (*Needle insertion(s) without injection(s); 1 or 2 muscle(s)*).

CPT codes 20560 and 20561 are clinically similar services associated with dry needling that were reviewed last year for CY 2020. We finalized work RVUs of 0.32 and 0.48 respectively for these two codes following our review of their associated RUC recommendations, while noting that dry needling services were non-covered by Medicare unless otherwise specified through a national coverage determination (NCD) (84 FR 62722 through 62724). Like the acupuncture codes, CPT codes 20560 and 20561 were updated to active payment status in the April 2020 PFS Quarterly Update to reflect the Medicare coverage of acupuncture for chronic low back pain. We note that CPT codes 97810 and 97813 share the identical work time values with CPT code 20561, and that CPT codes 97811 and 97814 differ from CPT code 20560 by only 1 minute of work time, 15 minutes as compared to 16 minutes. Although we do not imply that codes with similar work times must equate to a one-to-one or linear relationship in the valuation of work RVUs, we believe that, since the two components of work are time and intensity, clinically related services with similar intensities and work times should, generally speaking, be valued similarly. Due to the similar clinical nature of these services and their nearly identical work times, we believe that it is more accurate to propose crosswalking CPT codes 97810 through 97814 to the work RVUs of the Dry Needling codes, which were finalized last year, as opposed to proposing work RVUs from 2004, which were never reviewed by CMS.

The RUC did not make any recommendations and we are not proposing any changes to the direct PE inputs for CPT codes 97810 through 97814.

(49) Chronic Care Management Services (CPT Code 994XX and HCPCS Code G2058)

We established payment for HCPCS code G2058 (*Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month*) in the CY 2020 PFS final rule (84 FR 62690). At the January 2020 RUC meeting, specialty societies requested a temporary crosswalk through CY 2021 between the value established by CMS for HCPCS code G2058 and the value of new CPT code 994XX (with a descriptor identical to G2058). The Chronic Care Management code family will be resurveyed during CY 2020 and is expected to be presented for review as part of the 2022 RUC review process.

For CY 2021, we are proposing the RUC-recommended work RVU of 0.54 and the RUC-recommended direct PE inputs for CPT code 994XX.

(50) External Counterpulsation (HCPCS Code G0166)

In the CY 2020 PFS proposed rule (84 FR 40516), an external stakeholder nominated HCPCS code G0166 as potentially misvalued due to concerns that the PE RVUs for this code did not fully reflect the total resources required to deliver the service and CMS proposed G0166 as potentially misvalued. The RUC reviewed the direct PE inputs for HCPCS code G0166 at the October 2019 RUC meeting.

We are proposing the RUC-recommended preservice period, service period and postservice period with refinements. We propose to replace CA010 (obtain vital signs) during the postservice of service period with CA023 (monitor patient following procedure/service, no multitasking).

For the equipment items, we are proposing to update the price of the ''EECP, external counterpulsation system'' (EQ012) equipment to $101,247.50 based on an average of the five invoices submitted along with the recommendations. We note that the EQ012 equipment is the only current equipment item in our direct PE database with an equipment utilization rate of 25 percent and the only equipment item with a utilization rate under 50 percent. Although we are not proposing to change the equipment utilization rate, we are soliciting feedback from commenters regarding the utilization rate for the EQ012 equipment to help us understand why it should differ from all other medical equipment.

We also received invoices for a series of additional equipment items: An EECP service contract, an EECP compression equipment package, and an EECP electrical equipment package. We are not proposing to establish a price for the EECP service contract, as service contracts are considered to be an administrative expense and a form of indirect PE under our methodology. As for the two equipment packages, there were a number of unusual factors involving these items that created difficulties for our equipment methodology. Both equipment packages had a suggested utilization rate of 25 percent, half of our typical utilization rate of 50 percent, and both had a suggested useful life duration of only 3 months. As we stated in section II.B. of this proposed rule, Determination of Practice Expense RVUs, we have concerns that assigning very low useful life durations to this type of equipment would fail to maintain relativity with other equipment on the PFS. We also noted that the equipment cost per minute formula was designed under the assumption that each equipment item would remain in use for a period of several years and depreciate over that span of time. Our current equipment formula is not designed to address cases in which equipment is replaced multiple times per year, and we believe that applying a multi-year depreciation in these situations would not be reflective of market pricing. Although we agree that these costs should be reflected in the pricing of HCPCS code G0166, we believe that the very frequent replacement of the items in the two equipment packages makes them a poor fit under our equipment methodology.

Therefore, we are proposing to treat the two EECP equipment packages as supplies instead of treating them as equipment. We are proposing to establish the EECP compression

equipment package (SD341) as a supply with a cost of $645 based on an average of the submitted invoices, and proposing to establish the EECP electrical equipment package (SD342) as a supply with a cost of $500 again based on an average of the submitted invoices. Based on information provided by stakeholders, we are proposing a supply quantity of 1/325 for these two items (0.00308) based on the supply being used on average five times per day and replaced every 3 months (5 uses * 5 days * 13 weeks = 325). We believe that assigning these two items as supplies rather than equipment more accurately captures the unusual circumstances associated with providing this service.

(51) Molecular Pathology Interpretation (HCPCS Code G0452)

At the October 2018 RUC meeting, the Relativity Assessment Workgroup (RAW) identified HCPCS code G0452 (*Molecular pathology procedure; physician interpretation and report*) as potentially misvalued on a CMS/Other screen. The RUC had never reviewed HCPCS code G0452 and assumptions regarding work and time were based upon a 1995 vignette. In addition, the specialty society noted that the technology available for furnishing the service, as well as the patient population receiving the service, had changed since the code was valued by CMS.

The RUC requested a physician work survey be completed for the October 2019 RUC meeting. It was during the October meeting that the work and PE values for HCPCS code G0452 were reviewed and recommended.

For CY 2021, we are proposing the RUC-recommended work RVU of 0.93 and the RUC-recommended direct PE inputs for HCPCS code G0452.

(52) Evaluation and Management, Observation and Provision of Self-Administered Esketamine (HCPCS Codes G2082 and G2083)

In the CY 2020 PFS final rule (84 FR 63102 through 63104), we issued an interim final rule with comment period (IFC) to establish coding and payment for E/M, observation, and the provision of self-administered Esketamine to facilitate beneficiary access to care for treatment-resistant depression as efficiently as possible. We created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020 on an interim final basis. For CY 2020, we established RVUs for these services that reflect the relative resource costs associated with the E/M, observation and provision of the self-administered esketamine product. The HCPCS G-codes are described as follows: HCPCS code G2082 (*Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation*) and HCPCS code G2083 (*Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation*).

In developing the interim final values for these codes, we used a building block methodology that sums the values associated with several codes. For the overall E/M and observation elements of the services, we incorporated the work RVUs, work time and direct PE inputs associated with a level two office/outpatient visit for an established patient, CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; 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. Typically, 10 minutes are spent face-to-face with the patient and/or family*), which has a work RVU of 0.48 and a total work time of 16 minutes, which is based on a pre-service evaluation time of 2 minutes, an intraservice time of 10 minutes, and a postservice time of 4 minutes.

We also incorporated CPT codes 99415 (*Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour (List separately in addition to code for outpatient Evaluation and Management service)*) and 99416 (*Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; each additional 30 minutes (List separately in addition to code for prolonged service)*) in which neither code has a work RVU, but includes direct PE inputs reflecting the prolonged time for clinical staff under the direct supervision of the billing practitioner.

Additionally, to account for the cost of the provision of the self-administered esketamine as a direct PE input, we incorporated the wholesale acquisition cost (WAC) data from the most recent available quarter. For HCPCS code G2082, we are using a price of $590.02 for the supply input that describes 56 mg (supply code SH109) and for HCPCS code G2083, we are using a price of $885.02 for the supply input describing 84 mg of esketamine (supply code SH110).

We sought comment on the interim final values we established for HCPCS codes G2082 and G2083, including the assigned work RVUs, work times, and direct PE inputs. We received public comments on this policy. The following is a summary of the comments we received and our responses.

Comment: Overall, commenters were supportive of CMS establishing coding and payment for E/M, observation and the provision of self-administered esketamine. However, a few commenters were not in support of the proposal, noting that IV ketamine is cheaper and has been proven to be more effective than esketamine.

Response: We appreciate the support for our interim final rule with comment period. We continue to believe that it is in the public interest to ensure beneficiaries have access to new, potentially life-saving treatment for treatment-resistant depression (TRD) using esketamine. Therefore, we are proposing to maintain HCPCS codes G2082 and G2083 that describe E/M, observation and the provision of self-administered esketamine.

Comment: Several commenters suggested including psychotherapy, CPT codes 90833 and 90836, in the valuation of HCPCS codes G2083 and G2083.

Response: We disagree that psychotherapy should be included in the valuation of HCPCS codes G2082 and G2083. HCPCS codes G2082 and G2083 were created to establish coding and payment for E/M, observation and the provision of self-administered esketamine to facilitate beneficiary access to care for treatment-resistant depression as efficiently as possible. However, practitioners who furnish other allowable, billable services, including psychotherapy, on the same day as an E/M, observation and provision of self-administered esketamine service can bill separately for those services using other codes.

Comment: Some commenters recommended that esketamine should

have its own J code in addition to the G codes.

Response: HCPCS codes G2082 and G2083 are bundled services that include, as discussed previously, the E/M, observation and the provision of self-administered esketamine. The self-administered esketamine is considered a supply item for this bundled service. Therefore, esketamine cannot be billed separately along with HCPCS codes G2082 and G2033 under the PFS.

Comment: Several commenters disagreed with the use of 99212 to establish codes G2082 and G2083. Commenters suggested using 99213, 99214, and/or 99215 instead of 99212. Some commenters indicated that the intraservice work time of 10 minutes is insufficient, and one commenter stated a minimum of 20 minutes would be more appropriate. Another commenter suggested unbundling the code and, in part, indicated that face-to-face visits with the psychiatrist are not required at each visit.

Response: We appreciate the feedback received from the commenters regarding the E/M elements of the service. We have considered the wide range of recommendations that were received from commenters regarding the E/M elements of the service. One commenter indicated that there is variability in performance and level of E/M services associated with the service (in which self-administered esketamine is provided and observed). Another commenter noted that a face-to face visit with the psychiatrist is not required at each visit, while other commenters recommended using E/M CPT codes up to 99215. We continue to believe that the building block methodology we used incorporating CPT code 99212 is appropriate for valuing this service. Therefore, we are not proposing to change the E/M element of the service by incorporating the work RVUs, work time and direct PE input associated with a level two office/outpatient visit for an established patient, CPT code 99212.

Comment: Many commenters urged CMS to ensure PFS payment rates are sufficient to capture the complexity and time for the provision of esketamine.

A commenter recommended unbundling all the services. The commenter stated that the way the bundled payments are currently constructed fails to recognize the possible variability of E/M services that may be required, the time and effort required of clinical staff to monitor the patient during the lengthy observation period, and the amount of pre- and post-service work required. The commenter also stated that bundling the physician E/M services and the observation services performed by clinical staff is problematic and including the medication in the bundle is problematic because in many instances the psychiatrist may not be incurring the cost of the medication. The commenter stated that clinical staff time and effort comprise a significant and separate service, including not only the time spent observing and actively monitoring the patient's condition for possible adverse side-effects (that is, nausea, vomiting, escalation in blood pressure), but also extensive pre- and post-service preparation that does not appear to have been included as part of the bundled payment and is not described by existing CPT codes.

The commenter recommended increasing the proposed valuation of clinical staff time to more appropriately account for the clinical staff time and the effort required for pre-, intra-, and post- service work. This includes acquisition of the drug, delivery of the medication to the patient, and the observation of the self-administration, followed by active monitoring of the patient's condition (vitals, etc.) for a minimum of 2 hours, the commenter suggested that the more appropriate comparison for the clinical staff time related to the 2-hour observation period is 95076, *Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug or other substance); initial 120 minutes of testing* (110 minutes intra service time; PE RVU 1.81). Both services, the G2082 and G2083 codes and the 95076, require a lengthy observation time (minimum of 2 hours) with clinical staff monitoring for adverse side-effects. The total PE RVU of the 95076 is 1.81 RVUs versus 0.51 RVUs (99415 × 1, 99416 × 2 or 0.27 + (0.12 × 2) = 0.51 RVUs) of the combined 99415 and 99416. The associated add-on code for 95076 is 95079, *Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug or other substance); each additional 60 minutes of testing (List separately in addition to code for primary procedure)* (40 minutes intra-service time; PE RVU 0.99), which would account for additional time for this service when required. Procedurally these services are similar in staff time, staff type and effort, and both are reported separately from the E/M service. The commenter requested that we use the PE RVUs for the 95076 and the 95079 in lieu of the 99415 and 99416 in calculating the values for the clinical staff component, to more accurately reflect the time and effort of the clinical staff in the observation of the patient.

Response: After consideration of comments requesting that we reconsider aspects of our current valuation for these services, including at least 2 hours of post-administration observation, we believe some of the refinements discussed by stakeholders may be appropriate to improve payment accuracy and help ensure that beneficiaries who need esketamine for treatment have access to it. Based on our review of the Spravato Prescribing Information, Medication Guide and REMS requirements, the FDA-approved conditions/requirements indicate that the drug is only available as an integral component of a physician's service.[8] [9] [10] Spravato is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients.[11] Therefore, we continue to believe this treatment should be paid for as a bundled service. In consideration of the comment urging us to account for clinical staff time spent observing and actively monitoring the patient for possible side-effects, along with pre- and post-service preparation, we are proposing to refine the direct PE inputs of HCPCS codes G2082 and G2083, in part, by using the clinical labor time for CPT codes 95076 and the 95079 in lieu of the clinical labor time of CPT codes 99415 and 99416. We are specifically proposing 150 minutes of observation time for HCPCS codes G2082 and G2083 based on the sum of the clinical labor for CPT code 95076 (110 minutes) and CPT code 95079 (40 minutes). This would replace our previous interim final valuation of 30 minutes of observation time based on the sum of the clinical labor for CPT code 99415 (15 minutes) and two billings of CPT code 99416 (8 minutes). We are seeking comment on this proposal. Additionally, under circumstances where the health care professional supervising the self-administration and observation does not also provide the esketamine product, the physician or practitioner cannot report HCPCS codes G2082 or G2083. Rather, the visit and the extended observation (by either the billing professional or clinical staff) could be reported using the existing E/M codes that describe the visit and the prolonged

[8] *https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=386.*

[9] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/211243s003lbl.pdf.*

[10] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/211243s003lbl.pdf#page=38.*

[11] *https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=386.*

service of the professional or the clinical staff.

Comment: One commenter urged CMS to align the HCPCS codes G2082 and G2083 for a visit for the provision of esketamine with prescribing recommendations from the drug manufacturer that include at least 2 hours of post-administration observation until a patient is safe to leave the facility. Another commenter questioned whether the codes should be valued using CPT codes 99213, 99214 and even 99215, with 99354 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; first hour (List separately in addition to code for office or other outpatient Evaluation and Management or psychotherapy service)) and 99355 (Prolonged evaluation and management or psychotherapy service(s) (beyond the typical service time of the primary procedure) in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (List separately in addition to code for prolonged service)).

Response: As previously stated, we are proposing to continue valuing HCPCS codes G2082 and G2083, in part, on the basis of a level 2 established patient office/outpatient E/M visit. However, as previously stated, after considering comments regarding the esketamine post-administration observation time, we are proposing to refine the direct PE inputs of HCPCS codes G2082 and G2083, in part, by using the clinical labor time for CPT codes 95076 and the 95079, specifically proposing 150 minutes of observation time. We are seeking comment on this proposal.

Comment: Some commenters indicated that the proposed PE inputs do not reflect the costs of, and overall drug cycle management needed to safely administer, esketamine. One commenter indicated that, after conducting an analysis associated with each patient encounter to include: Physician time and technician time, reception time, rent, furniture, monitoring, electronic health record (EHR), supplies, waste management, etc., their direct overhead cost is $1000 per patient per encounter, not including direct cost and management of the drug. Therefore, the commenter recommends we revise payment by adding 20 percent to the direct expense and mandatory overhead costs of $1000 per patient encounter. Some commenters indicated that the proposed PE inputs do not reflect the costs of initial capital requirements for ongoing resources, maintaining the Risk Evaluation and Mitigation Strategy (REMS) standards with the FDA and overall drug cycle management needed to safely administer esketamine. Specifically, one commenter indicated that Spravato will need to be delivered in the community setting. A typical community psychiatry practice does not have a large enough physical plant to accommodate a 2 hour monitoring period, requiring a lease or purchase of additional space. In addition, Spravato requires administrative support for medication procurement, appropriate storage equipment (for example, Pyxis machine or similar) to mitigate abuse and diversion potential, medically appropriate staffing (for the required observation of self-administration, multiple vital signs checks, completion of REMS monitoring forms and other administrative requirements of the REMS, and discharge assessment), and equipment and services including a chair that can recline and controlled substance waste removal compliance. One commenter indicated that the pricing methodology used for esketamine, whether WAC, ASP or compendia pricing, does not take into account the costs associated with full-management of the drug cycle including ordering, storage, inventory tracking, billing, etc. Therefore, the commenter recommends valuing the bundled esketamine by adding 20 percent to ASP.

Response: Under our PE methodology, the costs identified by the commenter for reception time, rent, furniture, electronic health records (EHRs), and waste management are all types of indirect costs. This means that they are not individually allocable to a particular patient for a particular service, and therefore they are not summed up as separate itemized direct costs for codes such as HCPCS codes G2082 and G2083. CMS is still paying practitioners for these costs through our indirect PE methodology; we note that for a typical HCPCS code, indirect costs make up roughly 75 percent of the total PE. If we were to itemize administrative costs such as rent and furniture as direct costs, we would be double counting them in violation of our standard PE methodology. As previously discussed, we are proposing to refine the direct PE inputs of HCPCS codes G2082 and G2083, in part, by using the clinical labor time for CPT codes 95076 and 95079, in lieu of the clinical labor time of CPT codes 99415 and 99416 to account for the clinical staff time, such that the proposed refinements would increase the clinical labor time from 30 minutes to 150 minutes. We believe this refinement would account for the clinical staff time and efforts including the acquisition and delivery of the medication to the patient as required by the REMS.

Comment: One commenter requested clarification on whether payment is fixed for 2020 or whether the payment will be adjusted to reflect 2020 changes in WAC, for example updated data made available from the most recent quarter. The commenter also questioned whether regulatory changes made under the PFS to values of the component services would also be applied to the G codes, for example, whether changes to values of the E/M codes would also be incorporated into the RVU inputs for G codes. For instance the outpatient E/M values are set to increase in 2021, and the commenter asked whether that increase would automatically be included in the valuation of the bundle, and whether the payment currently ascribed to the bundle for the cost of the medication be updated if the input prices for the services change over time.

Response: Historically, supply input prices are updated on a code-by-code basis and periodically through annual notice and comment rulemaking. The prices, including for a variety of pharmaceutical products, are not routinely updated like Part B drugs paid under the ASP methodologies. For the supply inputs for the esketamine product used in developing rates for HCPCS codes G2082 and G2083, we used the most recent available quarter of WAC data for 2020 pricing, but we anticipate using either data reported for purposes of determining payments under section 1847A of the Act (such as ASP) or compendia pricing information (such as WAC) in future years. Since we reviewed and are proposing refinements to HCPCS codes G2082 and G2083 for the CY 2021 rulemaking cycle, we propose to update the payment to reflect the most recent available quarter of WAC data for CY 2021 pricing, and propose to update the payment to reflect the E/M values (CPT code 99212) for CY 2021. Therefore, to account for the cost of the provision of the self-administered esketamine as a direct PE input, we incorporated the wholesale acquisition cost (WAC) data from the most recent available quarter. For HCPCS code G2082, we propose to update the supply input that describes 56 mg (supply code SH109) from a price of $590.02 to $616.93 and for HCPCS code G2083, we propose to update the price from $885.02 to $928.38 for the supply input

describing 84 mg of esketamine (supply code SH110).

Comment: One commenter indicated that the CMS approach to the E/M component of the interim G codes includes inputs associated with an established patient for the first visit or any subsequent treatment, and requested clarification that, if reasonable and necessary, the health care provider could complete an E/M service that is distinct from the E/M services necessary for esketamine administration, and in such an event, separate E/M service would be eligible to be paid separately with E/M codes.

Response: Given that HCPCS codes G2082 and G2083 already take into account E/M services in their valuations, it would be duplicative to bill for a separate E/M code along with HCPCS codes G2082 and G2083. However, other reasonable and necessary E/M services may be furnished and billed for a patient on dates before and after HCPCS code G2082 or G2083, for example, when the services are furnished in the course of treating and diagnosing treatment-resistant depression.

After considering the comments we received, we are proposing to refine the values for HCPCS codes G2082 and G2083 using a building block methodology that sums the values associated with several codes. For the overall E/M and observation elements of the services, we are incorporating the work RVUs, work time and direct PE inputs associated with a level two office/outpatient visit for an established patient, CPT code 99212. We are also proposing to include the clinical labor for CPT 95076 and 95079 (in lieu of CPT codes 99415 and 99416 as detailed earlier); and to account for the cost of the provision of the self-administered esketamine as a direct PE input, we are proposing to incorporate the wholesale acquisition cost (WAC) data from the most recent available quarter. We are seeking comment on this updated payment proposal and valuation of HCPCS code G2082 and G2083.

(53) Bundled Payments Under the PFS for Substance Use Disorders (HCPCS Codes G2086, G2087, and G2088)

In the CY 2020 PFS final rule (84 FR 62673), we finalized the creation of new coding and payment describing a bundled episode of care for the treatment of Opioid Use Disorder (OUD). The codes and descriptors we finalized for CY 2020 were:

- HCPCS code G2086: *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 G2087: *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 G2088: *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).*

As noted in the CY 2020 PFS final rule (84 FR 62673), if a patient's treatment involves MAT, this 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.

We have received requests to expand these bundled payments to be inclusive of other SUDs, not just OUD. We agree that doing so could expand access to needed care. We are proposing to expand these bundled payments to be inclusive of all SUDs. To accomplish this, we are proposing to revise the code descriptors for HCPCS codes G2086, G2087, and G2088 by replacing ''opioid use disorder'' with ''a substance use disorder.'' The payment and billing rules would otherwise remain unchanged. We note that HCPCS codes G2086, G2087, and G2088 were added to the Medicare Telehealth list in the CY 2020 PFS final rule (84 FR 62628). The proposed revised code descriptors are:

- HCPCS code G2086: *Office-based treatment for a substance 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 G2087: *Office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- HCPCS code G2088: *Office-based treatment for a substance 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).*

Additionally, in the CY 2020 PFS final rule we stated that we anticipate that the services described by HCPCS codes G2086, G2087, and G2088 would often be billed by addiction specialty practitioners, but note that these codes are not limited to any particular physician or nonphysician practitioner (NPP) specialty. We also noted that consultation was not a required condition of payment for these codes, but that consultation with a specialist could be counted toward the minutes required for billing HCPCS codes G2086, G2087, and G2088 (84 FR 62674). Although it is not a requirement for billing the code, we encourage that practitioners consult with specialists in cases where it is warranted and refer the patient to specialty care as needed.

We note that while these codes describe treatment for any SUD, information about which specific SUDs are being treated would provide valuable information that can help assess local, state, and national trends and needs. We believe it is important that the diagnosis codes listed on the claim form reflect all SUDs being treated, however, we also do not wish to add any additional burden on practitioners related to claims submission, therefore, we are seeking information on whether there are sources of data we could explore in order to provide this information. We are also seeking information on whether there are differences in the resource costs associated with furnishing services for the various SUDs, and accordingly whether there is a need for more stratified coding to describe these services. We note that in some instances, the CPT Editorial Panel has created CPT codes to replace G codes created by CMS, and that we would welcome such input on these services. We look forward to receiving public comments on this proposal in order to help evaluate whether more granular coding is needed.

(54) Initiation of Medication Assisted Treatment (MAT) in the Emergency Department (HCPCS Code GMAT1)

In the CY 2020 PFS proposed rule (84 FR 40545), we sought comment on the use of medication assisted treatment (MAT) in the emergency department (ED) setting, including initiation of MAT and the potential for either referral or follow-up care, to better understand typical practice patterns to help inform whether we should consider making separate payment for such services in future rulemaking. We note that the term MAT generally refers to treatment of OUD that includes both an FDA-approved medication for the treatment of OUD and behavioral/psychosocial treatment, but that care provided in the ED typically would include medication for the treatment of OUD and referral or linkage to primary care or a hospital-

based bridge clinic for continuation of medication and potentially other services, including counseling and other psychosocial services.

The public comments received in response to the comment solicitation were supportive of us making a proposal, several citing research that indicates improved outcomes for patients who initiate medications for the treatment of OUD in the ED. One commenter noted that by implementing this treatment regimen, practitioners can address a patient's immediate withdrawal symptoms, which allows time to coordinate care and provide a referral to substance use disorder specialists and other community resources who can appropriately carry out long-term treatment. Another commenter cited that the national rate of overdose-related visits seen in EDs nearly doubled between 2005 and 2014 and noted that hospital-based care represents a critical opportunity to initiate treatment and connect patients with OUD to care, noting that patients who receive information about drug treatment in the hospital post-overdose are more likely to seek treatment.[12] The commenter also cited a randomized clinical trial that showed that more patients were engaged in treatment 30 days after buprenorphine was initiated in the ED and coupled with a referral, compared to interventions that did not include buprenorphine.[13] Another study found that ED induction of buprenorphine was more cost-effective than either brief intervention or referral upon discharge.[14] One commenter suggested that CMS institute a G-code to address this coding gap in the short term, while a more permanent solution is pursued to address this site-of-service specification.

We are persuaded by the comments received in response to our comment solicitation that this work is not currently accounted for in the existing code set. To account for the resource costs involved with initiation of medication for the treatment of opioid use disorder in the ED and referral for follow-up care, we are proposing to create one add-on G-code to be billed with E/M visit codes used in the ED setting. This code would include payment for assessment, referral to ongoing care, follow-up after treatment begins, and arranging access to supportive services, but we note that the drug itself would be paid separately. The proposed code is:

- HCPCS code GMAT1: *Initiation of medication for the treatment of opioid use disorder in the emergency department setting, including assessment, referral to ongoing care, and arranging access to supportive services (List separately in addition to code for primary procedure).*

To price this service, we are proposing to use a direct crosswalk to the work and direct PE inputs for HCPCS code G0397 (*Alcohol/subs interv >30 min*), which is assigned a work RVU of 1.30. We believe that the work and PE described by this crosswalk code is similar in nature and magnitude to the services described in HCPCS code GMAT1. We note that unlike the requirements for reference code, we are not proposing a required number of minutes to bill HCPCS code GMAT1. We welcome comment on this proposal and whether we should consider a different valuation to account for the resource costs involved with these services.

(55) Percutaneous Creation of an Arteriovenous Fistula (AVF) (HCPCS Code G2170 and G2171)

We received a comment in response to the CY 2020 PFS proposed rule (84 FR 40481), as well as inquiries from stakeholders, requesting that we establish new coding for the percutaneous creation of an arteriovenous fistula (AVF) used for dialysis access.

For CY 2019, based on two new technology applications for arteriovenous fistula creation, we established two new HCPCS codes to describe the two modalities of this service. Specifically, we established HCPCS code C9754 (*Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed)*) and HCPCS code C9755 (*Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed*). The HCPCS codes were created for institutional payment systems, and thus do not allow for payment for the physician's work portion of the service. Stakeholders have stated that the lack of proper coding to report the physician work associated with these procedures is problematic, as physicians are either billing an unlisted procedure code, or are billing other CPT codes that do not appropriately reflect the resource cost associated with the physician work portion of the service. Stakeholders stated that separate coding for physician payment will allow billing when the procedures are furnished in either a physician office or an institutional setting, and be paid under the respective payment systems, as appropriate. We have recognized that the lack of appropriate coding for this critical physician's service has become an even greater burden given the PHE that was declared effective January 27, 2020 for the COVID–19 epidemic. In order to mitigate potential health risks to beneficiaries, physicians and practitioners as a result of having this procedure performed in an institutional setting, we have created two HCPCS G codes for percutaneous creation of an arteriovenous fistula (AVF). The codes are contractor priced and effective July 1, 2020. This will allow for more accurate billing and coding of a crucial physician service that could then be performed in both institutional and office settings, thus mitigating unnecessary risk to beneficiaries, physicians and practitioners caused by disease transmission. The HCPCS G codes are described as follows:

- HCPCS G code G2170 (*Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed.*)
- HCPCS G code G2171 (*Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, venography, and/or ultrasound, with*

[12] Agency for Healthcare Research and Quality, ''Statistical Brief #219: Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009–2014,'' (2017), *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf.*

[13] Gail D'Onofrio et al., ''Emergency Department–Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence Randomized Clinical Trial,'' *JAMA* 16, no. 313 (2015): 2002–2010, *https://www.ncbi.nlm.nih.gov/pubmed/25919527.*

[14] Susan Busch et al., ''Cost Effectiveness of Emergency Department-Initiated Treatment for Opioid Dependence'', *Journal of Addiction* 11, no. 112 (2017), *https://www.ncbi.nlm.nih.gov/pubmed/28815789.*

radiologic supervision and interpretation, when performed.)

We are proposing to maintain contractor pricing for these HCPCS codes for CY 2021, however, we are also seeking information from stakeholders on the resource costs involved in furnishing the services described by HCPCS codes G2170 and G2171 to ensure proper payment for these physician's services, for consideration in future rulemaking. We note that under the Outpatient Prospective Payment System (OPPS) these services are assigned to APC 5193, which for CY 2020 has an assigned payment rate of $15,938.20.

(56) Insertion, Removal, and Removal and Insertion of Implantable Interstitial Glucose Sensor System (Category III CPT Codes 0446T, 0447T, and 0448T)

Category III CPT codes 0446T, 0447T, and 0448T describe the services related to the insertion, removal, and removal and insertion of an implantable interstitial glucose sensor from subcutaneous pocket, in a subcutaneous pocket via incision. The implantable interstitial glucose sensors are part of systems that can allow real-time glucose monitoring, provides glucose trend information, and signal alerts for detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The codes that describe the implantation, removal, and removal and implantation of implantable interstitial glucose sensors are currently contractor-priced.

- Category III CPT code 0446T (Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training);
- Category III CPT code 0447T (Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision); and
- Category III CPT code 0448T (*Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation*).

In the CY 2020 PFS final rule (84 FR 62627), we requested information from stakeholders to ensure proper payment for this important physician's service and welcomed recommendations on appropriate valuation for these services to be considered in future rulemaking.

We are proposing to establish national payment amounts for the codes describing the insertion, removal, and removal and insertion of an implantable interstitial glucose sensor, effective January 1, 2021. We are proposing a work RVU of 1.14 for Category III CPT code 0446T, a work RVU of 1.34 for Category III CPT code 0447T, and work RVU of 1.91 for Category III CPT code 0448T based on a crosswalk to the work RVUs, work time, and direct PE inputs of CPT codes 11981 (*Insertion, non-biodegradable drug delivery implant*), 11982 (*Removal, non-biodegradable drug delivery implant*), and 11983 (*Removal with reinsertion, non-biodegradable drug delivery implant*), respectively, due to the similar clinical nature of these procedures.

We are also proposing to include one supply and one equipment item to the direct PE inputs crosswalked from CPT codes 11981–11983. We are adding a new ''implantable interstitial glucose sensor'' (supply code SD334) for Category III CPT codes 0446T and 0448T to include the supply costs of the ''implantable interstitial glucose sensor'' (supply code SD334) included in these procedures, which we propose to price at $1,500.00, based on information we received from stakeholders. We are also proposing to include the smart transmitter associated with the use of this implantable interstitial glucose sensor. We propose to price the smart transmitter involved in furnishing this service by using a similar equipment item finalized in the CY 2019 PFS final rule (83 FR 59624) as a proxy, the ''heart failure patient physiologic monitoring equipment package'' (EQ392); the EQ392 has a price of $1,000.00, and is similarly used for long term remote monitoring of patients. We are proposing to use the EQ392 equipment as a proxy for the valuation of the smart transmitter associated with the implantable interstitial glucose sensor, to which we are assigning a time of 25,920 minutes for EQ392 in Category III CPT codes 0446T and 0448T. This time is derived from 60 minutes per hour times 24 hours per day times 90 days per billing quarter, divided by 1 minute of equipment use out of every 5 minutes of time. We are not including either the implantable interstitial glucose sensor or the EQ392 equipment proxy for Category III CPT code 0447T, as it describes only a removal procedure.

We are seeking comment on the proposed values for these Category III CPT codes (0446T, 0447T, and 0448T), and we are seeking comment on the appropriateness and accuracy of the proposed work RVUs, work times, and direct PE inputs.

BILLING CODE 4120–01–P

TABLE 24: Proposed CY 2021 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	0.00	-	1.14	Yes
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision	0.00	-	1.34	Yes
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	0.00	-	1.91	Yes
10004	Fine needle aspiration biopsy, without imaging guidance; each additional	0.80	0.80	0.80	No
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	1.46	1.63	1.46	No
10006	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion	1.00	1.00	1.00	No
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	1.81	1.81	1.81	No
10008	Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion	1.18	1.18	1.18	No
10009	Fine needle aspiration biopsy, including CT guidance; first lesion	2.26	2.43	2.26	No
10010	Fine needle aspiration biopsy, including CT guidance; each additional lesion	1.65	1.65	1.65	No
10011	Fine needle aspiration biopsy, including MR guidance; first lesion	C	C	C	No
10012	Fine needle aspiration biopsy, including MR guidance; each additional lesion	C	C	C	No
10021	Fine needle aspiration biopsy, without imaging guidance; first lesion	1.03	1.20	1.03	No
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion	11.49	12.40	11.49	No
11970	Replacement of tissue expander with permanent implant	8.01	8.01	7.49	No
11971	Removal of tissue expander without insertion of implant	3.41	7.02	6.50	No
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle	18.23	17.99	17.99	No
19316	Mastopexy	11.09	11.09	11.09	No
19318	Breast reduction	16.03	16.03	16.03	No
19325	Breast augmentation with implant	8.64	8.64	8.12	No
19328	Removal of intact breast implant	6.48	7.44	6.92	No
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)	8.54	9.00	9.00	No
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)	13.99	11.00	10.48	No
19342	Insertion or replacement of implant on separate day from mastectomy	12.63	11.00	10.48	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)	18.50	15.36	14.84	No
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy	9.17	10.00	9.17	No
19371	Peri-implant capsulectomy, breast, complete, including removal of all intra-capsular contents	10.62	10.81	9.98	No
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)	10.41	12.00	11.17	No
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	20.72	19.60	19.60	No
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	20.72	19.60	19.60	No
28820	Amputation, toe; metatarsophalangeal joint	5.82	4.10	3.51	No
28825	Amputation, toe; interphalangeal joint	5.37	4.00	3.41	No
29822	Arthroscopy, shoulder, surgical; debridement, limited, 1 or 2 discrete structures (eg, humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])	7.60	7.03	7.03	No
29823	Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures (eg, humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])	8.36	7.98	7.98	No
30XX0	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)	NEW	2.80	2.80	No
324X0	Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed	NEW	4.00	3.18	No
33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only	7.90	6.75	6.75	No
33991	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal	11.63	8.84	8.84	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	puncture				
33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), separate and distinct session from insertion	3.75	3.55	3.55	No
33993	Repositioning of percutaneous right or left heart ventricular assist device, with imaging guidance, at separate and distinct session from insertion	3.26	3.10	3.10	No
339X1	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only	NEW	6.75	6.75	No
339X2	Removal of percutaneous right heart ventricular assist device, venous cannula, separate and distinct session from insertion	NEW	3.00	3.00	No
33XX0	Transcatheter atrial septostomy (TAS) for congenital cardiac anomalies to create effective atrial flow, including all imaging guidance by the proceduralist, when performed, any method (eg, Rashkind, Sang-Park, balloon, cutting balloon, blade)	NEW	14.00	14.00	No
33XX1	Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); initial intracardiac shunt	NEW	20.00	20.00	No
33XX2	Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (eg, atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); each additional intracardiac shunt location	NEW	10.50	8.00	No
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple	2.39	2.39	2.39	No
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	4.57	4.57	4.57	No
558XX	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound	NEW	20.00	17.73	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	guidance				
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)	7.97	13.48	11.63	No
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)	11.66	13.51	11.66	No
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)	17.03	18.02	17.03	No
57XX0	Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect	NEW	0.81	0.81	No
67028	Intravitreal injection of a pharmacologic agent (separate procedure)	1.44	1.44	1.44	No
697X1	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); bilateral	NEW	4.27	4.27	No
697XX	Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral	NEW	3.00	3.00	No
70030	Radiologic examination, eye, for detection of foreign body	0.17	0.18	0.18	No
70450	Computed tomography, head or brain; without contrast material	0.85	0.85	0.85	No
70460	Computed tomography, head or brain; with contrast material	1.13	1.13	1.13	No
70470	Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections	1.27	1.27	1.27	No
71250	Computed tomography, thorax, diagnostic; without contrast material	1.16	1.16	1.08	No
71260	Computed tomography, thorax, diagnostic; with contrast material(s)	1.24	1.24	1.16	No
71270	Computed tomography, thorax, diagnostic; without contrast material, followed by contrast material(s) and further sections	1.38	1.38	1.25	No
712X0	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)	NEW	1.16	1.08	No
74300	Cholangiography and/or pancreatography; intraoperative, radiological supervision and interpretation	0.36	0.32	0.27	No
74328	Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation	0.70	0.47	0.47	No
74329	Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation	0.70	0.50	0.47	No
74330	Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation	0.90	0.70	0.56	No
75820	Venography, extremity, unilateral, radiological supervision and interpretation	0.70	1.05	1.05	No
75822	Venography, extremity, bilateral, radiological supervision and interpretation	1.06	1.48	1.48	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
75984	Change of percutaneous tube or drainage catheter with contrast monitoring (eg, genitourinary system, abscess), radiological supervision and interpretation	0.72	0.83	0.83	No
7615X	Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report	NEW	0.00	0.00	No
76513	Ophthalmic ultrasound, diagnostic; anterior segment ultrasound, immersion (water bath) B-scan or high resolution biomicroscopy, unilateral or bilateral	0.66	0.60	0.53	No
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day	0.00	0.00	0.00	No
77520	Proton treatment delivery; simple, without compensation	C	0.00	C	No
77522	Proton treatment delivery; simple, with compensation	C	0.00	C	No
77523	Proton treatment delivery; intermediate	C	0.00	C	No
77525	Proton treatment delivery; complex	C	0.00	C	No
91200	Liver elastography, mechanically induced shear wave (eg, vibration), without imaging, with interpretation and report	0.27	0.21	0.21	No
92227	Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral	0.00	0.00	0.00	No
92228	Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral	0.37	0.32	0.32	No
9225X	Imaging of retina for detection or monitoring of disease; with point-of-care automated analysis with diagnostic report; unilateral or bilateral	NEW	0.00	0.00	No
92584	Electrocochleography	0.00	1.00	1.00	No
925X1	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; cervical (cVEMP)	NEW	0.80	0.80	No
925X2	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; ocular (oVEMP)	NEW	0.80	0.80	No
925X3	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; cervical (cVEMP) and ocular (oVEMP)	NEW	1.20	1.20	No
92X51	Auditory evoked potentials; screening of auditory potential with broadband stimuli, automated analysis	NEW	0.25	N	No
92X52	Auditory evoked potentials; for hearing status determination, broadband stimuli, with interpretation and report	NEW	1.00	1.00	No
92X53	Auditory evoked potentials; for threshold estimation at multiple frequencies, with interpretation and report	NEW	1.50	1.50	No
92X54	Auditory evoked potentials; neurodiagnostic,	NEW	1.05	1.05	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	with interpretation and report				
93000	Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report	0.17	0.17	0.17	No
93005	Electrocardiogram, routine ECG with at least 12 leads; tracing only, without interpretation and report	0.00	0.00	0.00	No
93010	Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only	0.17	0.17	0.17	No
93224	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional	0.52	0.39	0.39	No
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)	0.00	0.00	0.00	No
93226	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report	0.00	0.00	0.00	No
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional	0.52	0.39	0.39	No
93306	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography	1.50	1.46	1.46	No
93623	Programmed stimulation and pacing after intravenous drug infusion	2.85	2.04	0.98	No
93662	Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation	2.80	2.53	1.44	No
93750	Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (eg, drivelines, alarms, power surges), review of device function (eg, flow and volume status, septum status, recovery), with programming, if performed, and report	0.92	0.85	0.75	No
93XX0	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	NEW	0.50	0.50	No
93XX1	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording	NEW	0.00	0.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	(includes connection and initial recording)				
93XX2	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report	NEW	0.00	0.00	No
93XX3	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation	NEW	0.50	0.50	No
93XX4	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	NEW	0.55	0.55	No
93XX5	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	NEW	0.00	0.00	No
93XX6	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report	NEW	0.00	0.00	No
93XX7	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation	NEW	0.55	0.55	No
94010	Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation	0.17	0.17	0.17	No
94060	Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator administration	0.27	0.22	0.22	No
94617	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; with electrocardiographic recording(s)	0.70	0.70	0.70	No
94618	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; without electrocardiographic recording(s)	0.48	0.48	0.48	No
94621	Cardiopulmonary exercise testing, including measurements of minute ventilation, CO2 production, O2 uptake, and electrocardiographic recordings	1.42	1.42	1.42	No
94640	Pressurized or nonpressurized inhalation treatment for acute airway obstruction for therapeutic purposes and/or for diagnostic purposes such as sputum induction with an aerosol generator, nebulizer, metered dose inhaler or intermittent positive pressure breathing (IPPB) device	0.00	0.00	0.00	No
94667	Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung	0.00	0.00	0.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	function; initial demonstration and/or evaluation				
94668	Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; subsequent	0.00	0.00	0.00	No
94669	Mechanical chest wall oscillation to facilitate lung function, per session	0.00	0.00	0.00	No
946X0	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; without electrocardiographic recording(s)	NEW	0.49	0.49	No
95012	Nitric oxide expired gas determination	0.00	0.00	0.00	No
97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient	0.60	-	0.48	No
97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)	0.50	-	0.32	No
97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient	0.65	-	0.48	No
97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)	0.55	-	0.32	No
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	0.93	0.93	0.93	Yes
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	1.42	1.60	1.60	Yes
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	2.43	2.60	2.60	No
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	3.17	3.50	3.50	Yes

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	on the date of the encounter				
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	0.18	0.18	0.18	No
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	0.48	0.70	0.70	Yes
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	0.97	1.30	1.30	No
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	1.50	1.92	1.92	Yes
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	2.11	2.80	2.80	No
994XX	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; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month	NEW	0.54	0.54	No
99XXX	Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been	NEW	0.61	0.61	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	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				
G0166	External counterpulsation, per treatment session	0.00	0.00	0.00	No
G0452	Molecular pathology procedure; physician interpretation and report	0.37	0.93	0.93	No
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	0.48	-	0.70	Yes
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	0.48	-	0.70	Yes
GAVF1	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed	NEW	-	0.00	No
GAVF2	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	NEW	-	0.00	No
GCOL1	Initial or subsequent psychiatric collaborative care management, first 30 minutes in a 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	NEW	-	0.77	No
GMAT1	Initiation of medication assisted treatment in the emergency department setting, including assessment, referral to ongoing care, and arranging access to supportive services (List separately in addition to code for primary	NEW	-	1.30	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	procedure)				
GOTP1	Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	NEW	-	0.00	No
GOTP2	Take-home supply of auto-injector naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	NEW	-	0.00	No
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)	NEW	-	0.33	No

TABLE 25: Proposed CY 2021 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)
10005	Fna bx w/us gdn 1st les	EF015	mayo stand	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10005	Fna bx w/us gdn 1st les	EF023	table, exam	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
10005	Fna bx w/us gdn 1st les	EQ250	ultrasound unit, portable	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.30
10007	Fna bx w/fluor gdn 1st les	ED050	Technologist PACS workstation	NF		49	47	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.04
10007	Fna bx w/fluor gdn 1st les	EF015	mayo stand	NF		44	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10007	Fna bx w/fluor gdn 1st les	EL014	room, radiographic-fluoroscopic	NF		44	34	E2: Refined equipment time to conform to established policies for highly technical equipment	-22.75
10009	Fna bx w/ct gdn 1st les	EF015	mayo stand	NF		52	50	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10021	Fna bx w/o img gdn 1st les	EF015	mayo stand	NF		29	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	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)
10021	Fna bx w/o img gdn 1st les	EF023	table, exam	NF		29	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
28820	Amputation of toe	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-4.81
28820	Amputation of toe	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	5	2	L1: Refined time to standard for this clinical labor task	-1.11
28820	Amputation of toe	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	5	2	L1: Refined time to standard for this clinical labor task	-1.11
28820	Amputation of toe	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.11
28820	Amputation of toe	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.48
28820	Amputation of toe	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-3.70
28825	Partial amputation	L037D	RN/LPN/MTA	F	Coordinate	20	10	L8: Standard preservice	-3.70

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)
	of toe				pre-surgery services (including test results)			clinical labor time for procedures with 0/10 day global periods	
28825	Partial amputation of toc	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	5	2	L1: Refined time to standard for this clinical labor task	-1.11
28825	Partial amputation of toe	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	5	2	L1: Refined time to standard for this clinical labor task	-1.11
28825	Partial amputation of toe	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-4.81
28825	Partial amputation of toe	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.11
28825	Partial amputation of toe	L037D	RN/LPN/MTA	F	Complete pre-proccdurc phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.48
67028	Injection eye drug	L038A	COMT/COT/RN/CST	NF	Clean room/equipment by clinical staff	5	3	L1: Refined time to standard for this clinical labor task	-0.76
712X0	Ct thorax lung cancer scr c-	L037D	RN/LPN/MTA	NF	Coordinate post-	6	4	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)
					procedure services				
712X0	Ct thorax lung cancer scr c-	L046A	CT Technologist	NF	Provide education/obtain consent	3	2	L1: Refined time to standard for this clinical labor task	-0.46
76513	Oph us dx ant sgm us uni/bi	L038A	COMT/COT/RN/CST	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	2	G1: See preamble text	-0.38
76513	Oph us dx ant sgm us uni/bi	L038A	COMT/COT/RN/CST	NF	Provide education/obtain consent	3	2	G1: See preamble text	-0.38
77401	Radiation treatment delivery	ER119	Lead Room	NF		19	0	G1: See preamble text	-0.87
77401	Radiation treatment delivery	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	5	3	L1: Refined time to standard for this clinical labor task	-0.74
9225X	Img rta detc/mntr ds poc aly	L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	2	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-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)
93XX0	Ext ecg>48hr<7d rec scan a/r	L037A	Electrodiagnostic Technologist	NF	Perform proccdurc/service---NOT directly related to physician work time	36	31	G1: See preamble text	-1.85
93XX0	Ext ecg>48hr<7d rec scan a/r	SB022	gloves, non-sterile	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-0.25
93XX2	Ext ecg>48hr<7d scan a/r	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	24	19	G1: See preamble text	-1.85
93XX4	Ext ecg>7d<15d rec scan a/r	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly rclatcd to physician work time	36	31	G1: See preamble text	-1.85
93XX4	Ext ecg>7d<15d rec scan a/r	SB022	gloves, non-sterile	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-0.25
93XX6	Ext ecg>7d<15d scan a/r	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT	24	19	G1: See preamble text	-1.85

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)
					directly related to physician work time				
99202	Office/outpatient visit new	ED021	computer, desktop, w-monitor	NF		34	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.22
99203	Office/outpatient visit new	ED021	computer, desktop, w-monitor	NF		43	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.28
99204	Office/outpatient visit new	ED021	computer, desktop, w-monitor	NF		54	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.35
99205	Office/outpatient visit new	ED021	computer, desktop, w-monitor	NF		67	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.43
99211	Office/outpatient visit est	ED021	computer, desktop, w-monitor	NF		17	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.11
99212	Office/outpatient visit est	ED021	computer, desktop, w-monitor	NF		28	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.18

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)
99213	Office o/p est low 20-29 min	ED021	computer, desktop, w-monitor	NF		36	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.23
99214	Office o/p est mod 30-39 min	ED021	computer, desktop, w-monitor	NF		51	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
99215	Office/outpatient visit est	ED021	computer, desktop, w-monitor	NF		62	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.40
99XXX	Prolng off/op e/m ea 15 min	ED021	computer, desktop, w-monitor	NF		15	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.10
G0166	Extrnl counterpulse, per tx	EQ012	EECP, external counterpulsation system	NF		83	80	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-2.30
G0166	Extrnl counterpulse, per tx	L037D	RN/LPN/MTA	NF	Monitor patient following procedure/service, no multitasking	0	3	L1: Refined time to standard for this clinical labor task	1.11
G0166	Extrnl counterpulse, per tx	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	0	G1: See preamble text	-1.11

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)
G0166	Extrnl counterpulse, per tx	SD341	EECP compression equipment package	NF		0	0	G1: See preamble text	1.99
G0166	Extrnl counterpulse, per tx	SD342	EECP electrical equipment package	NF		0	0	G1: See preamble text	1.54

TABLE 26: Proposed CY 2021 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time

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)
28820	Amputation of toe	EF014	light, surgical	NF		58	52	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
28820	Amputation of toe	EF015	mayo stand	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
28820	Amputation of toe	EF031	table, power	NF		58	52	E15: Refined equipment time to conform to changes in clinical labor time	-0.10
28820	Amputation of toe	EQ110	electrocautery-hyfrecator, up to 45 watts	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
28820	Amputation of toe	EQ138	instrument pack, medium ($1500 and up)	NF		67	61	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
28820	Amputation of toe	EQ235	suction machine (Gomco)	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
28820	Amputation of toe	EQ240	tourniquet system (Zimmer1200)	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.18
28825	Partial amputation	EF014	light, surgical	NF		58	52	E15: Refined equipment time to conform to	-0.03

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)
	of toe							changes in clinical labor time	
28825	Partial amputation of toe	EF015	mayo stand	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
28825	Partial amputation of toe	EF031	table, power	NF		58	52	E15: Refined equipment time to conform to changes in clinical labor time	-0.10
28825	Partial amputation of toe	EQ110	electrocautery-hyfrecator, up to 45 watts	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
28825	Partial amputation of toe	EQ138	instrument pack, medium ($1500 and up)	NF		67	61	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
28825	Partial amputation of toe	EQ235	suction machine (Gomco)	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
28825	Partial amputation of toe	EQ240	tourniquet system (Zimmer1200)	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.18
67028	Injection eye drug	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-	NF		19	17	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)
			sensors, NIST certificates						
67028	Injection eye drug	EL005	lane, exam (oph)	NF		19	17	E15: Refined equipment time to conform to changes in clinical labor time	-0.25
712X0	Ct thorax lung cancer scr c-	ED050	Technologist PACS workstation	NF		35	34	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
9225X	Img rta detc/mntr ds poc aly	ED061	camera, retinal, for remote imaging	NF		14	13	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
9225X	Img rta detc/mntr ds poc aly	EF030	table, motorized (for instruments-equipment)	NF		14	13	E15: Refined equipment time to conform to changes in clinical labor time	0.00
93XX0	Ext ecg>48hr<7d rec scan a/r	ED021	computer, desktop, w-monitor	NF		100	95	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
93XX2	Ext ecg>48hr<7d scan a/r	ED021	computer, desktop, w-monitor	NF		100	95	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
93XX4	Ext ecg>7d<15d rec scan a/r	ED021	computer, desktop, w-monitor	NF		128	123	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
93XX6	Ext ecg>7d<15d	ED021	computer, desktop, w-	NF		128	123	E15: Refined equipment time to conform to	-0.03

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)
	scan a/r		monitor					changes in clinical labor time	

TABLE 27: Proposed CY 2021 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
67028, 92352, 92353	phenylephrine 2.5% ophth (Mydfrin)	SH056	$3.77	$5.46	45%	2	3,080,085
76510, 76512, 76513, 76529	ultrasonic biometry, B-scan	EQ247	$14,655.63	$26,647.50	82%	2	204,408
77401	Superficial radiation therapy system	ER045	$201,875.00	$204,999.67	2%	3	206,144
91200	Fibroscan with printer	ER101	$130,425.22	$102,494.87	-21%	6	30,527
G0166	EECP, external counterpulsation system	EQ012	$120,954.23	$101,247.50	-16%	2	88,907
G2082	Esketamine (56 mg vial)	SH109	$590.02	$616.93	5%	1	0
G2083	Esketamine (84 mg vial)	SH110	$885.02	$928.38	5%	1	0
34 codes	electrosurgical generator, gastrocautery	EQ113	$11,375.00	$36,180.00	218%	4	-
90 codes	endoscope disinfector, rigid or fiberoptic, w-cart	ES005	$36,556.97	$27,500.00	-25%	3	-
254 codes	scope video system (monitor, processor, digital capture, cart, printer, LED light)	ES031	$36,306.00	$70,673.38	95%	37	-
363 codes	suction machine (Gomco)	EQ235	$779.61	$3,195.85	310%	4	-

TABLE 28: Proposed CY 2021 New Invoices

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
30XX0	Absorabable nasal implant and delivery device	SA133	1,995.00	1	9
324X0	Coaxial Biopsy Set	SC108	49.00	1	1,324
324X0	Pleural Plug kit	SA132	315.00	1	1,324
37238, 37239	venous stent system	SD340	1,750.00	10	6,592
57XX0	computer aided spectral imaging system (colposcopy)	ER117	32,000.00	1	79
57XX0	disposable speculum, medium	SD337	5.80	1	79
67028	povidone soln (Betadine), single-use dropper	SJ094	2.31	1	3,080,085
67028	needle, 32g	SC109	0.59	3	3,080,085
697XX, 697X1	kit, eustachian tube procedure	SA134	2,010.00	7	74
697XX, 697X1	eustachian tube balloon	SD338	83.01	8	74
7615X	Radiation Dosimetry Kit	EQ401	17,182.50	2	7,178
76513	Ophthalmic Ultrasound Biomicroscope (UBM Probe)	ER118	10,995.00	1	14,581
76513	ClearScan ultrasound water-filled condom probe cover	SB055	10.50	1	14,581
77401	Lead Room	ER119	17,236.00	1	206,144
77401	Lead Blocking Shield Kit	ER120	3,348.06	1	206,144
77520, 77522, 77523, 77525	Proton Treatment Vault	ER115	19,001,914.00	1	77,768
77520, 77522, 77523, 77525	Proton Treatment Delivery System	ER116	30,400,000.00	1	77,768
92X51	AABR-automated auditory brainstem response screening system	EQ396	20,000.00	1	0
92227, 92228, 9225X	camera, retinal, for remote imaging	ED061	14,156.68	3	2,391
92584	ECochG electrode	SD335	24.21	1	10,213
925X1, 925X2, 925X3	VEMP module	ED062	2,000.00	1	254
93XX0, 93XX2, 93XX4, 93XX6	extended external ECG patch, medical magnetic tape recorder	SD339	413.24	0	229,813
946X0, 94617, 94010, 94060	PFT System with PC and printer	EQ397	37,527.15	1	1,688,997
95012	sensor, filter, mouthpiece, nitric oxide	SD336	10.33	10	126,914

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
95012	monitoring system, nitric oxide	EQ398	1,500.00	4	126,914
99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215	Portable stand-on scale	EF048	1,343.85	1	204,303,328
G0166	EECP compression equipment package	SD341	645.00	17	88,907
G0166	EECP electrical equipment package	SD342	500.00	1	88,907
G0452	Sequence data analytics (alignment/variant calling) and reporting software	ED063	28,800.00	1	0

TABLE 29: Proposed CY 2021 No PE Refinements

HCPCS	Description
10004	Fna bx w/o img gdn ea addl
10006	Fna bx w/us gdn ea addl
10008	Fna bx w/fluor gdn ea addl
10010	Fna bx w/ct gdn ea addl
10011	Fna bx w/mr gdn 1st les
10012	Fna bx w/mr gdn ea addl
11960	Insert tissue expander(s)
11970	Rplcmt tiss xpndr perm implt
11971	Rmvl tis xpndr wo insj implt
19307	Mast mod rad
19316	Suspension of breast
19318	Reduction of large breast
19325	Breast augmentation w/implt
19328	Rmvl intact breast implant
19330	Rmvl ruptured breast implant
19340	Insj breast implt sm d mast
19342	Insj/rplcmt brst implt sep d
19357	Tiss xpndr plmt brst rcnstj
19370	Revj peri-implt capsulc brst
19371	Peri-implt capslc brst compl
19380	Revj reconstructed breast
27130	Total hip arthroplasty
27447	Total knee arthroplasty
29822	Sho arthrs srg lmtd dbrdmt
29823	Sho arthrs srg xtnsv dbrdmt
30XX0	Rpr nsl vlv collapse w/implt
324X0	Core ndl bx lng/med perq
33990	Insj perq vad l hrt arterial
33991	Insj perq vad l hrt artl&ven
33992	Rmvl perq left heart vad
33993	Reposg perq r/l hrt vad
339X1	Insj perq vad r hrt venous
339X2	Rmvl perq right heart vad
33XX0	Tas congenital car anomal
33XX1	Tis crtj cgen car anomal 1st
33XX2	Tis crtj cgen car anomal ea
43239	Egd biopsy single/multiple
45385	Colonoscopy w/lesion removal
558XX	Abltj mal prst8 tiss hifu
57282	Colpopexy extraperitoneal
57283	Colpopexy intraperitoneal
57425	Laparoscopy surg colpopexy
57XX0	Cam cervix uteri drg colp
697X1	Nps surg dilat eust tube bi
697XX	Nps surg dilat eust tube uni
70030	X-ray eye for foreign body
70450	Ct head/brain w/o dye
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
71250	Ct thorax dx c-
71260	Ct thorax dx c+
71270	Ct thorax dx c-/c+
75820	Vein x-ray arm/leg

HCPCS	Description
75822	Vein x-ray arms/legs
75984	Xray control catheter change
7615X	Med physic dos eval rad exps
91200	Liver elastography
92227	Img rta detcj/mntr ds staff
92228	Img rta detc/mntr ds phy/qhp
92584	Electrocochleography
925X1	Vemp test i&r cervical
925X2	Vemp test i&r ocular
925X3	Vemp tst i&r cervical&ocular
92X51	Aep scr auditory potential
92X52	Aep hearing status deter i&r
92X53	Aep thrshld est mlt freq i&r
92X54	Aep neurodiagnostic i&r
93000	Electrocardiogram complete
93005	Electrocardiogram tracing
93010	Electrocardiogram report
93224	Ecg monit/reprt up to 48 hrs
93225	Ecg monit/reprt up to 48 hrs
93226	Ecg monit/reprt up to 48 hrs
93227	Ecg monit/reprt up to 48 hrs
93306	Tte w/doppler complete
93750	Interrogation vad in person
93XX1	Ext ecg>48hr<7d recording
93XX3	Ext ecg>48hr<7d rev&interpj
93XX5	Ext ecg>7d<15d recording
93XX7	Ext ecg>7d<15d rev&interpj
94010	Breathing capacity test
94060	Evaluation of wheezing
94617	Exercise tst brncspsm w/ecg
94618	Pulmonary stress testing
94621	Cardiopulm exercise testing
94640	Airway inhalation treatment
94667	Chest wall manipulation
94668	Chest wall manipulation
94669	Mechanical chest wall oscill
946X0	Exercise tst brncspsm wo ecg
95012	Exhaled nitric oxide meas
994XX	Chrnc care mgmt svc ea addl
G0452	Molecular pathology interpr

BILLING CODE 4120–01–C

I. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit category for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 PFS final rule (84 FR 62630 through 62677), we implemented coverage requirements and established new codes describing the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We established new codes for and finalized bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. We are monitoring Medicare enrollment by OTPs and utilization of the new benefit to ensure that Medicare beneficiaries have appropriate access to care. For CY 2021, we are proposing several refinements and seek to provide clarification on certain issues that stakeholders have brought to our attention.

2. Definition of OUD Treatment Services

In the CY 2020 PFS final rule (84 FR 62631 through 62635), we finalized a definition of ''OUD treatment services'' that reflects the statutory definition in section 1861(jjj)(1)(A) of the Act, which defines covered OUD treatment services to include oral, injected, and implanted opioid agonist and antagonist treatment

medications approved by the Food and Drug Administration (FDA) under section 505 of the FFDCA for use in the treatment of OUD. There are three drugs currently approved by FDA for the treatment of opioid dependence: Buprenorphine; methadone; and naltrexone. In the CY 2020 PFS final rule, we noted that we had received comments supporting the proposed definition of OUD treatment services but also requesting that CMS include naloxone to treat opioid overdose in that definition as a medication used in treatment of OUD. Although we did not finalize including naloxone in the definition of OUD treatment services in that final rule, we indicated that as we continue to work on refining this new Medicare benefit, we would consider including additional drugs in the definition of OUD treatment services under our discretionary authority in section 1861(jjj)(1)(F) of the Act to include other items and services the Secretary determines are appropriate. After further consideration, we have determined that it is appropriate to propose to extend the definition of OUD treatment services to include opioid antagonist medications, such as naloxone, that are approved by FDA under section 505 of the FFDCA for emergency treatment of opioid overdose.

Naloxone is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.[15] [16] Naloxone should be given to a person who shows signs of an opioid overdose or when an overdose is suspected. FDA-approved naloxone products for overdose reversal are effective in reversing opioid overdose, including fentanyl-involved opioid overdoses, although overdoses involving potent (for example, fentanyl) or large quantities of opioids may require higher-than-normal doses of naloxone or repeated administration to reverse overdose.[17]

Naloxone attaches to opioid receptors and reverses and blocks the effects of other opioids.[18] FDA has approved injectable naloxone, intranasal naloxone, and naloxone auto-injector as emergency treatments for opioid overdose. The nasal spray is a prefilled, needle-free device that requires no assembly and can deliver a single dose into each nostril with two sprays. The auto-injector is injected into the outer thigh to deliver naloxone to the muscle (intramuscular). These forms of naloxone can easily be administered by persons who do not have medical training and they may be prescribed to a patient who is receiving medication-assisted treatment (MAT) for OUD, especially if the patient is considered to be at risk for opioid overdose.[19] Both the nasal spray and naloxone auto-injector are packaged in a carton containing two doses to allow for repeat dosing if needed.[20] [21]

The U.S. Surgeon General Jerome M. Adams, M.D., M.P.H. has released a public health advisory stating that, ''Research shows that when naloxone and overdose education are available to community members, overdose deaths decrease in those communities. Therefore, increasing the availability and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths and, when combined with the availability of effective treatment, to ending the opioid epidemic.'' [22]

We are proposing to add naloxone to the definition of OUD treatment services in order to increase access to this important emergency treatment and to allow OTPs to be paid under Medicare for dispensing naloxone to Medicare beneficiaries who are receiving other OUD treatment services from the OTP. Under this proposal, beneficiaries receiving OUD treatment services from the OTP would be able to receive naloxone from the OTP under the OUD treatment services benefit, to the extent it is medically reasonable and necessary as part of their OUD treatment. We note that naloxone is already covered under Medicare Part D. In 2017, 72.5 percent of all Medicare beneficiaries were enrolled in Medicare Part D plans.[23] However, we believe allowing beneficiaries to access this important emergency treatment at the OTP may help decrease barriers to access because there currently are no copayments for services furnished by OTPs and beneficiaries would not need to visit a separate provider to access naloxone.

Accordingly, to align with efforts to end the opioid epidemic, under the discretionary authority in section 1861(jjj)(1)(F) of the Act, we propose to amend the definition of OUD treatment services at § 410.67(b) by adding § 410.67(b)(8) to include opioid antagonist medications that are approved by FDA under section 505 of the FFDCA for the emergency treatment of known or suspected opioid overdose. We are proposing to amend the definition of OUD treatment services under the discretionary authority in section 1861(jjj)(1)(F) of the Act rather than the authority under section 1861(jjj)(1)(A) of the Act because section 1861(jjj)(1)(A) of the Act pertains to opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by FDA under section 505 of the FFDCA for use in the treatment of opioid use disorder. Naloxone is not one of the three drugs currently approved by FDA for the treatment of opioid dependence (buprenorphine, methadone, and naltrexone); and, as a result, we do not believe naloxone fits the criteria of section 1861(jjj)(1)(A) of the Act. We seek comment on our proposal to expand the definition of OUD treatment services.

Additionally, we agree with the public health advisory quoted previously that community education related to overdose prevention is needed to address the opioid crisis. We believe that prevention and community education efforts would increase awareness of treatment options and could play a role in decreasing opioid overdose deaths. We welcome comments on whether the definition of OUD treatment services should be further revised to include overdose education. Additionally, we welcome comments on whether payment for providing overdose education to the beneficiary and/or the beneficiary's family or partner should be considered to be included in the current weekly bundled payments for episodes of care or whether we should consider establishing an add-on payment for education related to overdose prevention when such services are furnished by OTPs. We are specifically seeking information related to what inputs we might consider in developing the payment rate for such a service, such as payment amounts for similar services under the PFS, if we were to include this type of education as part of the proposed new add-on codes for naloxone discussed later in this section (HCPCS codes GOTP1 and GOTP2). For example, in order to establish a payment rate for education related to overdose prevention for the beneficiary and/or

[15] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf.*

[16] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209862lbl.pdf.*

[17] *https://store.samhsa.gov/system/files/sma18-4742.pdf.*

[18] *https://www.drugabuse.gov/publications/drugfacts/naloxone.*

[19] *https://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone.*

[20] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf.*

[21] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209862lbl.pdf.*

[22] *https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html.*

[23] *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.*

beneficiary's family or partner, we could consider a crosswalk to the Medicare payment rate for CPT code 96161 *(Administration of caregiver-focused health risk assessment instrument (e.g, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument).* The current non-facility payment rate under the PFS for CPT code 96161 is $2.53.

a. Proposed Adjustment Made to the Bundled Payments for OUD Treatment Services

Consistent with our proposal to expand the definition of OUD treatment services to include opioid antagonist medications indicated for the emergency treatment of known or suspected opioid overdose, we believe it is appropriate to propose changes to the payment rates for the bundled payments to reflect the costs of these medications. Therefore, we propose to adjust the bundled payment rates through the use of add-on codes to account for instances in which OTPs provide Medicare beneficiaries with naloxone. We believe that beneficiaries receiving naloxone will need a supply at the start of treatment and would only require refills later if the supply is used in an emergency. As a result, we would not expect naloxone to be provided weekly to all patients, but only on an as-needed basis. Accordingly, we believe that making payment for naloxone through the use of an add-on code is the most accurate approach to pricing rather than including the costs of these medications as part of the bundled payment rates for all episodes of care.

We propose to adopt the following add-on G codes:

- *HCPCS code GOTP1:* Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
- *HCPCS code GOTP2:* Take-home supply of auto-injector naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.

We are proposing to adopt an approach similar to the pricing methodology that was used to price the drug component of the bundled payments in the CY 2020 PFS final rule to determine the payment rate for these proposed new add-on codes for naloxone. In the CY 2020 PFS proposed rule (84 FR 40530), we explained that 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. Therefore, we believe it is appropriate to use a similar methodology to determine the payment rates for the add-on codes for naloxone as we adopted in the CY 2020 PFS final rule for purposes of determining the payment rate for the drug component of the bundled payments because it provides our best estimate of an OTP's cost in dispensing naloxone.

In the CY 2020 PFS final rule, we adopted a policy under which we apply the methodology set forth in section 1847A of the Act to determine the payment amount for the drug component of the bundled payment for an episode of care that includes implantable or injectable medications, except that the payment amount shall be 100 percent of the average sales price (ASP), if ASP is used. For oral medications, the payment for the drug component is based on 100 percent of ASP, if ASP data are available. However, if ASP is not available, the payment amount for methadone will be based on the TRICARE rate and the payment amount for oral buprenorphine is calculated using the national average drug acquisition cost (NADAC).

Drug Pricing for Nasal Naloxone

Consistent with the approach that we adopted for pricing the drug component of the weekly bundled payments, we are proposing to price the add-on code describing the take home supply of nasal naloxone, HCPCS code GOTP1, using the same methodology we previously adopted for pricing the drug component of an episode of care that include implantable or injectable medications. Accordingly, the payment methodology would be based upon the methodology set forth in section 1847A of the Act, except that payment amounts determined based on ASP and wholesale acquisition cost (WAC) would not include any add-on percentages. We recognize that nasal naloxone is not an oral, implantable or injectable medication; however, ASP data are available. As noted in the CY 2020 PFS final rule (84 FR 62653), we believe using ASP provides a transparent and public benchmark for manufacturers' pricing as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions as noted in section 1847A(c)(2) of the Act) and is the only pricing methodology that includes off-invoice rebates and discounts as described in section 1847A(c)(3) of the Act. Therefore, we believe ASP to be the most market-based approach to set drug prices. We seek public comment on our proposal to use ASP+0 to price the add-on payment for nasal naloxone and other potential sources of pricing data for nasal naloxone either generally or specifically with respect to acquisition by OTPs.

Drug Pricing for Auto-Injector Naloxone

We are proposing to price the add-on code describing the take-home supply of auto-injector naloxone, HCPCS code GOTP2, using the lowest pricing available (the lower of ASP + 0, WAC + 0, or NADAC). Currently, there is no ASP or NADAC reported or calculated for auto-injector naloxone. Accordingly, we propose to use WAC + 0 to determine the pricing for the add-on payment for auto-injector naloxone. We believe 100 percent of WAC is a closer estimate of the actual acquisition cost for OTPs compared to WAC with an add-on percentage because, as defined in section 1847A(c)(6)(B) of the Act, WAC does not include prompt pay discounts, rebates or reductions in price. Thus, there should be no need to pay an add-on percentage to ensure OTPs are reimbursed for their acquisition costs for auto-injector naloxone. However, in the future, we believe using the lowest pricing available for auto-injector naloxone may be most appropriate, because if ASP and/or NADAC pricing were to become available for auto-injector naloxone, they would be more reflective of actual costs than a list price.

We note that auto-injector naloxone is available in both a generic and brand name version. We considered comparing the Medicare Part D utilization for each formulation to determine the frequency with which the generic and brand name versions might dispensed by OTPs. However, because the generic auto-injector naloxone is rather new to the marketplace,[24] there are limited utilization data available for the generic product. Based on historical information reflecting a trend of increased generic utilization uptake,[25] we believe that in most cases where the auto-injector naloxone is prescribed and dispensed by OTPs to beneficiaries, it will be the generic formulation of the product. Therefore, we believe using the price for the generic formulation is a reasonable approach to pricing the proposed add-on code for auto-injector naloxone and will ensure that beneficiaries who need this drug as part of their treatment for OUD have access to it and that OTPs receive a reasonable payment for dispensing the drug. Accordingly, we are proposing to use the price of the generic formulation, determined as WAC + 0, to pay for auto-injector naloxone when the drug is provided by an OTP as part of an episode of care. We seek comment on our proposed pricing methodology to pay for auto-injector naloxone and other potential sources of pricing data for auto-injector naloxone either generally or specifically with respect to acquisition by OTPs.

Frequency Limit

We note that Medicare Part D allows prescription drug plans to place quantity limits (QL) on most drugs, including on naloxone. While most Part D plans do not limit the amount of naloxone a beneficiary is able to receive in a given month, when they do, they most frequently allow a plan enrollee a maximum of 4 units per 30 days (2 boxes of 2 units). In the current contract year (2020) only 22 percent of Medicare Part D formularies apply a QL to naloxone (115/535 formularies), while for the 2021 contract year only 19 percent of Part D formularies plan to apply a QL to this product (106/564 formularies). However, a review of Part D claims data shows that beneficiaries who use naloxone most frequently use only one box (2 units) within a 30-day period even though nearly all plans would have permitted additional doses. Under TRICARE, auto-injector naloxone is covered for a maximum quantity of one carton at retail network pharmacies for up to a 30-day supply.[26] We believe it would be appropriate to apply a similar limit on the frequency of the add-on payment for naloxone dispensed by OTPs. We believe that applying a frequency limit would assist in enhancing patient safety and discourage misuse, waste and abuse. Furthermore, we believe such a limitation is reasonable because there are other services that OTPs should already be performing, and which are already included in the weekly bundled payments for episodes of care, such as counseling and individual and group therapy, that should limit the need for this emergency treatment. However, we do not want to limit access to naloxone when it is a medically reasonable and necessary part of the treatment for OUD. Therefore, we propose to limit Medicare payment to OTPs for naloxone to one add-on code (HCPCS code GOTP1 or GOTP2) every 30 days to the extent that it is medically reasonable and necessary. We seek comment on whether this proposed limit is reasonable and whether special circumstances may arise under which more frequent payment is medically reasonable and necessary and the types of circumstances that should qualify for more frequent payment. However, we note that we also expect OTPs and their treating practitioners will use their clinical judgment as to whether there may be cases in which a referral to a higher level of care may be needed for some beneficiaries in order to reduce the risk of overdose and the need for more frequent emergency treatment. We propose to add § 410.67(d)(4)(i)(E) to describe payment for a take-home supply of opioid antagonist medications that are approved by FDA under section 505 of the FFDCA for the emergency treatment of known or suspected opioid overdose.

We invite public comments on the proposed pricing for nasal naloxone and auto-injector naloxone. We also seek comment on our proposal to limit payment for the proposed add-on codes for take-home supplies of these medications to once every 30 days to the extent that it is medically reasonable and necessary.

Additionally, we seek comment on whether we should consider creating a code and establishing an add-on payment for injectable naloxone. We note that all three forms of naloxone (injectable, auto-injector, and nasal spray) are FDA-approved and may be considered as options for community distribution and use by individuals with or without medical training to stop or reverse the effects of an opioid overdose.[27] If we were to establish an add-on payment for injectable naloxone, we would consider using the same methodology we adopted for pricing the drug component of an episode of care that includes implantable or injectable medications, as described in § 410.67(d)(2)(i)(A).

Table 30 details the proposed coding and summarizes the proposed payment amounts for nasal naloxone and auto-injector naloxone.

[24] *https://kaleo.com/in-the-news/authorized-generic-for-evzio-naloxone-hcl-injection-to-be-available-at-a-reduced-list-price-of-178/.*

[25] In 2015, approximately 87 percent of prescriptions filled under Part D were for generic drugs, compared with 61 percent in 2007. *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.*

[26] *https://www.express-scripts.com/static/formularySearch/2.9.6/#/formularySearch/drugSearch.*

[27] *https://www.fda.gov/news-events/press-announcements/statement-continued-efforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose.*

TABLE 30: OTP Code Descriptors and Proposed Approximate Payment Amounts*

HCPCS	Descriptor	Total Payment
GOTP1	Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$89.63
GOTP2	Take-home supply of auto-injector naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$178

* Drug pricing subject to change pending additional data. Nasal naloxone drug costs are calculated using ASP data, auto injector naloxone drug costs are calculated using the lowest pricing available (the lower of ASP + 0, WAC + 0, or NADAC), the proposed price used is the WAC + 0 for the generic auto-injector naloxone. The estimated payment amounts in Table 30 are based on data files posted at the time of the drafting of this proposed rule. We will develop the final pricing for CY 2021 using the most recent data files available at the drafting of the CY 2021 PFS final rule.

Duplicative Payment

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 under our proposal, OTPs would be able to provide naloxone to Medicare beneficiaries and bill for it as an add-on to the bundled payment. Consistent with § 410.67(e), the beneficiary's copayment amount would remain zero. We also realize that naloxone may also be appropriately available to beneficiaries through other Medicare benefits, including, for example, Medicare Part D, under which the beneficiary would be responsible for the applicable cost sharing. As discussed in the CY 2020 PFS final rule (84 FR 62664) and codified at § 410.67(d)(5), we define duplicative payment to involve only those circumstances where medications that are delivered, administered or dispensed to a beneficiary are paid as part of the OTP bundled payment, and where the delivery, administration or dispensing of the same medication (that is, same drug, dosage and formulation) is also separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service. Because we are proposing to pay for naloxone as an add-on to the weekly bundled payment, any payment to an OTP for naloxone would be duplicative if the same medication is separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service. Consistent with § 410.67(d)(5), CMS would recoup any duplicative payment made to an OTP for naloxone.

Additionally, we understand that some OTPs negotiate arrangements whereby community pharmacies supply MAT-related medications to OTPs. However, as we stated in the CY 2020 PFS final rule, if the OTP provides reasonable and 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. Thus, naloxone billed by an OTP as an add-on to the bundled payment should not be reported to or paid under a Part D plan. We expect that OTPs will take reasonable steps to prevent duplicative payment for naloxone furnished under their care by ensuring it is not reported or billed under a different Medicare benefit. We intend to monitor for duplicative payments, and would take appropriate action as needed when and if such duplicative payments are identified.

3. WAC Pricing

Section 1834(w) of the Act gives the Secretary significant discretion to establish bundled payment rates for OUD treatment services. In the CY 2020 PFS final rule, we finalized a payment methodology for the drug component of the bundled payment rates for OUD treatment services, under which we use the payment methodology set forth in section 1847A of the Act (which bases most payment on ASP) to set the payment rates for implantable and injectable drugs and limited the payment amount for these drugs to 100 percent of the volume-weighted ASP for a drug category or code, if ASP is used. We codified this payment methodology at § 410.67(d)(2)(i)(A).

Section 1847A of the Act provides for the use of other payment methodologies when ASP is not available, including WAC and average manufacturer price (AMP). In the CY 2020 PFS final rule, we limited payments to OTPs for injectable and implantable drugs to 100 percent of ASP, but did not otherwise diverge from the payment methodology that would apply under section 1847A of the Act. In this proposed rule, we believe that it is necessary to amend the OTP drug pricing methodology in order to limit WAC-based payments to 100 percent of WAC. As discussed previously, we are proposing to use WAC pricing to determine the payment rate for the add-on code for the auto-injector naloxone. Although none of the drugs that are currently included in the drug component of an episode of care is currently paid based on WAC, we believe it is possible that we may use WAC to determine the payment for the drug component of an episode of care in the future, and want to establish, in advance, the methodology that would apply for purposes of determining the payment rate.

As authorized under section 1847A of the Act, some Part B drugs are paid based on WAC. For example, for single source drugs, payment is 106 percent of the lesser of WAC or ASP (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), 103 percent of WAC is used. Additionally, there are some instances where drugs lack ASP data for reasons other than being new, for example, in cases where the manufacturer had no sales in a reporting quarter. In those situations, the Medicare payment method varies, but in some cases, the payment may be 106 percent of the WAC.[28] As we stated in the CY 2020 PFS final rule (84 FR 62651), 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

[28] *http://www.medpac.gov/-blog-/requiring-reporting-of-sales-price-data/2019/06/14/payment-for-part-b-drugs.*

to the clinical care of the patient, such as the drug's profit margin for a provider. The WAC is defined in section 1847A(c)(6)(B) as the manufacturer's list price for a drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price. A drug's WAC is ultimately controlled by the manufacturer. Unlike ASP, a drug's WAC does not incorporate prompt-pay or other discounts. If discounts are available on drugs reimbursed by Medicare at 106 percent of WAC, then Medicare is paying more for drugs than it otherwise would under the ASP-based formula.[29] Therefore, consistent with our existing policy to set the payment amount at 100 percent of the ASP, if ASP is used to determine the payment for the drug component of an episode of care, we are proposing that when WAC-based pricing is used, the payment amount shall be WAC + 0. We are proposing to amend the provision at § 410.67(d)(2)(i)(A) to reflect this limitation.

We welcome comments on this proposed alternative pricing methodology when the payment for an implantable or injectable medication included in the drug component of an episode of care is determined using the methodology set forth in section 1847A of the Act, and ASP pricing data are not available.

4. Billing and Payment Policies

a. Institutional Claim Forms

We have received several requests to allow OTPs to bill on an institutional claim form. We were informed by representatives from the state of New York that all OTPs in New York state bill on institutional claim forms, not just those that are part of a hospital system. Given the public health need related to the opioid epidemic, we are exploring claims processing flexibilities requested by some OTPs that would allow them to bill services on institutional claims. See also section III.B. of this proposed rule, OTP Provider Enrollment Regulation Updates for Institutional Claim Submissions, for a discussion related to OTP enrollment as it relates to institutional claims. There would be no differences in coverage or payment between services billed on the institutional claim form versus the professional claim form. We note that the National Uniform Billing Committee (NUBC) approved a new Type Of Bill (087x) for Freestanding Non-residential Opioid Treatment Program provider billing, as well as a new condition code (89) for Opioid Treatment Program/ Indicates claim for opioid treatment program services, to be used on hospital based OTP claims (TOB 013x and 085x). We are seeking information on the reasons this flexibility is necessary for OTPs, and will address any changes to provider billing policies in subsequent claims processing instructions.

b. Periodic Assessments

In the CY 2020 PFS final rule (84 FR 62634), we stated that we understood that intake activities and periodic assessments are integral services for the establishment and maintenance of OUD treatment for a beneficiary at an OTP, and therefore, we believed it was reasonable to include these services in the definition of OUD treatment services. Accordingly, we finalized a definition of OUD treatment services in § 410.67(b) that reflected the required intake activities and periodic assessments. We stated it was our understanding that these services are furnished much less frequently than the other services included in the weekly bundled payments; therefore, we created add-on G codes to describe these services, which would allow us to make more targeted payments for these services. We noted that the add-on code describing intake activities should only be billed for new patients (that is, patients starting treatment at the OTP). We agreed with the commenters that the level 4 office/outpatient E/M visits for new and established patients are a good approximation of the services provided at intake and during periodic assessments at OTPs based on the expected acuity of patients with OUD receiving services at OTPs, who are likely to have multiple co-morbidities and present with problems that are of moderate to high severity and require medical decision making of moderate complexity. The finalized add-on codes are HCPCS code G2076 (*Intake activities; including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized health care professional under the supervision of a program physician or qualified personnel that includes preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho-social, economic, legal, or other supportive services that a patient needs, conducted by qualified personnel*) and HCPCS code G2077 (*Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment*). The medical services described by these add-on codes can be furnished by a program physician, a primary care physician or an authorized healthcare professional under the supervision of a program physician or qualified personnel such as nurse practitioners (NPs) and physician assistants (PAs). The other assessments, including psychosocial assessments can be furnished by practitioners who are eligible to do so under state law and their scope of licensure. We noted that to bill for the add-on code, the services need to be medically reasonable and necessary and that OTPs should document the rationale for billing the add-on code in the patient's medical record (84 FR 62647).

We have received inquiries from stakeholders related to what activities would qualify to bill the add-on code for periodic assessments, HCPCS code G2077. In the CY 2020 PFS final rule (84 FR 62647), we noted that the add-on code describing periodic assessments can be billed for each periodic assessment performed for patients that require multiple assessments during an episode of care, such as patients who are pregnant or postpartum. We noted that in order to bill for the add-on code, the services would need to be medically reasonable and necessary and that OTPs should document the rationale for billing the add-on code in the patient's medical record. Based on our understanding of the typical resources costs involved in furnishing periodic assessments, we priced HCPCS code G2077 based on a crosswalk to a level 4 office/outpatient E/M visit. Consistent with our understanding of the expected acuity of patients with OUD receiving services at OTPs, including the likelihood of the patient having multiple co-morbidities and presenting with problems that are of moderate to high severity and requiring medical decision making of moderate complexity, as well as the associated payment rate assigned to this code, we believe it is important for the clinician to be able to visually assess the patient as part of any periodic assessment. Therefore, for CY 2021, we are proposing that in order to bill for HCPCS code G2077, a face-to-face medical exam or biopsychosocial assessment would need to have been performed. Accordingly, we are proposing to amend the definition of periodic assessment in § 410.67(b)(7) to

[29] *http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf.*

provide that the definition is limited to a face-to-face encounter.

Additionally, we note that in the May 8th COVID–19 IFC, CMS revised § 410.67(b)(7) on an interim final basis to allow periodic assessments to be furnished during the PHE for the COVID–19 pandemic via two-way interactive audio-video communication technology and, in cases where beneficiaries do not have access to two-way audio-video communication technology, to permit the periodic assessments to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met. We believe that allowing periodic assessments to be furnished via two-way interactive audio-video communication technology beyond the conclusion of the PHE for the COVID–19 pandemic would help to expand access to care for patients who may have a difficult time getting to the OTP in person. Therefore, in this proposed rule, we are proposing to revise § 410.67(b)(7) to allow periodic assessments to be furnished via two-way interactive audio-video communication technology, provided all other applicable requirements are met. We note that we are currently permitting the use of audio-only telephone calls to furnish these services during the PHE for the COVID–19 pandemic, because we believe it is important to maintain access to these services while the public is following infection control guidelines to stay at home and practice social distancing, and not all beneficiaries receiving OUD treatment services from OTPs may have access to interactive audio-video communication technology. However, we do not believe this flexibility will be needed in order to ensure access after the PHE ends. Therefore, under this proposal, the flexibility to use audio-only telephone services to furnish periodic assessments would not be permitted once the PHE for the COVID–19 pandemic has ended. We note that we would consider payment for any periodic assessment-related services furnished via audio-only telephone calls to be included in the bundled payment, but that audio-only telephone services would not qualify for billing HCPCS code G2077 after the end of the PHE for the COVID–19 pandemic. We are seeking input from the public on whether we should consider continuing to make add-on payments for audio-only periodic assessments furnished by OTPs after the conclusion of the PHE for the COVID–19 pandemic, and if so, whether the payment rate for audio-only services should reflect any differences in resource costs.

c. Date of Service

In the CY 2020 PFS final rule (84 FR 62641), we defined an episode of care as a 1-week (contiguous 7-day) period at § 410.67(b). We have received inquiries related to the date of service used on claims for the weekly bundles and add-on codes, particularly related to an approach that many providers informed us they use, which is to establish a ''standard billing cycle'' in which episodes of care for all patients at that OTP begin on the same day of the week. We do not believe that the definition of an episode of care that was finalized for CY 2020 precludes the use of a ''standard billing cycle.'' Therefore, OTPs may choose to apply a standard billing cycle by setting a particular day of the week to begin all episodes of care. In this case, the date of service would be the first day of the OTP's billing cycle. If a beneficiary starts treatment at the OTP on a day that is in the middle of the OTP's standard weekly billing cycle, the OTP may still bill the applicable code for that episode of care provided that the threshold to bill for the code has been met. Alternatively, OTPs may choose to adopt weekly billing cycles that vary across patients. Under this approach, the initial date of service will depend upon the day of the week when the patient was first admitted to the program or when Medicare billing began. Therefore, under this approach of adopting weekly billing cycles that vary across patients, when a patient is beginning treatment or re-starting treatment after a break in treatment, the date of service would reflect the first day the patient was seen and the date of service for subsequent consecutive episodes of care would be the first day after the previous 7-day period ends. For the codes describing add-on services (HCPCS codes G2076–G2080), the date of service should reflect the date that service was furnished; however, if the OTP has chosen to apply a standard weekly billing cycle, the date of service for codes describing add-on services may be the same as the first day in the weekly billing cycle.

We note that this approach is consistent with earlier guidance that was issued in the OTP Billing and Payment Fact sheet that is posted on the CMS OTP web page (*https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf*).

d. Coding

We recognize the importance of allowing OTPs to become accustomed to billing Medicare using the coding that was established in the CY 2020 PFS final rule; however, we remain interested in refining the code set through future rulemaking, including stratifying the coding and associated payment amounts to account for significant differences in resource costs among patients, especially in relation to amounts of expected counseling. In the CY 2020 PFS final rule (84 FR 62645), we finalized an add-on code to describe an adjustment to the bundled payment when additional counseling or therapy services are furnished, HCPCS code G2080. This add-on code may be billed when counseling or therapy services are furnished that substantially exceed the amount specified in the patient's individualized treatment plan. We have received feedback from stakeholders noting a range of OTP attendance patterns that represent a continuum of care and service intensity, noting significant differences in services received during the induction phase versus the maintenance phase. We also understand that patients' needs for service may fluctuate over time, depending on a variety of factors and circumstances. We welcome comments on how we might better account for differences in resource costs among patients over the course of treatment. We will consider the comments received in developing any proposed refinements to our coding policies in future rulemaking.

5. Annual Updates

In the CY 2020 PFS final rule (84 FR 62667 through 62669), we finalized a policy under which the payment for the drug component of episodes of care will be determined using the most recent data available at the time of ratesetting for the applicable calendar year. The payment for the non-drug component of the bundled payment for OUD treatment services will be updated annually based upon the Medicare Economic Index. The list of the payment rates for OUD treatment services furnished by OTPs, with the annual update applied for CY 2021, is available in the file called CY 2021 OTP Proposed Payment Rates on the CMS website under downloads for the CY 2021 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html.* Additionally, we note that the current rates, as finalized in the CY 2020 PFS final rule, both with and without locality adjustments, can be found on the CMS OTP web page under Billing and Payment at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-*

Payment/Opioid-Treatment-Program/billing-payment.

III. Other Provisions of the Proposed Rule

A. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions, and a Comment Solicitation on Payment for Specimen Collection for Covid–19 Tests

1. Background on the Clinical Laboratory Fee Schedule

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS), with certain exceptions, under section 1833(a), (b), and (h) of the Act. Under the previous payment system, CDLTs were paid based on the lesser of: (1) The amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous payment system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U), and reduced by a multi-factor productivity adjustment and other statutory adjustments, but were not otherwise updated or changed. Coinsurance and deductibles generally do not apply to CDLTs paid under the CLFS.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. In the June 23, 2016 **Federal Register** (81 FR 41036), we published a final rule entitled Medicare Clinical Diagnostic Laboratory Tests Payment System (CLFS final rule), that implemented section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' The first data collection period occurred from January 1, 2016 through June 30, 2016. The first data reporting period occurred from January 1, 2017 through March 31, 2017. On March 30, 2017, we announced a 60-day period of enforcement discretion for the application of the Secretary's potential assessment of Civil Monetary Penalties (CMPs) for failure to report applicable information with respect to the initial data reporting period. This announcement is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

In the CY 2018 PFS proposed rule (82 FR 34089 through 34090), we solicited public comments from applicable laboratories and reporting entities to better understand the applicable laboratories' experiences with data reporting, data collection, and other compliance requirements for the first data collection and reporting periods. We discussed these comments in the CY 2018 PFS final rule (82 FR 53181 through 53182) and stated that we would consider the comments for potential future rulemaking or guidance.

As part of the CY 2019 Medicare PFS rulemaking, we finalized two changes to the definition of ''applicable laboratory'' at § 414.502 (see 83 FR 59667 through 59681, 60074; 83 FR 35849 through 35850; 83 FR 35855 through 35862). First, we excluded Medicare Advantage (MA) plan payments under Part C from the denominator of the Medicare revenues threshold calculation, in an effort to broaden the types of laboratories qualifying as an applicable laboratory. Specifically, excluding MA plan payments could allow additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C to meet the majority of Medicare revenues threshold and potentially qualify as an applicable laboratory (if they also meet the low expenditure threshold) and report data to CMS during the data reporting period. Because MA plan payments are now excluded from the total Medicare revenues calculation, the denominator amount (total Medicare revenues) would decrease. If the denominator amount decreases, the likelihood increases that a laboratory would qualify as an applicable laboratory. This is because the laboratory's PFS and CLFS revenues are being compared to a lower total Medicare payment amount (than what they would have been compared to if MA plan payments remained in the denominator). Second, consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as an applicable laboratory and report data we also amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill.

2. Payment Requirements for Clinical Diagnostic Laboratory Tests

In general, under section 1834A of the Act, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to CMS during the data reporting period, and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides for a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new advanced diagnostic laboratory test (ADLT) or new CDLT) can be reduced as compared to the payment rates for the preceding year. Under the provisions enacted by section 216(a) of PAMA, for the first 3 years after implementation (CY 2018 through CY 2020), the reduction cannot be more than 10 percent per year, and for the next 3 years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year. Under section 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not ADLTs, the data collection period, data reporting period, and payment rate update occur every 3 years. As such, the second data collection period for CDLTs that are not ADLTs occurred from January 1, 2019 through June 30, 2019, and the next data reporting period was scheduled to take place from January 1, 2020 through March 31, 2020, with the next update to the Medicare payment rates for these tests based on that reported applicable information scheduled to take effect as of January 1, 2021.

Section 216(a) of PAMA established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. As defined in § 414.502, an ADLT is a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory, and cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. Also, an ADLT must meet either Criterion (A), which implements section 1834A(d)(5)(A) of the Act, or Criterion (B), which

implements section 1834A(d)(5)(B) of the Act, as follows:

- *Criterion (A):* The test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins; when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies); provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and may include other assays; or:
- *Criterion (B):* The test is cleared or approved by FDA.

Generally, under section 1834A(d) of the Act, the Medicare payment rate for a new ADLT is equal to its actual list charge during an initial period of 3 calendar quarters. After the new ADLT initial period, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, under section 1834A(d)(3) of the Act, updates to the Medicare payment rates for ADLTs occur annually instead of every 3 years.

Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule (81 FR 41036 through 41101) and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.html.*

3. Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Section 105(a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116–94, enacted on December 20, 2019), and section 3718 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L. 116–136, enacted on March 27, 2020), made revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs under section 1834A of the Act. Additionally, the CARES Act made revisions to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 105(a)(1) of the FCAA amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2021 through March 31, 2021; the 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. Section 105(a)(1) of the FCAA also specified that the data collection period that applies to the data reporting period of January 1, 2021 through March 30, 2021 would be the period of January 1, 2019 through June 30, 2019, which is the same data collection period that would have applied absent the amendments. In addition, section 105(a)(2) of the FCAA amended section 1834A(b)(3) of the Act regarding the phase-in of payment reductions to provide that payments may not be reduced by more than 10 percent as compared to the amount established for the preceding year through CY 2020, and for CYs 2021 through 2023, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. These statutory changes were consistent with our regulations implementing the private payor rate-based CLFS (81 FR 41036; § 414.507(d)).

Subsequently, section 3718 of the CARES Act further amended the data reporting requirements for CDLTs that are not ADLTs and the phase-in of payment reductions under the CLFS. Specifically, section 3718(a) of the CARES Act amended section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by one additional year, to require data reporting during the period of January 1, 2022 through March 31, 2022. As amended by the CARES Act, section 1834A(a)(1)(B) of the Act now provides that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that—(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2021; (ii) reporting is required during the period beginning January 1, 2022, and ending March 31, 2022; and (iii) reporting is required every 3 years after the period described in clause (ii).

The CARES Act does not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2022 through March 31, 2022) will be based on the data collection period of January 1, 2019 through June 30, 2019. In § 414.502, the current definition of data collection period is defined as the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period. Additionally, in § 414.502 the data reporting period is defined as the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period. Unless we revise our current definitions of data collection period and data reporting period, the definitions will be incorrect with regard to the data collection period that applies to the next data reporting period. Therefore, in section III.A.4. of this proposed rule, ''Proposed Conforming Regulatory Changes,'' we are proposing to revise the definitions of data collection period and data reporting period in § 414.502 to reflect that the data collection period will be January 1, 2019 through June 30, 2019 for the data reporting period of January 1, 2022 through March 31, 2022.

Section 3718(b) of the CARES Act further amends the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extends the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2024. It further amends section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2021 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 3718(b) of the CARES Act further amends section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2022 through 2024, instead of CYs 2021 through 2023.

4. Proposed Conforming Regulatory Changes

In accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we are proposing to make certain conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we are proposing to revise § 414.502 to update the definitions of both the data collection period and data reporting period, specifying that for the data reporting period of January 1, 2022 through March 31, 2022, the data collection period is January 1, 2019 through June 30, 2019. We are also proposing to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every 3 years beginning January 2022. In addition, we are proposing to make conforming changes to our requirements for the phase-in of payment reductions to reflect the CARES Act amendments. Specifically, we are proposing to revise § 414.507(d) to indicate that for CY 2021, payment may not be reduced by

more than 0.0 percent as compared to the amount established for CY 2020, and for CYs 2022 through 2024, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

5. Comment Solicitation on Payment for Specimen Collection for COVID–19 Clinical Diagnostic Tests

In the ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final with comment period (IFC) (85 FR 19256 through 19258), which published in the April 6, 2020 **Federal Register**, we established that Medicare will pay a nominal specimen collection fee and associated travel allowance to independent laboratories for the collection of specimens for COVID–19 clinical diagnostic laboratory testing for homebound and non-hospital inpatients. This policy provides independent laboratories with additional resources to provide COVID–19 testing and helps with efforts to limit patients' exposure to the general population and alleviate patients' unease with leaving the home. To identify specimen collection for COVID–19 testing specifically, we established two new level II HCPCS codes, Code G2023 (*specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV–2) (Coronavirus disease [COVID–19]), any specimen source*); and G2024 (*specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-Cov–2) (Coronavirus disease [COVID–19]), from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source*), for independent laboratories to use when billing Medicare for the nominal specimen collection fee for COVID–19 testing for the duration of the COVID–19 PHE.

We indicated in the April 6, 2020 IFC that this specimen collection fee policy was established for the duration of the Public Health Emergency (PHE) for the COVID–19 pandemic (85 FR 19256). We are requesting comments on whether we should delete HCPCS Codes G2023 and G2024 once the COVID–19 PHE ends. Comments received may inform a future proposal. Specifically, we are seeking public input on why these codes, and their corresponding payment amounts, which are higher than the nominal fees for specimen collection for other conditions, would be necessary or useful outside of the context of the PHE. We are particularly interested in why separate, increased payment for specimen collection specifically for COVID–19 tests, in contrast to other tests, might be needed following the end of the PHE.

B. OTP Provider Enrollment Regulation Updates for Institutional Claim Submissions

1. Modifications to OTP Enrollment Process

a. Background

Under 42 CFR 424.510, a provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the Form CMS–855 (OMB Control No. 0938–0685) application 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 CMS or its MACs reviews and verifies to determine whether the provider or supplier meets all Medicare requirements. (The specific Form CMS–855 application (of which there are several variations) to be completed will depend upon the type of provider or supplier submitting said application.) This process of enrollment helps ensure that: (1) All prospective providers and suppliers are carefully screened and vetted; and (2) unqualified providers and suppliers are kept out of the Medicare program, which helps protect the Trust Funds and Medicare beneficiaries. Indeed, without this process, billions of taxpayer dollars might be paid to fraudulent or otherwise non-compliant parties.

b. Completion of Form CMS–855

Existing § 424.67 outlines a number of enrollment requirements for OTPs. One requirement, addressed in § 424.67(b)(1), is that OTPs must complete the Form CMS–855B application (Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers; OMB #0938–0685) to enroll in Medicare. The reference to the Form CMS–855B in § 424.67(b)(1) was predicated in part on the assumption that OTPs would generally submit the CMS–1500 claim form (Health Insurance Claim Form; OMB Control No.: 0938–1197) to receive payment for their services. However, as mentioned previously in section II.I.4. of this proposed rule, we have received requests to allow OTPs to bill for services on an institutional claim form (specifically, the 837I). To do so, these OTPs would have to enroll in Medicare via the Form CMS–855A (Medicare Enrollment Application for Institutional Providers (OMB #0938–0685)). To account for circumstances where an OTP wishes to pursue Form CMS–855A enrollment for the reason stated above, we propose the following revisions to § 424.67:

- Current § 424.67(b)(1) states that a newly enrolling OTP must fully complete and submit the Form CMS–855B application (or its successor application). We propose to revise this paragraph to state that the newly enrolling OTP must fully complete and submit, as applicable, the Form CMS–855A or Form CMS–855B application (or their successor applications).
- Existing § 424.67(b)(1)(ii) requires the OTP to certify compliance with the requirements and standards described in paragraphs § 424.67(b) and (d) via the Form CMS–855B and/or the applicable supplement or attachment thereto. We propose to revise this paragraph such that the OTP must certify compliance with the above-referenced requirements and standards via the Form CMS–855A or Form CMS–855B (as applicable) and/or the applicable supplement or attachment thereto.
- Existing § 424.67(b)(5) requires the OTP to report on the Form CMS–855B and/or any applicable supplement all OTP staff who meet the definition of ''managing employee'' in § 424.502. We propose to change this to state that the OTP must report on the Form CMS–855A or Form CMS–855B (as applicable) and/or any applicable supplement all OTP staff who meet the said definition.

We believe these revisions would accomplish two objectives. First, they would permit OTPs to submit a Form CMS–855A in lieu of a Form CMS–855B based on their preferred method of billing. Second, they would confirm that the requirements of § 424.67 apply to all OTPs regardless of whether they complete the Form CMS–855A or the Form CMS–855B.

c. Screening Activities Associated With Risk Designation

Section 424.518 outlines provider enrollment screening categories and requirements based on our assessment of the degree 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 presents, the greater the degree of scrutiny with which we will screen and review enrollment applications submitted by providers or suppliers within that category. There are three levels of screening addressed in § 424.518: Limited; moderate; and high.

Irrespective of which level a provider or supplier type falls within, the MAC performs certain minimum screening functions upon receipt of an initial enrollment application, a revalidation application, or an application to add a new practice location. These include:

- Verification that the provider or supplier meets all applicable federal regulations and state requirements for their provider or supplier type.
- State license verifications.
- Database reviews 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.

Providers and suppliers at the moderate and high categorical risk levels must also undergo a site visit. Moreover, 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 (FBI) 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 with such provider or supplier types.

For newly enrolling OTPs, those that have been fully and continuously certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) since October 23, 2018 fall within the moderate level of categorical screening. OTPs that have not been so certified since the aforementioned date are subject to the high screening level. We recognize that certain providers and suppliers have already enrolled as OTPs via the Form CMS–855B—and, accordingly, undergone a site visit and, if applicable, fingerprinting—but would seek to newly enroll via the Form CMS–855A should our proposals be finalized. (Said enrollment would be considered ''new'' for purposes of enrollment because the OTP would be enrolling via a different variation of the Form CMS–855.) While not seeking to minimize the importance of the enhanced screening activities associated with the moderate and high categorical levels, we do not wish to unduly burden currently enrolled OTPs that would pursue Form CMS–855A enrollment as an OTP. More specifically, we do not believe such OTPs should have to undergo another site visit and, if applicable, fingerprinting when they previously did so as an OTP via their original Form CMS–855B enrollment. This, in our view, would constitute an unnecessary expenditure of CMS, MAC, and OTP resources. We add that the same would hold true if, in the future, an OTP that is enrolled via the Form CMS–855A under revised § 424.67(b) decides to change to a Form CMS–855B enrollment. In both cases, we believe a duplication of effort should be avoided to the extent consistent with safeguarding the integrity of the Medicare program.

Existing § 424.67(b)(3) states that an enrolling OTP must successfully complete the assigned categorical risk level screening required under, as applicable, § 424.518(b) and (c) (which outline the screening requirements for newly enrolling parties in, respectively, the moderate and high categorical levels). Given the foregoing discussion, we propose several changes to § 424.67(b)(3). First, we would re-designate existing § 424.67(b)(3) as new § 424.67(b)(3)(i), though with an exception to its requirements. Second, new paragraph (b)(3)(ii) (which would address this exception) would state that currently enrolled OTPs that are changing their OTP enrollment from a Form CMS–855B to a Form CMS–855A, or vice versa, must successfully complete the limited level of categorical screening under § 424.518(a) if the OTP has already completed, as applicable, the moderate or high level of categorical screening under § 424.518(b) or (c), respectively. Third, we propose to redesignate existing § 424.518(a)(1)(xii) through (xvii) as § 424.518(a)(1)(xiii) through (xviii). Fourth, new § 424.518(a)(1)(xii) would add OTPs that fall within the purview of new paragraph (b)(3)(ii) to the provider and supplier types subject to limited risk categorical screening.

d. Additional OTP Enrollment Clarifications Regarding the Form CMS–855A

We propose three additional clarifications related to our previously mentioned OTP enrollment provisions. To incorporate these into § 424.67, we would redesignate existing paragraphs (c), (d), (e), and (f) as paragraphs (d), (e), (f), and (g), respectively. The three clarifications would be included in new paragraph (c).

With the redesignation of existing paragraph (d) as paragraph (e), we also propose to change the reference to:

- Paragraph (d) in existing paragraph (b)(1)(ii) to paragraph (e).
- Paragraph (d)(1) in existing paragraph (d)(2)(i) to paragraph (e)(1) in redesignated paragraph (e)(2)(i).)

(1) Single Enrollment

We propose in new § 424.67(c)(1) that an OTP may only be enrolled as such via the Form CMS–855A or the Form CMS–855B but not both. The OTP, in other words, must opt for either Form CMS–855A enrollment or Form CMS–855B enrollment. This is to help ensure that the OTP does not bill twice for the same service via separate claim vehicles (specifically, the CMS–1500 and the 837I).

(2) Effective Date of Billing

Section 424.520(d) outlines the effective date of billing privileges for newly enrolling OTPs (and certain other provider and supplier types). This date is the later of: (1) The date of the OTP's filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date that the OTP first began furnishing services at a new practice location. In a similar vein, § 424.521(a) states that OTPs (and certain other provider and supplier types) may retrospectively bill for services when the OTP 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 through 5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

In light of proposed § 424.67(c)(1) (and as further explained in the collection of information section of this proposed rule), we anticipate that a number of OTPs would end their existing enrollment and apply as a new OTP via, as applicable, the Form CMS–855A or Form CMS–855B. Given this, we believe it is important to clarify for stakeholders the new enrollment's effective date of billing. Accordingly, at § 424.67, we propose in new paragraph (c)(2) that if a Form CMS–855B-enrolled OTP changes to a Form CMS–855A enrollment, or vice versa, the effective date of billing that was established for the OTP's prior enrollment under §§ 424.520(d) and 424.521(a) would be applied to the OTP's new enrollment. This would allow OTPs that have been

unable to bill for furnished services via their preferred claim form (and have consequently chosen to delay the submission of these claims for services) to do so retroactive to the effective billing date of its prior enrollment. To illustrate, suppose an OTP initially enrolled via the Form CMS–855B in 2020. The effective date of billing was April 1, 2020. Wishing to submit an 837I claim form for the services it has provided since April 1, 2020 the OTP elects to end its Form CMS–855B enrollment and enroll via the Form CMS–855A pursuant to revised § 424.67. It successfully does the latter in March 2021. Under § 424.67(c)(2), the billing effective date of the Form CMS–855A enrollment would be retroactive to April 1, 2020. We note, however, that the time limits for filing claims found in § 424.44 would continue to apply. Specifically, all Medicare Part A and Part B claims must be filed within 1 calendar year after the date of service unless one of a very limited number of exceptions applies. Switching from a Form CMS–855B enrollment to a Form CMS–855A enrollment, or vice versa, is not grounds for an exception.

We recognize, of course, that not every OTP that seeks to change its enrollment will have chosen to withhold submission of all of its claims under its prior enrollment. (Using our example in the previous paragraph, the OTP may have submitted some claims via the CMS–1500 while planning to eventually submit the remaining ones via the 837I.) Irrespective of this, CMS has long had operational safeguards in place to prevent double-billing for the same service. Said protections would be used in the scenario described in proposed § 424.67(c)(2) so that claims submitted under the prior enrollment could not be resubmitted under the new one.

(3) Application Fee

As stated in § 424.514, prospective and revalidating institutional providers that are submitting a Medicare enrollment application generally must pay the applicable application fee in accordance with § 424.514. (For CY 2020, the fee amount is $595.) We define the term ''institutional provider'' in § 424.502 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.

We have already noted that OTPs currently complete the Form CMS–855B to enroll in Medicare. They are considered ''institutional providers'' (as defined in § 424.502) and must pay an application fee, a requirement addressed in existing § 424.67(b)(2). Since the existing OTPs referenced in new paragraph (c)(2) would, as stated previously, be enrolling as new providers via the Form CMS–855A or Form CMS–855B (as applicable), we believe they would fall within the scope of both (1) the aforementioned definition of ''institutional provider'' and (2) § 424.514(a)(1); as described therein, § 424.514(a)(1) applies to prospective institutional providers that are submitting an initial application. To clarify this issue for the OTP community, we propose to add language to § 424.67(b)(2) stating that compliance with the application fee requirements in § 424.514 would also apply to those OTPs enrolling under the circumstances described in § 424.67(c)(2).

We emphasize that the flexibilities described in this section III.B. are complementary to those in section II.I. (''Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs))'' regarding OTP billing via the 837I. Our OTP enrollment revisions are intended to facilitate greater flexibility for OTPs should the proposals in section II.I. be finalized.

C. Payment for Principal Care Management (PCM) Services in Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. RHC and FQHC Payment Methodologies

RHC and FQHC visits generally are face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which time one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, nurse practitioners (NPs), physician assistants (PA), certified nurse midwives (CNMs), clinical psychologists (CPs), and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient. A Transitional Care Management (TCM) service can also be an RHC or FQHC visit. In addition, a Diabetes Self-Management Training (DSMT) service or a Medical Nutrition Therapy (MNT) service furnished by a certified DSMT or MNT program may also count as an FQHC visit. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per visit payment.

RHCs are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). In general, the A/B Medicare Administrative Contractor (MAC) calculates the AIR for the year for each RHC by dividing total allowable costs by the total number of visits for all patients. Productivity, payment limits, and other factors are also considered in the calculation. Allowable costs must be reasonable and necessary and may include practitioner compensation, overhead, equipment, space, supplies, personnel, and other costs incident to the delivery of RHC services. The AIR is subject to a payment limit, except for certain provider-based RHCs that have an exception to the payment limit.

FQHCs were paid under the same AIR methodology until October 1, 2014, when, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Affordable Care Act), they began to transition to an FQHC PPS system in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF).

b. Care Management Services in RHCs and FQHCs

In the CY 2018 final rule with comment period (83 FR 59683), we finalized revisions to the payment methodology for Chronic Care Management (CCM) services furnished by RHCs and FQHCs and established requirements for general Behavioral Health Integration (BHI) and psychiatric Collaborative Care Management (CoCM) services furnished in RHCs and FQHCs, beginning on January 1, 2019. Specifically, we revised § 405.2464(c) to permit RHCs and FQHCs to bill for care management services (HCPCS codes G0511 and G0512).

HCPCS code, G0511, is a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month.

The payment amount for HCPCS code G0511 is set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. The 3 codes are CPT 99490 (*20 minutes or more of CCM services*), CPT 99487 (*60 minutes or more of complex CCM services*), and CPT 99484 (*20 minutes or more of BHI services*).

In the CY 2019 final rule with comment period, we added CPT code 99491 (*30 minutes or more of CCM furnished by a physician or other qualified health care professional*) as a general care management service and included it in the calculation of HCPCS code G0511. Beginning January 1, 2019, the payment for HCPCS code G0511 is set at the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491 and is updated annually based on the PFS amounts. Additional information on CCM requirements is available on the CMS Care Management web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html,* and on the CMS RHC and FQHC web pages at *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html* and *https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html.*

2. Proposed Requirements for PCM Services in RHCs and FQHCs

In the CY 2020 PFS final rule with comment (84 FR 62692), we established a separate payment for PCM services. PCM services include comprehensive care management services for a single high-risk disease or complex condition, typically expected to last at least 3 months and may have led to a recent hospitalization, and/or placed the patient at significant risk of death. Beginning January 1, 2020, practitioners billing under the PFS can bill for PCM services using HCPCS codes G2064 or G2065.

HCPCS code G2064 is for at least 30 minutes of PCM services furnished by physicians or non-physicians during a 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.

HCPCS code G2065 is for at least 30 minutes of PCM services furnished by clinical staff under the direct supervision of a physician or non-physician practitioner 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.

A national stakeholder organization representing rural health clinics has requested that RHCs be allowed to furnish and bill for PCM services. We agree that there can be significant resources involved in care management for a single high risk disease or complex chronic condition, and that the requirements for the new PCM codes are similar to the requirements for the care management services described by HCPCS code G0511. These are services that do not currently meet the requirements for an RHC or FQHC billable visit, and they provide an array of care management services that are not generally included in the RHC AIR or the FQHC PPS. Therefore, we are proposing to add HCPCS codes G2064 and G2065 to G0511 as a comprehensive care management service for RHCs and FQHCs starting January 1, 2021. The payment rate for HCPCS G0511 is the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487, 99484, and 99491), and we propose that these 2 new codes be added to the calculation of the G0511 payment rate.

3. Other Options Considered

We also considered creating a separate G code for PCM services. We did not choose this approach because PCM and CCM are similar services and grouping them together is consistent with an integrated approach to care with reduced reporting requirements. As we stated in the CY 2018 PFS final rule, if a new care management code is proposed and subsequently finalized for practitioners billing under the PFS, we would review the new code to determine if it should be included in the calculation of the RHC and FQHC General Care Management Code. The determination of whether a new care management code should be added to the codes used to determine the payment rate is based on the applicability of the service in RHCs and FQHCs, and may result in either an increase or decrease in the payment amount for HCPCS code G0511.

4. Implementation

If this proposal is finalized as proposed, RHCs and FQHCs that furnish qualified PCM services would also be able to bill the services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2021. The payment rate for HCPCS code G0511 would continue to be the average of the national non-facility PFS payment rates for the RHC/FQHC care management and general behavioral health codes (CPT codes 99484, 99487, 99490, and 99491). HCPCS G2064 and G2065 would be added to G0511 to calculate a new average for the national non-facility PFS payment rate. The payment rate for HCPCS code G0511 would be updated annually based on the PFS amounts for these codes.

D. Changes to the Federally Qualified Health Center Prospective Payment System (FQHC PPS) for CY 2021: Proposed Rebasing and Revising of the FQHC Market Basket

1. Background

Section 10501(i)(3)(A) of the Affordable Care Act added section 1834(o) of the Act to establish a payment system for the costs of FQHC services under Medicare Part B based on prospectively set rates. In the Prospective Payment System (PPS) for FQHC final rule published in the May 2, 2014 **Federal Register** (79 FR 25436), we implemented a methodology and payment rates for the FQHC PPS. Beginning on October 1, 2014, FQHCs began to transition to the FQHC PPS based on their cost reporting periods, and as of January 1, 2016, all FQHCs are paid under the FQHC PPS.

Section 1834(o)(2)(B)(ii) of the Act requires that the payment for the first year after the implementation year be increased by the percentage increase in the Medicare Economic Index (MEI). Therefore, in CY 2016, the FQHC PPS base payment rate was increased by the MEI. The MEI is based on 2006 data from the American Medical Association (AMA) for self-employed physicians and was used in the PFS sustainable growth rate (SGR) formula to determine the conversion factor for physician service payments. (See the CY 2014 PFS

final rule (78 FR 74264) for a complete discussion of the 2006-based MEI). Section 1834(o)(2)(B)(ii) of the Act also requires that beginning in CY 2017, the FQHC PPS base payment rate will be increased by the percentage increase in a market basket of FQHC goods and services, or if such an index is not available, by the percentage increase in the MEI.

Beginning with CY 2017, FQHC PPS payments were updated using a 2013-based market basket reflecting the operating and capital cost structures for freestanding FQHC facilities (hereafter referred to as the FQHC market basket). A complete discussion of the 2013-based FQHC market basket can be found in the CY 2017 PFS final rule (81 FR 80393 through 80403).

For this CY 2021 PFS/FQHC proposed rule, we propose to rebase and revise the 2013-based FQHC market basket to reflect a 2017 base year. The proposed 2017-based FQHC market basket is primarily based on Medicare cost report data for FQHCs for 2017, which are for cost reporting periods beginning on and after October 1, 2016, and prior to September 31, 2017. We propose to use data from cost reports beginning in FY 2017 because these data are the latest available complete data for purposes of calculating cost weights for the market basket at the time of rulemaking.

In the following discussion, we provide an overview of the proposed FQHC market basket, describe the proposed methodologies for developing the operating and capital portions of the 2017-based FQHC market basket, and provide information on the proposed price proxies. We then present the CY 2021 market basket update based on the proposed 2017-based FQHC market basket.

2. Overview of the 2017-Based FQHC Market Basket

Similar to the 2013-based FQHC market basket, the proposed 2017-based FQHC market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix (that is, intensity) of goods and services purchased over time are not measured. The index itself is constructed using three steps. First, a base period is selected (in this proposed rule, we propose to use 2017 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe. As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish FQHC services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a FQHC hiring more nurse practitioners to accommodate the needs of patients would increase the volume of goods and services purchased by the FQHC, but would not be factored into the price change measured by a fixed-weight FQHC market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect a recent mix of goods and services that FQHCs purchase (FQHC inputs) to furnish inpatient care.

3. Development of the 2017-Based FQHC Market Basket Cost Categories and Weights

We are inviting public comments on our proposed methodology, discussed below, for deriving the proposed 2017-based FQHC market basket.

a. Use of Medicare Cost Report Data

We are proposing a 2017-based FQHC market basket that consists of eleven major cost categories and a residual derived from the 2017 Medicare cost reports (CMS Form 224–14, OMB Control Number 0938–1298) for FQHCs, hereafter referred to as the 2014 Medicare Cost Report form. The eleven cost categories are FQHC Practitioner Wages and Salaries, FQHC Practitioner Employee Benefits, FQHC Practitioner Contract Labor, Clinical Staff Wages and Salaries, Clinical Staff Employee Benefits, Clinical Staff Contract Labor, Non-Health Staff Compensation, Medical Supplies, Pharmaceuticals, Fixed Capital and Moveable Capital. The residual category reflects all remaining costs not captured in the 11 cost categories such as non-medical supplies and utilities for example. We note that for the 2013-based FQHC market basket, we estimated six cost categories from the Medicare cost reports (CMS Form 222–92, OMB Control Number 0938–0107), hereafter referred to as the 1992 Medicare cost report form: FQHC Practitioner Compensation, Clinical Staff Compensation, Non-Health Staff Compensation, Pharmaceuticals, Fixed Capital and Moveable Capital.

The resulting 2017-based FQHC market basket cost weights reflect Medicare allowable costs. We define Medicare allowable costs for freestanding FQHC facilities as the total expenses reported on: Worksheet A, Columns 1 and 2, lines 1 through 7 and lines 9 through 12; Worksheet A, Column 1, lines 23 through 36; and Worksheet S3 Part II, Columns 1 and 2, lines 2 through 14. We note that we continue to exclude Professional Liability Insurance (PLI) costs from the total Medicare allowable costs because FQHCs that receive section 330 grant funds also are eligible to apply for medical malpractice coverage under Federally Supported Health Centers Assistance Act (FSHCAA) of 1992 (Pub. L. 102–501) and FSHCAA of 1995 (Pub. L. 104–73 amending section 224 of the Public Health Service Act).

Below, we summarize how we derive the eleven major cost category weights. Prior to estimating any costs, we remove any providers that did not report any total gross patient revenues as reported on the FQHC cost report Worksheet F–1, line 1, column 4.

(1) FQHC Practitioner Wages and Salaries Costs

A FQHC practitioner is defined as one of the following occupations: Physicians; nurse practitioners (NPs); physician assistants (PAs); certified-nurse midwife (CNMs); clinical psychologist (CPs); and clinical social workers (CSWs). We propose to derive FQHC Practitioner Wages and Salaries costs as the sum of direct care costs salaries as reported on Worksheet A, column 1, lines 23, 25, 26, 29, 30, and 31. These lines represent the wages and salaries costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. For the 2013-based FQHC market basket, we

estimated FQHC Practitioner Total Compensation costs based on a similar methodology using cost data reported on Worksheet A of the 1992 Medicare cost report form (81 FR 80394) for specific details on the prior methodology.

(2) FQHC Practitioner Employee Benefits Costs

Effective with the implementation of the 2014 Medicare cost report form, we began collecting Employee Benefits and Contract Labor data on Worksheet S–3, part II and propose to derive FQHC Practitioner Employee Benefits costs using data obtained from that worksheet. Approximately 66 percent of FQHCs included in the sample of FQHCs reporting Salary costs also reported data on Worksheet S–3, part II for 2017. We continue to encourage all providers to report these data on the Medicare cost report. Therefore, we propose to calculate FQHC Practitioner Employee Benefits costs using Worksheet S–3, part II data. Specifically, we propose to use data from Worksheet S–3, part II, column 2, lines 2, 3, 4, 7, 8, and 9 to derive FQHC Practitioner Employee Benefits costs. These lines represent the employee benefits costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. Our analysis of the Worksheet S–3, part II data submitted by these FQHCs indicates that we had a large enough sample to enable us to produce a reasonable Employee Benefits cost weight.

For the 2013-based FQHC market basket, we did not have data at the level of detail to separately estimate FQHC Practitioner Employee Benefits costs, and instead computed FQHC Practitioner Total Compensation costs, which reflected costs for wages and salaries, employee benefits, and contract labor together. Anytime direct costs can be obtained for a cost category directly from the Medicare Cost Reports we consider that to be a technical improvement to the market basket weight methodology as it allows the index to reflect the relative shares specific to the provider type. Therefore, we believe this proposed method of separately estimating FQHC Practitioner Employee Benefits is a technical improvement over the 2013-based FQHC market basket.

(3) FQHC Practitioner Contract Labor Costs

FQHC Practitioner Contract labor costs are primarily associated with direct patient care services. Contract labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described below. Approximately 60 percent of FQHCs reported contract labor costs on Worksheet S–3, part II, which we believe is an adequate sample size to enable us to produce a reasonable FQHC Practitioner Contract Labor cost weight. Therefore, we propose to derive the FQHC Practitioner Contract Labor costs for the proposed 2017-based FQHC market basket from data reported on Worksheet S–3, part II, column 1, lines 2, 3, 4, 7, 8, and 9. These lines represent the contract labor costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. We also add in the costs for physician services under agreement as reported on Worksheet A, column 2, line 24 to derive the total FQHC Practitioner Contract Labor cost weight in the proposed 2017-based FQHC market basket.

For the 2013-based FQHC market basket, we did not have data at the level of detail to separately estimate FQHC Practitioner Contract Labor costs and instead computed FQHC Practitioner Total Compensation costs, which reflected costs for wages and salaries, employee benefits, and contract labor together. As noted previously, anytime direct costs can be obtained for a cost category directly from the Medicare Cost Reports we consider that to be a technical improvement to the market basket weight methodology as it allows the index to reflect the relative shares specific to the provider type. Therefore, we believe this proposed method of separately estimating FQHC Practitioner Contract Labor is a technical improvement over the 2013-based FQHC market basket.

(4) Clinical Staff Wages and Salaries Costs

Clinical Compensation includes any health-related clinical staff who does not fall under the definition of a FQHC Practitioner described in paragraph. We propose to derive Clinical Staff Wages and Salaries costs as the sum of direct care costs salaries as reported on Worksheet A, column 1, lines 27, 28, 32, 33, 34, 35, and 36. These lines represent the wages and salaries costs for visiting registered nurses (RNs), visiting licensed practical nurses (LPNs), laboratory technicians, registered dietician/Certified DSMT/MNT educators, physical therapists (PTs), occupational therapists (OTs), and other allied health personnel.

- For the 2013-based FQHC market basket, we estimated a clinical staff total compensation cost based on a similar methodology using cost data reported on Worksheet A of Medicare Cost Report form CMS–222–92, (see 81 FR 80394 for specific details on the prior methodology).

(5) Clinical Staff Employee Benefits Costs

Effective with the implementation of the 2014 Medicare cost report form, we began collecting employee benefits and contract labor data on Worksheet S–3, part II and propose to derive clinical staff employee benefits costs using data obtained from that worksheet. Approximately 64 percent of FQHCs included in the sample of FQHCs reporting salary expenses also reported data on Worksheet S–3, part II for 2017. We continue to encourage all providers to report these data on the Medicare cost report. Therefore, we propose to calculate clinical staff employee benefits costs using Worksheet S–3, part II, column 2, lines 5, 6, 10, 11, 12, 13, and 14. These lines represent the employee benefits costs for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel.

- For the 2013-based FQHC market basket, we did not have data at the level of detail to separately estimate clinical staff employee benefits costs and instead computed clinical staff total compensation costs, which reflected costs for wages and salaries, employee benefits, and contract labor together. We believe this proposed method of separately estimating clinical staff employee benefits is a technical improvement over the 2013-based FQHC market basket.

(6) Clinical Staff Contract Labor Costs

We propose to derive the clinical staff contract labor costs for the proposed 2017-based FQHC market basket from data reported on Worksheet S–3, part II, column 1, lines 5, 6, 10, 11, 12, 13, and 14 to derive clinical staff contract labor costs. These lines represent the contract labor costs for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel.

For the 2013-based FQHC market basket, we did not have data at the level of detail to separately estimate clinical staff contract labor costs and instead computed clinical staff total compensation costs, which reflected costs for wages and salaries, employee benefits, and contract labor together. We believe this proposed method of separately estimating FQHC clinical staff contract labor is a technical improvement over the 2013-based FQHC market basket.

(7) Non-Health Staff Compensation Costs

Non-Health Staff Compensation includes wage and salary costs for personnel in general service cost centers including: Employee Benefits department; Administrative & General; Plant Operation & Maintenance; Janitorial; Medical Records; Pharmacy; Transportation; and Other General Services. Specifically, non-health staff compensation costs are derived as the sum of compensation costs as reported on Worksheet A, column 1 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12. Additionally, we add a portion of employee benefit costs reported on Worksheet A, line 3, column 2 accounting for the non-health staff. We estimate the ratio of non-health staff related wages and salaries as a percentage of total wages and salaries. We then apply the percentage of non-health staff related wages and salary costs to the total employee benefits costs (Worksheet A, line 3, column 2) for each FQHC. We believe this is a reasonable estimate of non-health staff employee benefits. We propose to only use the costs from column 1 for most of the general service cost centers other than employee benefits since we believe that there are noncompensation costs reported in column 2 (such as maintenance and janitorial supplies). The remaining other costs for the general service categories are reflected in the remaining proposed cost categories as explained in more detail below.

(8) Pharmaceuticals Costs

We propose to calculate pharmaceuticals costs using the non-salary costs for the pharmacy cost center reported on Worksheet A, column 2, line 9. We propose to exclude the costs for drugs charged to patients as reported on Worksheet A, line 67 since these drugs are not included in the Medicare allowable costs for the FQHC PPS and are separately reimbursed. For the 2013-based FQHC market basket we were not able to exclude non-reimbursable drug costs (such as drugs charged to patient costs) from the pharmacy cost weight as the 1992 Medicare cost report form did not capture these costs separately. We believe our proposed methodology is a technical improvement as it is more consistent with the FQHC PPS reimbursement.

(9) Medical Supplies

We propose to calculate medical supplies costs using the non-salary costs for the medical supplies cost center reported on Worksheet A, column 2, line 10. The medical supplies cost weight for the 2013-based FQHC market basket was derived based on the relative share of the medical supply costs in the MEI since these costs were not separately reported on the 1992 Medicare cost report form (81 FR 80395 through 80396). Since these costs are now directly reported by FQHC providers we believe the proposed method is a technical improvement to the method used in the 2013-based FQHC market basket.

(10) Fixed Capital

We propose that fixed capital costs be equal to costs reported on Worksheet A, line 1, column 2 of the Medicare Cost Report. A similar methodology was used for the 2013-based FQHC market basket.

(11) Moveable Capital Costs

We propose that moveable capital costs be equal to the capital costs as reported on Worksheet A, line 2, column 2. A similar methodology was used for the 2013-based FQHC market basket.

b. Proposed Major Cost Category Computation

After we derive costs for the major cost categories for each provider using the Medicare cost report data as previously described, we propose to trim the data for outliers. For each of the eleven major cost categories, we first are proposing to divide the calculated costs for the category by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of FQHC providers. For the 2017-based FQHC market basket (similar to the 2013-based FQHC market basket), we propose that total Medicare allowable costs would be equal to the total costs as reported on Worksheet A, Columns 1 and 2, lines 1 through 7 and lines 9 through 12; Worksheet A, Column 1, lines 23 through 36; and Worksheet S3 Part II, Columns 1 and 2, lines 2 through 14.

For the FQHC Practitioner Wages and Salaries, FQHC Practitioner Employee Benefits, FQHC Practitioner Contract Labor, Clinical Staff Wages and Salaries, Clinical Staff Employee Benefits, Clinical Staff Contract Labor, Non-Health Staff Compensation, Pharmaceuticals, Medical Supplies, Fixed Capital, and Moveable Capital cost weights, after excluding cost weights that are less than or equal to zero, we propose to then remove those providers whose derived cost weights fall in the top and bottom 5 percent of provider-specific derived cost weights to ensure the exclusion of outliers. A 5 percent trim is the standard trim applied to the mean cost weights in all CMS market baskets and is consistent with the trimming used in the 2013-based FQHC market basket. After the outliers have been excluded, we sum the costs for each category across all remaining providers. We then are proposing to divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the 2017-based FQHC market basket for the given category. This trimming process is done for each cost weight separately.

Finally, we propose to calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the eleven major cost categories listed. We refer readers to Table 31 for the resulting proposed cost weights for these major cost categories.

TABLE 31: Major Cost Categories as Derived from Medicare Cost Reports

Major Cost Categories	Proposed 2017-Based FQHC Cost Report Weights (Percent)	2013-Based FQHC Market Basket (Percent)
FQHC Practitioner Compensation*	*30.0*	31.7
FQHC Practitioner Wages & Salaries	20.5	-
FQHC Practitioner Employee Benefits	4.5	-
FQHC Practitioner Contract Labor	4.9	-
Clinical Compensation*	*16.2*	9.5
Clinical Wages & Salaries	12.4	-
Clinical Employee Benefits	3.0	-
Clinical Contract Labor	0.8	-
Non-Health Staff Compensation*	25.4	27.4
Pharmaceuticals	3.9	5.1
Medical Supplies	2.4	-
Fixed Capital	4.7	4.5
Moveable Capital	1.9	1.7
All Other (Residual)	15.5	20.1

*Employee Benefits weight from the 2013-based FQHC Market Basket (10.7 percent), which was derived from the Medicare Cost Reports (81 FR 80395) and distributed across the three compensation categories: FQHC Practitioner, Clinical Staff, and Non-Health Staff based on the relative shares of each category.
Note: Totals may not sum to 100.0 due to rounding

The total compensation cost weight of 71.6 percent (sum of FQHC Practitioner Compensation, Clinical Compensation, Non-health Staff Compensation) calculated from the Medicare cost reports for the proposed 2017-based FQHC market basket is approximately 3.0 percentage point higher than the total compensation cost weight for the 2013-based FQHC market basket (68.6 percent). The 2017-based cost weight for FQHC Practitioners and Non-Health Staff are each about 2 percentage points lower compared to the 2013-based FQHC market basket, while the clinical staff compensation cost weight is about 7 percentage points higher. Part of the reason for the shift in the weights between compensation categories may be due to the change to the FQHC Medicare cost report form. On the 1992 Medicare cost report form (used for the 2013-based FQHC market basket), there were four open ended ''fill-in'' categories for healthcare staff costs and costs under agreement. Since we were unable to determine what specific category the ''other health care staff'' costs should be allocated to (that is, either FQHC practitioner, or clinical staff) we used a methodology where we applied the expenses for the ''other health care staff costs'' between the categories for FQHC practitioner and clinical staff, based on the relative shares of expenses for both categories, excluding the open-ended fill in lines of Worksheet A, lines 9–11 and line 15. This may have resulted in an over allocation of some of the 2013 expenses to the FQHC Practitioner category relative to the clinical staff. On the 2014 Medicare cost report form, there is no longer an ambiguous category for other direct patient care staff costs.

The proposed 2017-based Pharmaceuticals cost weight is roughly 1.2 percentage points lower than the cost weight in the 2013-based FQHC market basket. The pharmaceutical costs included in the weight for 2017-based FQHC market basket includes only non-salary costs reported in Pharmacy (under general services) (Worksheet A, line 9, column 2 on the 2014 Medicare cost report form). We believe the cost share is lower with the new data because there is more specificity on where to report reimbursable and non-reimbursable drugs.

As we did for the 2013-based FQHC market basket, we propose to allocate the contract labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs comprise both Wages and Salaries and Employee Benefits for both FQHC Practitioners and Clinical Staff. The contract labor allocation proportion for Wages and Salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. This rounded percentage is 82 percent for FQHC Practitioners and 80 percent for clinical staff. Therefore, we propose to allocate 82 percent of the FQHC Practitioner Contract Labor cost weight to the FQHC Practitioner Wages and Salaries cost weight and 18 percent to the FQHC Practitioner Employee Benefits cost weight. Similarly, we propose to allocate 80 percent of the clinical staff contract labor cost weight to the Clinical Staff Wages and Salaries cost weight and 20 percent to the clinical staff employee benefits cost weight. We refer readers to Table 32 that shows the proposed Wages and Salaries and Employee Benefits cost weights after Contract Labor cost weight allocation for the proposed 2017-based FQHC market basket.

TABLE 32: Wages and Salaries and Employee Benefits Cost Weights After Contract Labor Allocation

Major Cost Categories	Proposed 2017-Based FQHC Practitioner	Proposed 2017-Based Clinical Staff
Wages and Salaries	24.6	13.0
Employee Benefits	5.4	3.2
Compensation	30.0	16.2

*Totals may not sum due to rounding

c. Derivation of the Detailed Operating Cost Weights

To further divide the ''All Other'' residual cost weight of 15.5 percent estimated from the 2017 Medicare cost report data into more detailed cost categories, we propose to use the 2012 Benchmark Input-Output (I–O) ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 621100, Offices of Physicians, published by the Bureau of Economic Analysis (BEA). We note that the BEA benchmark I–O data is used to further disaggregate residual expenses in other CMS market baskets. Therefore, we believe the data from this industry are the most technically appropriate for disaggregation of the residual expenses since both physician offices and FQHCs provide similar types of care. These data are publicly available at *https://www.bea.gov/industry/input-output-accounts-data.* For the 2013-based FQHC market basket, we used the relative shares of certain categories from the 2006-based MEI (81 FR 80396).

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2012. The 2012 Benchmark I–O data are derived from the 2012 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[30] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I–O data, we propose to inflate the 2012 Benchmark I–O data forward to 2017 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 Benchmark I–O data. We repeated this practice for each year. We then calculated the cost shares that each cost category represents of the 2012 data inflated to 2017. These resulting 2017 cost shares were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the proposed 2017-based FQHC market basket. For example, the cost for Medical Equipment represents 7.2 percent of the sum of the ''All Other'' 2012 Benchmark I–O Offices of Physicians Expenditures inflated to 2017. Therefore, the Medical Equipment cost weight represents 7.2 percent of the proposed 2017-based FQHC market basket's ''All Other'' cost category (15.5 percent), yielding a Medical Equipment cost weight of 1.1 percent in the proposed 2017-based FQHC market basket (0.072×15.5 percent = 1.1 percent).

Using this methodology, we propose to derive six detailed FQHC market basket cost category weights from the proposed 2017-based FQHC market basket residual cost weight (15.5 percent). These categories are: (1) Utilities; (2) Medical Equipment; (3) Miscellaneous Products; (4) Professional, Scientific, and Technical Services; (5) Administrative Support and Waste Management Services; (6) All Other Services. We note that for the 2013-based FQHC market basket, we had Telephone and Postage cost weights. For the proposed 2017-based FQHC market basket, we propose to include Telephone and Postage costs in the Miscellaneous Products cost weight due to the small amount of costs in this category (each were less than .05 percent).

d. Proposed 2017-Based FQHC Market Basket Cost Categories and Weights

Table 33 shows the proposed cost categories and weights for the proposed 2017-based FQHC market basket compared to the 2013-based FQHC market basket.

[30] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

TABLE 33: Proposed 2017-Based FQHC Market Basket Cost Weights Compared to 2013-Based FQHC Market Basket Cost Weights

Cost Category	Proposed 2017-based FQHC Market Basket Cost Weight	2013-based FQHC Market Basket Cost Weight
Total	**100.0**	**100.0**
Compensation	**71.6**	**68.7**
FQHC Practitioner Compensation	**30.0**	**31.7**
FQHC Practitioner Wages and Salaries	24.6	-
FQHC Practitioner Employee Benefits	5.4	-
Clinical Staff Compensation	**16.2**	**9.5**
Clinical Staff Wages and Salaries	13.0	-
Clinical Staff Employee Benefits	3.2	-
Non-Health Staff Compensation	**25.4**	**27.4**
All Other Products	**10.0**	**16.1**
Pharmaceuticals	3.9	5.1
Utilities	0.5	1.4
Telephone	-	1.7
Postage	-	1.0
Medical Equipment	1.1	2.2
Medical Supplies	2.4	2.0
Miscellaneous Products	2.1	2.8
All Other Services	**11.8**	**9.0**
Professional, Scientific, and Technical Services	6.0	2.9
Administrative and Facilities Support Services	1.6	3.4
All Other Services	4.2	2.7
Capital-Related Costs	**6.6**	**6.1**
Fixed Assets	4.7	4.5
Movable Equipment	1.9	1.7

Note: Totals may not sum due to rounding.

4. Selection of Price Proxies

After developing the cost weights for the proposed 2017-based FQHC market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. For the majority of the cost weights, we base the price proxies on U.S. Bureau of Labor Statistics (BLS) data, as they produce indexes that best meet the criteria of reliability, timeliness, availability, and relevance, and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the North American Industry Classification System (NAICS) and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an

optimal way to stay abreast of the most current data available.

• *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

• *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

The CPIs, PPIs, and ECIs that we have selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 34 lists all price proxies that used in the proposed 2017-based FQHC market basket. Below is a detailed explanation of the price proxies we are proposing for each cost category weight, many of which are the same as those used for the 2013-based FQHC market basket.

a. Price Proxies for the Proposed 2017-Based FQHC Market Basket

(1) FQHC Practitioner Wages and Salaries

We propose to use the ECI for Wages and Salaries for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure price growth of this category. There is no specific ECI for physicians or FQHC Practitioners and, therefore, we propose to use an index that is based on professionals that receive advanced training similar to those performing at the FQHC Practitioner level of care. This index is consistent with the price proxy used to measure wages and salaries inflation pressure for physicians own time in the Medicare Economic Index (MEI) and is based on the MEI technical panel recommendation from 2012 (78 FR 74266 through 74271)). Additionally, this price proxy is consistent with the proxy used for FQHC practitioner compensation in the 2013-based FQHC market basket (81 FR 80397). We note that the 2013-based FQHC market basket has a single cost category for Total Compensation reflecting both wages and salaries and employee benefits costs for FQHC Practitioners and this single compensation category uses the similar price proxy, the ECI Total Compensation for Private Industry Workers in Professional and Related, reflecting both types of compensation costs together rather than separately (81 FR 80397).

(2) FQHC Practitioner Employee Benefits

We propose to use the ECI for Total Benefits for Private Industry Workers in Professional and Related to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU10162200000000I) and the relative importance of wages and salaries within total compensation. The 2013-based FQHC market basket did not include a separate category for FQHC Practitioner employee benefit costs.

(3) Clinical Staff Wages and Salaries

We propose to use the ECI for Wages and Salaries for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU10262000000000I) to measure the price growth of this cost category. This cost category consists of wage and salary costs for Nurses, Laboratory Technicians, and all other healthcare staff not included in the FQHC Practitioner compensation categories. Based on the clinical staff composition of these workers, we believe that the ECI for health-related workers is an appropriate proxy to measure wage and salary price pressures for these workers. We note that the 2013-based FQHC market basket has a single cost category for Total Compensation reflecting both wages and salaries and employee benefits costs for Clinical Staff and this single compensation category uses the similar price proxy, the ECI Total Compensation for all Civilian Workers in Health Care and Social Assistance, reflecting both types of compensation costs together rather than separately (81 FR 80398).

(4) Clinical Staff Employee Benefits

We propose to use the ECI for Total Benefits for all Civilian Workers in Health Care and Social Assistance to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU10162200000000I) and the relative importance of wages and salaries within total compensation. The 2013-based FQHC market basket did not include a separate category for Clinical Staff employee benefit costs.

(5) Non-Health Staff Compensation

We propose to continue to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU20100002200000I) to measure the price growth of this cost category. The Non-health Staff Compensation cost weight is predominately attributable to administrative and facility type occupations, as reported in the data from the Medicare cost reports. This is the same price proxy used in the 2013-based FQHC market basket (81 FR 80398).

(6) Pharmaceuticals

We propose to continue to use the PPI Commodities for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This price proxy is used to measure prices of Pharmaceuticals in other CMS market baskets, such as 2014-based Inpatient Prospective Payment System and 2014-based Skilled Nursing Facility market baskets. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(7) Utilities

We propose to continue to use the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(8) Medical Equipment

We propose to continue to use the PPI Commodities for Surgical and Medical Instruments (BLS series code WPU1562) as the price proxy for this category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(9) Medical Supplies

We propose to continue to use a 50/50 blended index that comprises the PPI Commodities for Medical and Surgical Appliances and Supplies (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG). The 50/50 blend is used in all market baskets where we do not have an accurate split available. We believe FQHCs purchase the types of supplies contained within these proxies, including such items as bandages, dressings, catheters, intravenous equipment, syringes, and other general disposable medical supplies, via wholesale purchase, as well as at the retail level. Consequently, we propose to combine the two aforementioned indexes to reflect those modes of purchase. This is the same blended price proxy used in the 2013-based FQHC market basket (81 FR 80398).

(10) Miscellaneous Products

We propose to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy is appropriate as it reflects a general level of inflation. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(11) Professional, Scientific, and Technical Services

We propose to continue to use the ECI for Total Compensation for Private Industry Workers in Professional, Scientific, and Technical Services (BLS series code CIU2015400000000I) to measure the price growth of this cost category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(12) Administrative and Facilities Support Services

We propose to continue to use the ECI Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(13) All Other Services

We propose to continue to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(14) Fixed Capital

We propose to continue to use the PPI Industry for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category (81 FR 80398). This is the same price proxy used in the 2013-based FQHC market basket. We believe this continues to be the most appropriate price proxy since fixed capital expenses in FQHCs should reflect inflation for the rental and purchase of business office space.

(15) Moveable Capital

We propose to continue to use the PPI Commodities for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category as this cost category represents nonmedical moveable equipment. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

c. Summary of Price Proxies of the Proposed 2017-Based FQHC Market Basket

Table 34 shows the cost categories and associated price proxies for the proposed 2017-based FQHC market basket.

TABLE 34: Cost Categories and Price Proxies for the Proposed 2017-Based FQHC Market Basket

Cost Description	Price Proxies
FQHC Practitioner Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Professional and Related
FQHC Practitioner Employee Benefits	ECI for Total Benefits for Private Industry Workers in Professional and Related
Clinical Staff Wages and Salaries	ECI for Wages and Salaries for All Civilian Workers in Health care and Social Assistance
Clinical Staff Employee Benefits	ECI for Total Benefits for All Civilian Workers in Health Care and Social Assistance
Non-Health Staff Compensation	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
Pharmaceuticals	PPI Special Index for Pharmaceuticals for Human Use, Prescription
Utilities	CPI-U for Fuels and Utilities
Medical Equipment	PPI Commodity Index for Surgical and Medical Instruments
Medical Supplies	Composite: PPI Commodity Index for Medical and Surgical Appliances and Supplies (50%) and CPI for Medical Equipment and Supplies (50%)
Miscellaneous Products	CPI-U for All items less food and energy
Professional, Scientific, and Technical Services	ECI for Total compensation for Private industry workers in Professional, Scientific, and Technical Services
Administrative and Facilities Support Services	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
All Other Services	ECI for Total Compensation for Private Industry Workers in Service Occupations
Fixed Capital	PPI Industry Index for Lessors of Nonresidential Buildings
Movable Capital	PPI Commodity Index for Machinery and Equipment

5. Proposed CY 2021 Productivity Adjusted Market Basket Update for FQHCs

For CY 2021 (that is, January 1, 2021 through December 31, 2021), we are proposing to use the proposed 2017-based FQHC market basket increase factor to update the PPS payments to FQHCs. Consistent with CMS practice, we estimated the market basket update for the FQHC PPS based on the most recent forecast from IGI. IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and multifactor productivity (MFP). We are proposing to use the update based on the most recent historical data available at the time of publication of the final rule. For example, the final CY 2021 FQHC update would be based on the four-quarter moving-average percent change of the 2017-based FQHC market basket through the second quarter of 2020 (based on the final rule's statutory publication schedule). For the proposed rule, we do not have the second quarter of 2020 historical data and, therefore, we will use the most recent projection available.

Based on IGI's first quarter 2020 forecast with historical data through the fourth quarter of 2019, the projected proposed 2017-based FQHC market basket increase factor for CY 2021 would be 2.5 percent. For comparison, the 2013-based FQHC market basket update is also projected to be 2.5 percent in CY 2021; this estimate is based on IGI's first quarter 2020 forecast (with historical data through the fourth quarter of 2019). The proposed 2017-based FQHC market basket and the 2013-based FQHC market basket are both projected to grow at the same rate for CY 2021, the difference in the average update factor over the last five historical years (2016–2020) is 0.0 percent.

Table 35 compares the proposed 2017-based FQHC market basket updates and the 2013-based FQHC market basket updates for CY 2016 through CY 2023.

TABLE 35: Proposed 2017-Based FQHC Market Basket and 2013-Based FQHC Market Basket Percent Changes, CY 2016 through CY 2023

	Calendar Year (CY)	Proposed 2017-Based FQHC Market Basket Index Percent Change	2013-Based FQHC Market Basket Index Percent Change
Historical data	CY 2016	2.2	2.2
	CY 2017	2.1	2.2
	CY 2018	2.3	2.3
	CY 2019	2.4	2.4
	CY 2020	2.8	2.7
	Average 2016-2020	**2.4**	**2.4**
Forecast	CY 2021	2.5	2.5
	CY 2022	2.9	2.8
	CY 2023	3.0	3.0
	Average 2020-2023	**2.8**	**2.8**

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.
Source: IHS Global Inc. 1st quarter 2020 forecast.

Section 1834(o)(2)(B)(ii) of the Act describes the methods for determining updates to FQHC PPS payment. We have included a productivity adjustment to the FQHC PPS annual payment update since implementation of the FQHC PPS (81 FR 80393) and we propose to continue to include a productivity adjustment to the proposed 2017-based FQHC market basket. We propose to use the most recent estimate of the 10-year moving average of changes in annual private nonfarm business (economy-wide) multifactor productivity (MFP), which is the same measure of MFP applied to other CMS Market Basket updates including the MEI. The BLS publishes the official measure of private nonfarm business MFP. (See *http://www.bls.gov/mfp* for the published BLS historical MFP data). For the final FQHC market basket update, we propose to use the most recent historical estimate of annual MFP as published by the BLS. Generally, the most recent historical MFP estimate is lagged two years from the payment year.

Therefore, we propose to use the 2019 MFP as published by BLS in the CY 2021 FQHC market basket update. We note that MFP is derived by subtracting the contribution of labor and capital input growth from output growth. Since at the time of development of the proposed rule the 2019 MFP was not yet published by BLS, we are proposing to use IGI's first quarter 2020 forecast of MFP. A complete description of the MFP projection methodology is available at *http://www.cms.gov/Research-Statistics-Dataand-Systems/Statistics-Trends-andReports/MedicareProgramRatesStats/MarketBasketResearch.html.*

Using IGI's first quarter 2020 forecast, the productivity adjustment for CY 2021 (the 10-year moving average of MFP for the period ending CY 2019) is projected to be 0.6 percent. Therefore, the proposed CY 2021 productivity-adjusted FQHC Market basket update is 1.9 percent, based on IGI's first quarter 2020 forecast with historical data through the fourth quarter of 2019. This reflects a 2.5-percent increase in the proposed 2017-based FQHC market basket and a 0.6-percent adjustment for productivity. For comparison, if we continue to use the 2013-based FQHC market basket, then the CY 2021 productivity-adjusted FQHC market basket update would also be 1.9 percent (2.5 percent FQHC market basket update less 0.6 percent MFP adjustment). Finally, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the CY 2021 market basket update and the MFP adjustment for the final rule.

E. Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention That Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

Opioid overdose deaths continue to impact communities across the United States. In 2018, about 47,000 Americans died as a result of an opioid overdose, where 32 percent of these deaths involved a prescription opioid.[31] In addition to the risk of death from overdose, opioids carry a number of other health risks, including respiratory depression, drowsiness, confusion, nausea, increased drug tolerance, and physical dependence. An estimated 1.7 million people in the United States have substance use disorders involving prescription opioid pain relievers.[32]

CMS has a vital role in addressing opioid use disorder prevention, treatment and recovery. The intent of the SUPPORT Act (Pub. L. 115–271, enacted on October 24, 2018) is to provide for opioid use disorder prevention, treatment and recovery. In section 2002 of the SUPPORT Act, Comprehensive Screening for Seniors, the Congress required the Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) to include screening for potential substance use disorders (SUDs) and a review of any current opioid prescriptions. We believe that these provisions are complementary to the existing components of the IPPE and AWV. We are proposing to add these new elements to the IPPE and AWV regulations, to draw attention to their importance and fulfil the section 2002 SUPPORT Act requirements. In this proposed rule, we provide background on the IPPE and AWV, discuss how the requirements of the SUPPORT Act are related to the IPPE and AWV, and make proposals to implement these provisions.

[31] Wilson N, Kariisa M, Seth P, et al. Drug and Opioid-Involved Overdose Deaths—United States, 2017–2018. MMWR Morb Mortal Wkly Rep 2020;69:290–297.

[32] Substance Abuse and Mental Health Services Administration. (2019). Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19–5068, NSDUH Series H–54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from *https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf.*

1. Background: IPPE and AWV

a. IPPE Required Elements

The IPPE is defined in section 1861(ww) of the Act and codified in regulations at § 410.16. The IPPE must be performed within 1 year after the effective date of a beneficiary's first Medicare Part B coverage period as stated in section 1861(hhh)(4)(G) of the Act. The IPPE includes all of the following services furnished to an eligible beneficiary by a physician or other qualified nonphysician practitioner (NPP) with the goal of health promotion and disease detection:

- Review of the beneficiary's medical and social history with attention to modifiable risk factors for disease, as those terms are defined in § 410.16.
- Review of the beneficiary's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified NPP may select from various available standardized screening tests designed for this purpose and recognized by national professional medical organizations.
- Review of the beneficiary's functional ability, and level of safety as those terms are defined in § 410.16 based on the use of appropriate screening questions or a screening questionnaire, which the physician or other qualified NPP may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.
- An examination to include measurement of the beneficiary's height, weight, body mass index, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the beneficiary's medical and social history, and current clinical standards.
- End-of-life planning upon agreement with the individual.
- Education, counseling, and referral, as deemed appropriate by the physician or qualified NPP, based on the results of the review and evaluation services described in § 410.16.
- Education, counseling, and referral, including a brief written plan such as a checklist provided to the individual for obtaining an electrocardiogram, as appropriate, and the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits.

b. AWV Required Elements

Section 1861(hhh) of the Act expanded Medicare coverage under Part B to include an AWV effective for services furnished on or after January 1, 2011. We codified the AWV at § 410.15.

The AWV is a wellness visit that focuses on identification of certain risk factors, personalized health advice, and referral for additional preventive services and lifestyle interventions (which may or may not be covered by Medicare). The elements included in the AWV differ from comprehensive physical examination protocols with which some providers may be familiar since it is a visit that is specifically designed to provide personalized prevention plan services as defined in the Act. The AWV includes a health risk assessment (HRA) and the AWV takes into account the results of the HRA.

The AWV may be performed when the beneficiary is no longer within 12 months after the effective date of his or her first Medicare Part B coverage period and when the beneficiary has not received either an IPPE or AWV within the past 12 months. The AWV may be performed by a physician, NPP (physician assistant, nurse practitioner, or clinical nurse specialist), medical professional (including a health educator, a registered dietitian, or nutrition professional, or other licensed practitioner) or a team of such medical professionals, working under the direct supervision of a physician. In summary, the first AWV includes the following:

- Review (and administration if needed) of a health risk assessment (as defined in § 410.15).
- Establishment of an individual's medical and family history.
- Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual.
- Measurement of an individual's height, weight, body-mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements as deemed appropriate, based on the beneficiary's medical and family history.
- Detection of any cognitive impairment that the individual may have, as that term is defined in § 410.15.
- Review of the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available standardized screening tests

designed for this purpose and recognized by national medical professional organizations.

• Review of the individual's functional ability and level of safety, based on direct observation or the use of appropriate screening questions or a screening questionnaire, which the health professional as defined in § 410.15 may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

• Establishment of the following:

++ A written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices, and the individual's health risk assessment (as that term is defined in § 410.15), health status, screening history, and age-appropriate preventive services covered by Medicare.

++ A list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical examination (as described under § 410.16), and a list of treatment options and their associated risks and benefits.

++ Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

++ At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

++ Any other element determined appropriate through the national coverage determination process.

In summary, subsequent AWVs include the following:

• Review (and administration, if needed) of an updated health risk assessment (as defined in § 410.15).

• An update of the individual's medical and family history.

• An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first AWV providing personalized prevention plan services or the previous subsequent AWV providing personalized prevention plan services.

• Measurement of an individual's weight (or waist circumference), blood pressure and other routine measurements as deemed appropriate, based on the individual's medical and family history.

• Detection of any cognitive impairment that the individual may have, as that term is defined in § 410.15.

• An update to the following:

++ The written screening schedule for the individual as that schedule is defined in paragraph (a) of § 410.15 for the first AWV providing personalized prevention plan services.

++ The list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first AWV providing personalized prevention plan services or the previous subsequent AWV providing personalized prevention plan services.

++ Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs as that advice and related services are defined in paragraph (a) of § 410.15.

++ At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

++ Any other element determined appropriate through the national coverage determination process.

2. Section 2002 of the SUPPORT Act Requirement

In section 2002 of the SUPPORT Act, sections 1861(ww) and 1861(hhh)(2) of the Act were amended to include a review of any current opioid prescriptions and screening for potential substance use disorders (SUD) as elements of the IPPE and AWV, effective January 1, 2020.

3. Proposal on Section 2002 of the SUPPORT Act Requirements

We are proposing to add the requirements of section 2002 of the SUPPORT Act to our regulations at § 410.15 and 410.16 for the AWV and IPPE, respectively.

Section 2002 of the SUPPORT Act, requires a review of any current opioid prescriptions as part of the IPPE and AWV. Such review includes a review of the potential risk factors to the individual for opioid use disorder, an evaluation of the individual's severity of pain and current treatment plan, educational information on non-opioid treatment options, and a referral to a specialist, as appropriate. Section 2002 of the SUPPORT Act also requires adding an element to the IPPE and AWV to include screening for potential SUDs. Along with the screening for SUD, a referral for treatment, as appropriate, was added to the AWV.

The definitions and conditions for and limitations on coverage of the IPPE outlined in § 410.16 includes a review of the beneficiary's medical and social history. The medical history is defined to include a review of current medications, which would include a review of current opioid prescriptions. Furthermore, social history is defined to include, at a minimum, a history of alcohol, tobacco, and illicit drug use. Illicit drug use may include the non-medical use of prescription drugs. The physician or other qualified health professional may then provide education, counseling, and referral, as deemed appropriate, based on the results of the review and evaluation services provided during the IPPE.

The definitions and conditions for and limitations on coverage of the AWV in § 410.15 includes a health risk assessment, which entails an evaluation of psychosocial risks, including but not limited to, depression/life satisfaction, stress, anger, loneliness/social isolation, pain, and fatigue. The patient's substance use, if applicable, could be reviewed as part of the health risk assessment. The AWV also covers establishment of, or an update to the individual's medical and family history. The medical history includes medication use, and may have included a review of any opioid prescriptions. The health professional may also establish or update a list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through the initial or subsequent AWV

or IPPE, and a list of treatment options and their associated risks and benefits. If the clinician detected, through the above methods for screening, that a patient was at high-risk for substance use disorder in the course of the visit, it would have been appropriate to note in the patient's IPPE written plan or the AWV personalized prevention plan and to have referred the patient for further assessment and treatment.

Awareness of a patient's use of substances, including nonmedical use of prescription drugs and illicit drug use, is an important aspect of the IPPE and AWV. In general, screening for potential SUDs may include screening questions, the use of a specific tool, screening for licit and/or illicit drugs (for example, alcohol, non-medical use of prescription opioids, methamphetamine, heroin, cocaine, and other substances), review of the beneficiary's medical and social history and medical records, or prescription drug monitoring program query when clinically indicated. Given the existing elements of the IPPE and AWV, we do not expect the new regulatory elements to add significant burdens on physicians and practitioners who furnish these services because review of medical and social history, risk factor identification, education, counseling, and referrals are already fundamental parts of the IPPE and AWV. The new regulatory elements elevate the importance of physicians' and other qualified health professionals' vigilance in identifying and addressing opioid risks and SUDs in Medicare beneficiaries.

4. Proposed Regulatory Text Changes

We are proposing to add elements to our regulations to reflect the provisions of section 2002 of the SUPPORT Act. Consistent with sections 1861(ww) and 1861(hhh)(2) of the Act, we propose to amend 42 CFR 410.15 and 410.16 by: (1) Adding the term ''screening for potential substance use disorders''; (2) Adding the term ''a review of any current opioid prescriptions'' and its definition; and (3) revising the ''Initial Preventive Physical Examination,'' ''first annual wellness visit providing personalized prevention plan services,'' and ''subsequent annual wellness visit providing personalized prevention plan services''.

(1) ''Screening for Potential Substance Use Disorders''

We propose to revise §§ 410.15 and 410.16 by adding the element ''Screening for Potential Substance Use Disorders'' and describing the proposed requirement as a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(2) Definition of ''A Review of Any Current Opioid Prescriptions''

We propose to revise §§ 410.15 and 410.16 by adding the element ''a review of any current opioid prescriptions'' and defining such term, consistent with section 1861(ww)(4) of the Act, as a review of any current opioid prescriptions, including a review of the potential risk factors to the individual for opioid use disorder, an evaluation of the individuals' severity of pain and current treatment plan, the provision of information on non-opioid treatment options, and a referral to a specialist, as appropriate.

(3) Proposed Changes to the ''Initial Preventive Physical Examination,'' ''First Annual Wellness Visit'' and ''Subsequent Annual Wellness Visit''

In §§ 410.15 and 410.16, we adopted the components of the IPPE and AWV, consistent with the statutory elements described in sections 1861(ww) and 1861(hhh)(2) of the Act. The initial preventive physical examination, first and subsequent annual wellness visits are meant to represent a beneficiary visit focused on prevention. Among other things, the IPPE and AWV encourages beneficiaries to obtain the preventive services covered by Medicare that are appropriate for them. First and subsequent AWVs also include elements that focus on the furnishing of personalized health advice and referral, as appropriate, to health education, preventive counseling services, or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions.

We are proposing to revise ''initial preventive physical examination,'' ''first annual wellness visit providing personalized prevention plan services,'' and ''subsequent annual wellness visit providing personalized prevention plan services'' by adding:

- In § 410.15(a):

++ A revised paragraph (xi) to the definition of the term ''First annual wellness visit providing personalized prevention plan services,'' and a revised paragraph (ix) to the definition of the term ''Subsequent annual wellness visit'' that would add furnishing of a review of any current opioid prescriptions as that term is defined in this section.

++ A new paragraph (xii) to the definition of ''First annual wellness visit providing personalized prevention plan services,'' and a new paragraph (x) to the definition of ''Subsequent annual wellness visit'' that would add screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

++ A new paragraph (xiii) to the definition of ''First annual wellness visit providing personalized prevention plan services,'' and a new paragraph (xi) to the definition of ''Subsequent annual wellness visit'' that would add any other element determined appropriate through the national coverage determination process.

- In § 410.16:

++ A revised paragraph (a)(6) to the definition of ''Initial preventive physical examination'' that would include a review of any current opioid prescriptions as that term is defined in this section.

++ A revised paragraph (a)(7) to the definition of ''Initial preventive physical examination'' that would add screening for potential substance use disorders to include a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

++ A new paragraph (a)(8) to the definition of ''Initial preventive physical examination'' that would add, education, counseling, and referral, as deemed appropriate by the physician or qualified nonphysician practitioner, based on the results of the review and evaluation services described in this section.

++ A new paragraph (a)(9) to the definition of ''Initial preventive physical examination'' that would include, education, counseling, and referral, including a brief written plan such as a checklist provided to the individual for obtaining an electrocardiogram, as appropriate, and the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in sections 1861(s)(10), (jj), (nn), (oo), (pp), (qq)(1), (rr), (uu), (vv), (xx)(1), (yy), (bbb), and (ddd) of the Act.

5. Summary

The initial preventive physical examination, first and subsequent annual wellness visits are designed to help prevent disease and disability based on the beneficiary's current health and risk factors. Increased payment values for the IPPE and AWV in alignment with increases to E/M services are being proposed in section II.F. of this proposed rule. Our proposals seek to incorporate the new AWV and IPPE requirements of section 2002 of the SUPPORT Act in a manner that is flexible for clinicians to provide

the care that is most appropriate for their patients. We look forward to receiving public comment on these proposals.

F. 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 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 § 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 2020 PFS final rule (84 FR 62568, 62900), we established for 2020 that Medicaid EPs are required to report on any six 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 six 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 Appendix 1 of this proposed rule, we propose to amend the list of available eCQMs for the CY 2021 performance period. To keep eCQM specifications current and minimize complexity, we propose to align the eCQMs available for Medicaid EPs in 2021 with those available for MIPS eligible clinicians for the CY 2021 performance period. Specifically, we propose that the eCQMs available for Medicaid EPs in 2021 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established for the MIPS CY 2021 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 (84 FR 62900; see also 83 FR 59452, 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 for both programs. 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 2021. We expect that this proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2021 to maintain current eCQM lists and specifications.

For 2021, we propose to again require (as we did for 2020) that Medicaid EPs report on any six 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 six 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 six 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 2020, we propose that for 2021, 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 MIPS quality performance category requirements 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 six eCQMs that are relevant, as was the policy in 2020.

In the CY 2020 PFS final rule (84 FR 62899–62900), 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 2021:

- 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 2021, 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 2020. As noted above, we propose to use the same three methods for identifying high priority eCQMs for the Medicaid Promoting Interoperability Program for 2021. 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.

Finally, we note that the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program is a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, or falls before a state-specific alternative date prior to October 31, 2021 that is specified in the SMHP, as described in § 495.332(f)(4). This 2021 eCQM reporting period will help ensure that states can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. (See 83 FR 59452, 59704 through 59706).

G. Medicare Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 to the Act to establish 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. (See 42 U.S.C. 1395jjj.) 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). Under the Shared Savings Program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements.

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (Pub. L. 114–255). The Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted on February 9, 2018), further amended section 1899 of the Act to provide for the following: Expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries, greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. 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 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule'')). A final rule, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act'', appeared in the November 23, 2018 **Federal Register** (83 FR 59452) (herein referred to as the ''November 2018 final rule'' or the ''CY 2019 PFS final rule''). In the November 2018 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 designating their primary care

provider and in the use of that designation 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) use 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).

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 and Uncontrollable Circumstances Policies for Performance Year 2017; 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 for the Shared Savings Program, including a 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.

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', which appeared in the April 6, 2020 **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31st COVID–19 IFC''), we removed the restriction which prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended, to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the public health emergency (PHE) for the COVID–19 pandemic (85 FR 19267 and 19268). In the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' which appeared in the May 8, 2020 **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the ''May 8th COVID–19 IFC''), we modified Shared Savings Program policies to: (1) Allow ACOs whose current agreement periods expire on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the COVID–19 PHE starting in January 2020.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. Refer to the CY 2020 PFS proposed rule for a summary of policies finalized in prior rules (84 FR 40705).

Policies applicable to Shared Savings Program ACOs for purposes of reporting for other programs have also continued to evolve based on changes in the law. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program (Pub. L. 114–10). In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) and related policies applicable to eligible clinicians who participate in the Shared Savings Program. These policies included requirements for Shared Savings Program ACOs regarding reporting for the MIPS Quality performance category and a policy that gives ACOs full credit for the MIPS Improvement Activities performance category based on their participation in the Shared Savings Program. We believe that the proposed changes would reduce ACO burden by establishing a smaller measure set, out of which ACO would only be required to actively report 3 measures. This would represent a significant reduction in reporting requirements from the 10 measures on which ACOs are currently required to actively report. Reporting for these measures would begin in January 2022, for the 2021 performance year. We believe this timeline would allow organizations sufficient time to prepare to report on the new measure set. In addition, the reporting options for the three ACO-reported measures would leverage existing MIPS collection types and more closely align existing CEHRT and registries used by ACOs and their clinicians, including use of APIs to submit data.

As a general summary, in this proposed rule, we are proposing to:

- Modify the approach to measuring ACO quality performance under the Shared Savings Program which includes:
  - ++ Applying the Alternative Payment Model (APM) Performance Pathway (APP) to Shared Savings Program ACOs.
  - ++ Revising the Shared Savings Program Quality Performance Standard.
  - ++ Changing the methodology for determining shared savings and shared losses based on ACO quality performance.
  - ++ Revising the approach to monitoring ACO quality performance and addressing ACOs that fail to meet the Quality Performance Standard.
  - ++ Updating the process used to validate ACO Quality Data Reporting.
  - ++ Updating the extreme and uncontrollable circumstances policy as it relates to quality performance.
- Update the definition of primary care services used in beneficiary assignment, and codify in regulations the adjustment that is made to an ACO's historical benchmark to reflect any changes to the beneficiary assignment methodology specified in 42 CFR part 425, subpart E, during an ACO's agreement period, including revisions to the definition of primary care services at § 425.402(c).
- Revise the policy for determining the amount of repayment mechanism arrangements for certain ACOs renewing to continue their participation under a two-sided model.

1. Quality and Other Reporting Requirements

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 establishing the Shared Savings Program, we adopted a quality measure set spanning four domains: Patient experience of care, care coordination/patient safety, preventative health, and at-risk population (76 FR 67872 through

67891). Since then, we have updated the measures that comprise the quality performance measure set for the Shared Savings Program through 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 (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. In the CY 2019 PFS final rule, we finalized that for performance years (or a performance period) starting in 2019 and subsequent years, 23 quality measures would be used to determine ACO quality performance (83 FR 59707 through 59715). The information used to determine ACO performance on these quality measures is 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) are currently 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 (Track 1 and Levels A through D of the BASIC track) of the Shared Savings Program that is not an Advanced APM, as well as those MIPS eligible clinicians participating in an ACO in a track, or payment model within a track (Track 2, Level E of the BASIC track, and the ENHANCED track, or the Medicare ACO Track 1+ Model (Track 1+ Model)) 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. Applying the Alternative Payment Model (APM) Performance Pathway (APP) to Shared Savings Program ACOs

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. In the CY 2017 PFS final rule, we finalized revisions to § 425.502 related to the quality performance standard and minimum attainment, including clarifying that the quality performance standard is the overall standard the ACO must meet to qualify to share in savings; defining the minimum attainment level for pay for performance measures at the 30th percent or 30th percentile of the quality performance benchmark and for pay for reporting measures at the level of complete and accurate reporting; specifying that only pay for performance measures are assessed on a sliding scale while pay for reporting measures earn the maximum number of points for a measure when the minimum attainment level is met (81 FR 80492 through 80494).

Currently, the quality performance standard is based on an ACO's experience in the program rather than its financial track. The quality performance standard is currently 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 under the Shared Savings Program. In the second or subsequent years of the ACO's 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 30 percent or the 30th percentile of the performance 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)).

In the CY 2020 PFS proposed rule (84 FR 40709 through 40713), we sought comment on how we might align the Shared Savings Program quality reporting requirements and scoring methodology more closely with the MIPS quality reporting and scoring methodology. We discussed utilizing the MIPS Quality performance category score to adjust shared savings and shared losses under the Shared Savings Program, as applicable. We also sought comment on a possible new approach to determining the threshold for minimum attainment. Under this potential policy, minimum attainment would 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 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 MIPS Quality performance category scores below 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, we sought comment on a potential policy under which ACOs with quality scores below the 4th decile of all MIPS Quality performance category scores would be subject to compliance actions and possible termination.

The majority of feedback received in response to our comment solicitation did not support this approach as it would hold ACOs to a higher standard to be eligible to share in savings, if earned. In addition, commenters that opposed aligning the Shared Savings Program quality score with the MIPS Quality performance category score, stated that significant restructuring of the Shared Savings Program quality performance requirements would introduce more confusion for ACOs that are also transitioning into new tracks under the December 2018 final rule. Commenters also expressed concern regarding the uncertainty associated with such an approach, as we had also proposed extensive revisions to MIPS as the program transitions to MIPS Value Pathways. Furthermore, commenters noted that ACOs are unique in that they are responsible for the total cost of care of their beneficiaries and should not be compared to clinicians in MIPS who are not participating in total cost of care programs.

Although we acknowledge the commenters' concerns, we note that 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, new measures, or both for purposes of assessing quality of care. The Shared Savings Program is now in its eighth performance year, and 85 percent of ACOs participating in the program are considered PY3 ACOs for purposes of quality reporting, with 65 percent of those ACOs participating in a second or subsequent agreement period. In light of

the maturity of the program and consistent with section 1899(b)(3)(C) of the Act, we believe that it is appropriate to require a higher standard of care in order for ACOs to continue to share in any savings they achieve. In addition, holding ACOs to a higher standard is in line with CMS' goals of incentivizing value-based care and driving the Medicare system to greater value and quality. However, after taking into consideration the stakeholder feedback, we also considered ways to reduce reporting burden, offer more flexibility in the way quality data can be reported and submitted, and create a more meaningful measure set that would focus on population health measures and be more outcome-oriented, while also including patient experience of care metrics.

The Alternative Payment Model Performance Pathway (APP) was designed for all MIPS APMs; but, it is also responsive to the concerns raised by commenters in their responses to our solicitation in the CY 2020 PFS proposed rule, while still taking into consideration the maturity of the Shared Savings Program, ACOs' quality performance over time, and the intent of section 1899(b)(3)(C) of the Act. The APP contains a narrower measure set than has previously been used for Shared Savings Program quality measurement, 6 measures versus the current 23 scored measures, and is specifically intended for use in APMs and population health. The design of the APP aligns with stakeholder interests expressed through comments on our solicitation about aligning the Shared Savings Program with MIPS in the CY 2020 PFS proposed rule. These comments suggested adopting a smaller, more focused measure set in recognition of the fact that APM Entities are incentivized through the terms of the respective APMs to improve value. The measure set proposed for the APP aligns with the Meaningful Measures framework by identifying measures that address the highest priorities for quality measurement and improvement, while also reducing reporting burden, promoting alignment of measures and consolidation of reporting requirements across CMS programs moving payment toward value, and identifying for consumers' key quality performance metrics. The measures proposed for inclusion in this set encompass the meaningful measure domains of patient voice, wellness and prevention, seamless communication, chronic disease management, and behavioral health. For these reasons, we believe that the proposed APP, along with the narrower measure set, which comprises it, would be appropriate to assess the quality performance of Shared Savings Program ACOs.

The construction of the proposed APP and the proposed measures within it are described in more detail later in this section. A detailed discussion of the proposal for use of the APP for MIPS APMs more generally is found at section III.C.3.b. of this proposed rule.

(1) APM Performance Pathway for Shared Savings Program ACOs

In response to stakeholder feedback and in order to improve alignment and integration with the Quality Payment Program policies and operations, align with CMS' Meaningful Measure Framework, increase participation in APMs and Advanced APMs by reducing reporting burden, and raise the quality performance standard under the Shared Savings Program, we are proposing to revise the Shared Savings Program quality performance standard effective for performance year 2021 and subsequent performance years. This proposed revision would align the Shared Savings Program quality performance standard with the proposed APP under the Quality Payment Program as participants in the Shared Savings Program would be required to report quality for purposes of the Shared Savings Program via the APP, which is described in more detail in section III.C.3.b. of this proposed rule. At a high level, the APP would replace the current Shared Savings Program quality measure set to streamline reporting requirements for Shared Savings Program ACOs and would be a complementary path to the MIPS Value Pathways. The APP is designed to reduce reporting burden, create new scoring opportunities for participants in MIPS APMs, and encourage participation in APMs.

Under this new approach, ACOs would only need to report one set of quality metrics that would satisfy the reporting requirements under both MIPS and the Shared Savings Program. There would not be separate quality reporting requirements under the Shared Savings Program, as under this proposed new approach the quality measures reported for purposes of the APP would be used to determine the quality performance of the ACO for purposes of the Shared Savings Program, which is used for purposes of calculating shared savings and also shared losses, where applicable. We believe this approach of streamlining the quality reporting requirements under the Shared Savings Program while maintaining alignment with the Quality Payment Program will help ACOs and their participating providers and suppliers dedicate their finite resources to engaging in efforts to improve quality and reduce costs for their assigned beneficiary population. In addition, we believe that using a single methodology to measure quality performance under both the Shared Savings Program and MIPS would allow ACOs to better focus on increasing the value of healthcare, improving care, and engaging patients. It would also reduce burden as ACOs would be able to track to a smaller set of measures under a unified scoring methodology.

Under the APP proposed in section III.C.3.b. of this proposed rule, eligible clinicians in Shared Savings Program ACOs would continue to receive full credit for the improvement activities performance category in 2021 based on their performance of activities required under § 425.112 of the Shared Savings Program regulations, as they do under current MIPS scoring policy. Eligible clinicians participating in the Shared Savings Program are not currently assessed on 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 would continue to be weighted at zero percent. The four categories in the proposed APP framework would be weighted as follows: Quality: 50 percent; PI: 30 percent; IA: 20 percent; and Cost: 0 percent.

Under the APP proposed in section III.C.3.b. of this proposed rule, the MIPS Quality performance category score would be calculated for ACOs based on MIPS benchmarks, which are used for other non-ACO group and individual reporters and reflect the method of data submission (for example, eCQM measures have benchmarks calculated using EHR data). ACOs would be scored on the measures they report and would receive zero points for those measures they do not report. For example, if an ACO reported all three measures it is actively required to report but did not field a CAHPS for MIPS survey measure, the ACO would receive zero points for the CAHPS for MIPS survey measure, and that zero would be included in its MIPS Quality performance category score, along with its performance rates on the three measures it did actively report as well as the two claims-based measures included in the APP measure set. This approach aligns with scoring under MIPS, rather than the current Shared Savings Program quality performance scoring methodology, which uses quality benchmarks established specifically for the Shared

Savings Program and awards zero points for quality for ACOs that report some but not all of the required measures. We believe that this approach would be less punitive for ACOs than the current quality performance standard, under which ACOs that fail to completely report all quality measures receive a zero score for quality. We also believe that alignment with the MIPS scoring methodology would reduce the burden on ACOs of tracking to two different scoring methodologies. However, if an ACO does not report any of the three APP measures it is required to actively report and does not field a CAHPS for MIPS survey the ACO would not meet the quality performance standard for purposes of the Shared Savings Program and would not be able to share in savings and would owe maximum losses, if applicable. If an ACO does not report any of the three measures it is required to actively report and does not field a CAHPS for MIPS survey, we do not believe that the remaining two claims-based measures in the APP core measure set would be sufficient to assess the quality of care provided by an ACO to its assigned beneficiaries and would likely not allow the ACO to achieve a MIPS Quality performance category score at or above the 40th percentile. Under this proposal, there would be no quality ''phase in.'' All ACOs, regardless of performance year and agreement period, would be scored on all the measures in the APP for purposes of the Shared Savings Program quality performance standard.

For MIPS scoring purposes, an ACO that fails to report via the APP would receive a zero in the Quality performance category under MIPS. If an ACO fails to report via the APP on behalf of its ACO participants then the ACO participants could report outside the ACO, on behalf of the MIPS eligible clinicians who bill through the TIN of the ACO participant and receive a MIPS Quality performance category score calculated at the ACO participant level. If ACO participants report outside the ACO via the APP, they would continue to get full credit for IA based on ACO participation. If ACO participants choose to report outside the ACO via a different MIPS reporting option, then regular MIPS scoring rules would apply (that is, automatic full credit for I.A. and zero cost category weight would not be applied).

Under this proposal, for performance year 2021 and subsequent performance years, ACOs would be assessed on a smaller measure set. The measures ACOs would be scored on would decrease from 23 measures to 6 measures and the number of measures on which ACOs would be required to actively report would be reduced from 10 to 3.

ACOs would report under the APP on the following 3 measures:

- Quality ID#: 001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%);
- Quality ID#: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and
- Quality ID#: 236 Controlling High Blood Pressure.

ACOs would report these measures via a submission method of their choice that aligns with the MIPS data submission types for groups at § 414.1325(c) (direct, login and upload, or a third-party intermediary, described at § 414.1400, submitting on behalf of the ACO). As discussed in section IV.A.3.c.(1) of this proposed rule, we are proposing to remove the CMS Web Interface from the MIPS data submission types for groups beginning with the 2021 MIPS performance year. Medicare Part B claims is not an available submission type for ACOs as it is limited to TINs consisting of 15 or fewer eligible clinicians. ACOs would receive a score of between 3 to 10 points for each measure that meets the data completeness and case minimum requirements, which would be determined by comparing measure performance to established benchmarks. In addition, ACOs would need to field a CAHPS for MIPS survey and would be measured on two claims-based measures: The Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups; and the All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions (MCC). Please see Table 36 and section III.C.3.b. of this proposed rule for full details on the measures proposed under the APP framework.

TABLE 36: Measures included in the Proposed APM Performance Pathway Measure Set

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Measure # TBD	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions

As noted above, the measures proposed for inclusion in the measure set for the APP align with the Meaningful Measures framework by identifying the highest priorities for quality measurement and improvement with the goals of reducing burden, promoting alignment, moving payment toward value, and identifying key quality performance metrics for consumers. The proposed measures encompass the meaningful measure domains of patient voice, wellness and prevention, seamless communication, chronic disease management, and behavioral health. We also believe that the measures included in the APP are appropriate to assess the quality performance of Shared Savings Program ACOs as they focus on the management of chronic health conditions that are high priority and have high prevalence among the population of Medicare beneficiaries assigned to ACOs. We also believe that the measure set chosen for inclusion within the APP would move the quality measure set used in the Shared Savings Program toward a more outcome based, primary care focused measure set. In addition to creating a pathway that would reduce reporting burden for ACOs and allow their participating MIPS eligible clinicians to meet requirements under MIPS through a smaller measure set, requiring ACOs to report through the APP would also eliminate differences in the way ACOs are scored under the Shared Savings Program, as compared to the way their MIPS eligible clinicians are scored under MIPS.

We note that under the current Shared Savings Program quality scoring methodology, the CAHPS for ACOs survey is counted as ten separate measures, while under the APP, the CAHPS for MIPS survey would be counted as one. We continue to value the patient voice and believe it should play a significant role in quality scoring. Using the CAHPS for MIPS survey would achieve that goal while further aligning the way in which the quality performance of ACOs and their MIPS eligible clinicians is scored under the Shared Savings Program and under MIPS, respectively. Under the current Shared Savings quality scoring methodology, the 10 CAHPS for ACOs survey measures are scored as one domain, which makes up 25 percent of the Shared Savings Program quality score. In contrast, under our proposed approach, the CAHPS for MIPS survey would be counted as one measure out of the 6 measures that would be included in the calculation of the ACO's quality score under the APP. Both of these approaches have a similar weighting, which maintains the relevance of patient voice. We believe that the proposed approach under the APP of combining the CAHPS survey measures into a single measure for quality scoring purposes would allow Shared Savings Program ACOs to effectively target resources toward improving their assigned beneficiaries' experience of care in the areas for improvement on which they choose to focus, rather than having to track to ten separate survey measures, as is currently required by the CAHPS for ACOs used under the Shared Savings Program. We believe this approach strikes the right balance in reducing burden on ACOs and their participating providers and suppliers while preserving the patient's voice.

Shared Savings Program ACOs are currently required to report on a set of ten measures via the CMS Web Interface. While these measures were appropriate for use in the program in the past because they are primary care focused, we now recognize that the majority of the measures have highly clustered performance. This means that they cannot meaningfully distinguish quality performance across groups or ACOs. We recognize the value in the use of primary care-focused measures and in developing the proposed measure set for use under the APP, we have sought to preserve the measures we believe most reflect high priority quality measurement areas while also placing more emphasis on outcome-based claims measures, which minimize

reporting burden and reflect greater opportunity for improvement.

In addition to the measures listed in Table 36, based on recommendations from MedPAC in its 2015 Report to Congress: Medicare and the Health Care Delivery System,[33] we are considering adding a ''Days at Home'' measure that is currently under development, to the APP core measure set in future years, once it has been through the MAP pre-rulemaking process. Any future additions to the measure set, including to add a ''Days at Home'' measure would be proposed and finalized through notice and comment rulemaking.

We welcome public comment on our proposal to apply the APP framework to determine the quality performance of Shared Savings Program ACOs.

In addition, we note that we have received feedback from a few ACOs, including ACOs that have a significant number of beneficiaries in long-term care facilities or who are chronically ill or high-risk home bound patients, that the measures ACOs are required to report are not always applicable to their patient population. Although we are proposing to require ACOs to report via the APP, we are also seeking comment on an alternative approach that could be used in the event the three measures ACOs are required to actively report on are not applicable to their beneficiary population and there are more appropriate measure available under MIPS. Under this alternate approach, ACOs could opt out of the APP and report to MIPS as an APM entity. If the ACO decides to report as an APM entity to MIPS outside of the APP, CAHPS for MIPS would become optional; however, the ACO would be required to report PI and IA and would also be subject to cost under MIPS. In the event an ACO decides to report as an APM entity to MIPS outside the APP, we would use the ACO's MIPS Quality performance category score to determine if the ACO met the Shared Savings Program quality performance standard.

We seek comment on this alternative reporting approach for ACOs in the event the three measures ACOs are required to actively report are not applicable to their beneficiary population.

c. Shared Savings Program Quality Performance Standard

The quality performance standard is the minimum performance level ACOs must achieve in order to share in any savings earned, avoid maximum losses under certain payment tracks, and avoid quality-related compliance actions. We are proposing to increase the level of quality performance that would be required for all ACOs to meet the Shared Savings Program quality performance standard. We believe the proposed changes would simplify the Shared Savings Program quality performance standard and are also consistent with the statutory requirement that we seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures or both (section 1899(b)(3)(C) of the Act). We are proposing to increase the quality performance standard for all ACOs to achievement of a quality performance score equivalent to the 40th percentile or above across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. We are excluding entities/providers eligible for facility-based scoring from the overall MIPS quality score because facility-based scoring is determined using the Hospital Value Based Purchasing (HVBP) Total Performance Score (TPS) which includes quality and cost.

Given that the statute requires that we seek to increase the quality performance standard over time, we believe changing the quality performance standard from the 30th percentile on one measure in each domain to a requirement that ACOs achieve a quality performance score equivalent to the 40th percentile or above across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, is the next incremental step in increasing the quality performance standard. Under the current Shared Savings Program quality measurement methodology, 99.6 percent or 546 ACOs participating in the program in 2018 met the quality performance standard of complete and accurate reporting for ACOs in the first year of their first agreement period or the 30th percentile on one measure in each domain, for ACOs in their second or subsequent years of participation in the program. Of these ACOs, 425 were ACOs in second or subsequent years of participation in the program for which most quality measures were scored as pay-for-performance (P4P). We analyzed quality measure data from 2018 to simulate how many ACOs would achieve a quality performance score that was at or above the 40th percentile of MIPS Quality performance category scores. Based on our analysis using 2018 data to simulate 2021 MIPS Quality performance category scores, we estimate 95 percent of ACOs would achieve a quality performance score at or above the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scores. We recognize that this impact could change if the 40th percentile across all MIPS Quality performance category scores improves relative to ACOs' quality performance scores, or alternatively if ACOs, particularly ACOs at risk of failing, respond to the methodology change by boosting their performance. The impact could range from 98 percent of ACOs achieving a quality performance score at or above the 40th percentile to 92 percent of ACOs reflecting the respective extreme scenarios assumed in the previous sentence.

Eligible clinicians participating in Shared Savings Program ACOs who obtain QP status would continue to be exempt from MIPS, and therefore, would not be subject to APP scoring under MIPS. For eligible clinicians in an ACO that is participating in a track (or payment model within a track) that is an Advanced APM who do not meet the threshold to earn QP status but do meet the lower payment and patient count threshold to achieve Partial QP status, the ACO can elect to report on behalf of the Partial QPs, and the Partial QPs would be subject to a MIPS payment adjustment under the APP framework. Conversely, if an ACO does not elect to report for the Partial QPs, they would not receive a MIPS score or payment adjustment and would have no reporting responsibilities for MIPS. Utilizing the MIPS Quality performance category scoring methodology to assess the quality performance for purposes of the Shared Savings Program of ACOs participating in tracks (or payment models within a track) that qualify as an Advanced APM would not change whether the 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.

We propose to specify in a new section of the Shared Savings Program regulations at § 425.510, policies on the application of the APP to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021. This new section would include a general provision specifying that CMS establishes quality performance measures to assess the quality of care furnished by the ACO. If the ACO demonstrates to CMS that it has satisfied the quality performance

[33] *http://medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf.*

requirements, and meets all other applicable requirements, the ACO is eligible to receive shared savings. This general provision also indicates that CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. This new section of the regulations would also specify the requirement that ACOs must report quality data via the APP established under § 414.1367 according to the method of submission established by CMS. In addition, this new section of the regulation would also specify that CMS retains the right to audit and validate quality data reported by an ACO according to § 414.1390 of this chapter.

We also propose to specify in a new section of the Shared Savings Program regulations at § 425.512 provisions for determining the ACO quality performance standard for performance years beginning on or after January 1, 2021. We propose to specify that the quality performance standard is the overall standard the ACO must meet in order to be eligible to receive shared savings for a performance year. Further, we propose to specify that for all ACOs, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367, according to the method of submission established by CMS and achievement of a quality performance score equivalent to the 40th percentile or above across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. In addition, we propose to specify that if an ACO does not report any of the three of the measures ACOs are actively required to report and does not field a CAHPS survey, the ACO would not meet the quality performance standard.

In addition, we propose to modify the existing Shared Savings Program regulation at § 425.508, on incorporating quality reporting requirements related to the Quality Payment Program. We propose to add a provision applicable to 2021 and subsequent performance years, which specifies that ACOs must submit quality data via the APP established under § 414.1367 to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category. We also propose related technical and conforming modifications to § 425.508.

We seek comment on our proposal to revise the Shared Savings Program quality performance standard.

d. Use of ACO Quality Performance in Determining Shared Savings and Shared Losses

Section 1899(d)(1)(A) of the Act specifies an ACO is eligible to receive a shared savings payment for a portion of the savings generated for Medicare, provided that the ACO meets both the quality performance standards established by the Secretary and achieves the required level of savings against its historical benchmark. Section 1899(d)(2) of the Act provides the authority for the actual payments for shared savings under the Shared Savings Program. Specifically, if an ACO meets the quality performance standards established by the Secretary (according to section 1899(b)(3) of the Act), and meets the savings requirements, a percent (as determined appropriate by the Secretary) of the difference between the estimated average per capita Medicare expenditures in the year, adjusted for beneficiary characteristics, and the benchmark for the ACO, may be paid to the ACO as shared savings and the remainder of the difference shall be retained by the Medicare program. The Secretary is required to establish limits on the total amount of shared savings paid to an ACO. We have also incorporated performance-based risk in the form of shared losses into certain financial models using the authority under section 1899(i)(3) of the Act to use other payment models.

The Shared Savings Program's one-sided shared savings only models, and two-sided shared savings and shared losses models are specified in subpart G of the Shared Savings Program regulations. For agreement periods beginning on July 1, 2019, and in subsequent years, eligible ACOs may participate under either: (1) The BASIC track, which includes a glide path consisting of five levels (Levels A through E) that allows eligible ACOs to begin under a one-sided model (Level A or Level B) and incrementally phases-in higher levels of risk and potential reward (Levels C, D, or E) (§ 425.605); or (2) the ENHANCED track, a two-sided model with the highest level of risk and potential reward (§ 425.610). Further, according to the May 8th COVID–19 IFC (85 FR 27574 and 27575), ACOs that entered a first or second agreement period with a start date of January 1, 2018, whose participation agreements expire December 31, 2020, may elect to extend their agreement period for an optional fourth performance year, spanning January 1, 2021, to December 31, 2021. This includes ACOs that entered agreement periods under Track 1 (a one-sided model), Track 2 (a two-sided model), and the ENHANCED track. Further, this option to elect a 12-month extension of the agreement period also applies to ACOs participating in the Track 1+ Model whose participation agreements expire December 31, 2020.

Under the Shared Savings Program regulations, for both one-sided models and two-sided models, CMS uses the ACO's quality performance to determine the ACO's eligibility to receive shared savings, and the rate at which ACOs share in these savings. We base the final shared savings rate on the ACO's quality performance. For ACOs meeting the quality performance standard, the final shared savings rate is equal to the product of the ACO's quality score and the maximum sharing rate. The maximum sharing rate is specific to the ACO's track/level of participation as follows: 50 percent for ACOs participating in Track 1;[34] 60 percent for ACOs participating in Track 2;[35] 40 percent for ACOs participating in Level A or Level B of the BASIC track;[36] and 50 percent for ACOs participating in Levels C, D, or E of the BASIC track;[37] and 75 percent for ACOs participating in the ENHANCED track.[38] The upside of the Track 1+ Model is based on Shared Savings Program Track 1; therefore, a maximum sharing rate of 50 percent applies to Track 1+ Model ACOs.[39]

Depending on the track, the ACO's quality performance may also be used to determine the amount of the ACO's shared losses, for ACOs under two-sided models. ACOs participating in the Track 1+ Model, and Level C, D, or E of the BASIC track are subject to a fixed shared loss rate (also referred to as the loss sharing rate) of 30 percent regardless of quality performance.[40] Under Track 2 and the ENHANCED track, the shared loss rate is calculated as one minus the ACO's final shared savings rate based on quality performance, up to a maximum of 60 percent or 75 percent, respectively, and the shared loss rate

[34] Refer to § 425.604(d).

[35] Refer to § 425.606(d).

[36] Refer to § 425.605(d)(1)(i)(A), (d)(1)(ii)(A).

[37] Refer to § 425.605(d)(1)(iii)(A), (d)(1)(iv)(A), (d)(1)(v)(A).

[38] Refer to § 425.610(d).

[39] Refer to the Track 1+ Model Participation Agreement, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf.*

[40] Provisions specifying the shared loss rate for two-sided models of the BASIC track are specified in § 425.605(d)(1)(iii)(C), (d)(1)(iv)(C), (d)(1)(v)(C). The shared loss rate applicable to Track 1+ Model ACOs is specified in the Track 1+ Model Participation Agreement.

may not be less than 40 percent for both tracks.[41] For ENHANCED track ACOs, this 40 percent minimum shared loss rate is expressly stated in the current regulations, whereas for Track 2 ACOs, it is the implicit minimum shared loss rate as calculated based on the inverse of the maximum final shared savings rate for the track. Track 2 and ENHANCED track ACOs that do not meet the quality performance standard for the performance year will be accountable for shared losses based on the highest shared loss rate for their track.

In light of the proposed changes to the Shared Savings Program's quality performance standard addressed elsewhere in section III.G.1. of this proposed rule, we also propose modifications to the regulations that specify the circumstances under which an ACO will qualify for a shared savings payment based on its quality performance and the determination of the rate at which the ACO will share in savings based on its quality performance.

For all tracks, we propose to specify, in revisions to the regulations, the requirements that must be met for an ACO to qualify for a shared savings payment for performance years beginning on or after January 1, 2021. We propose that to qualify for shared savings, an ACO must meet the minimum savings rate requirements established for the track/level, meet the proposed quality performance standard described in section III.G.1.c. of this proposed rule, and otherwise maintain its eligibility to participate in the Shared Savings Program under part 425. We propose to revise §§ 425.604(c) (Track 1), 425.605(c) (BASIC track), 425.606(c) (Track 2), and 425.610(c) (ENHANCED track) to reflect these requirements.

We also propose revisions to the provisions establishing the final sharing rate for all tracks. We propose that for performance years beginning on or after January 1, 2021, if an ACO that is otherwise eligible to share in savings meets the proposed quality performance standard as described in section III.G.1.c. of this proposed rule, the ACO will share in savings at the maximum sharing rate according to the applicable financial model, up to the performance payment limit. We propose that if the ACO fails to meet the proposed quality performance standard, the ACO would be ineligible to share in savings. We propose to specify these policies in revisions to the provisions governing Track 1 (§ 425.604(d)), the BASIC track (§ 425.605(d)(1)(i)(A) (Level A), (d)(1)(ii)(A) (Level B), (d)(1)(iii)(A) (Level C), (d)(1)(iv)(A) (Level D), (d)(1)(v)(A) (Level E)), Track 2 (§ 425.606(d)), and the ENHANCED track (§ 425.610(d)).

We also propose modifications to the methodology for determining shared losses under Track 2 and the ENHANCED track, for performance years beginning on or after January 1, 2021, to account for the proposed revisions to the quality performance standard. If the ACO meets the quality performance standard as proposed (see section III.G.1.c. of this proposed rule), we would determine the shared loss rate as follows:

- *Step 1:* Calculate the quotient of the MIPS quality performance category points earned divided by the total MIPS quality performance category points available.
- *Step 2:* Calculate the product of the quotient described in step 1 and the sharing rate for the relevant track, either 60 percent for Track 2 or 75 percent for the ENHANCED track.
- *Step 3:* Calculate the shared loss rate as 1 minus the product determined in step 2. Consistent with the existing structure of the financial models: Under Track 2, the shared loss rate may not exceed 60 percent, and may not be less than 40 percent; under the ENHANCED track, the shared loss rate may not exceed 75 percent, and may not be less than 40 percent.

Under this proposed approach, for an ACO that meets the quality performance standard we would take into consideration the ACO's quality score when determining the ACO's share of losses. An ACO with a higher quality score would owe a lower amount of losses compared to an ACO with an equivalent amount of losses but a lower quality score, so long as the ACO's quality score results in a shared loss rate within the range between the minimum shared loss rate (40 percent) and the maximum shared loss rate (60 percent under Track 2, or 75 percent under the ENHANCED track). To the extent the ACO's quality score results in a shared loss rate outside these limits, the shared loss rate is set to the minimum or maximum rate (as applicable). We also propose to revise the regulation at § 425.606(f) to expressly state both the minimum and maximum shared loss rates for Track 2.

We propose that if the ACO fails to meet the quality performance standard as proposed (see section III.G.1.c. of this proposed rule), the shared loss rate would be 60 percent under Track 2 or 75 percent under the ENHANCED track. We believe this approach would maintain symmetry with the proposed approach to determining shared savings under Track 2 and the ENHANCED track based on quality performance. Thus, an ACO that fails to meet the quality performance standard would be ineligible to share in savings and would owe the maximum amount of shared losses.

We propose to specify these provisions for determining the shared loss rate under Track 2 and the ENHANCED track, for performance years beginning on or after January 1, 2021, through modifications to the regulations at §§ 425.606(f) and 425.610(f). We also propose technical and conforming changes to these provisions for clarity, and to specify that the current policy would continue to apply for purposes of determining the shared loss rate for Track 2 ACOs and ENHANCED track ACOs for performance years (or a performance period) beginning on or before January 1, 2020.

e. Compliance With the Quality Performance Standard

(1) Background

As discussed in more detail in section III.G.1.c. of this proposed rule, the quality performance standard is the minimum performance level ACOs must achieve in order to share in any savings earned, avoid maximum losses under certain payment tracks, and avoid quality-related compliance actions. Section 1899(d)(4) of the Act authorizes the Secretary to terminate an agreement with an ACO that does not meet the established quality performance standards. Through earlier rulemaking we established an approach to enforce ACO compliance with the quality performance standards, as specified in the Shared Savings Program regulations at § 425.316 (see 76 FR 67951, 80 FR 32818 and 32819, 81 FR 80492 through 80494).

To identify ACOs that do not meet the established quality performance standards, we review the ACO's quality data submission. Under our current policies, as specified in § 425.316(c), if an ACO does not meet quality performance standards or fails to report on one or more quality measures, in addition to actions set forth at §§ 425.216 and 425.218, we will take the following actions:

- The ACO may be given a warning for the first time it fails to meet the minimum attainment level on at least 70 percent of the measures, as determined under § 425.502, in one or more domains and may be subject to a corrective action plan (CAP). CMS may forgo the issuance of the warning letter

[41] Refer to §§ 425.606(f), 425.610(f).

depending on the nature and severity of the noncompliance and instead subject the ACO to actions set forth at § 425.216 or immediately terminate the ACO's participation agreement under § 425.218.

- The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet the quality performance standards in the following year, the agreement will be terminated.
- An ACO will not qualify to share in savings in any year it fails to report accurately, completely, and timely on the quality performance measures.

Further, according to § 425.224(b), in evaluating the eligibility of a renewing ACO or re-entering ACO to enter a new participation agreement with CMS for participation in the Shared Savings Program, we consider the ACO's history of noncompliance with the program's quality performance standard. For evaluating ACOs that entered into a participation agreement for a 3-year period, we consider whether the ACO failed to meet the quality performance standard during 1 of the first 2 performance years of the previous agreement period. For evaluating ACOs that entered into a participation agreement for a period longer than 3 years, we consider whether the ACO failed to meet the quality performance standard for 2 consecutive performance years and was terminated as specified in § 425.316(c)(2), or whether the ACO failed to meet the quality performance standard for 2 or more performance years of the previous agreement period, regardless of whether the years were consecutive.

The terms ''renewing ACO'' and ''re-entering ACO'' are defined in the regulations at § 425.20. We define renewing ACO to mean an ACO that continues its participation in the program for a consecutive agreement period, without a break in participation, because it is either: (1) An ACO whose participation agreement expired and that immediately enters a new agreement period to continue its participation in the program; or (2) an ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program. We define re-entering ACO to mean an ACO that does not meet the definition of a renewing ACO and meets either of the following conditions: (1) Is the same legal entity as an ACO that previously participated in the program and is applying to participate in the program after a break in participation, because the ACO's participation agreement expired without having been renewed, or the ACO's participation agreement was terminated under § 425.218 or § 425.220; or (2) is a new legal entity that has never participated in the Shared Savings Program and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list under § 425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date.

(2) Proposed Revisions

We have revisited the provisions of § 425.316(c) on monitoring compliance with quality reporting and performance requirements in light of our proposed modifications to the quality performance standard. We propose to modify the introductory text at § 425.316(c) to state that we will review an ACO's submission of quality measurement data to identify ACOs that are not meeting the applicable quality performance standard under §§ 425.500 or 425.512. Under the provision, as revised, we would retain the discretion to request additional documentation from an ACO, ACO participants, or ACO providers/suppliers. Further, we believe that in conjunction with our proposed changes to the quality performance standard, it is appropriate to strengthen our policies for compliance with the quality performance standard by broadening the conditions under which CMS may terminate an ACO's participation agreement when the ACO demonstrates a pattern of failure to meet the quality performance standard.

As currently structured, the regulation at § 425.316 does not specify what actions CMS will take when an ACO fails to meet the quality performance standard for multiple, nonconsecutive performance years, or 2 consecutive performance years that span 2 agreement periods (that is, the last performance year of an agreement period and the first performance year of the subsequent agreement period). Accordingly, we are proposing a new approach that CMS would follow to monitor for and address an ACO's continued noncompliance with the applicable quality performance standard for performance years beginning on or after January 1, 2021. Noncompliance with the quality performance standard during earlier performance years would continue to be subject to the rules currently set forth at § 425.316(c)(1) through (3), which we propose would be consolidated at § 425.316(c)(1). For performance years beginning on or after January 1, 2021, we propose that when CMS determines an ACO fails to meet the quality performance standard (as described in section III.G.1.c. of this proposed rule), CMS may take the actions prior to termination set forth at § 425.216, and may terminate the ACO's participation agreement according to § 425.218. In addition to the actions set forth at §§ 425.216 and 425.218, we propose to adopt a specific approach that CMS would follow to monitor for and address an ACO's continued noncompliance with the quality performance standard.

We propose that ACOs exhibiting a pattern of failure to meet the quality performance standard will be terminated from the program. Specifically, we propose to terminate an ACO's participation agreement when the ACO fails to meet the quality performance standard for 2 consecutive performance years within an agreement period or fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order. We also propose that we will terminate the participation agreement of a renewing ACO or a re-entering ACO if the ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period. In addition, we propose that we will terminate the participation agreement of a renewing ACO or a re-entering ACO if the ACO fails to meet the quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period. We propose to amend § 425.316(c)(2) to reflect this new approach.

Our proposal to terminate an ACO if it fails to meet the quality performance standard for 2 consecutive performance years within an agreement period is consistent with our current approach. However, we also propose to terminate an ACO's participation agreement if the ACO fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether these years are in consecutive order. In the December 2018 final rule (83 FR 67831), we extended participation agreements from 3-years to 5-years. ACOs participating under a 5-year agreement period may show a pattern of failure to

meet the quality performance standard in performance years that are not consecutive. Therefore, we believe it is important to continue to monitor ACOs throughout their 5-year agreement period and if an ACO fails to meet the quality performance standard for 3 nonconsecutive performance years we propose to terminate their participation agreement.

Additionally, we are concerned that a renewing ACO's quality performance results for the last performance year of the current agreement period will not be available for us to consider in reviewing the ACO's application to renew its agreement, as currently provided in § 425.224(b)(1)(ii)(A). We have a similar concern with respect to some re-entering ACOs (particularly, an ACO that notifies CMS of its decision to terminate its participation agreement and subsequently submits an application to re-enter the program for the next start date following the effective date of its termination). To prevent these ACOs from remaining in the program, despite a pattern of noncompliance with the quality performance standard, we propose that if we determine that the last performance year of the ACO's previous agreement period was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the prior agreement period, CMS would terminate the ACO's new participation agreement. For example, if an ACO failed to meet the quality performance standard in the first, third and fifth performance years of a 5-year agreement period, or failed to meet the quality performance standard in the fourth and fifth performance years of a 5-year agreement period, results for the fifth performance year would not be available until after the ACO has renewed and entered a new agreement period. In both examples, we would anticipate determining during the first performance year of the ACO's new agreement period that the ACO had failed to meet the quality performance standard for the last performance year of its previous agreement period. Therefore, CMS would terminate the ACO's new participation agreement during the first performance year of that agreement period.

Furthermore, we are concerned an ACO could have a pattern of failing to meet the quality performance standard for consecutive years spanning 2 agreement periods. Therefore, if a renewing or re-entering ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods (the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period), we propose to terminate the ACO's participation agreement. We would anticipate that quality performance results for the ACO's first performance year of its new agreement period would be available during the second performance year of the ACO's new agreement period. Therefore, CMS would terminate the ACO's new participation agreement during the second performance year of the new agreement period.

We recognize there is additional complexity in the application of these policies to a new ACO that is identified as a re-entering ACO because of its ACO participants' prior participation in another Shared Savings Program ACO. Under the proposed approach, we would apply to the re-entering ACO the other ACO's quality performance for previous years (prior to the start of the re-entering ACO's agreement period) and would terminate the re-entering ACO if the other ACO is determined to have failed to meet the quality performance standard in 2 consecutive performance years within an agreement period, or if the other ACO is determined to have failed to meet the quality performance standard for 3 performance years (in nonconsecutive order) within an agreement period. Consistent with the proposed approach, this could occur in circumstances when the other ACO's most recent performance year of failed quality performance is determined after the start of the new, re-entering ACO's agreement period. Further, under the proposed approach, we would also consider whether the other ACO failed to meet the quality performance standard in the most recent performance year prior to the start of the new, re-entering ACO's agreement period, and whether the new, re-entering ACO also fails to meet the quality performance standard for its first performance year. Because these 2 performance years of failed quality performance would be consecutive, we would terminate the participation of the new, re-entering ACO.

Because a significant percentage of the ACO participants in the new, re-entering ACO were previously participating in this other ACO, we believe it is appropriate to hold the new, re-entering ACO accountable for the quality performance of the other ACO. According to the definition of re-entering ACO, more than 50 percent of the entity's ACO participants must have participated together in the same ACO within a 5-performance year lookback period. As a result, over half of the new, re-entering ACO's ACO participants can be considered to have contributed to the failed quality performance of this other ACO. If we were to disregard the recent failed quality performance of this other ACO, these ACO participants would be allowed to continue participation in the Shared Savings Program as part of the new, re-entering ACO, and potentially take advantage of program flexibilities, despite a pattern of noncompliance with the quality performance standard.

We propose implementing these policies starting with performance year 2021 and subsequent years. We acknowledge that an ACO currently participating under a performance agreement spanning 5-years could fail the quality performance standard for a performance year starting in 2019 under § 425.502. The same ACO could then again fail the quality performance standard under the proposed § 425.512 in performance years 2021 and 2023. In this scenario, the ACO will have failed the quality performance standards for 3 nonconsecutive years under the same agreement period, but the ACO would not be terminated in this scenario because the proposed policies would apply starting with performance year 2021. However, if the ACO decides to apply as a renewing or re-entering ACO, we would review its history of noncompliance with the requirements of the Shared Savings Program as provided under § 425.224(b)(1) when determining whether to approve its application.

Under the current regulation at § 425.316(c)(3), an ACO will not qualify to share in savings in any year in which it fails to report accurately, completely, and timely on the quality performance measures. Consistent with the proposed revisions to the quality performance standard under the Shared Savings Program discussed in section III.G.1.c. of this proposed rule, we propose to specify in the proposed new provision at § 425.512 that, for performance years beginning on or after January 1, 2021, an ACO will not qualify to share in savings in any year it fails to meet the quality performance standard.

The termination of an ACO's participation agreement for failure to meet the quality performance standard under the proposed approach described in this section of the proposed rule, would also make the ACO subject to the payment consequences of early termination as specified in § 425.221(b). Under § 425.221(b)(1)(ii), if the participation agreement is terminated at any time by CMS under § 425.218, the ACO is not eligible to receive shared

savings for the performance year during which the termination becomes effective. Under § 425.221(b)(2)(ii)(B), an ACO participating under a two-sided model whose participation agreement is terminated by CMS under § 425.218 is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective. These policies would apply whenever an ACO is terminated for non-compliance with the quality performance standard in accordance with § 425.316(c).

We propose to revise § 425.316(c) to incorporate this proposed approach for monitoring ACO compliance with the quality performance standard for performance years beginning on or after January 1, 2021. We also propose to make other technical and conforming changes to the regulations at § 425.316(c). In particular, we propose to amend the existing provisions for monitoring ACO compliance with the quality performance standards to specify that those provisions are applicable to performance years (or a performance period) beginning on or before January 1, 2020.

We also continue to believe in the importance of considering an ACO's history of noncompliance with the quality performance standard in evaluating the eligibility of a renewing ACO or a re-entering ACO to enter a new agreement period under the Shared Savings Program. In light of our proposed changes to § 425.316(c), we propose to make conforming changes to § 425.224(b)(1)(ii)(A), which authorizes CMS to approve or deny a renewing ACO's or re-entering ACO's application to participate in the Shared Savings Program based on an evaluation of the ACO's history of non-compliance with the quality performance standard. Specifically, we propose to revise § 425.224(b)(1)(ii)(A) to state that as part of its evaluation of a renewing or re-entering ACO's history of noncompliance with the requirements of the Shared Savings Program, we will evaluate whether the ACO demonstrated a pattern of failure to meet the quality performance standards or met any of the criteria for termination under §§ 425.316(c)(1)(ii) or 425.316(c)(2)(ii).

f. Updating the Process Used To Validate ACO Quality Data Reporting

In the CY 2017 PFS final rule, we finalized modifications to the quality measures validation audit process. These modifications changed the overall audit process from a 3-phased medical record review to an audit conducted in a single phase. Under our current process, if selected for an audit, an ACO must provide beneficiary medical records data to substantiate the quality data reported by the ACO. As part of the audit, CMS calculates an overall audit match rate, which is derived by dividing the total number of audited records that match the information reported in the CMS Web Interface by the total number of the medical records audited. For example: (1) If the ACO has an audit match rate of 90 percent or above it will pass the audit; (2) if the ACO has an audit match rate of less than 90 percent, but greater than 80 percent, the ACO may be required to submit a CAP under § 425.216 for CMS approval; (3) if the ACO has an audit match rate of less than 80 percent, absent unusual circumstances, we will adjust the ACO's overall quality score proportional to the ACO's audit match rate, which may have implications for the ACO's financial reconciliation.

Under our proposal to align the quality reporting requirements under the Shared Savings Program with quality reporting under the APP framework, we believe it would be appropriate to also align with the MIPS Data Validation and Audit (DVA) process (§ 414.1390). Rather than continuing to validate ACO quality data reporting under the Shared Savings Program, we believe that it would be more appropriate for MIPS to validate the data submitted by ACOs for the three measures in the APP framework, as ACOs will be able to select the submission method for these measures and the MIPS DVA is based on submission method. We believe streamlining the approach to data validation and audit would minimize administrative burden associated with the audit for ACOs as they would only need to track to one validation process, and for ACOs in a track (or payment model within a track) that does not meet the definition of an Advanced APM, the results of the audit would be applicable for purposes of both the Shared Savings Program and MIPS.

We propose to address the audit and validation of data used to determine the ACO's quality performance in a new provision we are proposing to add to the Shared Savings Program regulations at § 425.510(c). Specifically, we propose that CMS would retain the right to audit and validate the quality data reported by an ACO under § 425.510(b) according to § 414.1390.

g. Changes to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2021

As discussed in section III.G.1.c. of this proposed rule, we are proposing to make changes to the quality performance standard for the Shared Savings Program for the performance year beginning on January 1, 2021, and subsequent performance years. However, we continue to believe it is appropriate to adjust the quality performance scores for ACOs affected by extreme and uncontrollable circumstances. Accordingly, we propose to update the extreme and uncontrollable circumstances policy under the Shared Savings Program consistent with our proposal to align the quality reporting requirements for the Shared Savings Program with the proposed APP. Specifically, for performance year 2021 and subsequent performance years, we would set the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, to equal the 40th percentile MIPS Quality performance category score. If the ACO is able to report quality data and meet the MIPS data completeness and case minimum requirements, we would use the higher of the ACO's MIPS Quality performance category score or the 40th percentile MIPS Quality performance category score. If an ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we would apply the 40th percentile MIPS Quality performance category score. We believe this approach is appropriate as it aligns with the threshold for meeting the quality performance standard allowing impacted ACOs to share in savings at their maximum sharing rate. We acknowledge that using the 40th percentile may not offer the same level of protection for ACOs incurring losses that would receive the higher of their ACO quality score or the mean ACO score under the current policy. Our simulation of the 2018 MIPS quality data shows that the mean MIPS quality performance category score is between the 45th and 46th percentile, which is lower than the ACO quality mean score under the current scoring methodology. However, for ACOs in Track 2 and the ENHANCED track under which shared losses are determined based in part on an ACO's quality performance, ACOs are also afforded relief from shared losses through the application of the extreme and uncontrollable circumstances policy under which shared losses are reduced based on the percentage of the year and percentage of assigned beneficiaries impacted by an

extreme and uncontrollable circumstance.

Under the proposed revisions to the quality reporting requirements, we will no longer generate a CMS Web Interface quality reporting sample for ACOs because ACOs will no longer be reporting measures via the Web Interface; therefore, we propose to determine the percentage of the ACO's performance year assigned beneficiary population that was affected by an extreme and uncontrollable circumstances based on the quarter four list of assigned beneficiaries, rather than the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, which is currently used. We believe that using the quarter four list of assigned beneficiaries is an appropriate alternative because the file is generated after the end of the fourth quarter and would offer a more complete representation of the population of assigned beneficiaries that reside in an area that is impacted by an extreme and uncontrollable circumstance during the performance year. We seek comment on these proposed revisions to the extreme and uncontrollable circumstances policy for performance year 2021 and subsequent performance years.

In addition, we are soliciting comment on a potential alternative extreme and uncontrollable circumstances policy for performance year 2022 and subsequent years that would continue to incentivize reporting but also acknowledge the challenges presented by extreme and uncontrollable circumstances. We are considering creating an extreme and uncontrollable circumstances methodology that would adjust the amount of shared savings determined for affected ACOs that complete quality reporting but do not meet the quality performance standard or that are unable to complete quality reporting. This methodology would be similar to the methodology currently used to adjust for extreme and uncontrollable circumstances when calculating the amount of shared losses for impacted ACOs. Under this alternative approach, instead of determining that ACOs are affected by an extreme and uncontrollable circumstances if 20 percent of their beneficiaries or their legal entity are located in an area impacted by an extreme and uncontrollable circumstance and determining shared savings using the higher of the ACO's own quality score and the mean ACO quality score, we would determine shared savings for an affected ACO by multiplying the maximum possible shared savings the ACO would be eligible to receive based on its financial performance and track (or payment model within a track) by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance. To illustrate this potential approach, we provide an example of a hypothetical ACO, ACO A, which in this example was impacted by an extreme and uncontrollable circumstance that lasted for six months of the year and during that time, 50 percent of its assigned beneficiaries resided in the impacted area. For this example, we assume that ACO A did not quality report and would have earned $100,000 in shared savings if it had met the quality performance standard. In this example, we would multiply the percentage of the total months in the performance year impacted by the extreme and uncontrollable circumstance by the percentage of the ACO's assigned beneficiaries who resided in the impacted area by the amount of shared savings if the ACO had met the quality performance standard; 0.50 * 0.50 * $100,000 = $25,000. Under this alternative, ACO A's shared savings would be $25,000.

As another example, if ACO B were impacted by an extreme and uncontrollable circumstance for nine months of the year, had 50 percent of its assigned beneficiaries residing in the impacted area, and did report quality data but did not meet the quality performance standard of a score equivalent to a MIPS Quality performance category score at the 40th percentile, and ACO B would have earned $100,000 in shared savings if it had met the quality performance standard; 0.75 * 0.50 * $100,000 = $37,500. Under this alternative, ACO B's shared savings would be $37,500.

As illustrated by the above examples, under this potential future approach, the amount of shared savings that an ACO impacted by an extreme and uncontrollable circumstance would be eligible to receive would be greater than the amount an ACO that was not disaster impacted would be eligible to receive if it did not report quality or did report quality but did not obtain a score equivalent to a MIPS Quality performance category score at or above the 40th percentile. An ACO that was not disaster impacted and that either did not report quality or did report quality but did not obtain a quality performance category score equivalent to or higher than a MIPS Quality performance category score at or above the 40th percentile would not meet the quality performance standard and would not be eligible to receive any shared savings. In contrast, an ACO impacted by an extreme and uncontrollable circumstance would be eligible to receive an adjusted amount of shared savings, even if it did not quality report or did report quality but had a quality performance score that was lower than the 40th percentile of MIPS Quality performance category scores. The final amount of shared savings would be dependent on the degree to which the ACO's assigned beneficiaries were disaster impacted during the relevant performance year.

If an ACO impacted by an extreme and uncontrollable circumstance does not report quality or does not meet the quality performance standard of a quality performance score equivalent to a MIPS Quality performance category score at or above the 40th percentile and owes shared losses, then the existing extreme and uncontrollable circumstances methodology that applies when calculating the amount of shared losses would help to mitigate those losses. We note that historically the majority of disaster-impacted ACOs report quality. For example, for performance years (or a performance period) starting in 2019, when all ACOs were determined to be impacted by the PHE for COVID–19, which was declared during the quality reporting period, 98.7 percent of ACOs completely reported via the CMS Web interface. Given the historically high rates of quality reporting by ACOs impacted by extreme and uncontrollable circumstances and the fact that, under our proposed revisions to the quality performance standard, ACOs would share in the maximum level of savings available under their track (or payment model within a track) if they meet the quality performance standard, we believe it is important to consider an extreme and uncontrollable circumstances policy that looks at the actual impact of an extreme and uncontrollable circumstance on a disaster-impacted ACO, and provides for an adjusted amount of shared savings if the ACO does not report or does not meet the quality performance standard.

We seek comment on this potential alternative extreme and uncontrollable circumstances policy for future years.

We propose to specify our proposed policies for addressing the effect of extreme and uncontrollable circumstances on ACO quality performance for performance year 2021 and subsequent performance years in the proposed new provision at

§ 425.512. In addition, we propose to include policies that parallel the existing policies, as specified in § 425.502(f), for determining when an extreme and uncontrollable circumstance has occurred and identifying affected ACOs. In particular, we propose to include a provision, similar to the current provision at § 425.502(f)(1), to establish our policies for determining whether an ACO has been an affected by an extreme and uncontrollable circumstance. We also propose to include a provision, similar to the provision at § 425.502(f)(2), to establish the policies that would apply for calculating an affected ACO's quality performance score. Similar to the existing provision at § 425.502(f)(3), we propose to specify that we would apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred, and the affected areas. Consistent with the existing policy under § 425.502(f)(4), this new provision would also specify that we have sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity.

h. Proposed Technical Changes To Incorporate References to Revised Quality Performance Standard

We propose to make certain technical, conforming changes to the following provisions to reflect our proposal to add new sections of the regulations at § 425.510 on the application of the APP to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021, and § 425.512 on determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

- Under subpart A, which specifies general provisions governing the Shared Savings Program:

++ In § 425.100(b), the general description of ACOs that are eligible to receive payments for shared savings under the program would be revised for clarity and to add a reference to § 425.512. In the description of the quality performance standard that must be met for the ACO to be receive payment for shared savings, we propose to specify that the quality performance standards established under § 425.500 are applicable for performance years (or a performance period) beginning on or before January 1, 2020, and that the proposed quality performance standard under § 425.512 is applicable for performance years beginning on or after January 1, 2021.

++ In § 425.112(b)(2)(i), the provision specifying the ACO must have processes to promote patient engagement including to address compliance with patient experience of care survey requirements, would be revised to add a reference to § 425.510.

- Under subpart C, which governs application procedures and the participation agreement, we would add a reference to § 425.510 in the provision at § 425.200(d) specifying that ACOs must submit measures in the form and manner required by CMS.
- Under subpart D, which specifies program requirements and beneficiary protections, we would add a reference to § 425.510 in § 425.302(a)(1) specifying requirements for data submission and certification.
- Under subpart G, which specifies the program's financial models for determining shared savings and shared losses (as applicable), we propose to revise the description of program requirements that phase-in over multiple agreement periods in § 425.600(f)(4). Under the proposed revisions to the quality performance standard, measurement of an ACO's quality performance would no longer phase-in over the course of the ACO's first agreement period from pay-for-reporting in the first performance year to pay-for-performance in all subsequent performance years; rather, all ACOs, regardless of performance year and agreement period, would be scored on all the measures in the APP. Therefore, we propose to revise § 425.600(f)(4)(i) to specify that the reference to the quality performance standard as described in § 425.502(a) is applicable for performance years (or a performance period) beginning on or before January 1, 2020.
- Under subpart I, which governs the reconsideration review process, we would add references to § 425.510, § 425.512, or both to § 425.800(a)(1), (a)(2) and (a)(6).

2. Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

a. Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) Codes Used in Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). However, the statute does not specify which kinds of services may be considered primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by CPT and HCPCS codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services, if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking to reflect additions or modifications to the codes that have been recognized for payment under the Medicare PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program.

In the June 2015 final rule (80 FR 32746 through 32748), we expanded the definition of primary care services to include two transitional care management (TCM) codes (CPT codes 99495 and 99496), and one chronic care management (CCM) code (CPT 99490). As discussed in the final rule, the TCM codes were established to pay a patient's physician or practitioner to coordinate the patient's care in the 30 days following a hospital or SNF stay. Including these codes in the definition of primary care services reflects our belief that the work of community physicians and practitioners in managing a patient's care following discharge from a hospital or nursing facility (NF) to ensure better continuity of care for these patients and help reduce avoidable readmissions is a key aspect of primary care.

In the CY 2016 PFS final rule (80 FR 71270 through 71273), we revised the definition of primary care services to exclude services billed under CPT codes 99304 through 99318, containing the place of service 31 modifier specifying that the service was furnished in a SNF. We also revised the definition of primary care services to include claims submitted by Electing Teaching Amendment (ETA) hospitals.

In the CY 2018 PFS final rule, we revised the definition of primary care services to include three additional CCM service codes, 99487, 99489, and

G0506, and four behavioral health integration (BHI) service codes, G0502, G0503, G0504 and G0507 (82 FR 53212 and 53213). We further revised the definition of primary care services in the November 2018 final rule. In the November 2018 final rule, we added new codes to the definition of primary care services (CPT codes 99497, 99498, 96160, 96161, 99354, and 99355, and HCPCS codes G0444, G0442, and G0443), and revised how we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF (83 FR 59964 through 59968).

For performance years beginning on January 1, 2019, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(iv) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

CPT codes:

(1) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(2) 99304 through 99318 (codes for professional services furnished in a NF; services identified by these codes furnished in a SNF are excluded).

(3) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(4) 99341 through 99350 (codes for evaluation and management services furnished in a patients' home for claims identified by place of service modifier 12).

(5) 99487, 99489 and 99490 (codes for chronic care management).

(6) 99495 and 99496 (codes for transitional care management services).

(7) 99497 and 99498 (codes for advance care planning).

(8) 96160 and 96161 (codes for administration of health risk assessment).

(9) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code).

(10) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

HCPCS codes:

(1) G0402 (the code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0463 for services furnished in ETA hospitals.

(4) G0506 (code for chronic care management).

(5) G0444 (codes for annual depression screening service).

(6) G0442 (code for alcohol misuse screening service).

(7) G0443 (code for alcohol misuse counseling service).

In the May 8th COVID–19 IFC (85 FR 27582 through 27586), we revised the regulations to add § 425.400(c)(2), specifying the definition of primary care services for purposes of beneficiary assignment for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the COVID–19 PHE defined in § 400.200, to include the foregoing codes specified in § 425.400(c)(1)(iv), as well as specified codes for remote evaluations, virtual check-ins, e-visits, and telephone evaluation and management services.

(2) Proposed Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes currently recognized for payment under the PFS, we believe it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes and make other technical changes to the definition of primary care services, for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years.

We propose to revise the definition of primary care services in the Shared Savings Program regulations to include the following additions: (1) Online digital evaluation and management CPT codes 99421, 99422, and 99423; (2) assessment of and care planning for patients with cognitive impairment CPT code 99483; (3) chronic care management code CPT code 99491; (4) non-complex chronic care management HCPCS code G2058 and its proposed replacement CPT code, if finalized through the CY 2021 PFS rulemaking; (5) principal care management HCPCS codes G2064 and G2065; and (6) psychiatric collaborative care model HCPCS code GCOL1, if finalized through the CY 2021 PFS rulemaking.

The following provides additional information about the CPT and HCPCS codes that we are proposing to add to the definition of primary care services used in assignment:

- *Online Digital Evaluation and Management Services (CPT codes 99421, 99422, and 99423):* In the CY 2020 PFS final rule (84 FR 62797), we finalized payment for new online digital assessment services, also referred to as ''E-Visits,'' beginning in CY 2020 for practitioners billing under the PFS. These services are non-face-to-face, patient-initiated communications using online patient portals. These digital assessment services are for established patients who require a clinical decision that otherwise typically would have been provided in the office. Practitioners who may independently bill Medicare for evaluation and management (E/M) services (for instance, physicians and NPs) can bill the following codes:

++ *99421 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes.)*

++ *99422 (Online digital evaluation and management service, for an established patient, for up to 7 days cumulative time during the 7 days; 11–20 minutes.)*

++ *99423 (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.)*

In the May 8th COVID–19 IFC (85 FR 27583), we stated that we believe it is appropriate to include these CPT and HCPCS codes in the definition of primary care services used for assignment for PY 2020 and any subsequent performance year that starts during the COVID–19 PHE because the services represented by these codes are being used in place of similar E/M services, the codes for which are already included in the list of codes used for assignment. We also explained our belief that it is important to include these services in our assignment methodology because we determine assignment to ACOs based upon where beneficiaries receive the plurality of their primary care services or whether they have designated an ACO professional as their primary clinician, responsible for their overall care, and hold ACOs accountable for the resulting assigned beneficiary population. Subsequent to the publication of the May 8th COVID–19 IFC, we have determined, based on the justification above, that these codes should be included in the definition of primary care services under § 425.400(c) permanently for purposes of determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years, and should not be linked to the duration of the COVID–19 PHE.

- *Assessment of and care planning for patients with cognitive impairment (CPT code 99483):* In the CY 2017 PFS final rule (81 FR 80252–54), we finalized a G-code that would provide separate payment to recognize the work of a physician (or other appropriate

billing practitioner) in assessing and creating a care plan for beneficiaries with cognitive impairment, such as from Alzheimer's disease or dementia, at any stage of impairment, G0505 (*Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home*). In the CY 2018 PFS final rule (82 FR 53077), we deleted the interim HCPCS code G0505 and replaced it with CPT code 99483 (*Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (e.g., Basic and Instrumental Activities of Daily Living), including decision-making capacity; Use of standardized instruments for staging of dementia (e.g., Functional Assessment Staging Test [FAST], Clinical Dementia Rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (e.g., home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neurocognitive symptoms, functional limitations, and referral to community resources as needed (e.g., rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family caregiver).*

CPT code 99483 includes the same elements included in the Level 5 E/M service CPT code 99215, such as, a comprehensive history, comprehensive exam, and high complexity medical decision-making. CPT code 99215 is included in the definition of primary care services used for assignment. Accordingly, we believe it would be appropriate to also include CPT code 99483 in the definition of primary care services used for assignment under § 425.400(c) for the performance year starting on January 1, 2021, and subsequent performance years.

- *Chronic Care Management (CPT code 99491):* In the CY 2019 PFS final rule (83 FR 59577), we finalized CPT code 99491 (*Chronic care management services, provided personally by a physician or other qualified healthcare professional, at least 30 minutes of physician or other qualified health care professional time, 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).* This code requires two or more chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, and that a comprehensive care plan has been established, implemented, revised or monitored by the billing practitioner for such patient. In earlier rulemaking, we finalized the inclusion of CCM CPT codes 99487, 99489, and 99490 (codes for chronic care management) in the definition of primary care services for the Shared Savings Program. Refer to the June 2015 final rule (80 FR 32746 through 32748), and CY 2018 PFS final rule (82 FR 53212 through 53213). ''Non-complex'' CCM services (CPT codes 99490 and 99491), and ''complex'' CCM services (CPT codes 99487 and 99489) share a common set of service elements, including the following: (1) Initiating visit, (2) structured recording of patient information using certified electronic health record technology (EHR), (3) 24/7 access to physicians or other qualified health care professionals or clinical staff and continuity of care, (4) comprehensive care management including systematic assessment of the patient's medical, functional, and psychosocial needs, (5) comprehensive care plan including a comprehensive care plan for all health issues with particular focus on the chronic conditions being managed, and (6) management of care transitions. They differ in the amount of clinical staff service time provided, the involvement and work of the billing practitioner, and the extent of care planning performed.[42] CPT code 99491 includes only time that is spent personally by the billing practitioner. Clinical staff time is not counted towards the required time threshold for reporting this code, whereas CPT codes 99487, 99489, and 99490 include time spent directly by the billing practitioner and by other clinical staff that counts toward the threshold clinical staff time required to be spent during a given month. Accordingly, CPT code 99491 cannot be reported for a beneficiary by a billing practitioner in the same month as CCM codes 99487, 99489, or 99490. Therefore, we believe it would be appropriate to propose to include CCM CPT code 99491 in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2021, and subsequent performance years, in order to capture these CCM services when attributing beneficiaries to an ACO.

- *Non-Complex CCM (HCPCS code G2058 and its proposed replacement CPT code):* In the CY 2020 PFS final rule (84 FR 62690), we finalized the creation of HCPCS code G2058 *(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). (Do not report G2058 for care management services of less than 20 minutes additional to the first 20 minutes of chronic care management services during a calendar month). (Use G2058 in conjunction with 99490). (Do not report 99490, G2058 in the same calendar month as 99487, 99489, 99491))* for additional time spent beyond the initial 20 minutes included in the current coding for CCM services. As described elsewhere in this proposed rule, we are proposing the adoption of the permanent CPT code to replace HCPCS code G2058. As described in previous rulemaking, practitioners who choose to use G2058 can report the initial 20 minutes of non-complex CCM under CPT code 99490 and receive increased payment for their work under HCPCS code G2058 (84 FR 62690). Since CPT code 99490 is currently included in the Shared Savings Program's definition of primary care services under § 425.400(c)(1)(iv), we are proposing to add G2058 to the definition, effective for performance years starting on or after January 1, 2021, because the services furnished during the additional time billed under HCPCS code G2058, would be expected to be substantially similar to the services furnished under CPT code 99490, and thus should also be

[42] Refer to CMS Medicare Learning Network, MLN Booklet ''Chronic Care Management Services'' (ICN MLN909188, July 2019); available at: *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf.*

considered for purposes of assignment under § 425.400 for the performance year starting on January 1, 2021, and subsequent performance years. If the proposal to adopt the permanent CPT code to replace HCPCS code G2058 is finalized, we would instead include that CPT code in the definition of primary care services used for purposes of assignment under § 425.400(c) for the performance year starting on January 1, 2021, and subsequent performance years.

• *Principal Care Management (HCPCS codes G2064 and G2065):* The CY 2020 PFS final rule (84 FR 62692 through 62697) introduced two new HCPCS codes (G2064 and G2065) for Principal Care Management (PCM) services. G2064 *(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),* for use by physicians and non-physician practitioners (NPPs), and G2065 *(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),* for use by clinical staff.

We expect that most services billed under these codes will be billed by specialists who are focused on managing patients with a single complex chronic condition requiring substantial care management. HCPCS code G2064 would be reported when, during the calendar month, at least 30 minutes of physician or other qualified health care professional time is spent on comprehensive care management for a single high-risk disease or complex chronic condition. HCPCS code G2065 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. Comprehensive care management codes require patients to have two or more chronic conditions and 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. By contrast, PCM services involve care management services for one serious chronic condition, typically expected to last between 3 months and a year, or until the death of the patient, that may have led to a recent hospitalization, and/or places the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. Specifically, we stated in the CY 2020 PFS final rule (84 FR 62693 through 62697) that we agree that the relativity between CCM CPT codes 99490 and 99491 should be preserved in PCM HCPCS codes G2064 and G2065 and crosswalked the relative value units for G2064 and G2065 to 99491 and 99490, respectively. 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 finalized that the full CCM scope of service requirements apply to PCM, including documenting the patient's verbal consent in the medical record. CCM services billed under code 99490 are currently included in the Shared Savings Program's definition of primary care services under § 425.400(c)(1)(iv), and as discussed previously, we are proposing to include CCM services billed under code 99491 for performance years starting on or after January 1, 2021; therefore, for the foregoing reasons, we also propose to add G2064 and G2065 to the definition of primary care services for the performance year starting on January 1, 2021, and subsequent performance years.

• *Psychiatric collaborative care model HCPCS code GCOL1:* In the CY 2017 PFS final rule (81 FR 80230–36), we established G-codes used to bill for monthly services furnished using the Psychiatric Collaborative Care Model (CoCM), an evidence-based approach to behavioral health integration that enhances ''usual'' primary care by adding care management support and regular psychiatric inter-specialty consultation. These G-codes were replaced by CPT codes 99484, 99492, 99493, and 99494, which we established for payment under the PFS in the CY 2018 PFS final rule (82 FR 53077 and 53078).

Elsewhere in this proposed rule, we are proposing to add a new HCPCS code GCOL1 *(Initial or subsequent psychiatric collaborative care management, first 30 minutes in a 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)* in response to stakeholders who have requested additional coding to capture shorter increments of time spent, for example, when a patient is seen for services, but is then hospitalized or referred for specialized care, and the number of minutes required to bill for services using the current coding is not met. Specifically, we are proposing to establish a G-code to describe 30 minutes of behavioral health care manager time. This code would describe one-half of the time described by the existing code that describes subsequent months of CoCM services, 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).

Because CPT code 99493 is currently included in the Shared Savings Program's definition of primary care services under § 425.400(c)(iv), we believe it is appropriate to add GCOL1 to the definition since the services furnished under this proposed new code would be expected to be substantially similar to the services furnished under CPT code 99493. Accordingly, contingent upon its finalization, we propose to add HCPCS code GCOL1 to the definition of primary care services for purposes of assignment under § 425.400 for the performance year starting on January 1, 2021, and subsequent performance years.

In the May 8th COVID–19 IFC (85 FR 27583), we revised the definition of primary care services used in the Shared Savings Program assignment methodology for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for the COVID–19 pandemic, as defined in § 400.200, to include the following additions: (1) HCPCS code G2010 (*remote evaluation of patient video/images*); (2) HCPCS code G2012 (*virtual check-in*); and (3) CPT codes 99441, 99442, and 99443 (*telephone evaluation and management services*).

We considered adding HCPCS codes 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)* and G2012 *(Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report E/M 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)* to the definition of primary care services for purposes of assignment under § 425.400 for the performance year starting on January 1, 2021, and subsequent performance years; however, while we recognize the importance of the flexibility these HCPCS codes provide during the PHE, we do not believe they should be added to definition of primary care services for purposes of assignment under § 425.400 on a permanent basis. In the context of the PHE for the COVID–19 pandemic, when brief communications with practitioners and other non-face-to-face services could mitigate the need for an in-person visit that could represent an exposure risk for vulnerable patients, health care providers, and individuals in the community, we concluded that it was appropriate to include HCPCS codes G2010 and G2012 in the definition of primary care services used in assignment. However, outside the context of the PHE for the COVID–19 pandemic, we expect that these monitoring/check-in services for established patients will no longer replace primary care services because these separately billable brief communication-technology based services describe a check-in directly with the billing practitioner to assess whether an office visit is needed. When the PHE for the COVID–19 pandemic ends, these services would likely be replaced by an in-person primary care visit on which assignment would be based.

We seek comment on this issue and on the alternative approach of permanently including HCPCS codes G2010 and G2012 in the definition of primary care services used in assignment. We will consider the comments received in developing our policies for the final rule.

We note that we did not consider including CPT codes 99441, 99442, and 99443 in the definition of primary care services at § 425.400(c) on a permanent basis. Telephone evaluation and management services CPT codes 99441 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian 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.*); 99442 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian 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; 11–20 minutes of medical discussion.*); and 99443 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian 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; 21–30 minutes of medical discussion.*) are non-covered services when not provided during the PHE for the COVID–19 pandemic, as defined in § 400.200, and so could not be included in the definition of primary care services for purposes of assignment outside the context of the PHE.

We also propose to modify the definition of primary care services for purposes of assignment in the Shared Savings Program regulations to exclude advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting, for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. In the November 2018 final rule (83 FR 59964 through 59968), we finalized the inclusion of CPT code 99497 and the add-on code 99498 in the definition of primary care services. We did not propose any exceptions to place of service or provider type because there are no facility setting limitations or provider specialty limitations on these codes.[43] We have since received feedback from an ACO that, by not restricting place of service when using advance care planning codes in assignment, our methodology may inappropriately assign beneficiaries. Specifically, we are concerned that the inclusion of these CPT codes when the services are provided in an inpatient care setting may result in beneficiaries being assigned based on inpatient care rather than based on primary care by their regular health care providers. Based on an initial analysis using calendar year 2019 claims data, we observed the following frequencies for occurrence of place of service code 21, which identifies the place of service as an inpatient hospital, with CPT codes 99497 and 99498 in Part B claims: Over 13 percent of approximately 1.6 million Part B claims for CPT code 99497 had place of service code 21; over 48 percent of approximately 43,000 Part B claims for CPT code 99498 had place of service code 21. Operationally, we would exclude advanced care planning services claims billed under CPT codes 99497 and 99498 from use in the assignment methodology when there is

[43] Refer to CMS, Medicare Learning Network, ''Advance Care Planning'' (ICN MLN909289, August 2019); available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AdvanceCarePlanning.pdf*.

an inpatient facility claim in our claims files with dates of service that overlap with the date of service for the professional service billed under CPT code 99497 or add-on code 99498. A similar operational approach is currently used to exclude certain codes for professional services furnished in a SNF pursuant to § 425.400(c)(1)(iv)(A)(*2*), as described elsewhere in this section of this proposed rule.

We are also seeking comment on an alternative method for determining operationally whether advance care planning services are provided in an inpatient care setting. Specifically, we seek comment on whether to exclude advance care planning services identified by CPT code 99497 or add-on code 99498, or both, reported on claims with place of service code 21, which identifies the place of service as an inpatient hospital.[44] Based on initial analysis, we determined that this alternative approach would capture slightly fewer claims for advance care planning, compared to the proposed approach. We will consider any comments received on this alternative approach in developing our policies for the final rule.

We propose to specify a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(v) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(iv) with the proposed additional CPT and HCPCS codes, and reflecting the proposal to exclude advance care planning codes when provided in an inpatient setting in the new provision at § 425.400(c)(1)(v)(A)(*12*). We also propose that the new provision in § 425.400(c)(1)(v) would reflect technical modifications to the previously finalized descriptions of the CPT and HCPCS codes for consistency and clarity, including grammatical updates and ordering the codes sequentially. We propose the new provision at § 425.400(c)(1)(v) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. Further, we propose technical modifications to the introductory text in § 425.400(c)(1)(iv) to specify the applicability of this provision for determining beneficiary assignment for performance years (or a performance period) during 2019 and performance year 2020.

We seek comment on these proposed changes to the definition of primary care services used for assigning beneficiaries to Shared Savings Program ACOs for the performance year starting on January 1, 2021, and subsequent performance years. We also welcome comments on any other existing HCPCS or CPT codes, and new HCPCS or CPT codes proposed elsewhere in this proposed rule, that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

We note that, under § 425.212, an ACO is subject to all regulatory changes that become effective during the agreement period, with the exception of the following program areas, unless otherwise required by statute: (1) Eligibility requirements concerning the structure and governance of ACOs; and (2) calculation of sharing rate. As we have explained in earlier rulemaking, consistent with our authority under section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark for beneficiary characteristics and other factors as the Secretary determines appropriate, CMS adjusts an ACO's historical benchmark to account for any regulatory changes affecting assignment during the agreement period (80 FR 32730 through 32732). Accordingly, if we finalize any of the proposed changes to the definition of primary care services discussed in section III.G.2. of this proposed rule for purposes of beneficiary assignment applicable for the performance year starting on January 1, 2021, and subsequent performance years, we will adjust ACOs' historical benchmarks to account for these changes. Although it has been our historical practice to make these adjustments, the regulations establishing our benchmarking methodology do not explicitly describe these adjustments. We believe it is timely to propose conforming revisions to the regulations in §§ 425.601(a)(9), 425.602(a)(8), and 425.603(c)(8), to specify that CMS will adjust the ACO's historical benchmark to reflect any changes to the beneficiary assignment methodology specified in 42 CFR part 425, subpart E during an ACO's agreement period including revisions to the definition of primary care services in § 425.400(c). Further, in light of these proposed changes, we propose to make certain other technical changes to §§ 425.601, 425.602, and 425.603 for clarity and internal consistency.

b. Exclusion From Assignment of Certain Services Reported by FQHCs or RHCs When Furnished in Skilled Nursing Facilities (SNFs)

(1) Background

As we described in section III.G.2.a.(1) of this proposed rule, under the Shared Savings Program, we define primary care services in § 425.400(c)(1) and § 425.400(c)(2) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the specified HCPCS and CPT codes. In the November 2018 final rule (83 FR 59965 through 59968), we finalized a policy, specified in the regulation at § 425.400(c)(1)(iv)(A)(*2*) and effective for performance years starting on January 1, 2019, and subsequent performance years, to exclude services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF. As described in the earlier rulemaking, CPT codes 99304 through 99318 are used for reporting E/M services furnished by physicians and other practitioners in a SNF or NF (83 FR 59964).

In the November 2018 final rule, we explained our operational approach to excluding CPT codes 99304 through 99318 from use in the assignment methodology when such services are furnished in a SNF. We explained that we would exclude professional services claims billed under CPT codes 99304 through 99318 from use in the assignment methodology when there is a SNF facility claim in our claims files with dates of service that overlap with the date of service for the professional service (83 FR 59967). This exclusion methodology replaced the prior approach, established through earlier rulemaking (80 FR 71271 and 71272), which excluded from the definition of primary care services claims billed under CPT codes 99304 through 99318 when the claim included the place of service code 31 modifier, specifying that the service was furnished in a SNF.

In earlier rulemaking (see for example, 83 FR 59964 and 59965), we have explained our belief that excluding from assignment certain services rendered to beneficiaries during a SNF stay is appropriate because it helps to ensure that beneficiaries who receive care in a SNF are assigned to ACOs based on care received from primary care professionals in the community (including nursing facilities), who are typically responsible for providing care to meet the primary care needs of these beneficiaries. We previously explained that SNF patients are shorter stay patients who are generally receiving continued acute medical care and

[44] See for example, CMS.gov, Place of Service Code Set (updated October 2019); available at *https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.*

rehabilitative services. Although their care may be coordinated during their time in the SNF, they are then transitioned back into the community to the primary care professionals who are typically responsible for providing care to meet their primary care needs.

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, requires the Secretary to assign beneficiaries to ACOs participating in the Shared Savings Program based not only on their utilization of primary care services furnished by ACO professionals who are physicians but also on their utilization of services furnished by FQHCs and RHCs, effective for performance years beginning on or after January 1, 2019. The statute provides the Secretary with broad discretion to determine how to incorporate services provided by FQHCs and RHCs into the Shared Savings Program beneficiary assignment methodology.

In earlier rulemaking, we established and modified special assignment conditions for FQHCs and RHCs (see for example, 82 FR 53210 through 53212). According to § 425.404(b), for performance years starting on January 1, 2019, and subsequent performance years, under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC or RHC claim as a primary care service performed by a primary care physician. Therefore, according to the Shared Savings Program's step-wise claims-based assignment methodology, as specified in § 425.402(b), all services furnished by an FQHC or RHC to a beneficiary eligible for assignment to an ACO are considered in the first step of the assignment methodology. As specified in § 425.402(b)(3), under this first step, a beneficiary eligible for assignment is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are ACO professionals in any other ACO, or not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

Currently, the exclusion from beneficiary assignment of professional services claims with CPT codes 99304 through 99318, when there is an overlapping SNF stay, does not apply to services billed through FQHCs/RHCs. Because FQHC/RHC claims are submitted to CMS using institutional claim forms, we currently do not exclude these FQHC/RHC claims from assignment when a service billed under CPT codes 99304 through 99318 is provided concurrently with a SNF stay, as when claims for services billed under these codes are submitted by physicians and other practitioners. Rather, consistent with the requirement in § 425.404(b), we consider all FQHC/RHC claims for purposes of beneficiary assignment.

(2) Proposal

An ACO has raised concerns that our methodology for excluding primary care services billed under CPT codes 99304 through 99318 from use in beneficiary assignment when provided during a beneficiary's stay in a SNF does not apply to these services when billed by FQHCs. The ACO described a circumstance where ACO professionals, billing through ACO participant FQHCs, submitted claims using CPT codes 99304 through 99318 for services provided to patients in SNFs. Specifically, the ACO participant FQHCs' physicians provided services billed under these codes to beneficiaries in community SNFs. Following discharge from the SNF, these beneficiaries returned to receiving care from their regular primary care physicians (outside the ACO). However, because the SNF exclusion for services billed under CPT codes 99304 through 99318 does not apply to services furnished by FQHCs/RHCs, these beneficiaries were assigned to the ACO in which the FQHC was an ACO participant based on the services rendered in the SNF. We believe this result is contrary to the original intention of our policy of excluding claims billed under CPT codes 99304 through 99318 for professional services furnished during a SNF stay from consideration in the assignment methodology, as described in the background for this section.

Section 1899(c)(1) of the Act provides discretion for the Secretary to determine the appropriate method to utilize services provided by FQHCs and RHCs in conducting assignment for performance years beginning on or after January 1, 2019. We believe it is important to exclude claims for FQHC and RHC services that include CPT codes 99304 through 99318 from use in assignment when there is a SNF facility claim in our claims files with a date of service that overlaps with the date of FQHC or RHC services. Consistent with the previously established exclusion for claims billed under these codes when the services are provided to beneficiaries with an overlapping SNF stay, we believe it is important to exclude the same services from use in assignment when they are furnished by physicians and NPPs billing through an FQHC or RHC to beneficiaries in a SNF. This approach would better recognize that beneficiaries who receive care from physicians and NPPs billing through an FQHC or RHC during a SNF stay are expected to return to receiving primary care from the health care professionals typically responsible for meeting their primary care needs when they transition back into the community.

Therefore, we propose to revise the existing exclusion for professional services billed under CPT codes 99304 through 99318 that are furnished in a SNF to include services reported on an FQHC or RHC claim that includes CPT codes 99304 through 99318, when those services are furnished in a SNF. Operationally, the exclusion would occur when the following conditions are met:

(1) Either a professional service is billed under CPT codes 99304 through 99318, or an FQHC/RHC submits a claim including a qualifier CPT code 99304 through 99318; and

(2) A SNF facility claim is in our claims files with dates of service that overlap with the date of service for the professional service or FQHC/RHC service.

As discussed in section III.G.2.a.(2) of this proposed rule, we are proposing to incorporate the revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(v), applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. As part of this revised definition, we propose to incorporate the proposed revisions to the exclusion for CPT codes 99304 through 99318 when services are furnished in a SNF at § 425.400(c)(1)(v)(A)(*3*) to extend the exclusion to services identified by these codes reported on an FQHC or RHC claim when furnished in a SNF. This revision would also be applicable to determining assignment for the performance year starting on January 1, 2021, and subsequent performance years.

As we explained in section III.G.2.a.(2) of this proposed rule, we adjust the ACO's historical benchmark for changes in the program's assignment methodology occurring during the ACO's agreement period. If we finalize the proposed exclusion from beneficiary assignment of services reported by FQHCs or RHCs on claims that include CPT codes 99304 through 99318, when

furnished in a SNF, we will adjust ACOs' historical benchmarks to account for these changes.

Further, we believe the existing process is appropriately excluding from assignment professional services billed under CPT codes 99304 through 99318 when these services are provided to beneficiaries receiving SNF services in swing beds in Critical Access Hospitals (CAHs) or Electing Teaching Amendment (ETA) hospitals. Based on our operational experience:

- We exclude professional services billed under CPT codes 99304 through 99318 when such services are furnished for care of a beneficiary in a CAH swing bed; however, relatively few claims are identified for exclusion on this basis.
- We do not believe that ETA hospitals are billing for services furnished to beneficiaries in a SNF or swing bed setting by physicians and other practitioners that have reassigned their billing rights to ETA hospitals.

However, we solicit comment on whether additional exceptions are needed to ensure that all claims for services that include CPT codes 99304 through 99318 are excluded from assignment when those services are furnished to a beneficiary receiving SNF care, including when these professional services are billed by a Method II CAH or ETA hospital.

3. Reducing the Amount of Repayment Mechanisms for Eligible ACOs

a. Background

An ACO that will participate in a two-sided model must demonstrate that it has established an adequate repayment mechanism to provide CMS assurance of its ability to repay shared losses for which the ACO may be liable upon reconciliation for each performance year. The requirements for an ACO to establish and maintain an adequate repayment mechanism are described in § 425.204(f), and we have provided additional program guidance on repayment mechanism arrangements.[45] We established the repayment mechanism requirements through earlier rulemaking,[46] and most recently modified the repayment mechanism requirements in the December 2018 final rule (83 FR 67928 through 67938).

According to § 425.204(f)(4)(iv), in the case of an ACO that has submitted a request to renew its participation agreement and wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the amount of the repayment mechanism must be equal to the greater of the following: (1) The amount calculated by CMS in accordance with § 425.204(f)(4)(ii) at the time of renewal application; or (2) the repayment mechanism amount that the ACO was required to maintain during the last performance year of the participation agreement it seeks to renew. This approach ensures that a renewing ACO would remain capable of repaying losses incurred under its old agreement period (83 FR 67931). Based on our operational experience with implementing these policies, of 55 renewing two-sided model ACOs for a July 1, 2019, or January 1, 2020 start date, 43 ACOs (or 78.2 percent) elected to continue use of their existing repayment mechanism, and 22 (or 51.2 percent) of these ACOs had a higher existing repayment mechanism amount compared to the amount calculated for the new agreement period (determined at the time of renewal application).

Alternatively, to meet the requirements of § 425.204(f), a renewing ACO could establish a new repayment mechanism arrangement to support its participation in its new agreement period, in addition to maintaining its existing repayment mechanism. This option allows an ACO to establish a repayment mechanism to support its new agreement period at a potentially different amount (determined according to § 425.204(f)(4)(ii)) than the amount of the existing arrangement. However, under this approach there is a period of time during which the ACO must maintain multiple repayment mechanisms. The ACO must maintain the repayment mechanism established to support the ACO's previous agreement period until the term of the repayment mechanism arrangement expires, or conditions arise to allow for termination of the repayment mechanism according to § 425.204(f)(6)(iv) (see 83 FR 67933 through 67936). Once the repayment mechanism for the previous agreement period is closed, the ACO would only be required to maintain the repayment mechanism arrangement applicable to its current agreement period. An ACO could use this option to establish a repayment mechanism at a relatively lower amount (if applicable) for its current agreement period, while maintaining and eventually closing-out a repayment mechanism at a relatively higher amount needed for its previous agreement period.

As specified under § 425.204(f)(4)(iii), for agreement periods beginning on or after July 1, 2019, CMS recalculates the ACO's repayment mechanism amount before the second and each subsequent performance year in the agreement period based on the certified ACO participant list for the relevant performance year. We require an increase in the repayment mechanism amount if the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least 50 percent or $1,000,000, whichever is the lesser value. Under § 425.204(f)(4)(iii), an ACO cannot decrease the amount of its repayment mechanism during its agreement period as a result of changes in its composition.

In implementing the revised repayment mechanism rules, we have discovered some unintended consequences. Specifically, under § 425.204(f)(4), a renewing ACO that chooses to retain its higher repayment mechanism for a new agreement period might never be able to reduce its repayment mechanism even after the ACO has paid any shared losses incurred for performance years in the previous agreement period. Moreover, the ACO would have to maintain the higher repayment mechanism amount in future agreement periods unless the ACO opts to establish a new repayment mechanism. We did not intend this result.

More generally, based on our operational experience, many ACOs fully repay shared losses without use of their repayment mechanism arrangement. For example, of the eleven ACOs that owed shared losses for performance year 2018, CMS used the repayment mechanism for one ACO to support recoupment. Considering this experience, which suggests there may be low risk to the Shared Savings Program by allowing lower repayment mechanism amounts, and the potential reduction in burden on ACOs by lower repayment mechanism amounts, we believe it is appropriate to revisit the policies requiring renewing ACOs to retain higher repayment amounts when these amounts may no longer be needed to support their continued participation.

b. Proposed Revisions

We propose to establish two policies that would allow certain ACOs to benefit from a lower repayment mechanism amount than would otherwise be required under the current

[45] Medicare Shared Savings Program, Repayment Mechanism Arrangements, Guidance Document, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Repayment-Mechanism-Guidance.pdf* (herein Repayment Mechanism Arrangements Guidance).

[46] See 76 FR 67937 through 67940 (establishing the requirement for Track 2 ACOs). See 80 FR 32781 through 32785 (adopting the same general requirements for Track 3 ACOs with respect to the repayment mechanism and discussing modifications to reduce burden of the repayment requirements on ACOs).

regulations. The first policy would apply prospectively to any renewing ACO that uses an existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in its new agreement period. The second policy would permit certain ACOs whose agreement periods began July 1, 2019 or January 1, 2020 to elect to reduce the amount of their repayment mechanisms.

For a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, we propose to discontinue the policy specified under § 425.204(f)(4)(iv), which requires such an ACO to maintain its existing repayment mechanism amount if it is higher than the repayment mechanism amount calculated for the new agreement period in accordance with § 425.204(f)(4)(ii). We propose to revise the regulations to specify that we will determine the repayment mechanism amount for an ACO applying to renew its participation for an agreement period only according to the methodology currently specified in § 425.204(f)(4)(ii). Under this proposed approach, a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period would be required to have a repayment mechanism amount equal to the lesser of the following: (1) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

As specified in the May 8th COVID–19 IFC (85 FR 27574 and 27575), we are forgoing the application cycle for the January 1, 2021 start date. Therefore, if finalized, this proposed policy for determining the repayment mechanism amount for renewing ACOs would apply with the application cycle for an agreement period starting on January 1, 2022, and in subsequent years.

A renewing ACO could still choose to establish a new repayment mechanism arrangement for the amount calculated at the time of the renewal application to support its participation in its new agreement period and maintain its existing repayment mechanism at the previously required amount. Once the conditions arise for termination of the repayment mechanism arrangement supporting the ACO's previous agreement period, according to § 425.204(f)(6)(iv), only the arrangement supporting the ACO's current agreement period would remain.

We believe this proposed approach would reduce burden by allowing renewing ACOs that wish to continue use of their existing repayment mechanism to decrease their repayment mechanism amount if a higher amount is not needed to support their new agreement period. This proposal would prevent a higher repayment mechanism amount from following the ACO from one agreement period to the next, as is the case with the current approach. Further, an ACO would no longer need to establish another repayment mechanism for the ACO's new agreement period to ultimately get relief from the higher amount of its existing repayment mechanism arrangement, which the ACO would need to maintain until the conditions arise allowing for termination.

We recognize this proposal would reduce the amount available to support repayment of shared losses. The typical timing of issuance to ACOs of financial reconciliation, which includes performance results and written notification from CMS of the amount of shared losses owed (if any), is in the summer following the conclusion of the performance year. Renewing ACOs permitted to reduce the amount of their existing repayment mechanism may be notified of shared losses owed for their most recent prior performance year during the application review period and would be in the process of paying shared losses within 90 days of written notification from CMS of the amount owed (according to §§ 425.605(e)(3), 425.606(h)(3), 425.610(h)(3)). Further, at the time of renewal application, the ACO would be completing the last performance year of its existing agreement period, and financial reconciliation results for this performance year would likely be available during the summer of the ACO's first performance year of its new agreement period.

However, we believe this risk to CMS noted above is mitigated for a number of reasons. The Shared Savings Program's existing policies require ACOs to pay shared losses, in full, within 90 days of written notification from CMS of the amount owed (according to §§ 425.605(e)(3), 425.606(h)(3), 425.610(h)(3)). ACOs have an interest in fully paying the amount of shared losses owed within the 90-day payment window to remain in compliance with the Shared Savings Program's requirements and avoid compliance actions including involuntary termination from the program. CMS may terminate an ACO's participation agreement for reasons including, but not limited to, non-compliance with requirements in 42 CFR part 425 (§ 425.218(b)(1)), such as failure to repay shared losses owed according to the program's regulations and may take pre-termination actions as described in § 425.216. Under § 425.221(b)(2)(ii)(B), an ACO under a two-sided model whose participation agreement is terminated by CMS under § 425.218 is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective. ACOs must also repay shared losses owed to avoid accruing interest on any amount that remains unpaid after the 90-day payment window, and referral of an unpaid debt to the Department of Treasury for collection. Based on our operational experience, nearly all ACOs fully repay shared losses without use of their repayment mechanism arrangement.

Nevertheless, we are considering finalizing a policy that would require a renewing ACO to maintain its existing, higher repayment mechanism amount until the ACO has fully repaid the amount of shared losses determined to be owed for the most recent performance year for which financial reconciliation results are available. Under this approach, for instance, § 425.204(f)(4)(iv) would remain unchanged, and we would amend § 425.204(f)(4)(iii) to add a provision permitting a renewing ACO to reduce the amount of its repayment mechanism if, upon renewal of its participation agreement, it chose to use its existing repayment mechanism to demonstrate its ability to pay shared losses in the new agreement period, and was required under § 425.204(f)(4)(iv) to maintain its existing repayment mechanism at the amount applicable to the last performance year of the previous agreement period instead of the lower amount calculated for the new agreement period.

The Shared Savings Program regulations do not address the opportunity for a re-entering ACO, defined according to § 425.20, to use a repayment mechanism arrangement established to support its participation in an earlier agreement period to also support its participation in a new agreement period. We are considering finalizing provisions in the Shared Savings Program regulations specifying the conditions under which a re-entering ACO may use an existing

repayment mechanism arrangement to support its participation in a subsequent agreement period in the Shared Savings Program. Specifically, we are considering specifying a re-entering ACO identified as the same legal entity as an ACO that previously participated in the program may use its existing repayment mechanism to support its participation in a new agreement period in the Shared Savings Program. Since an individual ACO, identified as a legal entity, enters into a repayment mechanism arrangement with a financial institution, we do not believe this option for continued use of an existing repayment mechanism would be feasible for (and therefore would not be applicable to) a new legal entity identified as a re-entering ACO because more than 50 percent of its ACO participants were included on the ACO participant list under § 425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date. Further, we are considering specifying the same requirements would apply to both a renewing ACO, and a re-entering ACO identified as the same legal entity that previously participated in the Shared Savings Program (either an ACO whose participation agreement expired without having been renewed, or an ACO whose participation agreement was terminated under § 425.218 or § 425.220), for permitting use of an existing repayment mechanism arrangement to support the ACO's participation in a new agreement period in the Shared Savings Program.

We also propose to establish a policy that allows certain ACOs a one-time opportunity to decrease the amount of their repayment mechanisms. Under this proposal, an ACO that renewed its agreement period beginning on July 1, 2019, or January 1, 2020, may elect to decrease the amount of its repayment mechanism if (1) upon renewal, it elected to use an existing repayment mechanism to establish its ability to repay any shared losses incurred in its new agreement period and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated for the ACO's new agreement period; and (2) the recalculated repayment mechanism amount for performance year 2021 is less than the existing repayment mechanism amount. We note that this proposal would not need to be finalized if we finalize our alternate proposal to modify § 425.204(f)(4)(iii) as described above. The purpose of this new opportunity is to let any ACO that renewed for an agreement period beginning on July 1, 2019, or beginning on January 1, 2020, decrease its repayment mechanism amount before it seeks to renew its agreement under the new proposed policy, which if finalized, would be the first opportunity for the ACO to reduce its repayment mechanism amount.

To determine if an ACO that renewed for an agreement period beginning on July 1, 2019, or beginning on January 1, 2020, is eligible for the one-time opportunity to lower its repayment mechanism amount we propose to compare the recalculated amount of the ACO's repayment mechanism based on its certified ACO participant list for performance year 2021, calculated according to § 425.204(f)(4)(iii), to the ACO's existing repayment mechanism amount. If the recalculated repayment mechanism amount for performance year 2021 is less than the existing repayment mechanism amount, the ACO would be eligible to decrease the amount of its repayment mechanism to the recalculated amount. Under this approach, we would permit a decrease in the repayment mechanism amount even for relatively small differences in dollar amounts. An ACO may wish to maintain the existing amount of its repayment mechanism arrangement, particularly if the cost to the ACO of amending the arrangement outweighs the potential benefit of a nominal decrease in the amount of the repayment mechanism.

We propose that CMS would notify the ACO in writing that the ACO may elect to decrease the amount of its repayment mechanism. If our proposal is finalized, to allow a one-time opportunity for a repayment mechanism decrease by eligible ACOs that renewed for an agreement period beginning on July 1, 2019, or beginning on January 1, 2020, we anticipate we would notify an ACO of its opportunity to reduce its repayment mechanism amount after the start of performance year 2021. We also propose that an ACO must submit such election, together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS would review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of § 425.204(f).

Regarding the timeframe for an ACO to elect to decrease the amount of its repayment mechanism, we may require (for example) that an ACO submit its election, together with revised repayment mechanism documentation, within 30 days from the date of the written notice from CMS, particularly if prompt election is needed to ensure compliance with other program requirements. For instance, CMS may notify the ACO of its opportunity to decrease the amount of its repayment mechanism after using the ACO's existing repayment mechanism to support repayment of shared losses. In this case, prompt notification by the ACO of its election to decrease the amount of its repayment mechanism may be necessary if the ACO seeks to replenish the amount of its repayment mechanism to the permitted lower amount within the 90-day replenishment period according to § 425.204(f)(5), as discussed elsewhere in this section of this proposed rule. However, we recognize that there may be circumstances that necessitate a longer timeframe.

We propose to amend § 425.204(f)(4)(iv) to specify in paragraph (f)(4)(iv)(A) the proposed, revised methodology for determining the repayment mechanism amount for renewing ACOs that seek to use their existing repayment mechanism to support their continued participation in their new agreement period. We propose to add provisions in § 425.204(f)(4)(iv)(B) establishing policies that would allow eligible ACOs with July 1, 2019, or January 1, 2020 start dates to elect to lower the amount of their repayment mechanism arrangements.

We propose to amend § 425.204(f)(5), requiring an ACO to replenish the amount of funds available through the repayment mechanism within 90 days of use of the arrangement to repay any portion of shared losses, to specify that the resulting amount available through the repayment mechanism must be at least the amount specified by CMS in accordance with § 425.204(f)(4). For example, these revisions would allow an eligible ACO, that renewed its agreement period beginning on July 1, 2019, or January 1, 2020, to replenish the repayment mechanism to the lower amount determined by CMS, according to the proposed approach described in this section of this proposed rule. This proposed revision may also be relevant to a renewing ACO that is seeking to use its existing repayment mechanism to support its participation in its new agreement period. Specifically, if the renewing ACO's existing repayment mechanism is used to support payment of shared losses, based on financial reconciliation results available at the time of renewal application, CMS may permit the renewing ACO to replenish the amount of its existing repayment mechanism to the lower amount determined to be applicable for the ACO's new agreement period.

We also propose technical changes to § 425.204(f)(3)(iv) for clarity. This provision specifies that an ACO that has submitted a request to renew its participation agreement must submit as part of the renewal request documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period, and describes the conditions under which an ACO may use its current repayment mechanism to apply to the new agreement period. For clarity, we propose to specify under this provision that the duration of the existing repayment mechanism must be revised to comply with § 425.204(f)(6)(ii), and the amount of the repayment mechanism must comply with § 425.204(f)(4).

Further, we propose that an ACO must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism. Based on our operational experience, ACOs periodically request to close-out their existing repayment mechanisms and establish new repayment mechanisms to support their continued participation under a two-sided model. We have typically permitted these requests, under the following circumstances: We first ensure the ACO's new repayment mechanism meets the program's requirements and is fully executed; and then we permit cancellation of the repayment mechanism arrangement(s) being replaced. Further, when reviewing requested modifications to repayment mechanism documentation it is our practice to ensure that all the terms of the repayment mechanism are compliant with the program's policies. Therefore, we propose to revise the regulations in § 425.204(f)(3)(i) through (iii) to further specify that an ACO must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism.

4. Applicability of Policies to Track 1+ Model ACOs

The Track 1+ Model was established under the Innovation Center's authority at section 1115A of the Act, to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. The Track 1+ Model, which is a time-limited model that began on January 1, 2018, is based on Shared Savings Program Track 1, but tests a payment design that incorporates more limited downside risk, as compared to Track 2 and the ENHANCED track. We discontinued all future application cycles for the Track 1+ Model, as explained in earlier rulemaking (83 FR 68032 and 68033). As of January 1, 2020, there were 20 Track 1+ Model ACOs participating in performance year 3 of a 3-year agreement under the model. In the May 8th COVID–19 IFC (85 FR 27574 and 27575), we explained that we are forgoing the application cycle for a January 1, 2021 start date. To avoid a gap in participation for ACOs whose agreement period would otherwise end on December 31, 2020, we revised § 425.200(b)(3)(ii) to allow these ACOs to elect to extend their agreement period for an optional fourth performance year. Therefore, Track 1+ Model ACOs, among other ACOs whose agreement periods expire December 31, 2020, are eligible to voluntarily elect a 1-year extension of their agreement period for a fourth performance year from January 1, 2021, to December 31, 2021.

ACOs approved to participate in the Track 1+ Model are required to agree to the terms and conditions of the model by executing a Track 1+ Model Participation Agreement. See *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf.* Track 1+ Model ACOs are also required to have been approved to participate in the Shared Savings Program (Track 1) and to have executed a Shared Savings Program Participation Agreement. As indicated in the Track 1+ Model Participation Agreement, in accordance with our authority under section 1115A(d)(1) of the Act, we have waived certain requirements of the Shared Savings Program that otherwise would be applicable to ACOs participating in Track 1 of the Shared Savings Program, as necessary for purposes of testing the Track 1+ Model, and established alternative requirements for the ACOs participating in the Track 1+ Model. Unless stated otherwise in the Track 1+ Model Participation Agreement, the requirements of the Shared Savings Program under 42 CFR part 425 continue to apply. Consistent with § 425.212, Track 1+ Model ACOs generally are subject to all applicable regulatory changes, including but not limited to changes to the regulatory provisions referenced within the Track 1+ Model Participation Agreement that become effective during the term of the ACO's Shared Savings Program Participation Agreement and Track 1+ Model Participation Agreement, unless otherwise specified through rulemaking or amendment to the Track 1+ Model Participation Agreement. We note that the terms of the Track 1+ Model Participation Agreement also permit the parties (CMS and the ACO) to amend the agreement at any time by mutual written agreement.

Therefore, unless specified otherwise, the proposed changes to the Shared Savings Program regulations in this proposed rule that are applicable to Shared Savings Program ACOs within a current agreement period would apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 1, so long as the applicable regulation has not been waived under the Track 1+ Model. Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or the ENHANCED track have been incorporated for ACOs in the Track 1+ Model under the terms of the Track 1+ Model Participation Agreement, any proposed changes to those regulations discussed in this proposed rule would also apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 2 or the ENHANCED track. For example, the following proposed policies would apply to Track 1+ Model ACOs, if finalized:

- The application of the APP framework to determine the quality performance of Shared Savings Program ACOs (section III.G.1.c. of this proposed rule).
- The revisions to the Shared Savings Program quality performance standard. Specifically, under the proposed approach, the quality performance standard for Track 1+ Model ACOs would be set at a quality score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores (section III.G.1.c. of this proposed rule).
- The modifications to the regulations under § 425.604(c) specifying the circumstances under which a Track 1 ACO will qualify to receive a shared savings payment (section III.G.1.d. of this proposed rule).
- The modifications to the regulations under § 425.604(d) governing the determination of the final sharing rate for Track 1 ACOs (section III.G.1.d. of this proposed rule).
- The modifications to § 425.316 to allow CMS to identify ACOs that are not meeting the proposed, revised quality performance standard, and to require these ACOs to take actions to address their poor quality performance or face termination of their Shared Savings Program participation agreement (section III.G.1.e. of this proposed rule).

- The modifications to the policies governing the audit and validation of data used to determine the ACO's quality performance. Specifically, under the proposed new provision of the regulations at § 425.510(c), CMS would retain the right to audit and validate the quality data reported by an ACO according to § 414.1390 (section III.G.1.f. of this proposed rule).
- The proposed new provision of the regulations at § 425.512(b) to address the effect of extreme and uncontrollable circumstances on ACOs' quality performance (section III.G.1.g. of this proposed rule).
- The revisions to the definition of primary care services used in beneficiary assignment. If finalized, the revised definition would be applicable to Track 1+ Model ACOs for the performance year starting on January 1, 2021, and we would adjust the Track 1+ ACO's historical benchmark to reflect these policies (section III.G.2 of this proposed rule).
- The proposed changes to the CAHPS for ACOs reporting requirements for performance year 2020 (section III.I.1 of this proposed rule).

H. Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services

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, effective for January 1, 2021. Section 5012 of the Cures Act also added section 1834(u) to the Act, which establishes the payment and related requirements for home infusion therapy under this benefit. 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 of care described in section 1861(iii)(1) of the Act 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. We solicited comments in the CY 2020 PFS proposed rule (84 FR 40716) and the CY 2020 HH PPS proposed rule (84 FR 34694), 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 (home or otherwise) under Medicare Part B. We also invited comments on any additional interpretations of this notification requirement. We summarized the comments received in the CY 2020 PFS final rule (84 FR 62568) and the CY 2020 HH PPS final rule (84 FR 60478), and we stated we would take these comments into consideration as we continue developing future policy through notice-and-comment rulemaking.

Many commenters stated that physicians already routinely discuss the infusion therapy options with their patients and annotate these discussions in their patients' medical records. For home infusion therapy services effective beginning CY 2021, physicians are to continue with the current practice of discussing options available for furnishing infusion therapy under Part B and annotating these discussions in their patients' medical records prior to establishing a home infusion therapy plan of care. We are not proposing to create a mandatory form nor are we otherwise proposing to require a specific manner or frequency of notification of options available for infusion therapy under Part B prior to establishing a home infusion therapy plan of care, as we believe that current practice provides appropriate notification. However, if current practice is later found to be insufficient in providing appropriate notification to patients of the available infusion options under Part B, we may consider additional requirements regarding this notification in future rulemaking. We are referring stakeholders to the CY 2020 HH PPS final rule (84 FR 60478) for further information regarding the policies on home infusion therapy services beginning CY 2021 and for subsequent years.

I. Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020

Following the hurricanes and wildfires during 2017, we issued an IFC, entitled ''Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017,'' which appeared in the December 26, 2017 **Federal Register** (82 FR 60912) (hereinafter referred to as the ''December 2017 IFC''). The December 2017 IFC established a policy for determining quality performance scores for ACOs, when the ACO or its participating providers and suppliers were impacted by extreme and uncontrollable circumstances such as hurricanes, wildfires, or other triggering events, in performance year 2017, including the applicable quality reporting period for the performance year if the quality reporting period was not extended. In the CY 2019 PFS final rule, we extended the policies finalized in 2017 to performance year 2018 and subsequent performance years. In the March 31st COVID–19 IFC (85 FR 19267 and 19268), we updated the extreme and uncontrollable circumstances policy to eliminate the restriction that the policy applies only if the quality reporting period is not extended.

We determine whether an ACO has been impacted by an extreme and uncontrollable circumstance using the following criteria:

- 20 Percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance (§ 425.502(f)(1)(i)).
- The ACO's legal entity is physically located in an area identified as being affected by an extreme and uncontrollable circumstance under the Quality Payment Program (§ 425.502(f)(1)(ii)).

Under the current regulation at § 425.502(f)(2), ACOs that meet one or both of the above criteria will have their quality performance score set equal to the mean quality performance score for all Shared Savings Program ACOs for the relevant performance year. However, if the ACO completely and accurately reports all quality measures, we use the higher of the ACO's quality performance score or the mean quality performance score for all Shared Savings Program ACOs to calculate the ACO's quality performance score.

The Public Health Emergency (PHE) for the COVID–19 pandemic applies to all counties in the United States, therefore for performance year 2020 all ACOs are considered to be affected by an extreme and uncontrollable circumstance.

1. Proposed Changes to the CAHPS for ACOs Reporting Requirements for Performance Year 2020

In the March 31st COVID–19 IFC, we made updates to the Part C and Part D Star Rating Systems for 2021 and 2022 based on concerns that the COVID–19 pandemic would pose significant

challenges and safety concerns in successfully completing the CAHPS survey. It was noted that many of the survey administration protocols could not be completed remotely, requiring staff to work in mail facilities and call centers where telephone interviewers assemble in close quarters to perform the telephone administration of the survey. Accordingly, to be in compliance with social distancing, travel bans, quarantine, and promoting health and safety of all involved in CAHPS data collection, we amended regulations in parts 417, 422, and 423 to eliminate requirements for collection of CAHPS data in 2020 (85 FR 19271 and 19272).

The Shared Savings Program quality measure set for performance year 2020 includes 10 measures that are collected through the CAHPS for ACOs survey. The timeline for the CAHPS for ACOs survey includes: (1) Vendor training in late spring, (2) ACO vendor selection in early summer, and (3) data collection beginning in late fall. The PHE may affect both the PY 2020 CAHPS for ACOs sample frame and the administration of the PY 2020 survey. The CAHPS for ACO sample frame can include beneficiaries who are assigned to an ACO based on having received the plurality of their primary care visits from ACO professionals in that ACO or voluntary alignment to the ACO. Under our current process, the PY 2020 CAHPS for ACOs survey sample frame will be constructed based on primary care visits of assigned beneficiaries from July 2019 through June 2020.

We are concerned that the mix of beneficiaries included in the PY 2020 sample frame may be impacted by the COVID–19 pandemic because the time period used to identify eligible beneficiaries based on primary care visits overlaps with the PHE for the COVID–19 pandemic. Beneficiaries may be assigned to an ACO based on both in person office and telehealth primary care visits; however, during the pandemic, many beneficiaries may defer or skip primary care visits. As a result, the pandemic could reduce the pool of beneficiaries available for assignment to the ACO and eligible for the survey sample. The sampling methodology requires a beneficiary to have at least two primary care service visits, as well as meet other sampling criteria such as a visit with a primary care clinician or a specialist that provides primary care services used in assignment who delivered the plurality of primary care services (that is, the beneficiary's focal provider). In addition, the survey is typically administered in late fall of the performance year and beneficiaries are asked if they received health care from their focal provider in the last 6 months, if they answer no they skip over the survey questions evaluating the provider and office staff. Given our concerns regarding the decrease in primary care services in 2020, many beneficiaries could potentially have no office visits with their focal provider during this 6-month period and would be unable to fully complete the survey. A recent Commonwealth Health Study [47] showed that the number of primary care (in person or telehealth) visits were down by about 31 percent in the 2nd quarter of 2020 despite an upward trend in telehealth visits. Some ACOs have noted a significant decline in primary care service visits in the months used to produce the sample. This is supported by preliminary claims data that shows primary care services furnished by ACO professionals in Shared Savings Program ACOs were down by 26 percent from January-May 2020 and shows a greater decrease in visits from January-April, 2020. The decrease was observed even following the addition of codes for certain telehealth and virtual services to the ACO assignment specifications in the May 8th COVID–19 IFC (85 FR 27583 through 27586). We continue to monitor the impact that the changing mix of in person and telehealth visits has on assignment of beneficiaries to ACOs and any subsequent impact on sampling both in terms of the impact on the number of beneficiaries and composition of the beneficiary population assigned to an ACO.

Additionally, the atypical pattern of primary care utilization in past months potentially introduces non-random differences in the patient pool used to assess ACOs in 2020 compared to prior years. The current survey instrument may not accurately measure the shifts in care caused by the pandemic, such as increased use of telehealth creating the potential for under-reporting of experience. Patient experience for an atypical period of care may result in patient reports of experiences substantially different from previous years making it difficult to determine if observed differences are due to changes in the quality of care or due to pandemic-related changes in utilization or care delivery, compromising the use of the data to measure performance improvement over time. For example, 2020 patient reports and ratings of care may be more affected by general shortages of personnel and capacity rather than by the quality of care delivered by physicians and other staff.

Furthermore, even though the administration of the CAHPS for ACOs survey does not occur until late fall of PY 2020, we do not know how long the COVID–19 PHE will be in place or the long-term impacts of the PHE on the CAHPS for ACOs survey administration. The pandemic may negatively impact survey administration procedures and response rates. Vendor-specific revisions to the survey protocol may be warranted, such as allowing mail-only surveys, which could introduce a lack of standardization in survey administration, affecting the comparability of data collected by different vendors and could lead to decreased response rates affecting performance scores.

Taken together, the potential negative impacts of the COVID–19 pandemic detailed above could affect the size and generalizability of the survey sample, standardization of survey administration, and the utility of the data for purposes of measuring patient experience and performance improvement, thus leading to challenges in benchmarking and computing quality improvement scores for 2020.

We note that absent this proposal, all ACOs would be required to administer the CAHPS for ACOs survey and pay to contract with a CAHPS vendor, regardless of the impact of the PHE. The change in the number of visits and the resulting sampling impact will vary for ACOs based on their location. If ACOs have sample sizes less than the target sample size of 860 beneficiaries, all eligible beneficiaries would be included in the survey sample; therefore, ACOs could potentially be paying for a vendor and receiving CAHPS for ACOs scores that do not reflect the care provided by ACO providers/suppliers. In contrast, the CAHPS for MIPS survey is voluntary and MIPS groups and virtual groups may still choose to register to field a MIPS for CAHPS survey. MIPS groups that register for the CAHPS for MIPS survey and do not meet minimum sample requirements are not eligible to administer the survey.

Accordingly, in an effort to maintain consistency with public safety determinations made for the CAHPS survey that is used in Part C and Part D Star Ratings Systems in the March 31st COVID–19 IFC and address concerns about the negative impacts of COVID–19 on sample size and performance scores, we are proposing to modify our regulations to remove the requirement that ACOs field a CAHPS for ACOs survey for performance year 2020. Instead, we propose that ACOs

[47] *https://www.commonwealthfund.org/publications/2020/jun/impact-covid-19-pandemic-outpatient-visits-practices-adapting-new-normal.*

would automatically receive full points for each of the CAHPS survey measures within the patient/caregiver experience domain for performance year 2020. We acknowledge that this proposal is retroactive for performance year 2020. However, section 1871(e)(1)(A) of the Act allows for retroactive application of a substantive change when the failure to apply the change retroactively would be contrary to the public interest. Based on the concerns described above, we believe it is in the public interest not to require ACOs to field the CAHPS for ACOs survey. Accordingly, we propose to amend § 425.500(d) to add language stating that for performance year 2020 we waive the CAHPS for ACOs reporting requirement and will give all ACOs automatic credit for the CAHPS for ACOs survey measures.

We seek comment on our proposal to waive the CAHPS for ACOs reporting requirement and to give ACOs automatic credit for the CAHPS for ACOs survey measures for performance year 2020. For instance, we would be interested in hearing from ACOs and beneficiaries if there are other ways to conduct the survey that would mitigate the concerns listed above.

2. Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020

Multiple stakeholders have expressed concerns about the potential adverse impacts of the PHE for COVID–19 on ACOs, suggesting that we not use performance year 2020 data to assess the quality performance of ACOs, consider holding clinicians harmless from quality assessment and reporting, suspend quality data submission, or make the 2020 performance year a pay-for-reporting year to allow for an ongoing focus on quality while recognizing the unusual circumstances presented this year.

We understand stakeholders' concerns, but we believe that ACOs should be in a position to report CMS Web Interface measures for PY 2020 beginning in January 2021. All ACOs were determined to be impacted by the PHE for COVID–19, which was declared during the quality reporting period for performance years starting in 2019. However, 98.7 percent of ACOs completely reported CMS Web interface measures for 2019, including all 65 ACOs that were also impacted by a natural disaster during 2019 or the quality reporting period. We want to encourage reporting for performance year 2020 while still being cognizant of the impacts that the PHE for COVID–19 could have on quality reporting and quality performance. Accordingly, we believe the proposal described above that would give ACOs automatic full credit for the CAHPS for ACOs survey measures, in addition to our current extreme and uncontrollable circumstances policy, offers relief to ACOs for performance year 2020. All 10 CAHPS for ACOs survey measures are in one of the four domains used to calculate an ACO's quality performance score. This means 25 percent of an ACO's quality performance score for performance year 2020 would come from receiving full credit on the CAHPS for ACOs survey measures. In addition, each of the other three domains has at least one or more measures that is pay-for-reporting in performance year 2020, resulting in over 50 percent of the measures (14 out of 23) being assigned full points if the ACO completely and accurately reports quality data. Furthermore, for ACOs in their second or subsequent performance year, there is at least one measure in each domain that ACOs could receive full points for, providing they completely report quality data, ensuring they would achieve the minimum attainment level on at least one measure in each domain as required under § 425.502(d)(2)(iii) to be eligible to share in any savings. We believe this may address some of the concerns expressed by stakeholders about 2020 quality performance, as noted above. We believe it is in the public interest that we strongly encourage ACOs to report quality data because ACOs could otherwise share in any savings earned without being held accountable for the quality of care that they provide to the more than 11 million beneficiaries who receive care through Shared Savings Program ACOs. In addition to incentivizing the reporting of quality of care measures, we believe that it is critical to incorporate ACO performance on those measures into quality performance scoring for performance year 2020 in a meaningful way that also considers the impact of the current PHE.

However, we are also seeking comment on a potential alternative approach to scoring ACOs under the extreme and uncontrollable circumstances policy for performance year 2020 that we considered proposing. The intent of the Shared Savings Program extreme and uncontrollable circumstances policy is to mitigate any negative impact of an extreme and uncontrollable circumstance on an ACO's quality performance or ability to report quality data to CMS and the resultant effect on financial reconciliation due to emergency circumstances outside of the ACO's control. Changes in healthcare utilization during 2020 may impact sampling and ACO performance on the quality measures for reasons that include: (1) Increased healthcare utilization due to COVID–19; (2) reduced or delayed non-COVID–19 care due to advice to patients to delay routine and/or elective care; and (3) changes in non-COVID–19 inpatient utilization due to crowd-out. For the reasons enumerated above, we believe that the PHE for COVID–19 creates uncertainty regarding performance rates on the ACO quality measures for performance year 2020. Due to the changes in the healthcare landscape and the increased burden they present in providing care for all patients during the PHE for COVID–19, we recognize that the mean ACO performance rate in 2020 could be lower than it was in previous performance years. We therefore considered whether assigning the higher of an ACO's own 2020 quality score or the 2020 ACO mean to those ACOs that do not completely report quality and those whose quality score falls below the mean in 2020, consistent with our current extreme and uncontrollable circumstances policy, may disadvantage ACOs. Accordingly, below we are seeking comment on a potential change to the existing extreme and uncontrollable circumstances policy that we considered proposing.

The potential alternative modification we considered would be similar to the current policy, but would use the higher of an ACO's 2020 quality performance score or its 2019 quality performance score for ACOs that completely report quality data for 2020. For new ACOs that completely report quality data, we would continue to score them as pay-for-reporting and assign a quality score of 100 percent. ACOs that do not complete quality reporting would receive the 2020 ACO mean quality score as provided in § 425.502(f)(2). We believe that the potential change to use the higher of an ACO's 2020 quality performance score or its 2019 quality performance score, for ACOs that do completely report quality data for performance year 2020, could help to mitigate the impact of the PHE for COVID–19 on ACOs that report, but are not able to perform well during 2020. We also believe that assigning the 2020 ACO quality mean to ACOs that do not complete quality reporting would incentivize reporting by new ACOs that would receive 100 percent if they complete reporting, as well as by ACOs in their second or subsequent performance years that would have an

opportunity to receive a score that could be higher than the 2020 mean if they complete quality reporting.

As mentioned above, 98.7 percent of ACOs reported quality data for performance year 2019 despite being impacted by the PHE for COVID–19 during the 2019 CMS Web Interface data submission period. We note that preliminary data indicate that the 2019 mean ACO quality score will be 92 percent, which is comparable to the mean ACO quality scores from prior years. For example, the 2018 mean ACO Quality Score was 93 percent. As a result, we expect that for some ACOs in their second or subsequent performance year with consistently above average quality scores, assigning their 2019 quality performance score would result in a higher quality performance score for 2020 than the 2020 ACO mean quality score. However, as noted in section VIII.H.8. of this proposed rule, the proposed full credit for the CAHPS for ACOs measures that is described above would advantage all ACOs relative to applying only our current extreme and uncontrollable circumstances policy to mitigate the impact of the PHE for COVID–19.

We are soliciting comments on the following potential modifications to the extreme and uncontrollable circumstances policy for performance year 2020:

(1) If an ACO in a second or subsequent performance year completely and accurately reports the CMS Web Interface measures for performance year 2020, the ACO will receive the higher of its performance year 2020 ACO quality performance score that would include automatic full credit for the CAHPS for ACOs survey measures, as proposed in this section, or the score used in 2019 for purposes of financial reconciliation. For re-entering ACOs that terminated in their second or subsequent agreement period, the ACO will receive the higher of its most recent prior ACO quality performance score or its 2020 quality performance score.

(2) If an ACO in a second or subsequent performance year or a re-entering ACO that terminated in its second or subsequent agreement period does not completely and accurately report the CMS Web Interface measures for performance year 2020, the ACO will receive the 2020 ACO mean quality performance score.

(3) If an ACO in its first performance year in the program or a re-entering ACO that terminated in its first agreement period and is now in its first performance year of a new agreement period completely and accurately reports the CMS Web Interface measures, it will receive a quality performance score of 100 percent that reflects automatic full credit for the CAHPS for ACO survey measures, as proposed in this section.

(4) If an ACO in its first performance year or a re-entering ACO that terminated in its first agreement period and is now in its first performance year of a new agreement period, does not completely and accurately report the CMS Web Interface measures for performance year 2020, it will receive the 2020 mean ACO quality performance score.

We believe this potential alternative of modifying the extreme and uncontrollable circumstances policy to the higher of an ACO's 2020 quality performance score or its 2019 quality performance score would encourage all ACOs to report quality for performance year 2020, while also offering additional protections for ACOs in the event that quality performance scores for 2020 are adversely affected by the PHE for COVID–19. We believe this approach could help to address concerns about the potential for lower quality performance during performance year 2020 by continuing to benefit ACOs that perform well during 2020, and mitigating the impact for those that do not. ACOs that do not completely report quality would receive the 2020 mean ACO quality score, as provided under the current extreme and uncontrollable circumstances policy in § 425.502(f). As noted earlier, more than half of the measures in the Shared Savings Program quality measure set are pay-for-reporting for all ACOs for performance year 2020, which is higher than in previous years, and we believe this should also help to mitigate concerns regarding quality performance. Nevertheless, we recognize that the mean ACO quality performance rate in 2020 could be lower than it was in previous performance years. As a result, we believe this alternative could provide an incentive to encourage ACOs to completely and accurately report quality because they would be eligible to receive a score that may be higher than the 2020 ACO mean quality score. Accordingly, we seek comment on the potential modification to the extreme and uncontrollable circumstances policy for performance year 2020, as described above.

J. Proposal To Remove Selected National Coverage Determinations

In the August 7, 2013 **Federal Register** notice (78 FR 48164), we established the current procedures for requesting a National Coverage Determination (NCD) or reconsideration of an existing NCD. We described how the public may participate in the NCD process during the indicated comment period(s). We also established an expedited administrative process, using specific criteria, to remove NCDs older than 10 years, thereby allowing the local Medicare Administrative Contractors (MAC) to determine coverage.

We are now proposing to use the rulemaking process to continue to use the criterion established in 2013 to regularly identify and remove NCDs that no longer contain clinically pertinent and current information, in other words those items and services that no longer reflect current medical practice, or that involve items or services that are used infrequently by beneficiaries. We are proposing this change of vehicle because removing a NCD changes a substantive legal standard related to Medicare coverage and payment for items and services under section 1871(a)(2) of the Act. Eliminating an NCD for items and services that were previously covered means that the item or service will no longer be automatically covered by Medicare (42 CFR 405.1060). Instead, the coverage determinations for those items and services will be made by MACs. On the other hand, if the previous NCD barred coverage for an item or service under title XVIII (that is, national noncoverage NCD), a MAC would now be able to cover the item or service if the MAC determined that such action was appropriate under the statute. Removing a national non-coverage NCD may permit access to technologies that may now be beneficial for some uses. As the scientific community continues to conduct research which produces new evidence, the evidence base we previously reviewed may have evolved to support other policy conclusions.

Per the guidance issued in the 2013 notice, we may consider an older NCD for removal if, among other things, any of the following circumstances apply:

- We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- The technology is generally acknowledged to be obsolete and is no longer marketed.
- In the case of a noncoverage NCD based on the experimental status of an item or service, the item or service in the NCD is no longer considered experimental.
- The NCD has been superseded by subsequent Medicare policy.
- The national policy does not meet the definition of an ''NCD'' as defined in sections 1862(l) or 1869(f) of the Act.

• The benefit category determination is no longer consistent with a category in the Act.

We are interested in public comments that may identify other reasons for proposing to remove NCDs. We are also interested in whether the time-based threshold of ''older'' which was designated as 10 years in the 2013 notice continues to be appropriate or whether stakeholders believe a shorter period of time or some other threshold criterion unrelated to time is more appropriate.

The process of removal does not result in an NCD as that term is defined in sections 1869(f) and 1862(l) of the Act because there would be no uniform national decision about whether or not the particular item or service would be covered under Title XVIII of the Act. Rather, the initial coverage decision which is normally made for a specific beneficiary who has already received an item or service and has submitted a Medicare claim would be made by local contractors. For the reasons outlined above, we believe that allowing local contractor flexibility in these cases better serves the needs of the Medicare program and its beneficiaries.

Since the 2013 notice, we have removed NCDs on two occasions. First, in November 2013, we proposed 10 NCDs for expedited removal. After reviewing the comments, we issued a final decision memorandum in December 2014, removing 7 NCDs and retaining three. We last proposed removal of NCDs in March of 2015, proposing to remove 2 NCDs. Based on the comments, we removed one NCD and retained one. The proposals and final decisions related to these removals are located in the Medicare Coverage Database, available at *https://www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=7&mcdtypename=Expedited+Process+to+Remove+National+Coverage+Determinations&bc=AgAAAAAAAAAAAA%3d%3d&.*

It has been 5 years since we last evaluated older NCDs for removal. We continue to recognize the need to periodically review our policies and processes to ensure that we remain effective and efficient as well as open and transparent. We are aware that clinical science and technology evolve and that items and services that were once considered state-of-the-art or cutting edge may be replaced by more beneficial technologies or clinical paradigms. Additionally, proactively removing obsolete broad non-coverage NCDs removes barriers to innovation and reduces burden for stakeholders and CMS. In light of the Supreme Court's decision in *Azar* v. *Allina Health Services,* 587 U.S. ___, 139 S. Ct. 1804 (2019)), we have determined it would be appropriate to use the notice and comment rulemaking procedures described in section 1871(a)(2) of the Act to remove outdated or unnecessary NCDs.

In Table 37, we list the NCDs that we propose to remove. In addition to conducting an internal review to identify appropriate NCDs for removal, we received removal requests from a variety of external stakeholders, such as medical specialty societies, device manufacturers, beneficiaries, physicians and providers, and other interested individuals. Additionally, some of these topics were brought to our attention by the MAC medical directors. We solicit comment on the nine NCDs discussed in Table 37, as well as comments recommending other NCDs for CMS to consider for future removal.

TABLE 37: Proposed NCDs for Removal

NCD Manual Citation	Name of NCD
20.5	Extracorporeal Immunoadsorption (ECI) using Protein A Columns (01/01/2001)
30.4	Electrosleep Therapy
100.9	Implantation of Gastroesophageal Reflux Device (06/22/1987)
110.14	Apheresis (Therapeutic Pheresis) (7/30/1992)
110.19	Abarelix for the Treatment of Prostate Cancer (3/15/2005)
190.1	Histocompatability Testing
190.3	Cytogenetic Studies (7/16/1998)
220.2.1	Magnetic Resonance Spectroscopy (09/10/2004)
220.6.16	FDG PET for Inflammation and Infection (03/19/2008)

The following outlines each NCD and provides a summary of the rationale for removal. Each of the current NCDs below may be found in the Medicare National Coverage Determinations Manual located at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961.*

1. NCD #20.5 Extracorporeal Immunoadsorption (ECI) Using Protein A Columns (01/01/2001)

• *Circumstances/criterion:* We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.

• *Rationale:* Extracorporeal immunoadsorption (ECI), using Protein A columns, has been developed for the purpose of selectively removing circulating immune complexes (CIC) and immunoglobulins (IgG) from patients in whom these substances are associated with their diseases. The technique involves pumping the patient's anticoagulated venous blood through a cell separator from which 1–3 liters of plasma are collected and perfused over adsorbent columns, after which the plasma rejoins the separated, unprocessed cells and is re-transfused to the patient. ECI has been used to treat some diseases of inflammatory and autoimmune etiology. External stakeholders suggested this NCD may be outdated, with the therapeutic use of ECI constrained by the parameters of the NCD as the evidentiary base has continued to evolve. Also, the service is a specific type of therapeutic apheresis for the treatment of rheumatoid arthritis under certain conditions. The stakeholders recommended that this NCD should be removed in conjunction with removing NCD #110.14 Apheresis, which is discussed below. Removing the outdated CMS NCD for ECI and leaving

it to contractor discretion would provide flexibility for coverage considerations that are more responsive to the evolving evidentiary base improving appropriate access for Medicare beneficiaries.

2. NCD #30.4 Electrosleep Therapy

• *Circumstances/criterion:* The technology is generally acknowledged to be obsolete and is no longer marketed.

• *Rationale:* External stakeholders suggested this NCD may be outdated. This NCD predates the current NCD public notice standards and has no decision memorandum, no evidence review, and no bibliography. Additionally, the term ''Electrosleep therapy'' appears to be outdated, superseded by ''cranial electrotherapy stimulators (CES).'' In addition to a change in nomenclature, FDA's class level assigned to CES has also changed over time for indications of anxiety and/or insomnia, although not for depression. Given that the therapeutic area has progressed and ''Electrosleep Therapy'' does not have the same applicability, we propose to remove this NCD allowing local contractor discretion to consider coverage of newer technologies.

3. NCD #100.9 Implantation of Gastroesophageal Reflux Device (06/22/1987)

• *Circumstances/criterion:* We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.

• *Rationale:* External stakeholders suggested this NCD may be outdated. The 1987 Noncoverage NCD was determined based on a different device, the Angelchik device, which was a device implanted around the esophagus (under the diaphragm and above the stomach) that was secured by a circumferential tie strap. Implantable treatment for GERD initiated with Angelchik prosthetic rings came under scrutiny for high dysphagia rates and migration of the implant. It was removed from the market in 1990. New FDA market authorized devices for the indication of GERD have emerged since that time. However, some devices have a limited evidence base with respect to improving long-term patient outcomes. Nonetheless, there may be a role for implantable devices in the treatment of reflux. We believe that local contractor discretion provides an immediate avenue to potential coverage in appropriate candidates. Therefore, we believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.

4. NCD #110.14 Apheresis (Therapeutic Pheresis) (7/30/1992)

• *Circumstances/criterion:* We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.

• *Rationale:* Apheresis (also known as pheresis or therapeutic pheresis) is a medical procedure utilizing specialized equipment to remove selected blood constituents (plasma, leukocytes, platelets, or cells) from whole blood. The remainder is re-transfused into the person from whom the blood was taken. The apheresis NCD predates the current NCD public notice standards. No evidence review was published for this NCD to justify the specific list of conditions covered. Since the NCD is silent on non-coverage, the NCD is vague and open to interpretation and may not be applied uniformly. Furthermore, the scope of indications for apheresis has continued to develop since the origin of the NCD. Removing the outdated CMS NCD for apheresis and leaving it to contractor discretion will provide flexibility for coverage considerations that are more responsive to the evolving evidentiary base improving appropriate access for Medicare beneficiaries.

5. NCD #110.19 Abarelix for the Treatment of Prostate Cancer (3/15/2005)

• *Circumstances/criterion:* The technology is generally acknowledged to be obsolete and is no longer marketed.

• *Rationale:* Abarelix was approved in the Unites States in 2003 for restricted use as palliative treatment in men with advanced symptomatic prostate cancer and experiencing select complications (described in the FDA labeling). However, in response to reports of systemic allergic reactions, the GnRH antagonist, Abarelix, was voluntarily withdrawn from the U.S. market in 2005. Because Abarelix is no longer marketed in the U.S., the NCD no longer contains clinically pertinent and current information and should be removed.

6. NCD #190.1 Histocompatability Testing (08/01/1978)

• *Circumstances/criterion:* We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.

• *Rationale:* Histocompatibility testing involves matching or typing of the human leucocyte antigen (HLA) proteins. External stakeholders suggested that the texts within this NCD are now less frequently utilized and raised concerns of reducing provider burden as adjudication of the claims for certain diagnoses requires submission of medical records for each person tested. The techniques have evolved from conventional HLA cross-matching to include a range of techniques with different levels of matching, including HLA genotyping assays (polymerase chain reaction sequence-specific primer [PCR–SSP], sequence-specific oligonucleotide probe (SSOP), and sequence-based techniques [SBT] including next generation sequencing). Therefore, clinicians need to make sophisticated assessments related to the indication, their access to histocompatibility testing approaches, and appropriate avenues for billing. We propose removing this NCD which originated around conventional HLA cross-matching. This would allow local contractors discretion to accommodate clinical flexibility to better serve the needs of the Medicare program and its beneficiaries while streamlining and simplifying the billing and claims processing.

7. NCD #190.3 Cytogenetic Studies (7/16/1998)

• *Circumstances/criterion:* The NCD has been superseded by subsequent Medicare policy.

• *Rationale:* Cytogenetics involves examining stained chromosomes, and distinct chromosomal bands, to help identify structural abnormalities in chromosomes that might correspond to poor health outcomes. However, direct DNA analyses through DNA sequencing, such as Next Generation Sequencing (NGS) (*https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=372*), allows providers to read the exact order of nucleotide molecules that comprise DNA, enhancing the sensitivity and specificity in identifying abnormalities in the genetic sequence. As a result, the focus of NCDs has generally shifted from cytogenetic studies to genetic sequencing when detailed genetic information is of interest.

8. NCD #220.2.1 Magnetic Resonance Spectroscopy (09/10/2004)

• *Circumstances/criterion:* We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.

• *Rationale:* MRS can determine the relative concentrations and physical properties of a variety of biochemicals and has the potential to probe a wide

range of metabolic pathways in different human tissue. Although MRS is mostly used in assessing brain tissue, it also offers potential applicability to breast, prostate, hepatic, and other cancers. External stakeholders suggested this NCD may be outdated, noting the 2004 broad noncoverage determination for all indications was based on evidentiary review for one limited indication, the diagnosis of brain tumors. As the scientific evidence evolves and the clinical utility develops across various indications, the restrictive scope of the 2004 NCD may prohibit appropriate local coverage determinations.

9. NCD #220.6.16 FDG PET for Inflammation and Infection (03/19/2008)

- *Circumstances/criterion:* We believe that allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries.
- *Rationale:* The decision to use FDG PET for inflammation and infection is multifactorial and depends on: Whether conventional diagnostics have been unsuccessful, the stage of the underlying pathophysiological condition in the affected tissues, and the sensitivity and specificity of FDG PET to inform the differential diagnosis or course of disease, among other factors. For some inflammatory and infectious conditions, there is no overall agreement in the current literature about the added value of FDG PET for this indication. Conversely, leaving such determinations to local contractor discretion builds in flexibility to tailor coverage decisions to the pertinent facts of a patient's case and considering any added benefit of FDG PET in establishing a diagnosis and treatment plan that might link the PET imaging to an improved patient outcome.

In summary, we solicit comment on the proposal to remove each of the nine NCDs, as well as comments recommending other NCDs for CMS to consider for future removal. Additionally, we solicit public comments that may identify other reasons for proposing to remove NCDs. We solicit comments on whether the time-based threshold of ''older'' which was designated as 10 years in the 2013 notice continues to be appropriate or whether stakeholders believe a shorter period of time or some other threshold criterion unrelated to time is more appropriate. We request commenters include a rationale to support their comments. We will use the public comments to help inform our decision to take one of three actions on the nine NCDs proposed for removal:

- Remove the NCD, as proposed, allowing for coverage to be determined by the MACs.
- Retain the current policy as an NCD.
- Reconsider the NCD. Comments suggesting that the NCD should be revised, rather than eliminated, should include previously unreviewed evidence in order to support a change in national coverage.

K. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

1. Background

Since Part D was signed into law in 2003, electronic prescribing (e-prescribing or e-Rx) has been optional for physicians and pharmacies for prescriptions made for covered Part D drugs. However, Part D sponsors offering drug plans have been required to have the electronic capabilities to support electronic prescribing. We understand that issuing this regulation would uniquely affect physicians, although it may impact other prescribers under Part D. Given the majority of affected parties are physicians, we seek to use the CY 2020 PFS rulemaking to gain the insight and perspective of providers.

We track the volume of electronic prescriptions for controlled and non-controlled substances through our prescription drug event (PDE) processing system for Part D program claims. We have collected data on controlled substances and non-controlled substances since the United States' Drug Enforcement Administration (DEA) permitted the practice in 2010.[48]

However, while electronic prescribing has increased, the health care system faces a new threat. The United States is currently responding to an outbreak of respiratory disease caused by a novel (new) coronavirus now detected in 50 States and the District of Columbia. This virus has been named ''severe acute respiratory syndrome coronavirus 2'' (''SARS–CoV–2''), and the disease it causes has been named ''coronavirus disease 2019'' (''COVID–19''). In January 2020, the Secretary determined that a Public Health Emergency (PHE) exists for the United States to aid the nation's health care community in responding to COVID–19 (hereafter referred to as the PHE for the COVID–19 pandemic) and on April 21, 2020, the Secretary renewed, effective April 26, 2020, the determination that a PHE exists. In March, 2020, President Trump declared the COVID–19 pandemic a national emergency. Certain individuals, including older adults and persons with chronic conditions, who comprise a predominance of the Medicare beneficiary population, are at elevated risk of more severe illness and potential death from COVID–19. As a result of the PHE for the COVID–19 pandemic, and as the nation reopens, some individuals, such as those who are at high risk, may continue to practice self-isolation and social distancing.

We have implemented many regulatory and policy actions to swiftly aid the nation's healthcare system to effectively address the COVID–19 pandemic. These actions include new flexibilities for telehealth and other electronic technologies [49] to ease the burden on providers and assure appropriate care in a range of settings for beneficiaries. Also, the DEA has adopted certain new temporary flexibilities to allow DEA-registered practitioners to prescribe controlled substances without having to interact in person with patients, effective for the duration of the PHE for the COVID–19 pandemic.[50] For example, during the PHE for the COVID–19 pandemic, DEA permits DEA registered prescribers to issue controlled substance prescriptions to telemedicine patients who they have not seen in person under certain conditions, permits early refills of controlled substances permissible under state law, and allows prescribers to issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance. DEA's COVID–19 information page is available at *https://www.deadiversion.usdoj.gov/coronavirus.html.* The DEA has acknowledged the prevalence of paper prescribing and attempted to address some of the hardships it poses for prescribers and patients during the PHE for the COVID–19 pandemic.

We believe that social distancing is, in part, responsible for the increase in electronic prescribing for controlled substances (EPCS) during this PHE for the COVID–19 pandemic. In 2020, EPCS has increased to 50 percent of all PDEs being prescribed as compared to 38 percent in 2019.[51] With the use of electronic prescribing, a patient and provider can conduct a visit via

[48] See 75 FR 16284, including revisions adopted to 21 CFR 1304.04.

[49] See *https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf.*

[50] See *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf.*

[51] Based on Prescription Drug Event data processed through April 30, 2020.

telehealth and then have the prescription electronically transmitted to the pharmacy without having to see each other in-person and risk transmitting COVID–19. Some insurers, including Part D plans, may be permitting medication refills, including for controlled substances, earlier than usual or for a more extended period of time than was previously allowed. Pharmacies that were not previously doing so may deliver medications, or deliver at no charge, and communities and individuals have worked together to design ways for vulnerable persons to continue to receive access to prescribed medications in tandem with these new government and private sector flexibilities.

The DEA is also involved in regulating EPCS. In 2010, the DEA issued the ''Electronic Prescriptions for Controlled Substances'' interim final rule with request for comment (75 FR 16236) (hereinafter referred to as the ''2010 DEA EPCS interim final rule'') that provided practitioners with the option of writing prescriptions for controlled substances electronically. The rule also permitted pharmacies to receive, dispense, and archive these electronic prescriptions. Any electronic controlled substance prescription issued by a practitioner must meet the requirements in the 2010 DEA EPCS interim final rule. We note that not all electronic prescribing systems currently meet the DEA's requirements.

Since the issuance of the 2010 DEA EPCS interim final rule, we have seen a steady increase in the volume of controlled substance prescriptions submitted electronically. States have instituted electronic prescribing requirements; some include penalties for not using e-prescribing for controlled substances. As of 2020, all states in the U.S., and Washington DC allow electronic prescribing of controlled substances for schedules II through V.[52]

EPCS provides multiple advantages over the traditional processing of paper prescriptions.[53] [54] [55] [56] [57] [58] In addition to improving workflow efficiencies, electronic prescribing of controlled substances can deter and help detect prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes. It can also provide more timely and accurate data than paper prescriptions by avoiding data entry errors and pharmacy calls to a prescriber to clarify written instructions. By allowing for the direct transmission of EPCSs between providers and pharmacies or facilities, EPCS may also reduce the burden on prescribers who need to coordinate and manage paper prescriptions between staff, patients, facilities, other care sites, and pharmacies. In addition, EPCS (dispensed medication) data is transmitted to Prescription Drug Monitoring Programs (PDMPs), which can help inform providers of patients' medication history and can aid in clinical decision making at the time of prescribing and/or before the medication is dispensed by a pharmacy. It is also important to continue the assurance of privacy and security in the prescribing process, such as by controlling prescriber access through improved identity controls and authentication protocols. EPCS can also assure prescribers' identity more easily and may permit a single workflow for prescribing both controlled and non-controlled drugs, improving the overall prescribing process.[59]

From the patient standpoint, EPCS may reduce the logistical burden on patients who may otherwise be required to make multiple trips between providers and pharmacies to transport paper prescriptions when filling time-sensitive prescriptions while in pain or otherwise in need of medical treatment with controlled substances. EPCS can lessen the time needed to obtain prescriptions by minimizing trips to the physician to pick up paper prescriptions for refills and minimize transportation costs to and from the provider's office. EPCS identity and security requirement also assure prescribers, patients, and pharmacies that prescriptions are processed as intended. In addition to helping with the reduction in fraud previously described, EPCS minimizes the likelihood that prescriptions have been tampered with, since electronic prescriptions are securely transmitted directly to the pharmacy from health information technology, which minimizes the likelihood of exposure to patients or other third parties.

2. The Current EPCS Environment

Based on a published report of 2019 data reflecting the majority of prescribing activities across the country,[60] 97 percent of U.S. pharmacies were capable of processing EPCSs, yet only 49 percent of prescribers were capable of electronically prescribing controlled substances. The same report showed that 38 percent of controlled substance prescriptions were electronically prescribed, while 85 percent of non-controlled substances were electronically prescribed. Pain management specialists appear to be using electronic prescribing more often for opioids than other prescribers, and family practitioners are using electronic prescribing for opioids less often. Electronic prescribing also varies across practice size and ownership and among physicians who practice in groups owned by a health plan, health maintenance organizations (HMOs), hospital, or other healthcare entity. Use of the technology does not vary

[52] Schedule I drugs are not included in EPCS discussions because they have no currently accepted medical use. See *https://www.deadiversion.usdoj.gov/schedules/#define* for additional detail on definitions of controlled substances.

[53] Phillips *et al.,* ''Market Guide for Identity Proofing and Corroboration.'' April 24, 2018. Gartner, Inc. Retrieved from *https://www.fedscoop.com/gartner-guide-identity-proofing-corroboration-2018/* on April 30, 2020.

[54] Ryan, D. ''FinCEN: Know Your Customer Requirements.'' February 7, 2016. Harvard Law School Forum on Corporate Governance. Retrieved from *https://corpgov.law.harvard.edu/2016/02/07/fincen-know-your-customer-requirements/#2b* on April 30, 2020.

[55] Nix, M. ''Five Questions: Ken Whittemore Talks Past, Present & Future of E-Prescribing Controlled Substances.'' March 31, 2020. SureScripts. Retrieved from *https://surescripts.com/news-center/intelligence-in-action/opioids/five-questions-ken-whittemore-talks-past-present-future-of-e-prescribing-controlled-substances?utm_campaign=IIApercent2FBlog percent20Subscription&utm_source=hs_email&utm_medium=email&utm_content=85955401&_hsenc=p2ANqtz-8xs36u7xTFZ-ieOxJk3309SApbE7to_fnk1SZvz2jqwz0pA3k7TtW9byiOq2zBlheLInMOeajCMCKeQUTzcEDP79HEaeXI52QiadhAYAWU3Px2eZc&_hsmi=85955401* on April 30, 2020.

[56] Zhang et al. ''T2FA: Transparent Two-Factor Authentication.'' June 15, 2018. IEEE Access. Retrieved from *https://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=8386653* on April 30, 2020.

[57] Konoth R.K., Van Der Veen V., Bos H. (2017) How Anywhere Computing Just Killed Your Phone-Based Two-Factor Authentication. In: Grossklags J., Preneel B. (eds) Financial Cryptography and Data Security. FC 2016. Lecture Notes in Computer Science, vol. 9603. Springer, Berlin, Heidelberg. Retrieved from *https://link.springer.com/chapter/10.1007 percent2F978-3-662-54970-4_24* on April 30, 2020.

[58] Cal and Zhu. ''Fraud detections for online businesses: a perspective from blockchain technology.'' *Financial Innovation* (2016) 2:20. Retrieved from *https://link.springer.com/content/pdf/10.1186/s40854-016-0039-4.pdf* on April 30, 2020.

[59] HHS Office of the National Coordinator, The ONC Doctors' Perspective: Electronic Prescribing of Controlled Substances (EPCS) Is on the Rise, and We Must Work Together to Address Barriers to Use: *https://www.healthit.gov/buzz-blog/health-it/the-onc-doctors-perspective-electronic-prescribing-of-controlled-substances-epcs-is-on-the-rise-and-we-must-work-together-to-address-barriers-to-use.*

[60] Surescripts. ''National Progress Report 2019.'' March 2020. Retrieved from *https://surescripts.com/docs/default-source/national-progress-reports/7398_ab-v2_2019-npr-brochure.pdf* on April 20, 2020.

significantly between rural and urban areas, but it does vary between states.[61] Based on our analysis of the issue and conversations with the industry, we believe that this is associated with differences in regulations, penalties, waivers, populations, and culture.

The reasons for this disparity between capability and practice are varied. There may be challenges associated with clinicians' ability to electronically prescribe controlled substances within their normal workflow, reluctance to alter workflow habits, or reluctance to use new technology, but at this point, as mentioned earlier, most pharmacies are capable of processing EPCS. Some prescribers may rely on health care groups, clinics, and hospital systems to implement the necessary technology. There are also costs associated with the adoption of technology, which can disproportionately impact small or rural practices or pharmacies. Though EPCS uptake continues to grow in physicians and pharmacies,[62] [63] [64] clear gaps remain between capacity and adoption of electronic prescribing of controlled substances.

Substantial adoption of EPCS has occurred in the thirteen states that require it.[65] Some states have chosen to use penalties to increase prescribers' compliance with EPCS requirements. For example, New York mandated EPCS with a penalty for non-compliance and subsequently experienced an EPCS adoption rate for controlled substances of nearly 99 percent for pharmacies and 82 percent for prescribers in 2019.[66] We do not currently impose penalties for providers prescribing controlled substances under the Part D program who do not use e-prescribing. Rather, Part D plans may reject improper transactions or transactions that did not adhere to the CMS transaction standards.

3. E-Prescribing Standards

CMS adopted the first set of standards for e-prescribing for Part D, the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Version 5, Release 0 in the Medicare Program; E-Prescribing and the Prescription Drug Program, Final Rule, in 2005.[67] Since then CMS has continued to adopt updated e-prescribing standards [68] with the most recent standard described in a final rule published April 16, 2018 where we finalized an update of the Part D standards to NCPDP SCRIPT standard version 2017071 for e-Rx and medication history, effective January 1, 2020 (83 FR 16440).

We currently require that Part D plans support the NCPDP SCRIPT standard version 2017071 for certain defined e-prescribing transactions as finalized in the ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' final rule (83 FR 16440). This requirement became effective on January 1, 2020. Under CMS regulations, prescribers are required to use this standard when conducting e-prescribing for covered Part D drugs for Part D eligible individuals.

4. SUPPORT Act Requirements

Section 2003 of the SUPPORT Act generally mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. Section 2003 of the SUPPORT Act requires that the Secretary use rulemaking to specify circumstances and processes by which the Secretary may waive the EPCS requirement and provides the Secretary with authority to enforce and specify appropriate penalties for non-compliance with EPCS. The SUPPORT Act specifies some circumstances under which the Secretary may waive the electronic prescribing requirement with respect to controlled substances that are covered Part D drugs and also permits HHS to develop other appropriate exceptions. The circumstances that are listed in the statute under which the Secretary may waive the EPCS requirement are at section 1860D–4(e)(7) of the Act, as added by section 2003 of the SUPPORT Act, and include:

- A prescription issued when the practitioner and dispensing pharmacy are the same entity;
- A prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;
- A prescription issued by a practitioner who received a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;
- A prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;
- A prescription issued by a practitioner prescribing a drug under a research protocol;
- A prescription issued by a practitioner for a drug for which FDA requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;
- A prescription issued by a practitioner—

++ For an individual who receives hospice care under this title; and

++ That is not covered under the hospice benefit under this title; and

- A prescription issued by a practitioner for an individual who is—

++ A resident of a nursing facility (as defined in section 1919(a)); and

++ Dually eligible for benefits under this title and title XIX.

[61] HHS Office of the National Coordinator, The ONC Doctors' Perspective: Electronic Prescribing of Controlled Substances (EPCS) Is on the Rise, and We Must Work Together to Address Barriers to Use: *https://www.healthit.gov/buzz-blog/health-it/the-onc-doctors-perspective-electronic-prescribing-of-controlled-substances-epcs-is-on-the-rise-and-we-must-work-together-to-address-barriers-to-use.*

[62] Burger, M. ''Accelerating ePrescribing for Controlled Substances.'' HIT Perspectives: Controlled Substances, February 2014. Retrieved from *https://www.pocp.com/hitperspectives-controlled-substances/* on April 30, 2020.

[63] Imambaccus N., Glace S., Heath R. Increasing the uptake of electronic prescribing in primary care. BMJ Quality Improvement Reports 2017;6:u212185.w4870. doi:10.1136/bmjquality.u212185.w4870. Retrieved from *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5457970/pdf/bmjqir.u212185.w4870.pdf* on April 30, 2020.

[64] Monegain, B. ''E-prescribing takes off like a rocket.'' Healthcare IT News, June 18, 2015. Retrieved from *https://www.healthcareitnews.com/news/e-prescribing-takes-rocket* on April 30, 2020.

[65] Arizona, Connecticut, Florida, Indiana, Iowa, Maine, Minnesota, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, and Virginia have adopted mandates that will be in effect in 2020. DrFirst. Mandates Driving EPCS and PDMP Utilization. Accessed April 29, 2020. *https://drfirst.com/resources/regulatory-mandates/.*

[66] Surescripts, 2019 National Progress Report. Accessed April 29, 2020. *https://naspa.us/wp-content/uploads/2020/04/7398_2019-NPR-Brochure-Web-Final.pdf.*

[67] See 70 FR 67568.

[68] CMS regulations adopting updated versions of the NCPDP SCRIPT standard: 73 FR 18918 (NCPDP SCRIPT version 8.1); and 77 FR 688892 (NCPDP SCRIPT version 10.6).

In the Medicare Program: Electronic Prescribing for Controlled Substances; Request for Information, we are requesting feedback on the appropriate waivers and whether CMS should impose penalties for noncompliance with the EPCS mandate in its rulemaking, and what should be the penalties. We plan on using the important public feedback we receive from the Request for Information in future standalone rulemaking.

5. Proposed Timeframe for EPCS Adoption

Section 2003 of the SUPPORT Act mandates that EPCS begin on January 1, 2021. Due to this statutory mandate coupled with the aforementioned advantages provided by EPCS, we encourage all prescribers to conduct EPCS as soon as is feasible for them.

We believe that although EPCS is ultimately more efficient, implementing EPCS does take additional time and resources. Prescribers must follow all the DEA guidance established by the DEA and summarized at *https://deadiversion.usdoj.gov/ecomm/e_rx/.* The requirements for individual practitioners and those enrolled in group practices vary but in general, a prescriber will need to make sure that their current ePrescribing software can support EPCS and is accredited by the DEA accordingly. In addition, before providers are approved for EPCS, their identity must be validated, including that they are authorized to prescribe controlled substances, and that their DEA number and license are in good standing. This step is required even if they are already prescribing controlled substances on paper. They must also get two-factor authentication in place which can be accomplished through include a combination of passwords, tokens, mobile phones, smart cards, and/or fingerprint biometrics. The providers must often have approved software configured to process EPCS which may require another set of permissions. Once that's completed, providers can process electronic prescriptions of controlled substances using the agreed upon two-factor authentication for each transaction. There are software and workflow training involved at each step of the process. When writing prescriptions, they must talk to their patients about e-prescribing, so their patients are aware of the general mechanics of how it is conducted.

We also recognize that the current PHE for the COVID–19 pandemic presents additional EPCS challenges for some prescribers. We have seen that those prescribers who had already implemented EPCS capabilities have been able to increase the number of prescriptions electronically prescribed during the PHE. However, other provider groups have indicated that they do not anticipate being able to reschedule the EHR upgrades necessary to implement EPCS for at least three to four months, at which point practice resource limitations could make it difficult to deploy the necessary upgrades in a compressed timeframe. Other physician practices have indicated that complying with established EPCS identify proofing processes may be difficult because key personnel are unavailable or working offsite. We are sympathetic to the unique challenges faced by prescribers during this PHE for the COVID–19 pandemic. We also recognize the importance of EPCS and the statutory mandate. We believe that requiring EPCS by January 1, 2022 strikes the balance between not providing too large of a burden on providers and helping ensure that the benefits of EPCS are leveraged expeditiously. Furthermore, requiring EPCS by January 1, 2022 would allow time to solicit and consider important feedback from the previously discussed Request for Information that is necessary for implementation of the EPCS requirements for waivers from the requirements and penalties. This includes soliciting feedback from prescribers that we do not directly regulate under MA, and/or Part D, and who are not enrolled in Medicare or Medicaid. Section 1860D–4(e)(2)(E) of the Act requires the Secretary to adopt electronic standards for mandatory use by Part D plans. However, prior to the SUPPORT Act, which modified ePrescribing requirements with respect to schedules II through V controlled substances, all ePrescribing has been optional for physicians. As stated above, the statute provides the Secretary with the authority to develop any exceptions to EPCS that might be warranted, and to enforce and specify appropriate penalties for non-compliance with the requirement. We do not have an existing process for imposing penalties on non-compliant prescribers with respect to EPCS. In developing an entirely new penalty process we must make sure that it enforces the new EPCS requirement, allows for exceptions only when needed, but does not reduce beneficiary's access to needed drugs. Separate from this rule, we intend to conduct future standalone rulemaking that would address these topics.

Based on these considerations, we are proposing to amend § 423.160(a) by adding the requirement that all prescribers conduct electronic prescribing of Schedule II, III, IV, and V controlled substances using the NCPDP SCRIPT 2017071 standard by January 1, 2022, except in circumstances in which the Secretary waives the requirement. We are proposing that prescribers must use the NCPDP SCRIPT 2017071 standard because they are already required to use this standard when conducting e-prescribing for covered Part D drugs for Part D eligible individuals, and we believe that prescribers should use the same standard for their electronic prescribing of controlled substances.

We understand that the proposal to require electronic prescribing for controlled substances for covered Part D drugs under a prescription drug plan or MA–PD plan would uniquely affect physicians. As a result, we seek to gain the insight and perspective of prescribers and others. We welcome comments on this proposal, including the feasibility for prescribers to meet the proposed January 1, 2022 deadline. We are also soliciting comments regarding the impact of this proposal on overall interoperability and the impact on medical record systems. Finally, we are interested in receiving comments on whether the proposed change would be significant enough for a January 1 implementation date, which is required for all significant changes affecting Part D plans.

L. Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act

1. Background

Medicare Part B covers drugs under a limited drug benefit that includes drugs and biologicals defined in section 1861(t) of the Act. Medicare Part B drugs and biologicals fall into three general categories: Drugs and biologicals furnished incident to a physician's services, drugs and biologicals administered via a covered item of durable medical equipment (DME), and other drugs and biologicals specified by statute. Payment amounts for most separately payable Medicare Part B drugs and biologicals are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on.

Drugs (not including biologicals or biosimilar biological products, as defined in section 1847A of the Act) paid using the methodology in section 1847A of the Act fall into two broad and mutually exclusive categories: Multiple

source drugs and single source drugs. These terms are defined in statute and are further discussed in this section and the next section. In most cases the distinction between the multiple source drugs and single source drugs is fairly straightforward and is made as outlined in program instruction published in 2007 (*https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*): The payment limit under section 1847A of the Act for that biological product or single source drug is based on the pricing information for products produced or distributed under the applicable FDA approval. However, for a subset of drug products approved through the pathway established under section 505(b)(2) of the FFDCA, the distinction is less straightforward.

The drug approval pathway established under section 505(b)(2) of the FFDCA has existed since 1984, before the ASP payment methodology was established. The section 505(b)(2) pathway is provided for applications that contain full reports of investigations of safety and effectiveness, where at least some of the information for an approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. An application submitted pursuant to section 505(b)(2) (which we refer to as a ''section 505(b)(2) application'') may rely on FDA's finding of safety and/or effectiveness for a listed drug (an approved drug product) or published literature provided that such reliance is scientifically justified and the section 505(b)(2) applicant complies with the applicable statutory and regulatory requirements, including patent certification if appropriate. Unlike an ANDA for a generic drug, a 505(b)(2) application is not required to have the same labeling as the listed (approved) drug(s) that the application relied upon. However, some drugs approved through the pathway established under section 505(b)(2) of the FFDCA (which we refer to as ''section 505(b)(2) drug products'') share significant portions of the FDA-approved labeling with the listed (approved) drug(s) that the application submitted through section 505(b)(2) relied upon, for example prescribing information on safety, efficacy, and pharmacokinetics. In some cases, the section 505(b)(2) drug product shares significant portions of labeling with generic drugs that are paid as multiple source drugs under section 1847A of the Act. Examples of situations where a section 505(b)(2) drug product shares similar labeling to listed (approved) products include a sterile injectable drug product that had been sold as a lyophilized powder in a vial and was then approved for sale as a concentrated liquid in a vial, as well as a ready-to-use IV bag.

The number of drugs approved through the pathway established under section 505(b)(2) has been growing, from about 40 per year from 2011 to 2016, to about 60 in 2017, and 70 in 2018. Some of these approvals include drugs paid under Part B. Although we have assigned some section 505(b)(2) drug products to separate single source billing and payment codes, our payment approach for newly marketed section 505(b)(2) drug products, where an existing multiple source code descriptor describes the section 505(b)(2) drug product accurately, and where the active ingredient(s), the drug name, and portions of the prescribing information correspond to existing products that are assigned to and paid under a multiple source drug code, has been to assign the section 505(b)(2) drug products to the existing multiple source code. We believe that this approach, as described in more detail below, is consistent with statutory language in section 1847A of the Act. The definition of multiple source drug at section 1847A(c)(6)(C) of the Act states in part that for a multiple source drug, there are two or more drug products which are rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''). For purposes of Part B drug payment under section 1847A of the Act, we interpret this to mean that if there is an existing HCPCS billing code that includes two or more drug products which are rated therapeutically equivalent and meets the remaining conditions of the definition of a multiple source drug, that billing and payment code is a multiple source drug code, and the section 505(b)(2) drug product meets the definition of a multiple source drug in section 1847A(c)(6)(C) of the Act. The statutory language in sections 1847A(b)(3) and (6) of the Act provides discretion for CMS to assign additional drug products to a multiple source drug code. In other words, if a multiple source drug code exists, CMS is permitted to assign other multiple source drug products to that code for the purpose of payment as a multiple source drug under section 1847A of the Act. We note that if the drug product is described by a multiple source code, it meets the definition of multiple source drug at section 1847A(c)(6)(C) of the Act, and it does not meet the definition of a single source drug at section 1847A(c)(6)(D) of the Act, because the definition of a single source drug expressly excludes a multiple source drug in section 1847A(c)(6)(D)(ii) of the Act.

CMS has assigned section 505(b)(2) drug products to existing multiple source drug codes for Part B payment under section 1847A of the Act in limited situations, that is, where an existing multiple source code descriptor describes the section 505(b)(2) drug product, the active ingredient(s) correspond to one another, the section 505(b)(2) drug product's labeling, particularly the prescribing information, includes information (such as the drug description, dosage and administration, pharmacokinetics, and indications) from other drug products that are paid under the multiple source drug code, and the section 505(b)(2) drug product can be used and prescribed in a manner similar to other products in the multiple source drug code. This information is used to determine whether the section 505(b)(2) drug product can be billed and paid using the existing multiple source drug code. The determination is based on the discussion in the previous paragraph, that is, if there is an existing HCPCS billing code that includes two or more drug products which are rated therapeutically equivalent and meet the remaining conditions of the definition of a multiple source drug, that billing and payment code is a multiple source drug code. Consistent with the statutory language in sections 1847A(b)(3) and (6) of the Act, which provides discretion for CMS to assign additional drug products to a multiple source drug code, a section 505(b)(2) drug product can be assigned to the multiple source drug code. The section 505(b)(2) product assigned to the multiple source drug code meets the definition of a multiple source drug in section 1847A(c)(6)(C) of the Act. Thus, for the purpose of payment under Medicare Part B, the section 505(b)(2) drug product can be billed and paid under that existing multiple source code. However, in situations where there is no existing multiple source drug code that describes a section 505(b)(2) drug product, the section 505(b)(2) drug product is typically assigned to its own single source code.

2. Multiple Source Drug and Single Source Drug Codes

Section 1847A of the Act uses the terms drug and drug product. Consistent with the statutory definitions discussed at section 1847A(c)(6)(C) and (D) of the Act and program instruction published in 2007 (*https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/*

Downloads/051807_coding_annoucement.pdf), we have applied the terms multiple source drug and single source drug at the billing and payment code level, meaning that ''drug'' corresponds to a HCPCS or other applicable billing code and its descriptor, which typically includes the active ingredient(s) of the drug. The term ''drug product'' corresponds to individual packages of the drug as identified by the National Drug Code or other applicable alternative identifier.

The terms multiple source drug and single source drug are defined, respectively, in section 1847A(c)(6)(C) and (D) of the Act. Section 1847A(c)(6)(C) of the Act states that multiple source drug means, for a calendar quarter, a drug for which there are two or more drug products which are rated as therapeutically equivalent (under FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''); are pharmaceutically equivalent and bioequivalent, as determined by the FDA; and are sold or marketed in the United States during the quarter. Sections 1847A(c)(6)(E) and (F) of the Act establish conditions under which pharmaceutical equivalence and bioequivalence are met. The definition of multiple source drug in section 1847A of the Act can be interpreted to mean that once a multiple source drug code exists—that is, once there are two or more drug products that are therapeutically equivalent, pharmaceutically equivalent and bioequivalent, and CMS has assigned them to a multiple source drug code—then a subsequent product of the same drug—that is, a product that corresponds to the multiple source drug code's descriptor—can be assigned to such code even if the subsequent drug product is not, itself, therapeutically equivalent, bioequivalent or pharmaceutically equivalent. This is because in this case, the drug is multiple source, meaning that there are two or more products which are rated as therapeutically equivalent of that drug, as evidenced by the fact that the existing products are already assigned to the multiple source drug code. Once a drug product is assigned to a multiple source drug code, the product would not be assigned to a single source drug code because the definition of single source drug at section 1847A(c)(6)(D)(ii) of the Act states, in part, that a single source drug is a drug which is not a multiple source drug. Thus, when assigning drug products to multiple source and single source drug codes for the purpose of payment under section 1847A of the Act, we consider whether the product is described by an existing multiple source drug code first, and if the product is assigned to an existing multiple source drug code, its payment allowance will be determined based on the volume-weighted average ASPs of all drug products assigned to the code, rather than based solely on its own ASP (for example under a new single source code).

Sections 1847A(b)(3) and (6) of the Act provide that payment for multiple source drugs is determined for all drug products included within the same multiple source drug billing and payment code. For multiple source drugs, we calculate a volume weighted average sales price across all drug products assigned to a billing and payment code. This typically means that the ASP-based payment amount for a multiple source drug code includes generic and branded drug products within an individual code.

Consistent with sections 1847A(b)(3) and (6) of the Act and our interpretation of the definition of multiple source drug in section 1847A(c)(6) of the Act, we assign certain section 505(b)(2) drug products to existing multiple source drug codes. We determine whether to assign section 505(b)(2) drug products to multiple source or single source drug codes by comparing information about the section 505(b)(2) drug product to the descriptors for existing multiple source codes to which the drug products may be assigned for the purposes of payment amount determinations under section 1847A of the Act, as well as information about products already assigned to that descriptor. This information includes the products' active ingredients and labeling, particularly the prescribing information and, if necessary, additional sources such as the FDA's Approval Summary Review, which is a part of the FDA's application review files and is available at *https://www.accessdata.fda.gov/scripts/cder/daf/,* and drug compendia. The FDA's Approval Summary review can provide additional details about information that is found in the drug's labeling and prescribing information and other compendia can supplement the information that is found in labeling and provide information about off label use of a drug.

Our case by case determination about the assignment of certain section 505(b)(2) drug products to existing multiple source drug codes is based on the factors described in further detail in the bullet points below: First, the products' active ingredient(s), drug name and description; second, the products' labeling information; third, how they are ordered (prescribed) and used clinically. These factors are assessed as a whole, using the information (for example, active ingredient, labeling, compendia, and FDA Approval summary), to determine whether an existing multiple source drug code describes a section 505(b)(2) drug product and whether the product can be assigned to an existing multiple source drug code for the purpose of payment under section 1847A of the Act. The determination is based on the following:

- The active ingredient and drug name of the section 505(b)(2) drug product and other drug products in an existing multiple source drug code.
- The drug description and indications, particularly whether differences such as the salt form, additional ingredients, or uses exist.

The two bullet points above identify the section 505(b)(2) drug product and multiple source drug code and establish what is being compared so that the determination can proceed, if necessary. For example, if the active ingredients and drug names do not correspond, there would not be a reason to assign the section 505(b)(2) drug product to the multiple source drug code or to proceed further. We also note that the active ingredient of a drug is often included in the HCPCS code descriptor that is used to bill a drug product and to pay for it under section 1847A of the Act. The drug description is used, if necessary, to clarify what the actual active ingredient(s) are, whether there are minor differences, such as salt forms and other inactive ingredients that may affect how the product is used. This information may be helpful when considered with the information in the next two groups of bullet points as we consider labeling and uses of the drug products.

- The labeling information (and if necessary other material from sources such as the FDA's Application Review Files, including the FDA's Approval Summary Review and drug compendia), particularly pharmacokinetics, indications, adverse reactions, drug interactions, contraindications, warnings, precautions and clinical studies.

The bullet point above allows us to determine whether the same information, for example the same studies, were used to support the approval of the section 505(b)(2) drug product and to gauge how much of the labeling information from existing multiple source drug products appears in the section 505(b)(2) drug product's labeling. This information also supports the determination in the next bullet

point. The more labeling information that a section 505(b)(2) drug product has in common with drug products in an existing multiple source drug code, the more likely it is that the existing code describes the section 505(b)(2) drug product, such that CMS will assign it to that multiple source drug code for the purpose of payment under section 1847A of the Act.

- The dosage and administration, pharmacokinetics, indications, contraindications, warnings, drug interactions, and adverse reactions.

The bullet point above allows us to determine whether the section 505(b)(2) drug product is ordered and used in patient care in the same way as products assigned to a multiple source drug billing code. The dosage and administration, pharmacokinetics, and indications are particularly important because we consider whether a prescriber writes a prescription for the section 505(b)(2) drug product in the same way as drug products assigned to a multiple source drug code and whether the products could be used for the same uses. Typically, a prescription includes the following information: The drug, dose, route, and frequency. The quantity of a drug (or duration of therapy) and refills are also a part of a prescription, but are less of a factor for Part B where most drugs are used incident to a physician's services. Typically, drugs used incident to a physician's services are administered and billed as a very limited number of doses, often just one, are administered during a service, and the drug is not dispensed for the patient for use over an extended time period beyond an office visit or outpatient hospital visit. The elements in the bullet point reflect how a drug is used and administered in the care of patients and in turn determine how billing for the drug is accomplished; that is, whether an existing code descriptor describes a section 505(b)(2) drug product and can be used to bill for it.

As a simple example of our approach, if the active ingredient, dose, route and frequency of the section 505(b)(2) drug product are the same as those for drug products in a multiple source drug code, then it is likely that an existing code descriptor describes a section 505(b)(2) drug product and can be used to bill for it. The information does not have to be an exact match, for example different uses of a drug product may require different doses, routes or frequencies. However, if the section 505(b)(2) drug product and the multiple source drug products in the existing multiple source drug code could both be used for the same indication (potentially by way of off-label use), then billing for both with the existing HCPCS code would still be feasible. In such situations, similarities between labeling information such as whether the same studies were used to establish pharmacokinetic parameters may factor into the assessment. In summary, the information is used as a whole to determine whether the existing multiple source drug HCPCS code descriptor describes the section 505(b)(2) drug product or if a new HCPCS code would be needed describe the product for payment under Part B.

The information described in the bullet points above is usually sufficient for our determinations, but from time to time we may reach out to the drug manufacturer, seek post marketing data, or literature sources for additional information to assist us with understanding the information in the bullet points above and to assist with determinations in complicated situations, for example where indications vary, but it appears that the section 505(b)(2) drug product could still be used, administered and billed in the same manner as drug products assigned to an existing multiple source drug code.

We are aware that some section 505(b)(2) drug products are very different from previously approved products that may be used to support their approval. We do not assign all section 505(b)(2) drug products to existing multiple source drug codes. In circumstances where an existing code does not describe the section 505(b)(2) drug product and use of the existing code would not be suitable for billing and payment of the section 505(b)(2) product under Part B based on the assessment described above, the section 505(b)(2) drug product would not be assigned to the existing multiple source drug code. The following examples illustrate how we distinguish section 505(b)(2) drug products that are assigned to an existing multiple source drug code from those that are not. If a section 505(b)(2) drug product has the same active ingredient, same dose and dosing interval, and prescribing information and includes the same clinical studies (for example, the same patient number, same response rates and same adverse reaction frequencies) as drug products assigned to an existing multiple source drug code, the section 505(b)(2) drug product would be assigned to the multiple source code. However, if the section 505(b)(2) drug product has different pharmacokinetics, for example if it is a sustained release version of a drug that permits less frequent dosing compared to drug products in an existing multiple source drug code, or if the section 505(b)(2) drug product has additional active ingredients not found in the drug products in an existing multiple source drug code, the section 505(b)(2) drug product would not be described by the existing multiple source drug code. As a result, it would not be considered a multiple source drug under section 1847A(c)(6)(C) because there would not be at least two drug products for that drug that are therapeutically equivalent, pharmaceutically equivalent and bioequivalent; thus, the section 505(b)(2) drug product would be considered a single source drug and typically assigned to a single source drug code.

3. Proposal To Codify Existing Policy for Section 505(b)(2) Drug Products

Our approach (described in section 2) for the payment of section 505(b)(2) drug products has been in place for at least 12 years, and it is also consistent with the concept of paying similar amounts for similar services. It is based on the definitions of multiple source drug and single source drug in sections 1847A(c)(6)(C) and (D) of the Act and authority to assign drug products to billing and payment codes in sections 1847A(b)(3) and (6) of the Act as discussed in the sections above. A number of section 505(b)(2) drug products that are described by an existing multiple source drug code are priced significantly higher than comparable products. Two recently introduced section 505(b)(2) drug products that appear to be comparable to drug products in existing multiple source drug codes (using the approach described in the section earlier) have Medicare payment allowances that are approximately 10 times higher than that of the existing multiple source code. We believe that assigning section 505(b)(2) drug products that are described by existing multiple source drug HCPCS codes to those existing HCPCS codes is consistent with efforts to curb drug prices while limiting opportunities to ''game the regulatory process and the patent system in order to unfairly maintain monopolies.'' [69] Our approach also encourages competition among products that are competitors—that is, when they are described by one billing code and share similar labeling.

We are concerned about high payments for section 505(b)(2) drug products if they are assigned to unique separate HCPCS codes despite being described by existing multiple source

[69] *https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/.*

drug codes. We are also concerned about the effect of high payment amounts on individual beneficiaries' cost sharing payments for these products.

We propose to continue assigning certain section 505(b)(2) drug products to existing multiple source drug codes if the section 505(b)(2) products are described by existing multiple source drug codes consistent with our interpretation of the definition of multiple source drug in section 1847A(c)(6)(C) of the Act and the approach described above. As discussed in the previous section, where a section 505(b)(2) product is not itself therapeutically equivalent, pharmaceutically equivalent, or bioequivalent, as determined by FDA, to another drug product, we would nonetheless consider it to meet the definition of multiple source drug if, based on an assessment of its active ingredient, labeling, compendia, and other information, the product is described by the code descriptor for an existing multiple source drug code. That is, we would assess the section 505(b)(2) drug product's active ingredient(s), drug name, and description, whether the section 505(b)(2) drug product's labeling, particularly the prescribing information, includes information from other drug products that are paid under the multiple source drug code, and whether the section 505(b)(2) drug product is used and prescribed in a manner similar to other products in the multiple source drug code, in order to determine whether the section 505(b)(2) drug product is described by an existing multiple source drug code. We would not assign all section 505(b)(2) drug products to multiple source codes and would not assign section 505(b)(2) drug products to a single source drug code exclusively made up of single source drug products. We would also reevaluate and potentially revise previous payment (and coding) decisions to maintain consistency with our proposed approach, if finalized. Consistent with these proposals, we propose to revise the definition of multiple source drug in regulation text at 42 CFR 414.902 by amending the regulation text to state that multiple source drugs may include drug products described under section 505(b)(2) of the FFDCA and adding § 414.904(k) that describes the framework for our determination as discussed in this section of the preamble. We welcome comments on our proposals.

M. Updates to Certified Electronic Health Record Technology Due to the 21st Century Cures Act Final Rule

1. Background

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5, enacted February 17, 2009) authorized incentive payments to eligible professionals, eligible hospitals and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of Certified Electronic Health Record Technology (CEHRT). In 2010, the Office of the National Coordinator for Health Information Technology (ONC) launched the Health IT Certification Program (Certification Program) to provide for the certification of health IT. Requirements for certification are based on standards, implementation specifications, and certification criteria adopted by the Secretary. The Certification Program supports the use of certified health IT under the programs that we administer, including, but not limited to, the Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs), the Quality Payment Program (QPP), and the Hospital Inpatient Quality Reporting (IQR) Program. While these programs continue to require the use of certified health IT, the use of certified health IT has expanded to other government and non-government programs. Since 2019, for the Promoting Interoperability Programs and QPP, we have required the use of CEHRT as defined at 42 CFR 495.4 and 414.1305, respectively, which generally consists of EHR technology (which could include multiple technologies) certified under the Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition. Similarly, the Hospital IQR Program began requiring that hospitals use only 2015 Edition certification criteria for CEHRT with the CY 2019 reporting period/FY 2021 payment determination (83 FR 41607).

The 21st Century Cures Act final rule that appeared in the May 1, 2020 **Federal Register** (85 FR 25642 through 25961) finalized a number of updates to the 2015 Edition of health IT certification criteria (hereinafter referred to as the 2015 Edition Cures Update). We believe these updates to the 2015 Edition will enhance interoperability and patients' access to their electronic health information, consistent with section 4006(a) of the 21st Century Cures Act. The 21st Century Cures Act final rule both revises and adds new certification criteria that establish the capabilities and related standards and implementation specifications for the certification of health IT, as well as removing certain criteria. In this proposed rule, we propose to require that technology used to meet the CEHRT definitions must be certified in accordance with the updated certification criteria in the 21st Century Cures Act final rule.

The 2015 Edition Cures Update represents a limited set of changes relative to the overall set of health IT certification criteria that we currently require for the Promoting Interoperability Programs and QPP. These changes incorporate certain technical standards, including an e-prescribing standard required for alignment with other CMS programs, and other technical updates to existing 2015 Edition functionality that is already being used by many healthcare providers. For instance, updates to 2015 Edition certification criteria that referenced the Common Clinical Data Set (CCDS) regulatory definition to reference instead the United States Core Data for Interoperability (USCDI) standard do not require extensive changes to user-facing aspects of health IT already certified to these criteria (85 FR 25665).

For 2019 and subsequent years, the CEHRT definitions for the Promoting Interoperability Programs at § 495.4, and for QPP at § 414.1305, require the use of EHR technology certified under the Certification Program that meets the 2015 Edition Base EHR definition at § 170.102, and has been certified to certain other 2015 Edition health IT certification criteria as specified in the definitions, including criteria necessary to be a meaningful EHR user under the Promoting Interoperability Programs, and criteria necessary to report on applicable objectives and measures specified for the MIPS advancing care information performance category (now known as the Promoting Interoperability performance category). These updates finalized by ONC in the 21st Century Cures Act final rule impact criteria in the different elements of the CEHRT definitions, including certification criteria included in the 2015 Edition Base EHR definition for the Promoting Interoperability Program and the Quality Payment Program, as well as certification criteria necessary to be a meaningful EHR user under the Promoting Interoperability Programs, and criteria necessary to report on applicable objectives and measures

specified for the MIPS Promoting Interoperability performance category.

The 21st Century Cures Act final rule specified a number of timelines and compliance dates for health IT developers related to the 2015 Edition Cures Update. The rule finalized the removal of several certification criteria from the 2015 Edition that were also included in the Base EHR definition, upon the effective date of the final rule (June 30, 2020). For other certification criteria, the final rule finalized a limited period during which ONC-Authorized Certification Bodies (ONC–ACBs) may continue to issue certificates for these criteria to health IT developers, after which certification will no longer be available.

Where the 21st Century Cures Act final rule finalized updates to existing 2015 Edition criteria, or introduced new 2015 Edition criteria, ONC generally finalized that health IT developers will have 24 months from the publication date of the rule (until May 2, 2022) to make technology available that is certified to the updated, or new criteria. During this period, health IT developers are expected to continue supporting technology certified to the prior version of the certification criteria for use by their customers prior to implementing updates, and healthcare providers participating in the Promoting Interoperability Programs and QPP may use such technology for the purposes of these programs while working with health IT developers to implement updates in a manner that best meets their needs.

On April 21, 2020, in response to the COVID–19 public health emergency, ONC announced additional flexibility for health IT developers subject to the policies in the 21st Century Cures Act final rule (*https://www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf*). Specifically, ONC announced that it will exercise enforcement discretion regarding new requirements in the 21st Century Cures Act final rule until three months after each initial compliance date or timeline. During this period of enforcement discretion, healthcare providers participating in the Promoting Interoperability Programs and QPP would continue to be able to use technology certified to the 2015 Edition criteria that has not been updated yet.

Below, we provide an overview of updates in the ONC 21st Century Cures Act final rule that impact certification criteria included in the CEHRT definitions, and discuss associated timelines finalized in the 21st Century Cures Act final rule.

The 21st Century Cures Act final rule finalized removing the following criteria from the 2015 Edition of certification criteria upon the effective date of the final rule (June 30, 2020), which included removing these criteria from the 2015 Edition Base EHR definition (85 FR 25657–25660):

- ''Problem list'' at § 170.315(a)(6);
- ''medications'' at § 170.315(a)(7);
- ''medication allergies'' at § 170.315(a)(8); and
- ''smoking status'' at § 170.315(a)(11).

The final rule noted that functionality associated with these criteria is now widespread among health IT products, and is expected to remain in products absent certification. Accordingly, ONC sought to reduce burden associated with the certification program by removing these criteria (85 FR 25657 through 25660).

The 21st Century Cures Act final rule also removed the ''data export'' criterion at § 170.315(b)(6) from the Base EHR definition upon the effective date of the final rule (June 30, 2020) (85 FR 25668). However, this criterion will continue to be available for certification for 36 months after the publication date of the final rule. The 21st Century Cures Act final rule established a new criterion ''electronic health information export'' at § 170.315(b)(10). This new criterion requires a certified health IT module to electronically export all electronic health information (EHI), as defined in § 171.102, that can be stored at the time of certification by the product of which the health IT module is a part. A health IT developer of a certified health IT products which, at the time presented for certification, electronically stores EHI must certify such products to this new criterion and make these products available to their customers within 36 months after the publication of the 21st Century Cures Act final rule (by May 2, 2023). However, the new EHI Export criterion is not included in the Base EHR definition (85 FR 25690), and it is not associated with any objectives or measures in the Promoting Interoperability Programs or MIPS.

In the 21st Century Cures Act proposed rule, ONC proposed to remove several additional certification criteria associated with measures under the Promoting Interoperability Programs and MIPS from the 2015 Edition:

- ''Drug-formulary and preferred drug list checks'' at § 170.315(a)(10);
- ''secure messaging'' at § 170.315(e)(2); and
- ''patient-specific education resource'' at § 170.315(a)(13).

However, in order to allow participants in the Medicaid Promoting Interoperability Program to continue to have access to technology meeting 2015 Edition certification criteria for CEHRT required to be able to meet the measures for that program, ONC stated in the 21st Century Cures Act final rule that ONC–ACBs may continue to issue certificates for these criteria until January 1, 2022 (85 FR 25660 through 25662).

Specifically, we note that the latter two criteria are necessary for participants to meet two of the measures in the Medicaid Promoting Interoperability Program. The ''secure messaging'' criterion at § 170.315(e)(2) is required to meet Objective 6 (Coordination of Care through Patient Engagement) and Measure 2 (Secure Messaging) (80 FR 62852). Similarly, the ''patient-specific education resource'' at § 170.315(a)(13) is necessary to fulfill the requirements of Objective 5 (Patient Electronic Access to Health Information) and Measure 2 (Patient-Specific Education) (80 FR 62846). We are not proposing any changes to these measures, as the final year of the Medicaid Promoting Interoperability Program is 2021. Based on the phased approach that ONC finalized, Medicaid EPs may keep CEHRT that has been certified to those two criteria in 2021, which will enable them to report on these measures for the 2021 Medicaid Promoting Interoperability Program EHR reporting period. Health IT developers are encouraged to maintain the certified functionality for those two criteria through 2021, even if they move forward with updates to other criteria. Furthermore, the Secure Messaging measure is one of three measures within Objective 6, and EPs need only meet two of the measures (42 CFR 495.24(d)(6)(i)(B)). Even without the secure messaging functionality, an EP could meet the other two measures and fulfill the objective. There is no similar option for the Patient-Specific Education measure, which is required to meet Objective 5.

The ''drug-formulary and preferred drug list checks'' criterion is also currently associated with measures under the e-prescribing objective for the Medicare Promoting Interoperability Program and MIPS (80 FR 62882 and 83 FR 59817). As discussed below, since ONC will retire this criterion after January 1, 2022, this criterion would no longer be required for reporting e-prescribing measures for the Medicare Promoting Interoperability Program and MIPS, beginning in CY 2021 (85 FR 25678).

The 21st Century Cures Act final rule also finalized updates to a number of certification criteria which are currently associated with objectives and measures

under the Promoting Interoperability Program, as well as criteria that are included in the 2015 Edition Base EHR definition. In general, ONC finalized that health IT developers have 24 months from the publication date of the final rule to make technology certified to these updated criteria available to their customers (until May 2, 2022). During this time, developers are expected to continue supporting technology certified to the prior version of certification criteria for use by their customers.

The 21st Century Cures Act final rule updated several criteria to include references to the USCDI standard instead of the existing CCDS definition (85 FR 25670), and implemented related technical updates (85 FR 25671). These include the following criteria that may be applicable for a healthcare provider's technology to satisfy the CEHRT definitions:

- ''Transitions of care'' at § 170.315(b)(1);
- ''clinical information reconciliation and incorporation'' at § 170.315(b)(2);
- ''view, download, and transmit to 3rd party'' at § 170.315(e)(1);
- ''transmission to public health agencies—electronic case reporting'' at § 170.315(f)(5); and
- ''application access—all data request'' at § 170.315(g)(9).

The USCDI standard establishes a set of data classes and constituent data elements required to support interoperability nationwide and is designed to be expanded in an iterative and predictable way over time.[70] In finalizing version 1 of the USCDI, the 21st Century Cures Act final rule added three new data classes, ''allergies and intolerances,'' ''clinical notes,'' and ''provenance;'' and added several additional elements to ''patient demographics'' that were not defined in the CCDS (85 FR 25912).

With respect to the use of secure, standards-based APIs, the 21st Century Cures Act final rule finalized a new standards-based API criterion at § 170.315(g)(10), ''standardized API for patient and population services,'' which requires the use of FHIR Release 4 and several implementation specifications (85 FR 25742). Developers must make technology certified to this criterion available 24 months after the publication of the final rule (by May 2, 2022). This criterion replaces the existing ''application access—data category request'' certification criterion at § 170.315(g)(8). However, ONC–ACBs may continue to issue certificates for § 170.315(g)(8) for 24 months after the publication date of the final rule, permitting certification to both criteria during this transition period. The 21st Century Cures Act final rule also added the new API criterion at § 170.315(g)(10) to the 2015 Edition Base EHR definition.

The 21st Century Cures Act final rule also revised the ''electronic prescribing'' criterion at § 170.315(b)(3) to reference the NCPDP SCRIPT standard version 2017071 (85 FR 25678). As with the other updated criteria above, health IT developers have until 24 months after publication of the final rule (until May 2, 2022), to make technology certified to the updated criterion available to their customers. However, we note that ONC has discontinued certification of new products to the former electronic prescribing criterion using the NCPDP SCRIPT standard version 10.6, in order to align with CMS requirements for use of the updated NCPDP SCRIPT standard under Part D, adopted as of January 1, 2020 (85 FR 25679). Products that were previously certified may maintain certification status for up to 24 months as they are updating their products, and healthcare providers may continue to use these certified health IT modules for CMS program participation.

Finally, the 21st Century Cures Act final rule updated the certification criterion for clinical quality measures ''Clinical Quality Measures (CQMs)—Report'' at § 170.315(c)(3), which is included in the CEHRT definitions (85 FR 25686). These updates remove the HL7 QRDA standard requirements from the criterion, and instead require support for the CMS QRDA Implementation Guides, upon the effective date of the final rule (June 30, 2020).

For further discussion, we refer readers to the 21st Century Cures Act final rule at 85 FR 25642 through 25961.

As noted above, in general, health IT developers have up to 24 months from May 1, 2020 to make technology certified to the updated criteria available to their customers, plus the additional three-month period during which ONC will exercise enforcement discretion around compliance dates finalized in the 21st Century Cures Act final rule in response to the COVID–19 PHE. As a result, where the 21st Century Cures Act final rule requires health IT developers to make technology meeting new and updated certification criteria available by May 2, 2022, developers taking advantage of enforcement discretion would be permitted to delay making updated certified technology available until August 2, 2022. After this date, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified.

ONC expects that developers will introduce these updates into certified health IT products in the manner most appropriate for their customers, including through the course of normal maintenance, and developers are required to notify customers when technology certified to the updated criteria is available (85 FR 25642). As discussed in the 21st Century Cures Act final rule (85 FR 25666), healthcare providers may use the Certified Health IT Product List (CHPL) to identify the specific certification status of a product at any given time. The CHPL will distinguish existing 2015 Edition certification criteria from the new or revised criteria adopted in the 21st Century Cures Act final rule by referring to the new or revised criteria as the 2015 Edition Cures Update, allowing healthcare providers to identify if and when a specific Health IT Module has been updated. (*https://chpl.healthit.gov/*)

2. Updates to Certified Electronic Health Record Technology Requirements in the Promoting Interoperability Program, and Quality Payment Program Due to the 21st Century Cures Act Final Rule

In consideration of the updates made to the certification criteria as described in section III.N.1 of this proposed rule, we propose that the technology used by healthcare providers to satisfy the definitions of CEHRT at §§ 495.4 and 414.1305 must be certified under the Certification Program in accordance with the updated 2015 Edition of health IT certification criteria as finalized in the 21st Century Cures Act final rule (85 FR 25642). This would include technology used to meet the 2015 Edition Base EHR definition at § 170.102, technology certified to the criteria necessary to be a meaningful EHR user under the Promoting Interoperability Programs, and technology certified to the criteria necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, as specified in the CEHRT definitions.

As discussed above, the 21st Century Cures Act final rule finalized certain compliance dates for health IT developers, as well as establishing which versions of certification criteria meet certification requirements under the Certification Program for healthcare providers, based on those compliance dates. In other words, the 21st Century Cures Act final rule established

[70] For more information about the USCDI, see *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

timelines for (1) a transition period where technology certified to not-yet updated or updated versions of the same certification criteria would be considered certified, and (2) the date for which technology certified to only the updated version would be considered certified. A healthcare provider must use technology that is certified under the ONC Health IT Certification Program to meet the CEHRT definitions. Therefore, we propose that healthcare providers participating in the Promoting Interoperability Programs or QPP would be required to use only technology that is considered certified under the ONC Health IT Certification Program according to the timelines finalized in the Cures Act final rule.

For updated and new certification criteria included in the CEHRT definitions in §§ 495.4 and 414.1305, ONC has finalized that health IT may be certified to the current 2015 Edition certification criteria or the 2015 Edition Cures Update for a period of 24 months, as described in timelines finalized in the 21st Century Cures Act final rule (85 FR 25670). ONC then announced an additional 3 months during which ONC will exercise enforcement discretion in response to the COVID–19 PHE and continue to allow health IT certified to either version of the criteria to be considered certified. Therefore, under our proposal, during that same time period (up to 27 months from May 1, 2020, or until August 2, 2022), program participants may use technology certified to either version and that health IT will be considered certified under the ONC Health IT Certification Program.

While the 21st Century Cures Act final rule did not finalize a new Edition of certification criteria, this approach is similar to the prior policy for transition periods between Editions. For example, during the transition period in which the ONC Health IT Certification Program included both the 2014 Edition and the 2015 Edition, a health IT module certified to either Edition was considered certified and could be used by healthcare providers to meet the CEHRT definitions and demonstrate meaningful use (for instance, see 82 FR 38490 for a discussion of the CY 2018 transition between the 2014 and 2015 Editions for eligible hospitals and CAHs). After the end of the transition period, only health IT certified to the 2015 Edition could be used by healthcare providers to meet the CEHRT definitions and demonstrate meaningful use, and health IT modules certified to only the 2014 Edition were no longer considered certified under the ONC Health IT Certification Program.

In the same manner, after the current transition period ends in which health IT certified to either the existing 2015 Edition certification criteria or the 2015 Edition Cures Update criteria is considered certified, healthcare providers must use technology certified to only the updated version of the certification criteria finalized in the 21st Century Cures Act final rule to meet the CEHRT definitions and demonstrate meaningful use.

We provide the following discussion to support further understanding of how our proposals would impact healthcare providers with regard to the CEHRT definitions at §§ 495.4 and 414.1305 and demonstrating meaningful use. If our proposal is finalized, healthcare providers would only be able to use CEHRT that has been certified to the 2015 Edition Cures Update in order for a measure action to count in the numerator during a performance period after August 2, 2022 (reflecting the 24-month compliance deadlines finalized in the 21st Century Cures Act final rule, and the additional 3-month period of enforcement discretion described above). On or prior to August 2, 2022, healthcare providers participating in the Medicare Promoting Interoperability Program and QPP would be able to continue to use technology meeting existing 2015 Edition criteria to meet the CEHRT definition and to support program participation. During this period, healthcare providers could work with their health IT developers to plan for implementing CEHRT that meets the 2015 Edition Cures Update as soon as health IT developers make updated technology available. We believe this approach to updating the current 2015 Edition would allow healthcare providers and health IT developers adequate time to implement updates and plan for an effective transition, including planning ahead for reporting measure results to CMS for program participation.

For instance, during the CY2022 performance year, if a healthcare provider is implementing updates in a phased approach, they could plan to use a combination of updated and non-updated certified health IT for a 90-day reporting period prior to August 2, 2022, and then complete their first reporting period using only updated health IT modules in CY 2023. Similarly, if a healthcare provider planned to update all of their certified technology at one time and to engage in a more extensive testing and implementation period during CY 2022, they may also wish to complete a 90-day reporting period for CY 2022 prior to August 2 using non-updated health IT, and then complete their first reporting period using only updated health IT modules in CY 2023. If a healthcare provider moved to updated certified health IT prior to August 2, including for a reporting period in CY 2020 or CY 2021, they would be able to use the updated technology for a 90-day reporting period at any point, and would not be required to wait until after August 2, 2022.

Healthcare providers should refer to certification criteria and Conditions and Maintenance of Certification requirements in 45 CFR part 170 for details about the updated certification criteria and timelines for health IT developers associated with the criteria. These ONC Health IT Certification Program regulations specify the requirements for what health IT developers must make available to customers and associated timelines.

In previous rulemaking, to assist readers in identifying the requirements of CEHRT for the Promoting Interoperability Program and the MIPS Promoting Interoperability performance category objectives and measures, we provided tables identifying the 2015 Edition certification criteria required to meet those objectives and measures (for instance, see 83 FR 59817 for the MIPS Promoting Interoperability performance category). We note two instances in which updates in the 21st Century Cures Act final rule will affect information we have provided in past rulemaking regarding the certification criteria which support specific Promoting Interoperability objectives and measures. First, we note that the 21st Century Cures Act final rule is retiring the ''drug-formulary and preferred drug list checks'' criterion at § 170.315(a)(10), which is currently identified as supporting measures under the e-prescribing objective (80 FR 62882 and 83 FR 59817). ONC has finalized that health IT may be certified to this criterion only until January 1, 2022. (85 FR 25667) We believe the removal of this criterion from the Certification Program will have negligible impact on healthcare providers. As discussed in prior rulemaking related to the use of these functionalities by participants in CMS programs, healthcare providers have noted that while formulary checks are a promising approach, the utility of the specific functionality that is certified is not necessarily consistently applicable for all prescriptions (80 FR 62833). In addition, as it does not remove the product from the market, any healthcare providers who are using the current functionality may continue to use the technology for their purposes. Accordingly, we note that this certification criterion would no longer

be associated with the measures under the e-prescribing objective for the Promoting Interoperability Programs and MIPS, beginning with the CY 2021 performance period.

Second, under the new API certification criterion, ''standardized API for patient and population services'' at § 170.315(g)(10), which requires the use of FHIR Release 4, health IT developers have 24 months from the publication date of the 21st Century Cures Act final rule to make technology available that is certified to this new criterion, which is part of the 2015 Edition Base EHR definition. After 24 months, ONC will retire the current ''application access—data category request'' at § 170.315(g)(8), which is currently identified as supporting the ''Provide Patients Electronic Access to Their Health Information'' measure (80 FR 62882 and 83 FR 59817). As discussed above, health IT meeting either criteria will be considered certified during the 24-month period. Table 38 shows that either the existing criterion at § 170.315(g)(8), or the newly finalized criterion at § 170.315(g)(10), could be used by healthcare providers to complete the actions of the ''Provide Patients Electronic Access to Their Health Information'' measure for the Promoting Interoperability Programs and MIPS. Allowing healthcare providers the flexibility of using EHR technology that is certified to either criterion during this 2-year transition period would allow early adopters of the newly finalized criterion at § 170.315(g)(10), as well as those using technology meeting the existing certification criterion, to be able to meet the requirements of the Promoting Interoperability Programs and MIPS.

In light of the changes described above with respect to the ''E-prescribing'' and ''Provide Patients Electronic Access to Their Health Information'' measures and objectives for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, we are including Table 38, which provides details on the measures for the Promoting Interoperability Program for eligible hospitals and CAHs and the MIPS Promoting Interoperability performance category and the certification criteria that support each measure. We also include in Table 38 the certification criteria which support reporting of eCQMs. We note that Table 38 is only applicable for the measures under the Medicare Promoting Interoperability Program and for the Promoting Interoperability performance category of MIPS, and that Table 38 does not include all of the updated certification criteria included in the CEHRT definition as discussed in this proposed rule. For further discussion of changes to criteria under the CEHRT definition, we refer readers to the 21st Century Cures Act final rule (85 FR 25667).

TABLE 38: Medicare Promoting Interoperability Objectives and Measures, and 2015 Edition Certification Criteria

Objective	Measure	2015 Edition
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Bonus: Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party § 170.315(g)(7) Application access — patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access — all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(4)[1] Transmission to cancer registries § 170.315(f)(6)[2] Transmission to public health agencies — antimicrobial use and resistance reporting § 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
	Electronic reportable laboratory result reporting[2]	§ 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results
Electronic Clinical Quality Measures (eCQMs)	eCQMs for eligible clinicians, and eligible hospitals and CAHs	§ 170.315(c)(1) § 170.315(c)(2) § 170.315(c)(3)(i) and (ii) § 170.315(c)(3) (optional)

[1] = Specific to Eligible Clinicians (MIPS Promoting Interoperability performance category)
[2] = Specific to Eligible Hospitals and CAHs (Promoting Interoperability Program)

Last, we are proposing to revise two definitions of under § 414.1305. First, under the definitions of CEHRT, we propose to replace the reference to the ''Advancing Care Information'' performance category with the ''Promoting Interoperability'' performance category, to reflect the performance category name change that we made previously (83 FR 59785). Second, under the definition of Meaningful EHR user for MIPS, we propose to replace the reference to the ''Advancing Care Information'' performance category with the ''Promoting Interoperability'' performance category, to reflect the performance category name change that we made previously (83 FR 59785).

We believe each of these proposals supports our focus on promoting interoperability and continued alignment, and would reduce healthcare provider burden while providing flexibility to pursue innovative applications that improve care delivery. We are seeking public comment on all of the proposals discussed above.

3. Proposed Changes to Certification Requirements Under the Hospital IQR Program Due to the 21st Century Cures Act

a. Background and Previously Finalized Certification Requirements

To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program, previously referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509) for the measures we have previously adopted for the Hospital IQR Program measure set for the FY 2022 payment determination and subsequent years. We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

The Hospital IQR Program strives to put patients first by empowering patients to make decisions about their own healthcare along with their clinicians using information from data driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across the Department of Health and Human Services, we believe the Hospital IQR Program incentivizes hospitals to improve healthcare quality and value, while giving patients the tools and information needed to make the best decisions for themselves. The Hospital IQR Program measures assess clinical processes, patient safety and adverse events, patient experiences with care, care coordination, and clinical outcomes, as well as cost of care.

For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period. Hospital IQR Program file format requirements have progressed over time to support quality reporting based on data submitted from EHRs that use relevant, up-to-date, standards-based structured data capture. We updated our requirements with the adoption of new Editions of certified health IT, originally requiring hospitals submitting eCQM data to use the 2014 Edition certification criteria for CEHRT (79 FR 50252) and evolving to the current requirement that hospitals use 2015 Edition certification criteria for CEHRT for reporting eCQMs and hybrid measures (83 FR 41604 through 41607, and 84 FR 42507). In order to ease the transition between Editions of certified health IT, the Hospital IQR Program offered flexibility in file submission requirements, allowing the use of either the 2014 Edition or the 2015 Edition for multiple reporting periods (80 FR 49705 through 49708; 81 FR 57169 through 57170; 82 FR 38397 through 38391). As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57111), our goal is to align electronic quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, as much as feasible so that the reporting burden on healthcare providers will be reduced (82 FR 38392). In the past we noted that aligning the eCQM submission requirements of the Hospital IQR Program and the Promoting Interoperability Programs reduces burden for hospitals as they may report once and fulfill the requirements of both programs (84 FR 42599). We intend to continue to align the eCQM reporting requirements for the Hospital IQR Program and Promoting Interoperability Programs to reduce reporting burden (84 FR 42598 through 42601; 82 FR 38479).

b. Proposed Changes

Recently, through the 21st Century Cures Act final rule published on May 1 2020, ONC updated the 2015 Edition of health IT certification criteria (''2015 Edition Cures Update''). Specifically, the 21st Century Cures Act final rule finalized updates to existing 2015 Edition criteria and introduced new 2015 Edition criteria. As noted above in section III.N.1, in general, health IT developers have up to 24 months from May 1, 2020 to make technology certified to the updated and/or new criteria available to their customers. During this period, health IT developers are expected to continue supporting technology certified to the prior version of the certification criteria for use by their customers prior to updating their products (85 FR 25642 through 25961).

In April 2020, ONC announced its intention to exercise enforcement discretion as to the compliance dates finalized in the 21st Century Cures Act final rule.[71] As a result, where the 21st Century Cures Act final rule requires health IT developers to make technology meeting new and updated certification criteria available by May 2, 2022, developers taking advantage of enforcement discretion may be permitted to delay making updated certified technology available until August 2, 2022. After that date, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified.

Given the Hospital IQR Program's history of updating file submission requirements, we understand that transitioning to technology certified to a new Edition, or to an updated version of the same Edition of certification criteria, can be complex. Nevertheless, we believe that there are many benefits to using relevant, up-to-date, standards-based structured data capture with an EHR to support electronic clinical quality measurement. In addition, we believe it is important to continue to align with the eCQM reporting requirements for the Promoting Interoperability Programs (82 FR 38479, 84 FR 42598).

In this proposed rule for the Hospital IQR Program beginning with the CY 2020 reporting period/FY 2023 payment determination and for subsequent years, we are proposing to expand flexibility to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria for CEHRT as was previously finalized in the FY 2019 IPPS/LTCH final rule (83 FR 41537–41608), or (2) technology certified to the 2015 Edition Cures Update standards as finalized in the 21st Century Cures Act final rule(85 FR 25642 through 25961). We also refer readers to sections III.N.1 and III.N.2 for background and more details about the 2015 Edition Cures Update. We are proposing to adopt this flexible approach in order to encourage hospitals to implement the most up-to-date, standards-based structured data capture while also maintaining alignment with the Promoting Interoperability Program proposal. This proposal would allow hospitals that are early adopters of health IT certified to the 2015 Edition Cures Update criteria for CEHRT to implement those changes while still meeting Hospital IQR Program requirements. As mentioned above, in the 21st Century Cures Act final rule, ONC finalized that health IT developers will have 24 months from the publication date of the rule (that is, until May 2, 2022) to make technology available that is certified to the updated, or new criteria. We will revisit this topic in future rulemaking as necessitated by additional changes by ONC (for example should ONC only allow certification under the 2015 Edition Cures Update). We are seeking public comment on our proposal.

We note that, among other changes and of particular relevance to hospitals that participate in the Hospital IQR Program, the ONC 21st Century Cures Act final rule revises the clinical quality measurement criterion at § 170.315(c)(3) to refer to CMS QRDA Implementation Guides and removes the Health Level 7 (HL7®) QRDA standard requirements (85 FR 25645). Under the Hospital IQR Program, we previously encouraged health IT developers to test any updates on an annual basis, including any updates to the eCQMs and eCQM reporting requirements for the Hospital IQR Program based on the CMS QRDA I Implementation Guide for Hospital Quality Reporting (CMS Implementation Guide for QRDA) (82 FR 38393). The

[71] *https://www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf.*

CMS Implementation Guide for QRDA, program specific performance calculation guidance, and eCQM electronic specifications and guidance documents are available on the eCQI Resource Center website at *https://ecqi.healthit.gov/*. To be clear, the 21st Century Cures Act final rule removes the HL7® QRDA standards from the relevant health IT certification criteria, which now refers directly to the CMS Implementation Guides for QRDA standards bringing their requirements into closer alignment with what we encourage under the Hospital IQR Program. Based on our data, the majority of Hospital IQR Program participants already use the CMS QRDA I Implementation Guide for Hospital Quality Reporting for submission of eCQMs to the Hospital IQR Program. We believe this update results in health IT developers no longer needing to maintain certification to the Health Level 7 (HL7®) QRDA base standards in addition to using the CMS QRDA I Implementation Guide for the Hospital IQR Reporting.

N. Proposal To Establish New Code Categories

1. Background

Currently, there are four existing HCPCS Level II codes for buprenorphine/naloxone products (J0572–J0575), which describe groupings of products by different strengths as indicated on their FDA labels. When many payers assign a single payment rate to a single code, they typically do so under the expectation that the products can be substituted for one another in most clinical scenarios. We have received feedback from stakeholders that there is variability in bioequivalence between the products within the range of strengths listed in each code descriptor, meaning that products within a current code are not necessarily substitutes for one another, that is, they are not therapeutically equivalent. Therefore, to facilitate more accurate coding and more specific reporting of the variety of buprenorphine/naloxone products on the market, we are proposing an expanded series of codes to identify buprenorphine/naloxone products.

Specifically, we propose to establish 15 new code categories for use to report all currently marketed buprenorphine/naloxone products, based on strength as well as therapeutic equivalence reflected in Table 39.

TABLE 39: Proposed New Code Categories

HCPCS	Description
JXXX1	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 2mg; 0.5mg
JXXX2	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 4mg; 1mg
JXXX3	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 8mg; 2mg
JXXX4	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 12mg; 3mg
JXXX5	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal 2.1mg; 0.3mg (Bunavail)
JXXX6	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal 4.2mg; 0.7mg (Bunavail)
JXXX7	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal 6.3mg; 1.0mg (Bunavail)
JXXX8	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual 2mg; 0.5mg
JXXX9	Buprenorphine Hydrochloride; Naloxone Hydrochloride; tablet; sublingual 8mg; 2mg
JXX10	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 0.7mg; 0.18mg (Zubsolv)
JXX11	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 1.4mg; 0.36mg (Zubsolv)
JXX12	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 2.9mg; 0.71mg (Zubsolv)
JXX13	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 5.7mg; 1.4mg (Zubsolv)
JXX14	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 8.6mg; 2.1mg (Zubsolv)
JXX15	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 11.4mg; 2.9mg (Zubsolv)

As the existing 4 codes would be replaced with more specific codes in the new code series, we also propose to discontinue the existing codes in Table 40.

TABLE 40: Proposed Discontinued Codes

HCPCS	Description
J0572	Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine
J0573	Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine
J0574	Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine
J0575	Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine

The new code series would permit physicians and clinics to accurately bill insurers for the drug and dose utilized. For example, state Medicaid agencies would be able to more easily identify the drug dispensed, which would facilitate more efficient and accurate rebate invoicing for the Medicaid Drug Rebate Program. The expanded code series would also facilitate more specific and meaningful tracking of utilization of buprenorphine/naloxone products within and across their respective health insurance programs. We note that these coding proposals do not change Medicare coverage or payment policies for oral or sublingual buprenorphine codes. The drug products described by these codes are not separately payable under Medicare Part B.

O. Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

We propose to amend our regulation at § 410.79(e) to create more flexible MDPP policies that will apply during certain emergencies (Emergency Policy). In addition, we propose to amend § 424.210 to modify the definition of ''beneficiary engagement period'' and to address beneficiary engagement incentives that are furnished to MDPP beneficiaries who are receiving MDPP services virtually pursuant to the Emergency Policy.

1. Proposed Changes to § 410.79(b)

Through this proposed rule, we are proposing to amend the Medicare Diabetes Prevention Program (MDPP) expanded model to revise certain MDPP policies adopted in the March 31st COVID–19 IFC (85 FR 19230) that would apply during the remainder of the COVID–19 Public Health Emergency (PHE) and/or any future emergency period, and in an emergency area, as such terms are defined in section 1135(g) of the Act, where the Secretary has authorized section 1135 waivers for such emergency area and period (hereinafter referred to as an ''1135 waiver event'') where such 1135 waiver event may cause a disruption to in-person MDPP services (hereinafter referred to as an ''applicable 1135 waiver event''). We propose that we would determine that an 1135 waiver event could disrupt in-person MDPP services if MDPP suppliers would likely be unable to conduct classes in-person, or MDPP beneficiaries would likely be unable to attend in-person classes, for reasons related to health, safety, or site availability or suitability. Health and safety reasons may include avoiding the transmission of contagious diseases, compliance with laws and regulations during an 1135 waiver event, or the physical safety of MDPP beneficiaries or MDPP coaches as defined in § 424.205(a), during an 1135 waiver event. We propose that if we determine that an 1135 waiver event may disrupt in-person MDPP services, we would notify all impacted MDPP suppliers via email and other means as appropriate. Such notice would include the effective date when flexibilities described in § 410.79(e) would be available. We propose that the applicable 1135 waiver event would end on the earlier of the end of the emergency period (as defined in section 1135(g) of the Act) or the date we determine that the 1135 waiver event no longer disrupts in-person MDPP services under the proposed standard described above.

We temporarily amended the MDPP expanded model to revise certain MDPP policies in the March 31st COVID–19 IFC. These changes apply only during the COVID–19 PHE. The March 31st COVID–19 IFC permits certain beneficiaries to obtain the set of MDPP services more than once per lifetime, waives the 5 percent weight loss eligibility requirements, and allows certain MDPP suppliers to either pause the delivery of services or deliver virtual MDPP sessions on a temporary basis. We believe that establishing an Emergency Policy that applies more broadly will improve the current flexibilities for the remainder of the COVID–19 PHE and provide MDPP suppliers and MDPP beneficiaries with flexibilities to address any future applicable 1135 waiver events.

The proposed changes herein would preserve the March 31st COVID–19 IFC MDPP flexibilities and apply them to future 1135 waiver events, provide for additional flexibilities that would apply during the COVID–19 PHE and future 1135 waiver events, clarify certain policies adopted in the IFC, and end a flexibility that would become unnecessary in light of our other proposals. If finalized, the proposed flexibilities would supersede the flexibilities finalized in the March 31st COVID–19 IFC for the COVID–19 PHE, if the PHE is still in place when the CY 2021 PFS final rule becomes effective. If finalized, the proposed changes would be available to all future applicable 1135 waiver events, effective January 1, 2021.

We are proposing these changes to address MDPP supplier and MDPP beneficiary needs in response to the COVID–19 PHE and any future 1135 waiver events that result in an interruption to expanded model services delivered by MDPP suppliers and preventing MDPP beneficiaries from attending in-person sessions.

Throughout the original rulemaking for the MDPP expanded model, we sought to ensure that the set of MDPP services would be delivered in-person, in a classroom-based setting, within an established timeline. During that rulemaking, CMS prioritized establishing a structured service that, when delivered within the confines of the rule, would create the least risk of fraud and abuse, increase the likelihood of success for beneficiaries, and maintain the integrity of the data collected for evaluation purposes. Based on lessons learned during the COVID–19 PHE, we propose to allow temporary flexibilities that prioritize availability and continuity of services for MDPP suppliers and beneficiaries affected by extreme and uncontrollable circumstances that CMS determines may disrupt in-person MDPP services during an applicable 1135 waiver event using the standard articulated above. The overall intent of the proposed Emergency Policy is to minimize disruption of services for MDPP suppliers and beneficiaries.

The flexibilities proposed in this rule would be applicable to all MDPP beneficiaries and MDPP suppliers (as such terms are defined in § 410.79(b)). Although our Emergency Policy will permit MDPP services to be furnished entirely on a virtual basis, our Emergency Policy does not permit an MDPP supplier to furnish MDPP services virtually during the COVID–19 PHE or an applicable 1135 waiver event unless the MDPP supplier's preliminary or full CDC DPRP recognition authorizes the supplier to furnish services in-person. The MDPP supplier requirements at § 424.205 set forth parameters for suppliers to enroll in Medicare, including having any preliminary recognition established by the CDC for the purposes of the DPRP or full CDC DPRP recognition. The DPRP refers to a program administered by the CDC that recognizes organizations that are able to furnish the National Diabetes Prevention Program (National DPP) services, follows a CDC-approved curriculum, and meets CDC's performance standards and reporting requirements. The CDC assigns to each DPRP-recognized supplier an organizational code that specifies the service delivery mode (for example, in-person, online, distance learning, or combination). Because MDPP services are covered under Medicare only when they are furnished at least in part in-person, a supplier that does not have an organizational code authorizing in-person services (''virtual-only suppliers'') may not provide MDPP

services, either virtually or in-person. We do not believe it is appropriate to permit virtual-only suppliers to furnish MDPP services when the proposed Emergency Policy is in effect. This is because MDPP suppliers must remain prepared to resume delivery of MDPP services in-person when the proposed Emergency Policy is no longer in effect. Given the difficulty of predicting when the COVID–19 PHE or any applicable 1135 waiver event will end, virtual-only suppliers may not have sufficient time to obtain the CDC's authorization to furnish in-person services. Permitting virtual-only suppliers to furnish MDPP services during the COVID–19 PHE or an applicable 1135 waiver event could disrupt the provision of services to MDPP beneficiaries when services must resume on an in-person basis.

We are proposing to amend the MDPP regulations to provide for certain changes, including allowing MDPP suppliers to start new cohorts and allowing MDPP suppliers to either deliver MDPP services virtually or suspend in-person services and resume services at a later date during an applicable 1135 waiver event. In addition, these proposed changes permit certain MDPP beneficiaries to obtain the set of MDPP services more than once per lifetime, for the limited purposes of allowing a suspension in service due to an applicable 1135 waiver event and to provide the flexibilities that will allow MDPP beneficiaries to maintain eligibility for MDPP services despite a break in attendance.

In the March 31st COVID–19 IFC, we stated that we would allow MDPP suppliers to either deliver MDPP services virtually or suspend in-person services and resume services at a later date. In addition, we also provided in the March 31st COVID–19 IFC that the once per lifetime requirement waiver is only applicable to MDPP beneficiaries whose sessions were suspended or cancelled due to the PHE (that is, MDPP beneficiaries who were receiving the set of MDPP services as of March 1, 2020). However, we do not believe it is necessary to permit all MDPP beneficiaries to restart the set of MDPP services in all applicable 1135 waiver events, particularly if they elect to continue to receive services virtually. Therefore, we are proposing that MDPP beneficiaries who elect to receive MDPP services virtually in accordance with the MDPP Emergency Policy are not eligible to restart the set of MDPP services at a later date. This proposed policy would ensure that MDPP beneficiaries who continue to receive the set of MDPP services virtually during in an applicable 1135 waiver event cannot repeat the set of MDPP services at a later date, in accordance with the general once per lifetime limitation for the set of MDPP services established in § 410.79(c)(1)(i)(B).

We propose the following approach for permitting MDPP beneficiaries to resume or restart the set of MDPP services in the event in-person sessions are suspended, and the MDPP beneficiary does not elect to receive MDPP services virtually. MDPP beneficiaries who are in the first 12 months of the set of MDPP services as of the start of an applicable 1135 waiver event would be eligible to restart the set of MDPP services either at the beginning, or resume with the most recent attendance session of record, after the applicable 1135 waiver event has ended. MDPP beneficiaries who are in the second year of the set of MDPP services as of the start of the 1135 waiver event, would only be permitted to resume the set of MDPP services with the most recent attendance session of record. MDPP beneficiaries who are in the second year of the set of MDPP services would not be allowed to restart the set of MDPP services at the beginning.

We do not believe allowing MDPP beneficiaries who are already in the ongoing maintenance phase of MDPP to restart from the beginning aligns with the performance-based payment strategy upon which the expanded model relies to achieve savings. MDPP suppliers with beneficiaries who have successfully completed over half of the set of MDPP services have already benefited from the bulk of the permitted total performance-based payments. Allowing MDPP beneficiaries in the ongoing maintenance interval phase to restart the expanded model would result in an MDPP supplier being reimbursed for close to double the intended payment amount. Not only might this have a negative impact on the long term expanded model savings, this could result in beneficiaries being unfairly coerced into electing to start over instead of resuming the set of MDPP services where they left off. This proposal would apply prospectively only—that is, under the current MDPP regulations, as implemented in the IFC, we waived the once per lifetime requirement for MDPP beneficiaries who were receiving the set of MDPP services as of March 1, 2020 and whose sessions were suspended or canceled due to the COVID–19 PHE to obtain the set of MDPP services more than once per lifetime by electing to restart the set of MDPP services or resume with the most recent attendance session of record. We would retain that flexibility for those MDPP beneficiaries who were receiving the set of MDPP services as of March 1, 2020, as specified in current § 410.79(e)(3)(iii), which we are proposing to revise and renumber as § 410.79(e)(vi)(A). Finally, we propose that beneficiaries who elect to suspend the set of MDPP services at the start of an 1135 waiver event and subsequently choose to restart the MDPP set of services at the beginning or to resume with the most recent attendance session of record, may only make such an election once per 1135 waiver event. This proposed policy intends to ensure that MDPP beneficiaries may not suspend and re-start the MDPP set of services multiple times during the same 1135 waiver event, which would be contrary to the overall goal of the MDPP Emergency Policy, and to the goals of the MDPP expanded model as a whole.

We are proposing that the limit placed on the number of virtual make-up sessions described at § 410.79 would not apply during the remainder of the COVID–19 PHE or during any future applicable 1135 waiver event, so long as the virtual services are furnished in a manner that is consistent with the CDC DPRP standards for virtual sessions, follow the CDC-approved National DPP curriculum requirements, and the supplier has an in-person DPRP organizational code. We propose to amend the regulations to clarify that all sessions, including the first core session, may be offered virtually, not as ''virtual make-up sessions,'' but as a virtual class consistent with the in-person class curriculum, during the remainder of the COVID–19 PHE and any future applicable 1135 waiver event. The MDPP supplier could still only furnish a maximum of one session on the same day as a regularly scheduled session and a maximum of one virtual make-up session per week to the MDPP beneficiary. We propose that virtual sessions may be furnished to achieve both attendance goals and achieve weight-loss goals in the event that a qualifying weight measurement was obtained by one of the methods described herein. We propose that an MDPP supplier may offer to an MDPP beneficiary: 16 virtual sessions offered weekly during the core session period; 6 virtual sessions offered monthly during the core maintenance session interval periods; and 12 virtual sessions offered monthly during the ongoing maintenance session interval periods. MDPP suppliers may only furnish a maximum of one regularly scheduled session virtually and a maximum of one virtual make-up session per week to an MDPP beneficiary. This proposed rule

would increase the number of allowable virtual core sessions from 15 to 16. This change is due to the added proposed flexibility to allow MDPP suppliers to obtain weight measurements remotely (as described below) and to deliver the first core session virtually.

Under these temporary flexibilities, we propose that the requirement for in-person attendance at the first core-session would not apply. We propose that during the remainder of the COVID–19 PHE and any future applicable 1135 waiver events, MDPP suppliers may obtain weight measurements from MDPP beneficiaries through the following methods: (1) In-person, when the weight measurement can be obtained safely and in compliance with all applicable laws and regulations; (2) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission (commonly referred to as ''Bluetooth™ enabled''); or (3) self-reported weight measurements from a participant's own at-home digital scale. We propose that self-reported weights must be submitted via video, by the MDPP beneficiary to the MDPP supplier. The video must clearly document the weight of the MDPP beneficiary as it appears on his/her digital scale on the date associated with the billable MDPP session. Due to this additional flexibility, we propose that the waiver of the minimum weight loss requirements for beneficiary eligibility in the ongoing maintenance session intervals described in § 410.14(g)(3)(iv) of the March 31st COVID–19 IFC (85 FR 19230) be ended. Thus, effective January 1, 2021, all MDPP beneficiaries would be required to achieve and maintain the required 5 percent weight loss goal in order to be eligible for the ongoing maintenance sessions, even if the COVID–19 PHE remains in place as of that date.

We are proposing to amend our regulation at § 410.79(e). We seek comment on these proposals.

2. Proposed Changes to § 424.210

Under § 424.210(b), an MDPP supplier may furnish in-kind beneficiary engagement incentives to an MDPP beneficiary if certain requirements are satisfied. Among other requirements, the in-kind item or service must be furnished only during the ''engagement incentive period.'' The definition of ''engagement incentive period'' at § 424.210(a) states that the period begins when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary, and it ends on the earliest of the following: (1) When the MDPP services period ends as described in § 410.79(c)(3); (2) when the MDPP supplier knows the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier; or (3) The MDPP supplier has not had direct contact, either in-person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period. We recognize that the disruption to MDPP services caused by an applicable 1135 waiver event may cause an MDPP supplier not to have contact with an MDPP beneficiary for more than 90 consecutive calendar days. Therefore, we propose to amend the definition of ''engagement incentive period'' to further qualify when the period ends in the case of the COVID–19 PHE or an applicable 1135 waiver event. Specifically, we propose to amend paragraph (iii) in the definition to state that the MDPP supplier has not had direct contact, either in person by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period, unless the lack of direct contact is due to the suspension or cancellation of MDPP services under § 410.79(e) and the MDPP services are eventually resumed or restarted in accordance with § 410.79(e).

We solicit comments on when the engagement incentive period should end if the MDPP services are not eventually resumed. We are considering whether we should deem the incentive engagement period to end if the applicable 1135 waiver event or COVID–19 PHE remains in effect for a certain period of time, such as one year. At that point, for purposes of beneficiary engagement incentives, it may be more appropriate to terminate the engagement incentive period and permit a new engagement incentive period to begin if services are resumed or restarted in accordance with § 410.79(e). Alternatively, we note that the engagement incentive period can also end when the MDPP supplier knows that the MDPP beneficiary will no longer be receiving services from the MDPP supplier. We solicit comments on whether that provision eliminates any need to further clarify in regulation text when the engagement incentive period ends if MDPP services are not eventually resumed or restarted.

We also propose to amend § 424.210(b) to add a requirement governing the provision of an in-kind item or service as a beneficiary engagement incentive during the COVID–19 PHE or during an applicable 1135 waiver event. Specifically, we propose that if the item or service is furnished during the COVID–19 PHE or an 1135 waiver event that CMS has determined may disrupt in-person MDPP services, and the item or service is furnished to an MDPP beneficiary who is receiving MDPP services virtually, the MDPP beneficiary must be capable of using the item or service during the COVID–19 PHE or the 1135 waiver event, as applicable. We propose this requirement to deter abuse and to ensure that the incentives furnished during an 1135 waiver event will achieve their intended purpose and serve the goals of the MDPP expanded model. Some examples of usable beneficiary engagement incentives include vouchers for healthy food, wearable technology or ''wearables'' used to monitor an MDPP beneficiary's health such as heart rate, calories burned, or steps walked; examples of unusable beneficiary engagement incentives during an 1135 waiver event include gym memberships during lockdowns and stay-at-home orders. We solicit comments on whether this additional requirement is necessary in light of other requirements set forth in § 424.210(b).

Finally, for purposes of the proposed requirement at § 424.210(b)(9), we propose to define ''COVID–19 Public Health Emergency'' to mean the emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, related to the COVID–19 pandemic declared by the Secretary on January 27, 2020. Similarly, we propose to define ''1135 waiver event'' to mean an emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, for which the Secretary has authorized waivers under section 1135 of the Act. These definitions are consistent with how we propose to define the terms for purposes of § 410.79(e).

IV. Quality Payment Program

A. CY 2021 Updates to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the proposed rule sets forth proposed changes to the Quality Payment Program starting January 1, 2021, except as otherwise noted for specific provisions. The 2021 performance period/2023 payment year of the Quality Payment Program continues a transition as we build on the first few years of implementation of the Quality Payment Program to better focus our measurement efforts and to

reduce barriers to entry into Advanced APMs.

Participation in the Quality Payment Program rose in the second year. We saw 98 percent of eligible clinicians participate in MIPS in 2018 with 889,995 eligible clinicians receiving a payment adjustment, which exceeded our 2017 participation rates. In addition, 98 percent of eligible clinicians participating in MIPS received a positive payment adjustment for 2020 based on 2018 performance year results. Regarding performance in Advanced APMs, for the 2018 QP Performance Period, 183,306 eligible clinicians earned Qualifying APM Participant (QP) status while another 47 eligible clinicians earned partial QP status.[72] We are still finalizing 2019 numbers given the extended time period for 2019 data submission, a flexibility provided due to the COVID–19 public health emergency, and will provide updates later this year. We plan to continue developing Quality Payment Program policies that more effectively reward high-quality treatment of patients and increase opportunities for Advanced APM participation. We are moving forward with MIPS Value Pathways (MVPs) policy development as MVPs allow for a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to a specialty, medical condition, or a particular population being cared for. The MVPs use promoting interoperability as a foundational element and incorporate population health claims-based measures as feasible along with relevant measures and activities for the quality, cost, and improvement activities performance categories. We intended to begin transitioning to MVPs in the 2021 MIPS performance year; however, due to the 2019 Novel Coronavirus (COVID–19) pandemic public health emergency and resultant need for clinician focus on the response, our timeline has changed accordingly such that the proposal for initial MVPs will be delayed until at least the 2022 performance year. We support clinicians on the front lines by providing burden relief via extreme and uncontrollable circumstances policy exceptions for 2019 (85 FR 19277 through 19278) and 2020 (84 FR 62568). We are proposing to reduce the 2023 MIPS payment year performance threshold in section IV.A.3.e.(3) of this proposed rule, and are continuing to consider the extraordinary health system stresses resulting from the COVID–19 PHE as we propose 2021 performance year/2023 payment year policies for the Quality Payment Program.

As we make long-term improvements, evolve MIPS policies, and plan to implement MVPs in the future, we are supporting our objectives within the Patients Over Paperwork initiative and the National Quality Roadmap.[73] [74] In carrying out these initiatives, we are removing regulatory obstacles that get in the way of health care clinicians spending time with patients. As we develop MVP policies, we look to reduce MIPS reporting burden and increase efficiencies.

On May 15, 2020 the National Quality Roadmap was published by the Department of Health and Human Services (*https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf*) as directed by Executive Order 13877, Improving Price and Quality Transparency in American Healthcare to Put Patients First. The purpose of the Roadmap is to improve patient outcomes through enhanced effectiveness and efficiency of the healthcare quality system. The Roadmap is a means to accelerate change and advance the Administration's goals of ''improving transparency, reducing provider burden, allowing informed consumer decision-making, and ultimately improving the health of all Americans''. The Roadmap, which provides a public-private partnership opportunity, describes a strategy for establishing, adopting, and publishing common quality measurements, aligning inpatient and outpatient measures, and eliminating low-value or counterproductive measures. Specific actions are identified to drive change through coordinated governance and oversight, modernized data collection and reporting, and aligned measures reformation in federal quality programs. One of the actions called for is a systematic review of federal quality reporting and value-based payment programs, to identify opportunities leading to recommendations to reduce burden, promote efficiency and effectiveness, and accelerate the shift to value. The Roadmap also calls for stakeholder engagement through public convening and a Request for Information. Actions will be undertaken with the underpinning of the following principles:

- Quality Information is Available and Meaningful
- Balance Administrative Burden with the Goal of Obtaining Meaningful Information
- Alignment of Measurement Priorities
- Cohesive Measurement Stewardship
- Reward Innovation and Improvement
- Leverage What Works and Reform the Rest

The planned implementation of MVPs is noted in the Roadmap and we look forward to recommendations resulting from other Roadmap activities for streamlining quality reporting and value-based purchasing programs that can inform the implementation of the MVPs and promote alignment of quality measures across Federal programs.

As we work within MIPS to reduce barriers to clinician participation in Advanced APMs and meet CMS pay for value objectives, we are aligned with the Health Care Payment Learning & Action Network goal to accelerate the percentage of health care payments tied to quality and value in each market segment through the adoption of two-sided risk APMs.[75] MVPs will link quality and cost performance measurement and help clinicians begin to assess their ability to take on risk as in APMs.

In the May 1, 2020 **Federal Register**, HHS published two transformative rules: The 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule (85 FR 25642 through 25961); and 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 on the Federally-facilitated Exchanges, and Health Care Providers final rule (85 FR 25510 through 25640) that will give patients unprecedented safe, secure access to their health data. The two rules implement interoperability and patient access provisions of the bipartisan 21st Century Cures Act (Cures Act) and support the MyHealthEData initiative. MyHealthEData is designed to empower patients around a common aim, giving every patient access to their medical information so they can make better healthcare decisions. We expect that these rules, once implemented, will complement our future MVPs in providing more meaningful information to clinicians and patients.

[72] 2018 QPP Performance Data Infographic and *https://www.cms.gov/blog/2018-quality-payment-program-qpp-performance-results.*

[73] *https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.*

[74] *https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.*

[75] *https://hcp-lan.org/.*

b. Summary of Major Proposals

(1) Major MIPS Proposals

In the CY 2020 PFS final rule (84 FR 62948), we finalized a definition of a MIPS Value Pathway (MVP) as a subset of measures and activities established through rulemaking. The MIPS program aims to drive value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care. Within MIPS we intend to pay for health care services in a way that drives value by linking performance on cost, quality, and the patient's experience of care. We believe implementing the MVP framework will move MIPS along the ''path to value,'' transforming the MIPS program by better informing and empowering patients to make decisions about their healthcare and helping clinicians to achieve better outcomes, and by promoting robust and accessible healthcare data, and interoperability. In the CY 2020 PFS proposed rule (84 FR 40732 through 40745), we offered our vision of an MVP framework for a new evolution of the MIPS program based on this concept.

We have built the MIPS program to provide broad flexibility for clinician choice of measures and activities, data collection and submission types, and individual or group level participation. While these flexibilities contributed to very high participation levels, we believe the flexibility has inadvertently resulted in a complex MIPS experience for clinicians that is not producing the level of robust clinician performance information we envision that would meet patient needs and support clinician care improvements. We have heard from clinicians that MIPS requirements are confusing, burdensome, and that it is difficult to choose measures from the several hundred MIPS and QCDR quality measures that are meaningful to their practices and have a direct benefit to patients. We have also heard concerns from stakeholders that MIPS does not allow for sufficient differentiation of performance across practices due to clinician quality measure selection bias. These aspects detract from the program's ability to effectively measure and compare performance, provide meaningful feedback, and incentivize quality. MVPs are intended to lead to a simplified MIPS clinician experience, improve value, reduce burden, and better inform patient choice in selecting clinicians. We noted that 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. We posed a set of questions intended to help us to implement this vision as part of future rulemaking. We received extensive comments on these issues and are using those comments to guide the transition into this new framework. We intend to focus the future of MIPS on MVP implementation. We have limited our 2021 performance year proposals in light of the COVID–19 pandemic to promote program stability and lessen any distraction as clinicians focus on responding to this public health emergency. We are proposing policies in section IV.A.3. of this proposed rule related to:

- Developing MVPs
- Introducing the APM Performance Pathway (APP) for APM participant MIPS eligible clinicians to report to MIPS
- Updating the MIPS performance measures and activities; cost and quality category weights; and scoring policies
- Terminating the APM scoring standard

(a) MIPS Value Pathways and APM Performance Pathway

In this proposed rule, we propose updated MVP framework guiding principles in section IV.A.3.a.(1) of this proposed rule and MVP development criteria and processes in section IV.A.3.a.(2) of this proposed rule as we look towards the 2022 performance period to begin MVP implementation. We are also proposing in section IV.A.3.b. of this proposed rule an APP to start on January 1, 2021 that aligns with the MVP concept. The APP would be a voluntary pathway for reporting and scoring under MIPS that would allow APM participants to report a single quality measure set with broad applicability, receive an improvement activities credit, and have the cost performance category reweighted. We propose MIPS performance category weighting and scoring in the APP and a scoring hierarchy that recognizes the APP in section IV.A.3.e.(2) of this proposed rule. We are also proposing in section IV.A.3.c.(5)(a) of this proposed rule to eliminate the APM scoring standard for the 2021 performance year beginning January 1, 2021. This would allow APM participants to participate in MIPS as individuals, groups, Virtual Groups, or APM Entities, and they could report through any MIPS reporting and scoring pathway, see section IV.A.3.b.(3) of this proposed rule. We are also proposing in section IV.A.3.c.(5)(e) of this proposed rule, an extreme and uncontrollable circumstances exception policy that would be applicable to APM Entities beginning with the 2022 MIPS payment year.

In response to our MVP RFI in the 2020 PFS proposed rule (84 FR 40732 through 40745), we received a number of comments about the opportunity to participate in the development of MVPs and concerns about the speed of a transition to a new MVP framework. We have taken these concerns into consideration in sections IV.A.3.a.(2) and IV.A.3.a.(3) of this proposed rule when developing the policies proposed in this proposed rule. We had stated our intent to begin the transition to MVPs in the 2021 performance year by introducing initial MVPs, however, due to the 2019 Novel Coronavirus (COVID–19) pandemic Public Health Emergency (PHE), our timeline has changed. As we move forward with the transformation of the MIPS program in a manner that does not take away from the nation's response to the COVID–19 pandemic, we have limited our MVP-related proposals in this year's rule to those necessary for the collaborative development of MVPs. In section IV.A.3.a.(1) of this proposed rule, we propose to update the MVP guiding principles to respond to RFI suggestions and to reflect the ongoing evolution of MVP policies and further definition of the MVP framework.

We propose in section IV.A.3.a.(2) of this proposed rule, a process for collaboration on the development of MVPs, building on our discussions with clinician experts to develop a proposed list of MVPs for future MIPS rulemaking. We believe that collaboration with clinician experts will build a more cohesive and comprehensive set of MVPs. We propose a process for MVP candidate submissions in section IV.A.3.a.(2)(a)(iii) of this rule.

We recognize that the transition to MVPs will take time and will continue to evaluate the readiness of clinicians in making this transition, while balancing our strong interest in improving measurement and making MIPS more focused on value. We seek comment on our MVP criteria and MVP development process policies that will be considered for the final rule. For instance, we seek comment in section IV.A.3.a.(2) of this proposed rule on the proposed MVP co-development criteria, patient involvement, and MVP QCDR measures inclusion parameters.

(b) Other MIPS and APM Proposals

Although we look to move MIPS towards the future with the MVP

framework, in this year's proposed rule we propose to make what we believe are necessary Web Interface and quality measure updates, in sections IV.A.3.c.(1)(c) and IV.A.3.c.(1)(d) of this proposed rule, respectively. Additionally, we propose in section IV.A.3.d.(1)(b) of this proposed rule to maintain policies for scoring quality measures based on achievement as well as policies for measures that do not meet case minimum, data completeness requirements, or have a benchmark. For the Promoting Interoperability performance category, we are proposing a new optional measure. We are not proposing changes to scoring policies for the cost or improvement activities categories. We have heard repeatedly in response to each of our proposed rules that clinicians value stability in the program so as to not have to learn new program requirements each year and seek to limit the number of policy proposals for the 2021 MIPS performance year.

Additionally, we wish to highlight the following proposals for changes to MIPS beginning in the 2021 performance period.

- We propose in section IV.A.3.c.(1)(c) of this proposed rule to sunset the CMS Web Interface submission method under MIPS for groups and virtual groups in 2021 due to low MIPS participant utilization and the Medicare Shared Savings Program's discontinuation of Web Interface submission method.
- We propose in section IV.A.3.c.(1)(d) of this proposed rule to incorporate 2 new administrative claims outcome quality measures, address substantive changes to 112 existing MIPS quality measures, address changes to specialty sets, remove measures from specific specialty sets, and remove 14 quality measures from the MIPS program. We are proposing a total of 206 quality measures starting in the 2021 performance year.
- We propose in sections IV.A.3.c.(1)(e) and IV.A.3.c.(2)(b) of this proposed rule, inclusion of services provided via telehealth in quality and cost measurement, respectively, given the recent rise in volume of telehealth services.
- We propose in section IV.A.3.c.(2)(a) of this proposed rule, that the cost performance category will make up 20 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act, and the quality performance category weight would be 40 percent and 30 percent for each of those years, respectively (see section IV.A.3.c.(1)(b) of this proposed rule). For the 2023 MIPS payment year, we propose performance category redistribution policies in section IV.A.3.d.(2)(b)(iii) of this proposed rule similar to the redistribution policies as finalized for the 2022 MIPS payment year, with the modification that we will not redistribute more weight to the cost performance category in the final scoring calculation.
- We propose in section IV.A.3.c.(3)(b) of this proposed rule, beginning with the CY 2021 performance period and future years, we are proposing: (1) Changes to the Annual Call for Activities: An exception to the nomination period timeframe during a PHE; and a new criterion for nominating new improvement activities; (2) a process for HHS-nominated improvement activities; and (3) to modify two existing improvement activities.
- We propose in section IV.A.3.c.(4) of this proposed rule, to 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, for the 2024 MIPS payment year and each subsequent MIPS payment year; to update two Promoting Interoperability measures; and to continue reweighting the Promoting Interoperability performance category for non-physician MIPS eligible clinicians for the 2021 performance period. We propose at section IV.A.3.c.(4)(c)(ii) of this proposed rule a new Promoting Interoperability performance category Health Information Exchange (HIE) bi-directional exchange measure that would allow an eligible clinician to attest to participation in bi-directional exchange through an HIE using CEHRT functionality.
- We propose in section IV.A.3.d.(1)(b) of this proposed rule continuation of quality category scoring and bonus policies, adding flexibility for when measure specification or coding changes occur during the performance year, and continuing improvement scoring of the quality performance category comparing clinicians to a 30 percent baseline score if clinicians scored 30 percent or less. We propose in sections IV.A.3.d.(1)(b)(ii) and IV.A.3.d.(1)(b)(v) of this proposed rule benchmark and topped out scoring policy criteria options that are responsive to potential low reporting rates for the 2019 performance year due to the national public health emergency for COVID–19. We propose in section IV.A.3.d.(1)(b)(iii) of this proposed rule, a provision for an exception to the 20-case minimum for all administrative claims-based measures to allow scoring of measures that meet the specified case minimum.
- We propose in section IV.A.3.d.(2)(a)(iii) of this proposed rule to increase the maximum number of points available for the complex patient bonus for the 2020 performance period/2022 MIPS payment year due to the anticipated increase in patient complexity resulting from the national public health emergency for COVID–19.
- We propose in section IV.A.3.e.(3) of this proposed rule to reduce the performance threshold for the 2021 MIPS performance period/2023 MIPS payment year from 60 points—finalized in the CY 2020 PFS rule (84 FR 63037)—to 50 points in recognition of the COVID–19 impact on clinicians.
- We propose in section IV.A.3.g. of this proposed rule to modify third party intermediary requirements and remedial action and termination.
- We propose in section IV.A.4.b. and IV.A.4.c. of this proposed rule to clarify the APM Incentive Payment amount calculation basis and propose a hierarchy for recipient TIN affiliation identification when making the APM Incentive Payment. We also propose policies in section IV.A.4.c. of this proposed rule for MIPS eligible clinician scoring and a process for requesting updated APM Incentive Payment information in situations where a payee TIN cannot be identified, and to address situations where the QP's APM Incentive Payment was determined based solely on supplemental services payments and no Medicare claims for covered professional services were submitted during the incentive payment base period.
- We propose in section IV.A.4.e. of this proposed rule a change to the methodology for addressing prospectively aligned beneficiaries for Threshold Score calculations and QP determinations and to establish a targeted review process for QP determinations.

(2) Terms and Definitions

In addition, in § 414.1305, we are proposing to update the definitions of the following terms:

- Attestation (revision)
- Certified Electronic Health Record Technology (CEHRT) (revision)
- Collection type (revision)
- Full TIN APM (deletion)
- Low volume threshold (revision)

- Meaningful EHR user for MIPS (revision)
- MIPS APM (revision)
- Physician Compare (addition)
- Primary Care Services (addition)
- Submission type (revision)

These terms and definitions are discussed in the relevant sections of this proposed rule.

3. MIPS Program Details

a. Transforming MIPS: MIPS Value Pathways

(1) Overview

In this proposed rule, we are proposing updates to the MIPS Value Pathways (MVP) guiding principles (here in section IV.A.3.a.(1) of this proposed rule) and MVP development criteria and process (section IV.A.3.a.(2) of this proposed rule) that would guide MVP implementation beginning with the 2022 MIPS performance period/2024 MIPS payment year. We finalized in the CY 2020 PFS final rule (84 FR 62946) the definition of an MVP at § 414.1305 as ''a subset of measures and activities established through rulemaking'' and requested comments in a request for information (RFI) on a wide-ranging set of issues related to the eventual implementation of this concept within the MIPS program. We received RFI comments on many components of the MVP framework including the guiding principles, how MVPs and measures/activities are developed, and the transition and timeline to MVPs. The RFI comments have helped shape the following proposals for MVP implementation.

In the CY 2020 PFS final rule, we stated our intent to apply the MVP framework in the 2021 performance year (84 FR 62946); however, due to the COVID–19 pandemic national public health emergency, our timeline has changed (see section IV.A.3.a.(3) of this proposed rule). We want to move forward with the transformation of the MIPS program in a manner that does not take away from the nation's response to the COVID–19 pandemic, and so have limited our MVP related proposals in this rule to guidance necessary for the collaborative development of MVPs. We are deferring further MVP implementation to a future year. In particular, we now intend to propose an initial set of MVPs and implementation policies in our CY 2022 rulemaking cycle. We continue to envision a transformed MIPS program that increasingly makes MVPs available to clinicians with a burden reduction focus.

We intend to implement the MVPs while maintaining the MIPS participation options established through rulemaking for MIPS performance years 1 through 5. For purposes of this discussion, we refer to the established MIPS participation options collectively as ''traditional MIPS''.

As described in earlier rulemaking (84 FR 40732 through 40734), we are moving to MVPs to improve value, reduce burden, help patients compare clinician performance to inform patient choice in selecting clinicians, and reduce barriers to movement into APMs. We refer to ''value'' as a measurement of quality and patient experience of care as related to cost, and intend to promote value by paying for health care services in a manner that directly links performance on cost, quality, and the patient's experience of care. The MVP framework will move MIPS forward on the path to value through connecting the MIPS performance categories and by better informing and empowering patients to make decisions about their healthcare and helping clinicians to achieve better outcomes using robust and accessible healthcare data and interoperability.

We believe that MVPs can help address previous feedback from clinicians that MIPS is too complex and burdensome. Feedback related to confusing MIPS requirements, inadequate alignment of the MIPS performance categories, need for better performance comparability across all clinicians and for more meaningful data for patients has informed development of the MVP framework. MVPs will make MIPS more meaningful by allowing a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to a patient population, standardizing performance measurement of a specialty or a medical condition, and reducing the siloed nature of the traditional MIPS participation experience. We intend that MVPs help clinicians and practices prepare to take on and manage financial risk, as in Advanced APMs, as they build out their quality infrastructures that align with the MIPS performance categories and gain experience with cost measurement. Performance measure reporting for specific populations as in MVPs encourages practices to build an infrastructure with capabilities to compile and analyze population health data, a critical capability in assuming and managing risk. We believe that experience with MVPs, in which there is aligned measurement of quality (of care and of experience of care) and cost, continuous improvement/innovation within the practice, and efficient management and transfers of information, will help remove barriers to APM participation.

See infographic at *https://qpp.cms.gov/mips/mips-value-pathways* that provides an overview of our vision for the MIPS path to value future state. As shown in the infographic, MIPS is currently comprised of four siloed performance categories with many measure and activity choices (see left column of infographic), higher reporting burden and performance measurement that is not meaningfully aligned. An intermediate step (see middle column of infographic) is to move to value via building an MVP framework that is cohesive (connects the performance categories), lowers reporting burden, and focuses MIPS participation around MVPs that are meaningful to clinicians' practices, specialty or public health priority. The MVP framework incorporates a foundational layer consisting of Promoting Interoperability and administrative claims-based quality measures focused on population health, provides data and feedback to clinicians, and enhances information provided to patients. When MVPs are fully implemented (see right column of infographic), we envision a MIPS that is simplified, increases the voice of the patient, and facilitates movement into APMs. Over time we intend to provide greater amounts of population health measurement data using administrative claims information while decreasing the amount of clinician reported measurement data used for MIPS. To help realize these objectives, we are engaging with clinician professional organizations and front-line clinicians to develop the MVPs and proposing MVP development criteria and process as described in section IV.A.3.a.(2) of this proposed rule.

We envision that MVPs will be optional for clinicians when the included measures and activities within the MVP are applicable and available to their practice. Over the course of future performance periods as we transition to MVPs, the traditional MIPS participation option will continue to be available. We believe MVP reporting will reduce selection burden associated with choosing MIPS quality measures and activities to report; reduce reporting burden associated with fewer MIPS quality measures, cost measures and/or improvement activities to report than the traditional MIPS participation method; and further align across performance categories the measures and activities identified by specialists and patients as being meaningful and relevant. We intend to build a robust inventory of MVPs which are

meaningful to clinicians and expect that in the future we may propose that all MIPS eligible clinicians would be required to participate in MIPS either through an MVP or an APM Performance Pathway (APP) as discussed in section IV.A.3.b. of this rule.

We listed MVP guiding principles in the CY2020 PFS proposed rule (84 FR 40734) to define MVPs. We are proposing updating the guiding principles from the CY 2020 PFS proposed rule (84 FR 40734) to incorporate RFI comments and the evolution of the MVP framework. In response to the RFI, a few commenters specifically voiced their support of the stated MVP guiding principles. A few commenters suggested we expand the guiding principles to include patient focused wording because they believed the guiding principles, as written, may be applicable only to clinicians. Other suggestions were to: Include a statement supporting physicians and other clinicians to be assessed on MVPs that reflect their specialty training, sub-specialization and their individual or group priorities; remove ''eliminating burden related to selection of measures'' as a principle and instead allow some choice; consider the site of service in the comparative data; consider evidence-based guidelines as an MVP development resource; have comparable reporting burden in all MVPs; use social risk stratification and consider social determinants of health; supplement Principle 3 by stating explicitly ''high priority areas of morbidity and mortality''; and add alignment with other payment programs. One commenter acknowledged the benefit of comparative data but opposed any system that would come at the expense of physicians having to pay to collect and submit data on measures they do not find meaningful.

We propose changes to the MVP guiding principles as shown below. We propose to modify the first guiding principle by adding wording to further emphasize that MVP measures and activities are linked collectively and they enhance each other to the degree possible by adding the words ''connected, complementary'' to describe the MVP ''sets of measures and activities that are meaningful to clinicians.'' In addition, we propose to change ''simplify scoring'' to ''align scoring'' in the first guiding principle to acknowledge that as we initially transition to MVPs, we will not simplify but rather align scoring policies as we continue to have traditional MIPS available. We continue to include scoring simplification as part of our long-term vision and will consider ways to simplify as MVPs become widely available.

With regard to the commenter suggestion to add in clinician choice and to remove wording ''eliminating burden related to selection of measures'', the degree of choice of measures and activities within MVPs will be limited as we strive for standardization; however, we are proposing removing from the first guiding principle the qualification for burden reduction, ''related to selection of measures'', as we also intend to reduce reporting burden.

We have provided information about clinicians and groups on Physician Compare for a few years, beginning with the CY 2017 final rule (81 FR 77390 through 77398). Because so many clinicians participate in MIPS as groups, whereby the data received is for the overall performance of the group and not any specific individual clinicians, Medicare patients are not always able to learn information about their individual clinician, which we believe would be valuable in selecting a clinician for their care. In the CY 2020 PFS proposed rule we discussed our intent to put patients first and provide the information they need to be active decision-makers in their care and the resultant need for more comprehensive performance data at the individual clinician level (84 FR 40734). Whenever feasible, the MIPS program should provide meaningful information at the individual clinician level. We believe an appropriate step is the collection and assessment of more clinician or specific specialty information from multispecialty groups.

Therefore, we are proposing to update the second guiding principle to specify allowing the option of subgroup reporting for MVPs, which would permit subgroups of clinicians to select relevant MVP(s) to report measures and activities that are meaningful to their practices and to patients. As more MVPs become available, groups will be able to continue to participate in MIPS via subgroups to more fully reflect the breadth of services provided by the various clinician types within the group. Though we acknowledge that subgroup reporting is not currently an option for groups to use when reporting to MIPS, we believe that it is important to recognize and include multispecialty practices in guiding principle number 2 as we believe subgroup reporting will be crucial to MVP reporting in future years. Subgroup reporting would be a step towards individual reporting and would improve the meaning and robustness of the performance data used to incentivize high quality and cost-effective care and better provide information that patients can use to select clinicians.

As MVPs are intended to promote value and help patients with choosing clinicians, we agree with commenters that additional wording around the patient focus of MVPs in the guiding principles would further the point that engaging patients in their care, beyond informed consent, is paramount in the MVP Framework. Therefore, we propose to update guiding principle 3 to say that MVP measures should be selected to include the patient voice wherever possible. MVPs should support proactive communication and partnered decision-making between healthcare providers and patients, families, and caregivers and reinforce a care relationship that is based on trust and inclusion of individual values and beliefs. Along the lines of providing better information for patients, as stated above we propose to add wording to the guiding principle number 2 to highlight the importance of more comprehensive multispecialty reporting from subgroups as a step in improving comparative performance data.

We recognize some of the comments are aimed at ensuring high quality measures are used in MVPs. As we agree with commenters regarding strengthening the caliber of MVP measures, we are proposing to add a reference at guiding principle 3 to the Meaningful Measures framework to inform MVP measure selection.

We propose to add a new fifth guiding principle pointing to an important Meaningful Measures element of our future vision for reducing MVP reporting burden; the use of digital performance measure data submission technologies to indicate our commitment to leveraging digital innovations that reduce MIPS related clinician burden. Digital Quality Measures (dQMs) originate from sources of health information that are captured and can be transmitted electronically and via interoperable systems. Examples of digital sources include electronic health records (EHR), health information exchanges (HIEs), clinical registries, case management systems, electronic administrative claims systems, electronically submitted assessment data, and wearable devices. Electronic clinical quality measures or eCQMs (data derived from electronic medical records) are a subset of dQMs. The new proposed guiding principle reads, MVPs should support the transition to digital quality measures.

Regarding the MVP guiding principles commenter suggestion to add the idea that MVPs will allow clinicians to be

assessed according to their specialty and their individual or group priorities, we are not adding this wording as an MVP may focus on a condition or episode of care rather than a specialty; rather clinicians should be electing available MVPs that align with their priorities rather than us matching MVPs to individual practice priorities. The first guiding principle states MVPs should contain sets of measures and activities that are meaningful to clinicians (84 FR 40734). We believe this sufficiently addresses the commenter's suggestion. We did not include the commenter suggestion to add ''morbidity and mortality'' wording as we do not want to restrict what we mean by ''high priority measures'' to only morbidity and mortality measures. Regarding the equity comment, MVPs will provide comparative performance data that measures clinicians fairly and our policies at every level are developed and implemented to treat clinicians equitably. We are not adding new wording referring to alignment with other payment programs as we already refer to our intent that MVPs reduce barriers to APM participation in the guiding principles.

After review and consideration of RFI comments, we are retaining guiding principle 4 (84 FR 40734) and proposing to update guiding principles 1, 2, 3 and 5, as shown in italics, so that the guiding principles for MVPs reflect the following:

1. MVPs should consist of limited, *connected complementary* sets of measures and activities that are meaningful to clinicians, which will reduce clinician burden, *align* 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; *MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups.*

3. MVPs should include measures *selected using the Meaningful Measures approach and, wherever possible, the patient voice must be included,* to 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.

5. *MVPs should support the transition to digital quality measures.*

In section IV.A.3.a.(2)of this proposed rule, we describe our proposed method of creating MVPs. We intend to grow the number of available MVPs using the processes described in that section, maximizing our opportunity for expert input on the most meaningful measures and activities.

We continue our efforts to improve the healthcare of Medicare patients by allowing clinicians to focus on providing care for their patients and the measures and activities that best reflect their care. We look forward to continuing to work with stakeholders to improve the program and implement the vision of MVPs.

(2) MVP Development

(a) Process of Developing MVPs

In the CY 2020 PFS final rule (84 FR 62948), we finalized at § 414.1305 the definition of a ''MIPS Value Pathway'' to mean a subset of measures and activities established through rulemaking. We also clarified our intention to develop MVPs, to the extent feasible, in collaboration with stakeholders (84 FR 62947). Commenters urged us to work in tandem with clinicians and specialty societies to develop MVPs (84 FR 62948) and have supported the development of MVPs with robust stakeholder input and feedback opportunities. Stakeholders have also clearly emphasized the need for input during the design and implementation of MVPs. We believe it is important to emphasize that the transition to MVPs must occur gradually, without immediate elimination of the current MIPS program, as we continue to work collaboratively with stakeholders regarding MVP development. As MVPs are developed collaboratively with stakeholders, they must be created utilizing a consistent set of parameters and criteria, to ensure that MVPs are constructed and implemented in a uniform manner. In addition, we believe it is important to outline the methods in which collaboration and engagement may occur with stakeholders. Lastly, we intend on formulating a standardized process in which stakeholders can submit formal MVP candidates for CMS' consideration.

(i) MVP Development Criteria

In response to the RFI in the CY 2020 PFS final rule, we have received stakeholder comments that supported the move to MVPs with considerations to departing from the traditional reporting requirements of the existing MIPS program, such as reporting 6 quality measures for the Quality performance category. We had also received stakeholder comments through the RFI that supported the use of electronically available measures such as eCQMs and the use of QCDR measures to the extent feasible. Stakeholders also noted that it is important that the collection type of quality measures be considered as MVPs are designed. As a part of the MVP development process, consideration should be given to the four performance categories in MIPS, and whether the MVP has a clearly defined intent, offers value, and opportunity for improvement. We believe that as a part of MVP development, it is important to clearly identify linkages between the measures and activities within an MVP which will demonstrate the relevancy of measures and activities to the clinicians being captured within the MVP. Furthermore, as MVPs are developed it is important to factor in the appropriateness of the measures and activities being included and the comprehensibility of the MVP to clinicians and patients. Lastly, considerations must be given to existing criteria for measure and activity inclusion or removal, as established for each of the performance categories. For example, as described in the CY 2019 PFS final rule (83 FR 59763) for the quality performance category, quality measures that are identified as extremely topped out (reaching an average performance rate between 98 to 100 percent) will likely be removed from the program. We refer readers to the CY 2020 PFS final rule (84 FR 62949 through 63006) for discussion of previously finalized measure and activity requirements across the Quality, Cost, Improvement Activity, and Promoting Interoperability performance categories. In addition, we also refer readers to section IV.A.3.c. of this proposed rule for updates to the respective performance categories. Therefore, beginning with the 2022 MIPS performance period, we propose to develop and select MVPs using the following criteria:

- Utilization of Measures and Activities across Performance Categories:

(a) MVPs should include measures and activities from the Quality, Cost, and Improvement Activities performance categories.

(b) MVPs should include the entire set of Promoting Interoperability (PI) measures.

- Intent of Measurement:

(a) What is the intent of the MVP?

(b) Is the intent of the MVP the same at the individual clinician and group level?

(c) Are there opportunities to improve the quality of care and value in the area being measured?

(d) Why is the topic of measurement meaningful to clinicians?

(e) Does the MVP act as a vehicle to incrementally phase clinicians into APMs? How so?

(f) Is the MVP reportable by small and rural practices? Does the MVP consider reporting burden to those small and rural practices?

(g) Which Meaningful Measure Domain(s) does the MVP address?

- Measure and Activity Linkages with the MVP:

(a) How do the measures and activities within the proposed MVP link to one another? (For example, do the measures and activities assess different dimensions of care provided by the clinician?)

(b) Are the measures and activities related or a part of the care cycle or continuum of care offered by the clinicians?

(c) Why are the measures and activities most meaningful to the specialty?

- Appropriateness:

(a) Is the MVP reportable by multiple specialties? If so, has the MVP been developed collaboratively across specialties?

(b) Are the measures clinically appropriate for the clinicians being measured?

(c) Do the measures capture a clinically definable population of clinicians and patients?

(d) Do the measures capture the care settings of the clinicians being measured?

(e) Prior to incorporating a measure in an MVP, is the measure specification evaluated, to ensure that the measure is inclusive of the specialty or sub-specialty?

- Comprehensibility:

(a) Is the MVP comprehensive and understandable by the clinician or group?

(b) Is the MVP comprehensive and understandable by patients?

- Incorporation of the Patient Voice:

(a) Does the MVP take into consideration the patient voice? How?

(b) Does the MVP take into consideration patients in rural and underserved areas?

(c) How are patients involved in the MVP development process?

(d) To the extent feasible, does the MVP include patient-reported outcome measures, patient experience measures, and/or patient satisfaction measures?

- Measures and Improvement Activities Considerations: MIPS Quality Measures.

We are not prescriptive on the number of quality measures that are included in an MVP. In selecting quality measures, we do believe that consideration should be given to the following:

(a) Do the quality measures included in the MVP meet the existing quality measure inclusion criteria? *(For example, does the measure demonstrate a performance gap?)*

(b) Have the quality measure denominators been evaluated to ensure the eligible population is consistent across the measures and activities within the MVP?

(c) Have the quality measure numerators been assessed to ensure the measure is applicable to the MVP topic?

(d) To the extent feasible, does the MVP include outcome measures, or high priority measures in instances where outcome measures are not available or applicable? We encourage stakeholders to utilize our established pre-rulemaking processes, such as the Call for Measures, described in the CY 2020 PFS final rule (84 FR 62953 through 62955) to develop outcome measures relevant to their specialty if outcome measures currently do not exist and for eventual inclusion into an MVP.

(e) To the extent feasible, does the MVP include electronically specified clinical quality measures?

(f) To the extent feasible, does the MVP avoid including quality measures that are topped out?

(g) What collection types are the measures available through?

(h) What role does each quality measure play in driving quality care and improving value within the MVP? Provide a rationale as to why each quality measure was selected.

(i) How do the selected quality measures relate to other measures and activities in the other performance categories?

(j) To the extent feasible, specialty and sub-specialty specific quality measures are incorporated into the MVP. Broadly applicable (cross-cutting) quality measures may be incorporated if relevant to the clinicians being measured.

- Measures and Improvement Activities Considerations: Cost Measures:

(a) What role does the cost measure(s) play in driving quality care and improving value within the MVP? Provide a rationale as to why each cost measure was selected.

(b) How does the selected cost measure(s) relate to other measures and activities in other performance categories?

(c) If there are not relevant cost measures for specific types of care being provided (for example, conditions or procedures), does the MVP include broadly applicable cost measures (that are applicable to the type of clinician)?

(d) What additional cost measures should be prioritized for future development and inclusion in the MVP?

- Measures and Improvement Activities Considerations: Improvement Activities:

(a) What role does the improvement activity play in driving quality care and improving value within the MVP? Provide a rationale as to why each improvement activity was included.

(b) Describe how the improvement activity can be used to improve the quality of performance in clinical practices for those clinicians who would report this MVP.

(c) Does the improvement activity complement and/or supplement the quality action of the measures in the MVP, rather than duplicate it?

(d) To the extent feasible, does the MVP include improvement activities that can be conducted using CEHRT functions? The use of improvement activities that specify the use of technologies will help to further align with the CEHRT requirement under the Promoting Interoperability performance category.

(e) If there are not relevant specialty or sub-specialty specific improvement activities, does the MVP includes broadly applicable improvement activities (that is applicable to the clinician type) are used?

- Measures and Improvement Activities Considerations: Promoting Interoperability (PI) Measures:

(a) Must include the full set of PI measures.

The MVP development criteria was developed primarily with consideration with the MVP guiding principles, discussed above. In addition, we considered the spectrum of measures and activities available for MVP development, and the criteria used to include measures and activities within each of the respective performance categories. Through the collaborative process of co-developing MVPs with stakeholders, we have realized how crucial it is to establish a set of MVP development criteria that would standardize what is expected of MVPs and provide our evaluation criteria in a transparent manner. We believe that the aforementioned criteria will lead to the development of MVPs in a manner that is consistent and reliable. We seek comment on the MVP development criteria.

(ii) Capturing the Patient Voice

As a part of the MVP development process, we believe that it is important to develop MVPs in a manner that takes into consideration the patient's experience, satisfaction, and outcomes. We believe that MVPs should be constructed in a manner that should not only be understood by clinicians, but by patients who may use the ascertained information to make informed decisions regarding their health care providers. Therefore, beginning with the 2022 performance period, we propose that stakeholders that are developing MVPs to submit to CMS as candidate MVPs should include patients as a part of the MVP development process. Stakeholders should incorporate patients and/or patient representatives through means that may include, but are not limited to technical expert panels or an advisory committee as they work to construct their candidate MVPs prior to reaching out to CMS with a candidate submission. The process of involving patients as a part of the stakeholder's MVP development would be considered a pre-requisite for CMS to consider the candidate MVP for the upcoming performance period. By including patients and/or patient representatives in the MVP development process, we believe that patients will be able to voice how to make the outcomes of measurement meaningful to them. In addition to including patients as a part of the MVP development process, we encourage stakeholders to utilize several approaches to incorporate the patient perspective, such as using focus groups, in-depth interviews with patients, and informal listening sessions, to the extent feasible, for a comprehensive patient perspective. We seek comments on this proposal.

(iii) Candidate MVP Co-Development, Solicitation Process, and Evaluation

Through the Request for Information (RFI) on transforming MIPS in the CY 2020 PFS final rule we have learned of stakeholders interests in participating in the MVP development process. In summer 2019, we held numerous focus groups with front-line clinicians, specialty societies, advocacy groups, QCDRs, registries, and health IT vendors to listen to what stakeholders were looking for in regards to program simplification, burden reduction, and the intent of MVPs. In response to the CY 2020 PFS final rule, we received several requests from stakeholders who wanted to discuss their perspectives on MVPs and in some cases, walk us through potential MVP candidates from their specialty. Based on continuous stakeholder interest, we believe that a process must be implemented to ensure that stakeholder engagement and collaboration in the development of MVPs is consistent from an overall perspective.

To consider MVP candidates developed by stakeholders, we believe it is important to implement a streamlined approach to receive and evaluate potential MVPs. Therefore, beginning with the 2022 performance period, we propose that stakeholders should formally submit their MVP candidates formally utilizing a standardized template, which will be published in the QPP resource library for our consideration for future implementation. Stakeholders should submit all information including a description of how their MVP abides by the MVP development criteria as described in section IV.A.3.a.(2)(a)(i) of this proposed rule, and provide rationales as to why specific measures and activities were chosen to construct the MVP. We believe the utilization of a standardized template would help stakeholders understand what information is needed to evaluate the feasibility of the candidate MVP.

On an annual basis, we intend on hosting a public facing MVP development webinar, to remind stakeholders of MVP development criteria, the timeline, and process in which to submit a candidate MVP. While we believe that engagement with stakeholders regarding MVP candidates may occur on a rolling basis throughout the year, at CMS' discretion we will determine if an MVP is ready for inclusion in the upcoming performance period. As MVP candidates are received, they will be reviewed, vetted, and evaluated by CMS and our contractors. We intend on utilizing the MVP development criteria (discussed above) to determine if the candidate MVP is feasible. In addition to the MVP development criteria listed above, we will also vet the quality and cost measures from a technical perspective to validate that the coding in the quality measures and cost measure(s) include the clinician type being measured, and whether all potential specialty specific quality measures or cost measures were considered, with the most appropriate included. We may reach out to the stakeholder on an as-needed basis, should questions arise as we review. In addition, in continuing collaborative efforts, once we complete our internal evaluation, we will reach out to select stakeholders whose candidate MVP may be feasible for the upcoming performance period, to schedule a feedback loop meeting to discuss our feedback, and next steps that may include recommended modifications to the MVP candidate. Since MVPs must be established through rulemaking, as described at § 414.1305, CMS will not communicate to the stakeholder whether an MVP candidate has been approved, disapproved, or is being considered for a future year, prior to the publication of the proposed rule. We seek comment on the proposed process to solicit MVP candidates. In addition, we seek comment on how we could make this process more transparent in future years, for stakeholders that collaborate to develop MVP candidates and other MIPS stakeholders, should we consider the utilization of an advisory committee or technical expert panel to review MVP candidates, or the review of MVP candidates by an interdisciplinary committee, similar to what is used for the MIPS quality measures under the Call for Measures or a public process such as the NQF convened Pre-rulemaking process? We believe that integrating these steps into the process could provide greater transparency, however we are concerned that integrating these steps could further delay the incorporation of MVPs into the MIPS program. We seek feedback on the issue of furthering transparency into the MVP development process vs. timeliness of introducing MVPs into the MIPS program. Are stakeholders concerned with the possibility of delayed MVP implementation if these additional methods of review are implemented? If so, what are some strategies CMS should consider if we decide to implement additional methods of allowing public commentary on potential MVP candidates?

(b) Implementing Meaningful Measures in MVPs

(i) Incorporating Population Health Measures Into MVPs

In the CY 2020 PFS proposed rule (84 FR 40742 through 40743), we expressed our interest in incorporating population health measures calculated from administrative claims-based data as a part of the foundational layer within MVPs, in an effort to improve patient outcomes, reduce reporting burden and costs, better align clinician quality improvement efforts, and increase alignment with APMs and other payer performance measurement. Through the RFI, stakeholders expressed concerns with including population health measures due to concerns with reliability, validity, attribution, unintended consequences and/or risk adjustment of claims-based population health measures. We understand

stakeholder concerns around the population health measures that were previously considered, and are looking into ways to address and mitigate those concerns. We also received some support from stakeholders who agreed that population health measures will reduce administrative burden with the belief that these measures are not any less relevant to specialists. In MIPS, we currently have one administrative-claims based measure, the All-cause Hospital Readmission measure, which is calculated and scored for groups with 16 or more clinicians that meet a 200-patient case minimum, as described in the CY 2017 Quality Payment Program final rule (81 FR 77300). As described in Appendix 1 of this proposed rule, we are proposing to replace the All-cause Hospital Readmission measure with a Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups because the re-specified measure promotes a system level approach by clinicians, with a focus on high risk conditions such as COPD and heart failure. We refer readers to Appendix 1 of this proposed rule for detailed discussion of the newly proposed measure.

(ii) Incorporating QCDR Measures Into MVPs

In the CY 2020 PFS final rule, we sought comments from stakeholders as to whether QCDR measures should be considered for integration within MVPs. Stakeholders were generally supportive of including QCDR measures within MVPs, but others expressed concern that including QCDR measures within MVPs would require clinicians to use certain third party intermediaries which may cause additional burden for clinicians who may need to change their current reporting method and undertake additional costs associated with reporting through QCDRs. Under the existing MIPS program and as described at § 414.1330(a)(2), for a MIPS payment year, we can use approved QCDR measures as described under § 414.1400 to assess performance in the quality performance category. We continue to believe that the development of QCDR measures by QCDRs is important as it provides measures that are relevant, applicable, and meaningful to clinicians, and addresses gaps that are not addressed by measures available through the MIPS quality measure inventory. In envisioning MVP development for the 2022 performance period and future years, we believe it is important to consider the opportunity to include QCDR measures within MVPs. Prior to consideration of including the QCDR measure within a candidate MVP, QCDR measures must meet all existing criteria under § 414.1400(b)(3) and the criteria described at § 414.1400(b)(3)(v)(C)(*4*) that QCDR measures should be fully tested at the clinician level prior to the QCDR measure being included in an MVP. We refer readers to section IV.A.3.g.(2)(b)(iv) of this proposed rule for additional discussion of this requirement.

With regards to the timeline to which MVPs and QCDR measures may be established, we have identified differences with the timelines that each of these processes follow. As described in the CY 2020 PFS final rule (84 FR 62948), we finalized the definition of an MVP at § 414.1305 to mean a MIPS Value Pathway is a subset of measures and activities established through rulemaking. Furthermore, as described in the CY 2019 PFS final rule (83 FR 59900) and at § 414.1400(b)(1), entities that wish to self-nominate as a QCDR and submit QCDR measures for CMS consideration must do so within the 60-day self-nomination period that begins on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year. QCDR measures are typically reviewed and approved in the preceding months after the close of the self-nomination period. Therefore, we propose that beginning with the with the 2022 performance period, only QCDR measures that were approved in the previous year may be considered for inclusion within a candidate MVP. Furthermore, we propose that the QCDR measures included within a candidate MVP must meet the existing criteria that are currently established at § 414.1400(b)(3). In the traditional MIPS program, entities that meet the QCDR definition can develop QCDR measures to fulfill the quality performance category reporting requirements. We believe that QCDR measures can continue to fulfill the reporting requirements of the quality performance category within MVPs. Candidate MVPs should be submitted utilizing the process as described in section IV.A.3.a.(2)(a) of this proposed rule. Candidate MVPs that are approved for inclusion in the upcoming performance period must be proposed and finalized through notice-and-comment rulemaking. Candidate MVPs that include QCDR measures will also need to be proposed and finalized through notice-and-comment rulemaking in order to be available for reporting in the upcoming performance period. Therefore, in instances where MVPs are finalized through notice-and-comment rulemaking with QCDR measures, those QCDR measures would be eligible for 2-year QCDR measure approval as described at § 414.1400(b)(3)(vi).

In the CY 2018 PFS final rule (82 FR 53813), we finalized that beginning with the 2018 performance period and for future program years, that QCDRs may seek permission from another QCDR to use an existing QCDR measure that is owned by another QCDR.

(e) Reporting of MVPs Through Third Party Intermediaries

Through the MIPS program, QCDRs, qualified registries, and Health IT vendors support the reporting of the Quality, Promoting Interoperability, and Improvement Activity performance categories, as proposed and codified at § 414.1400(a)(2). We believe that third party intermediaries who support the aforementioned performance categories are able to support MVPs, since they will be comprised of measures and activities from these performance categories, as well as cost measures that are calculated by CMS (thereby requiring no additional effort by third party intermediaries). We believe allowing third party intermediaries to support MVPs will offer eligible clinicians and groups additional methods to report an MVP. We refer readers to section IV.A.3.g. of this proposed rule for additional discussion of these proposals.

Since QCDR and qualified registry applicants would be submitting their self-nomination application prior to the publication of the final rule, we will work to establish a process to allow QCDRs and qualified registries to identify and select which MVPs they can support following the publication of the final rule, if we finalize this policy. We seek comments on this proposal.

(6) Transition to MVPs

(a) Timeline for MVP Implementation

In response to the RFI in the CY 2020 PFS final rule, we have received comments from stakeholders that indicated a gradual implementation of MVPs. Through the MVP development process, we seek to collaborate with stakeholders in the development of MVPs that are meaningful and applicable to clinicians and groups. Therefore, we understand the need for an incremental approach as we transition eligible clinicians and groups to MVP reporting as they are implemented. In light of the COVID–19 pandemic, we have decided to delay the implementation of MVPs, and revisit

potential MVP implementation through future rulemaking, possibly beginning with the 2022 performance period. Although we believe in the importance of transforming the MIPS program to create greater meaning for clinicians, we understand that there are clinicians who are on the frontlines taking care of COVID–19 patients that should not be burdened with having to learn a new method of reporting for the MIPS program at this time. Overall, our goal is to gradually implement MVPs for all MIPS eligible clinicians and groups overtime, to ensure that MVPs are designed and available in a manner relevant to clinicians. We intend to continue to work closely with stakeholders to develop MVPs that are relevant to various specialties, and understand that a level of flexibility is needed to allow for meaningful reporting.

b. APM Performance Pathway

(1) Overview

In the CY 2020 PFS final rule (84 FR 62568), we finalized the MIPS Value Pathway framework as a means of reducing reporting burden, increasing meaningful measurement, and continuing to encourage movement through MIPS away from fee-for-service (FFS) payments and towards APMs. Burden reduction and meaningful measurement are important goals in relation to all eligible clinicians, and we recognize that the best means for achieving these goals may be different for MIPS eligible clinicians not yet joined an APM than for those MIPS eligible clinicians who already are participating in APMs and therefore have different reporting obligations. This is particularly true for eligible clinicians in Advanced APMs who are subject to MIPS either because they are Partial QPs for a year and elect to participate in MIPS or because they fall below the applicable Partial QP threshold for a performance year.

We are proposing at § 414.1367 to establish an APM Performance Pathway (APP) under MIPS beginning in the 2021 MIPS performance year, designed to provide a predictable and consistent MIPS reporting standard to reduce reporting burden and encourage continued APM participation.

(2) Applicability

We propose that the APP will be in effect beginning January 1, 2021, and would be an optional MIPS reporting and scoring pathway for MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of any APM Entity participating in any MIPS APM on any of the four snapshot dates (March 31, June 30, August 31, and December 31) during a performance period, beginning in the 2021 MIPS performance period.

(a) Reporting Through the APM Performance Pathway

Individual MIPS eligible clinicians who are participants in MIPS APMs may report through the APP at the individual level. Groups and APM Entities may report through the APP on behalf of their constituent MIPS eligible clinicians; however, the final score earned by the group through the APP would be applied only to those MIPS eligible clinicians who appear on a MIPS APM's Participation List or Affiliated Practitioner List on one or more snapshot dates. The final score applied to each individual MIPS eligible clinician would be the highest available final score for that clinician (TIN/NPI), or a Virtual Group score, if applicable, as discussed at IV.A.3.e. of this proposed rule.

As described further in section III.G.1. of this proposed rule, ACOs participating in the Medicare Shared Savings Program would be required to report through the APP for purposes of assessing their quality performance for that program, but MIPS eligible clinicians participating in these ACOs also would have the option of reporting outside the APP, or within it at an individual or group level, for purposes of being scored under MIPS, like all other MIPS APM participants. As the APP would be optional for purposes of MIPS scoring, under the proposal MIPS APM participants would be able to report through the APP or through any other available MIPS reporting mechanism they chose.

We refer readers to section IV.A.3.e. of this proposed rule for information concerning our proposed changes to the hierarchy that will apply when more than one final score is associated with a TIN/NPI.

We seek comment on this proposal.

(b) MIPS APMs

We propose to amend our definition of MIPS APM at § 414.1305 as an APM that meets the criteria in § 414.1367(b). We also propose to codify the following MIPS APM criteria at the new § 414.1367(b). We are proposing to maintain two criteria for MIPS APMs that currently are included at §§ 414.1370(b)(1) and (3) respectively, namely that: (1) An APM Entity participates in the APM under an agreement with CMS or through a law or regulation; and (2) the APM bases payment on quality measures and cost/utilization. However, under the proposed policy, for purposes of the MIPS performance period we would not depend on the availability of quality measure data reported directly to the APM, and we are not proposing to continue requiring that MIPS APMs be in operation and therefore collecting quality data for the entirety of the performance period. We also note that currently, to be a MIPS APM, § 414.1370(b)(2) requires that an APM must be designed such that its APM Entities include at least one MIPS eligible clinician on a Participation List, and does not include APMs that use only Affiliated Practitioner Lists. However, we believe that because we are not proposing to require reporting through the APP be done exclusively at the APM Entity level, it is not necessary to limit use of the APP to APM Entities alone. Therefore, we are proposing to expand the definition of MIPS APM to include those APMs in which there is only an Affiliated Practitioner List and that otherwise meet these proposed MIPS APM criteria.

We seek comment on this proposal.

(3) MIPS Performance Category Scoring in the APM Performance Pathway

In general, MIPS reporting and scoring requirements are applicable to all MIPS eligible clinicians, including those reporting through the proposed APP. However, the following reporting and scoring rules would apply only to those MIPS eligible clinicians, groups, or APM entities reporting through the APP.

(a) Quality Performance Category

We are proposing that, beginning in the 2021 performance period, MIPS eligible clinicians scored under the APP would be scored on the quality measure set finalized for such MIPS performance period.

For PY 2021, we are proposing the measures listed in Table 41 to be used for purposes of quality performance category scoring for the APP.

TABLE 41: APM Performance Pathway Quality Measure Set

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Quality ID:001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID: 236	Controlling High Blood Pressure	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Measure # TBD	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions

For those MIPS eligible clinicians, groups, or APM Entities for whom a given measure is unavailable due to the size of the available patient population or who are otherwise unable to meet the minimum case threshold for a measure, we are proposing to remove such measure from the quality performance category score for such MIPS eligible clinician, group, or APM Entity.

For MIPS eligible clinicians, groups, or APM Entities reporting through the APP, we are proposing to not apply the quality measure scoring cap at § 414.1380(b)(1)(iv) in the event that a measure in the APP measure set is determined to be topped out. Because the measure set is fixed, we do not believe it is appropriate to limit the maximum quality performance category available to them. Should an APP measure be determined to be topped out, we would at that time consider amending the APP quality measure set through future rulemaking, if appropriate.

We seek comment on this proposal.

In the CY 2020 PFS proposed rule, we sought comment on aligning the Shared Savings Program version of the Multiple Chronic Conditions (MCC) measure (that is, the ACO MCC) with the MIPS version of the MCC measure (see 84 FR 40711 and 40712). We noted that the MIPS MCC claims-based measure is similar to the ACO MCC currently used to assess ACO quality under the Shared Savings Program. The MIPS MCC and ACO MCC measures are similar because they both target patients with multiple chronic conditions, but the cohort, outcome, and risk model for the MIPS MCC measure varies from the ACO MCC measure. The cohort for the ACO MCC measure includes eight conditions whereas the MIPS MCC measure includes nine conditions, with the additional condition being 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.

In 2019, we added a revised MCC measure to the 2019 Measure under Consideration list for the Shared Savings Program for consideration by the Measure Applications Partnership (MAP) Clinician Workgroup. The revised MCC measure specifications aligned with the MIPS MCC measure by: (1) Adding a diabetes cohort; (2) excluding any admissions within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility; and (3) adjusting for the AHRQ SES index and specialist density social risk factors. The only remaining difference between the MIPS and Shared Savings Program versions of the measure would be attribution, which is program-specific. Attribution for Shared Savings Program ACOs uses the Shared Savings Program beneficiary assignment methodology, which emphasizes primary care. During the MAP discussion it was noted that the original ACO MCC measure has been in use in the Shared Savings Program since 2015, and the MAP expressed no concerns with respect to feasibility and implementation of the revised MCC measure. A measure has high reliability if it produces consistent results from multiple measurements, in other words, it reflects a signal, rather than random error associated with measurement. Reliability values range between zero (all error, little signal) to 1.0 (no error, all signal).[76] The median signal-to-noise reliability for all Shared Savings Program ACOs in 2018 was 0.96 ranging from 0.12 to 1.00 (IQR: 0.94–0.98), indicating an overall excellent reliability of the measure.[77]

The MAP final recommendation for this measure was ''conditional support for rulemaking.'' [78] We intend to take the revised measure through the National Quality Forum (NQF) endorsement process in 2020. Because the revisions would make the ACO MCC measure more aligned with the MIPS version and given the support received from the MAP, we propose to include the revised All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions measure in the APP measure set to be reported on by any Medicare ACO.

(b) Cost

In the CY 2017 Quality Payment Program final rule (81 FR 77256, 77265), we finalized at § 414.1370(g)(2) to waive the cost performance category under waiver authority at section 1115A(d)(1) of the Act for CMS Innovation Center

[76] Adams, John L., Ateev Mehrotra, and Elizabeth A. McGlynn, Estimating Reliability and Misclassification in Physician Profiling. Santa Monica, CA: RAND Corporation, 2010. *https://www.rand.org/pubs/technical_reports/TR863.html.*

[77] CMS used the 2018 Shared Savings Program ACO beneficiary assignment data to test the revised MCC measure. Here, reliability refers to measure score reliability of the revised MCC measure.

[78] *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.*

APMs, and at section 1899(f) of the Act for the Medicare Shared Savings Program. We are proposing to continue to waive the cost performance category under the same authorities because: (1) APM entities in MIPS APMs already are subject to cost performance assessment under their APMs, as the MIPS APM criteria would continue to include the assessment of participants based on cost; (2) MIPS APMs may measure cost performance in different ways than MIPS, for example, by basing cost on total cost of care, which measures a broader scope of cost or resource use than would necessarily be reflected in the narrower claims-based accountability standard under MIPS; and (3) MIPS APMs may attribute beneficiaries differently from MIPS for purposes of measuring cost, leading to an unpredictable degree of overlap between the sets of beneficiaries for whom the MIPS eligible clinicians would be responsible under their APM and under MIPS. We believe that with an APM Entity's finite resources for engaging in efforts to improve quality and lower costs for a specified beneficiary population under the APM, it is necessary to give the APM Entity the ability to identify a single beneficiary population to prioritize in its cost-saving efforts so that the goals and evaluation associated with the APM are as clear and free of confounding factors as possible. With this flexibility, MIPS eligible clinicians who are attempting to strategically transform their respective practices would not jeopardize their ability to succeed in either MIPS or under the terms of their APM. Therefore, by participating through the APP, the APM participant may indicate their intent to focus their resources on the beneficiary population and services identified by the terms of the APM rather than the population and services they would have been responsible for under the MIPS cost performance category. We seek comment on this proposal.

(c) Improvement Activities

We are proposing to assign a score for the Improvement Activities performance category for each MIPS APM, and that score will be applied to participant MIPS eligible clinicians reporting through the APP. In an effort to further reduce reporting burden for MIPS eligible clinicians in MIPS APMs and to better recognize improvement activities work performed through participation in MIPS APMs, we are proposing to assign a baseline score for each MIPS APM based on the improvement activity requirements of the particular MIPS APM. CMS would review the MIPS APM's requirements in relationship to activities specified under the generally applicable MIPS improvement activities performance category and assign for each MIPS APM an improvement activities performance category score that is applicable to all MIPS eligible clinicians reporting through the APP who are participants in the MIPS APM. To develop the improvement activities score for MIPS APMs, we would compare requirements of the APM with the list of Improvement Activities, described in § 414.1355(a), for the applicable year, and score those improvement activities as they would otherwise be scored according to § 414.1380(b)(3). Thus, points assigned to an APM participant MIPS eligible clinician participating in MIPS through the APP would be based, at least in part, on the documented terms and requirements of participation in the MIPS APM, such as under a participation agreement or regulation. In the event a MIPS APM participant does not actually perform an activity for which Improvement Activities credit would otherwise be assigned under this proposal, the MIPS APM participant would not receive credit for the associated Improvement Activity.

We would publish the assigned improvement activities scores for each MIPS APM on the CMS website prior to the beginning of the MIPS performance period. In the event that the assigned score for a MIPS APM does not represent the maximum improvement activities score, we propose that MIPS eligible clinicians reporting through the APP would have the opportunity to report additional improvement activities that then would be applied towards their scores.

We note that under section 1848(q)(5)(c)(ii) of the Act, a MIPS eligible clinician in an APM for a performance period automatically earns a minimum score of one half of the highest potential score for the improvement activities category for their participation in an APM for the performance period. Additionally, under section 1848(q)(5)(c)(i) of the Act, MIPS eligible clinicians participating in a patient-centered medical home model or comparable specialty practice, as determined by the Secretary for a performance period, automatically earn the highest potential score for the improvement activities category. These baseline scores would be automatically applied for all MIPS eligible clinicians who participate in an APM in accordance with § 414.1380(b)(3)(i) and (ii), respectively.

We seek comment on this proposal.

(d) Promoting Interoperability

We propose that the Promoting Interoperability performance category score would be reported and calculated in the same manner described at § 414.1375. We seek comment on this proposal.

(4) APP Performance Category Weights

We are proposing to continue to waive the requirement to weight each MIPS performance category as described in section 1848(q)(5)(E) of the Act using the waiver authority in sections 1115A(d)(1) and 1899(f) of the Act for CMS Innovation Center APMs and the Medicare Shared Savings Program, respectively. For reasons described in section IV.B.3.ii. of this proposed rule, we believe it is necessary to waive the cost performance category for MIPS eligible clinicians reporting to MIPS through the APP. As a result, it also would be necessary to waive the requirement to weight each MIPS performance category as described in section 1848(q)(5)(E) of the Act and to redistribute the cost performance category weight to the remaining performance categories to be scored for APM participants reporting through the APP.

We are proposing to reweight the performance categories for APM participants reporting through the APP to:

- Quality: 50 percent.
- Cost: 0 percent.
- Promoting Interoperability: 30 percent.
- Improvement Activities: 20 percent.

We believe these weights are appropriate as they generally align with the relative performance category weights under MIPS and MVPs in circumstances where the cost performance category has been reweighted to zero percent of the final score, and the cost performance category weight has been distributed proportionately among the remaining performance categories.

We propose to codify this proposal at § 414.1367(d)(1). We seek comment on these proposals.

(a) Reweighting a Performance Category

We recognize that there are certain circumstances when a MIPS eligible clinician, group, or APM Entity may be unable to complete reporting to MIPS due to, for example, extreme and uncontrollable circumstances, hardship, or the unavailability or inapplicability of measures due to practice size or other data limitations. Therefore, under the authority provided in section 1848(q)(5)(F) of the Act, it may become

necessary to reweight one or more performance categories.

In a case where the Promoting Interoperability performance category is reweighted to zero percent, we are proposing to reweight the quality performance category to 75 percent and the Improvement Activities performance category to 25 percent.

In a situation where the quality performance category is reweighted to zero percent, we are proposing to reweight the Promoting interoperability performance category to 75 percent and the improvement activities performance category to 25 percent.

We believe that these distributions appropriately value performance categories that require reporting on measures and measuring improvement, without disproportionately emphasizing one performance category over another. Furthermore, these performance category weights will contribute to a unified performance category reweighting policy throughout MIPS in the event of an Extreme and uncontrollable circumstance that requires the reweighting of cost and any other MIPS performance category.

We propose to codify this policy at § 414.1367(d)(2). We seek comment on these proposals.

(5) Scoring for APM Participants Reporting Through the APP

We propose that final scoring for APM participants reporting to MIPS through the APP would follow the same methodology as established for MIPS generally at § 414.1380. Specifically, we would continue to score each performance category and multiply each performance category score by the applicable performance category weight, and then calculate the sum of each weighted performance category score and apply any applicable adjustments.

We propose to codify this policy at § 414.1367(e).

(6) Performance Feedback for APM Participants Reporting Through the APP

We propose to make performance feedback available to MIPS eligible clinicians reporting through the APP according to the methods applicable to all MIPS eligible clinicians, as described in the 2017 QPP final rule (81 FR 77347).

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 2021 PFS proposed rule, we propose to:

- Weigh the quality performance category at 40 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year, at § 414.1330(b)(4) and (5), respectively.
- Sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the 2021 performance period.
- Make changes to the MIPS quality measure set as described in Appendix 1 of this proposed rule, including addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.
- Establish separate performance periods specific to administrative claims measures at § 414.1320(d)(1).
- Make changes to the CAHPS for MIPS survey to address the increased use of telehealth care.
- Expand telehealth codes used in beneficiary assignment for the CAHPS for MIPS beginning with the 2021 survey.

(b) Weight in the Final Score

Section 1848(q)(5)(E)(i)(I) of the Act, provides that 30 percent of the final score shall be based on performance for the quality performance category, in which the percentage points attributed to the final score for the quality and cost performance categories will both be equivalent at 30 percent, totaling 60 percent of the final score. The percentage points attributed to both the quality and cost performance categories are in tandem. For each year within the first five years of the MIPS program, the quality performance category performance percentage can be increased to more than 30 percent of the final score. The percentage increase of the quality performance category is equivalent to the decrease of the cost performance category.

As discussed in section IV.A.2.c.(2)(a) of this proposed rule, we propose to weight the cost performance category at 20 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 establish the weight of the quality performance category for the 2023 and 2024 MIPS payment years. At § 414.1330(b)(4), the percentage points attributed to performance in the quality performance category would comprise 40 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and at § 414.1330(b)(5), the percentage points attributed to performance in the quality performance category would comprise 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 would be modified over the next two years of the program will allow stakeholders to better plan and anticipate how the performance category scores would be calculated in future for MIPS eligible clinicians, groups, and virtual groups as we incrementally adjust the final score weights for the quality and cost performance categories. We solicit public comment on our proposals to incrementally reduce the weight of the quality performance category as we incrementally increase the weight of the cost performance category. Particularly, our proposal to adjust the percentage points attributed to the final score in the quality performance category to be comprised of 40 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and future years.

(c) Groups and Virtual Groups Reporting via the CMS Web Interface

At § 414.1335(a)(2), the CMS Web Interface measures is a collection type in which groups and virtual groups with 25 or more eligible clinicians are able to report data on a set of pre-determined quality measures. For the 2020 performance periods, the total number of CMS Web Interface measures required to complete reporting on is 10 CMS Web Interface measures (83 FR 59713 through 79715 and 59756). Each CMS Web Interface measure must have complete reporting (no partial reporting) on all 10 measures while quality measures in other collection types require the reporting of fewer measures. The reporting requirements for the CMS Web Interface measures are more stringent than other collection types for the quality performance category, which include reporting on a larger set of measures and a higher data completeness rate. At § 414.1335(a)(1)(i), it is established that groups and virtual groups reporting quality measures using non-CMS Web Interface measures collection types (such as Qualified Registries, Qualified Clinical Data Registries (QCDRs), electronic health records (EHRs), and Medicare Part B claims) are required to report on a minimum of 6 quality measures, including at least one outcome measure. The data completeness criteria for reporting

quality measures for Qualified Registry measures, QCDR measures, EHR measures, and Medicare Part B claims measures has a lower threshold compared to the CMS Web Interface measures. The data completeness criteria for the CMS Web Interface measures requires groups and virtual groups to report on the first 248 consecutively ranked beneficiaries in the sample for each measure (and if the sample of eligible assigned beneficiaries is less than 248, then the group or virtual group must report on 100 percent of assigned beneficiaries), and at least one measure for which there is Medicare patient data (at §§ 414.1335(a)(2) and 414.1340(c)). For the 2020 performance period, the data completeness criteria threshold for Qualified Registry measures, QCDR measures, EHR measures, and Medicare Part B claims measures is 70 percent of the MIPS eligible clinician, group, or virtual group's patients (and applicable Medicare Part B patients for Medicare Part B claims measures) that meet the measure's denominator criteria (at §§ 414.1340(a)(3) and 414.1340(b)(3)). Thus, groups and virtual groups submitting quality data through the CMS Web Interface measures report on a significantly larger number of patients compared to other collection types and such patients are identified in a sample by us (at § 414.1340(c)).

In section III.G.1.c. of this proposed rule, we discuss our proposal to revise the Medicare Shared Savings Program quality performance standard and align with the APP framework. With the proposed modifications to the Medicare Shared Savings Program quality performance standard, which include a proposal to transition to an APP for ACOs starting with the 2021 performance period as outlined in section III.G.1.b.(1) of this proposed rule, we conducted an assessment of the utilization of the CMS Web Interface measures as a collection type for groups and virtual groups participating in MIPS. As noted above, we recognize that the CMS Web Interface reporting requirements, which include the reporting on a larger set of measures and a higher data completeness rate, are more stringent than other collection types available under MIPS. Similar to the Medicare Shared Savings Program, for purposes of MIPS, we strive to align CMS Web Interface requirements across programs, where appropriate and applicable; reduce burden to MIPS eligible clinicians; create robust and meaningful quality measure sets that promote outcome based measures; and offer quality measures that are able to adequately and effectively assess performance such as ensuring that topped out measures are removed.

In assessing the utilization of the CMS Web Interface by groups and virtual groups, there has been a substantial decrease in participation each year since the inception of MIPS in the 2017 performance year. From the 2017 to 2019 performance years, the number of groups eligible to report quality measures via the CMS Web Interface (groups registered to utilize the CMS Web Interface) decreased by approximately 45 percent. Similarly, the number of groups utilizing the CMS Web Interface as a collection type has decreased by approximately 40 percent from the 2017 to 2019 performance years. It is not clear as to why groups and virtual groups are not seeking to participate in MIPS by submitting quality data for CMS Web Interface Measures. There could be various reasons explaining the decrease in CMS Web Interface participation such as MIPS offering several collection types that can be utilized by any individual MIPS eligible clinician, group, or virtual group to meet program requirements; the CMS Web Interface measure reporting requirements may be burdensome compared to other collection types/submission types; the measure set is limited to primary care; groups and virtual groups may have a preference to select their own measures to have performance assessed instead of a pre-determined measure set; or as a result of the CMS Web Interface measures being topped out, it may deter groups and virtual groups from participating because they would not fiscally benefit to be compared and assessed when there is little or no data variation in performance across ACOs, groups, and virtual groups.

Given the above factors, we considered the following two options in our assessment: Continue the utilization of the CMS Web Interface measures solely for groups and virtual groups while ACOs transition to APP participation; or sunset the utilization for the CMS Web Interface measures as a collection type for groups and virtual groups. Groups and virtual groups account for less than 20 percent of organizations utilizing the CMS Web Interface measures while ACOs participating in the Medicare Shared Savings Program or Next Generation ACO Model account for more than 80 percent. With an expected 80 percent reduction if our proposed revisions to the quality performance standard under the Shared Savings Program are finalized and a continued decrease in groups and virtual groups seeking to report quality data on CMS Web Interface measures, it is not fiscally viable, feasible, or sustainable for MIPS to continue to make available the CMS Web Interface measures as a collection type/submission type. A reduction in the number of organizations submitting quality data on CMS Web Interface measures does not equate to the reduction in direct costs associated with operating and maintaining the CMS Web Interface measures. To operate and maintain the CMS Web Interface measures solely for groups and virtual groups, there would be an increase in cost and needed resources under MIPS associated with the items such as the establishment and maintenance of CMS Web Interface benchmarks, assignment and sampling, technical support, and education and outreach; thus, there would be proportionally higher costs associated with the operationalization and maintenance of the CMS Web Interface with a significantly smaller number of groups and virtual groups utilizing the CMS Web Interface measures as a collection type/submission type.

In assessing the second option to sunset the CMS Web Interface measures as a collection type starting with the 2021 performance year, we would be aligning with the Medicare Shared Savings Program proposal to no longer utilize the CMS Web Interface as a means for assessing and scoring ACOs, groups, and virtual groups under the CMS Web Interface measures. We recognize that the sunset of the CMS Web Interface for groups and virtual groups may be burdensome to current groups and virtual groups submitting quality data on CMS Web Interface measures. Such groups and virtual groups would need to select a different collection type/submission type and redesign their systems to be able to interact with the new collection type/submission type. The timeframe for groups and virtual groups to select a new collection type/submission type and redesign their systems may be perceived as burdensome.

We believe that groups and virtual groups would be able to select a different collection type/submission type, including at least 6 quality measures that are similar to previously established CMS Web Interface measures and reflect their specialty, and prepare for the 2021 reporting period in advance of the reporting period starting in January of 2022. While there may be an initial increase in burden for current groups and virtual groups utilizing the CMS Web Interface measures having to transition to the utilization of a different collection type/submission type, we

recognize that we would also be reducing reporting requirements by no longer requiring groups and virtual groups to have to completely report on all pre-determined 10 CMS Web Interface measures; groups and virtual groups would be able to select their own measures to report, would be reporting data on at least 6 measures, and data completeness threshold would be 70 percent for each measure, which is a reduction in program requirements compared to completed reporting required for all CMS Web Interface measures. We believe that groups and virtual groups would be able to transition to the utilization of an available alternative collection type for the 2021 performance period. The type of data collected by groups and virtual groups for the 2020 performance period would be able to be captured by one of the available collection types such as an eCQM or MIPS CQM for the 2021 performance period. The 10 CMS Web Interface measures that are required for reporting under the 2020 performance period have an eCQM and MIPS CQM equivalent measure. For the 2021 performance period, there are 10 eCQMs and 9 CQMs that are equivalent to the 10 CMS Web Interface measures. We believe that groups and virtual groups would be able to identify at least 6 equivalent eCQMs or MIPS CQMs (or a combination) that capture the same type of data collected for the measures used in the CMS Web Interface. Also, such transition for groups and virtual groups could potentially be more beneficial. For example, if a measure from a different collection type (for example, MIPS CQMs) meets data completeness but may not meet case minimum, the measure would receive a score of 3; whereas, under the CMS Web Interface, any measure that did not meet reporting requirements would receive a score of 0.

The sunset of the CMS Web Interface measures would reduce burden on groups and virtual groups while aligning program requirements and scoring policies for MIPS and the Medicare Shared Savings Program, and removing CMS Web Interface measures that do not provide a meaningful means of assessing performance across groups, virtual groups, and ACOs. With the CMS Web Interface measures being topped out as noted above, we strive to remove measures that are topped out and establish a set of robust and meaningful measure sets that are available under the other collection types. We believe that the benefits groups and virtual groups would reap from transitioning to the utilization of other collection types starting with the 2021 performance year outweigh the initial disruption that would be experienced when the CMS Web Interface measures would be sunset. Based on our assessment, we are proposing at § 414.1325(c)(1) *et seq.* to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 performance period. Specifically, at § 414.1305, we are proposing to modify the definition of the terms collection type and submission type to remove the CMS Web Interface measures as an available option starting with the 2023 payment year. We propose to modify the definition of collection type to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures and for the 2019 through 2022 MIPS payment years, CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures. We propose to revise the definition of ''submission type'' to mean the mechanism by which the submitter type submits data to CMS, including, but not limited to: Direct; log in and upload; log in and attest; Medicare Part B claims; and for the 2019 through 2022 MIPS payment years, the CMS Web Interface. We solicit comment on this proposal.

(d) Selection of MIPS Quality Measures

Previously finalized MIPS quality measures can be found in the CY 2020 PFS final rule (84 FR 63205 through 63513); 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). Proposed changes to the MIPS quality measure set as described in Appendix 1 of this proposed rule, include the following: Addition of new measures; updates to specialty sets; removal of existing measures, and substantive changes to existing measures. For the 2021 performance period, we are proposing a measure set of 206 MIPS quality measures.

The new MIPS quality measures proposed for inclusion in MIPS for the 2021 performance period and future years are found in Table Group A of Appendix 1 of this proposed rule. For the 2021 performance year, we are proposing 2 new administrative claims outcome measures. In addition to the establishment of new individual MIPS quality measures, we also develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice. Our proposals for modifications to existing specialty sets and new specialty sets are outlined 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 specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 6, 2020,[79] we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 5 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 as a result, the recommendations that we agree with are being proposed in this proposed rule.

[79] Listserv messaging was distributed through the Quality Payment Program listserv on January 6, 2020, titled: ''CMS is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure and/or Revisions to the Existing Specialty Measure Sets for the 2021 Program Year of Merit-based Incentive Payment System (MIPS).''

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets and new specialty sets as outlined in Tables Group A and Group B of Appendix 1 of this proposed rule, we refer readers to Table Group C of Appendix 1 of this proposed rule for a list of quality measures and rationales for removal. For the 2021 performance period, we are proposing to remove 14 MIPS quality measures: 2 MIPS quality measures that are extremely topped out; 1 MIPS quality measure that is duplicative to another current quality measure; 1 MIPS quality measure that is duplicative to one of the new proposed MIPS quality measures; 2 MIPS quality measures that do not align with the Meaningful Measures Initiative; 5 MIPS quality measures that are no longer stewarded or maintained; 1 MIPS quality measure that does not meet current clinical guidelines; and 2 MIPS quality measures that are under the topped out lifecycle. 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.

Lastly, MIPS quality measures with proposed substantive changes can be found in Table Group D of Appendix 1 of this proposed rule. We are proposing substantive changes to 112 MIPS quality 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. Section 1848(q)(2)(D)(i)(II)(cc) of the Act requires all substantive measure changes to be proposed and identified through notice-and-comment rulemaking. In the CY 2017 Quality Payment Program final rule (81 FR 77137), we determined that substantive changes to measures (that is, measure specifications, measure title, and domain modifications) would be identified during the rulemaking process while maintenance changes that do not substantively change the intent of the measure (that is, updated diagnosis and procedure codes, definitions, and changes to patient population exclusions) would not be included in the rulemaking process.

We note that changes to measure Q134, Prevention Care and Screening: Screening for Depression and Follow-Up Plan (eCQM Specifications and CMS Web Interface Measure Specifications collection types), specifically the removal of SNOMED codes, were published in the eCQI Resource Center and the Value Set Authority Center (in May of 2018 for the eCQM Specifications) and on the CMS website (in December of 2018 for the CMS Web Interface Measure Specifications). While the current cycle of measure updates to MIPS quality measures is separate from the eCQM annual update process, we inadvertently recognized such update allowed MIPS eligible clinicians to meet performance of a follow-up plan by rescreening the patient who has a positive depression screen with an additional standardized depression screening tool. The change to the measure was continued for CY 2020. As a result, such changes were not identified during the CY 2019 PFS or CY 2020 PFS rulemaking cycles. The changes to measure Q134 (eCQM Specifications and CMS Web Interface Measure Specifications collection types) impact performance periods starting with 2019. For the 2019 and 2020 performance periods, measure Q134 applicable to the eCQM Specifications and CMS Web Interface Measures Specifications will be suppressed from scoring. To adequately capture the substantive changes to measure Q134 (eCQM Specifications and CMS Web Interface Measure Specifications collection types) through rulemaking for the 2021 performance period, we are identifying the substantive changes for this MIPS quality measure as outlined in Table Group D of Appendix 1 of this proposed rule.

(e) MIPS Performance Period

(i) Establishing Separate Performance Periods for Administrative Claims Measures Under the Quality Performance Category Beginning With the 2023 MIPS Payment Year

In the CY 2019 PFS final rule (83 FR 59745), we established at § 414.1320(d)(1) that beginning with the 2022 MIPS payment year, the performance period for the quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year. We noted that we established a one year performance period for measures in the quality performance category because a 1-year performance period would provide statistically larger sample sizes and more accurate and actionable information. As discussed in Table Group A of Appendix 1 of this proposed rule, we propose to add a new administrative claims measure of risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty. This measure was developed and tested using a performance period that was longer than a full calendar year in order to provide larger sample sizes, and more accurate and actionable information. Beginning with the 2021 performance year, this measure would have a 3-year performance period (consecutive 36-month timeframe) that would start on October 1 of the calendar year 3 years prior to the applicable performance year and conclude on September 30 of the calendar year of the applicable performance year, and proceeding with a 3-month numerator assessment period (capturing complication outcomes) followed by a 2-month claims run-out period. For example, the 3-year (36 consecutive months) performance period for this measure would span from October 1, 2018 to September 30, 2021 with a 90-day numerator assessment period followed by a 60-day claims run-out period.

To account for this measure and other future administrative claims measures that may have a performance period differing from 1 full calendar year, we propose to modify the definition of the performance period for the quality and cost performance categories at § 414.1320(d)(1) to be as follows: Beginning with the 2023 MIPS payment year, the performance period for the quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1). We note that while we have established a single performance period for measures and activities within each performance category in the MIPS program, we have established measure-specific performance periods in other programs, such as in the hospital value-based purchasing program, which includes measures of various performance periods (84 FR 42394 through 42395). We continue to believe that establishing a single performance period for measures requiring the submission of data optimizes operational efficiency for MIPS eligible clinicians, groups, and virtual groups that submit data on such measures. However, administrative

claims measures (proposal to add 2 new administrative claims measures found in Table Group A of Appendix 1 of this proposed rule: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate, and Risk-standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)); and proposal to remove the All-Cause Readmission measure found in Table Group C of Appendix 1 (was the only administrative claims-based measure) do not require the submission of data and are calculated by CMS based on administrative data. Thus, we believe that a different performance period should be considered on a measure-by-measure level for administrative claims measures. We seek public comment on our proposal to modify the definition of performance period for the quality and cost performance categories that would establish a separate performance period for administrative claims measures under the quality performance category.

(f) Quality Data Submission Criteria

(i) Performance Criteria for Quality Measures for Groups Electing To Report Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53629 through 53632) for previous finalized policies for the CAHPS for MIPS survey, specifically regarding the Summary Survey Measures (SSMs).

To address the PHE for the COVID–19 pandemic and the increased use of telehealth care, we propose the following changes to our policies related to the CAHPS for MIPS Survey:

- We propose to integrate one telehealth item into the CAHPS for MIPS Survey. Specifically, we propose to add a survey-based measure on telehealth that assesses patient-reported usage of telehealth services (for example, phone or video visit) to the performance year 2021 CAHPS for MIPS Survey.
- We also propose revisions to the CAHPS for MIPS Survey cover page to include a reference to care received in telehealth settings. This may help to ensure that patients who respond to the survey are reflecting on experiences of the care they received via telehealth in their responses. We are considering such changes for the performance year 2021 CAHPS for MIPS Survey administration.

To clarify the instructions in the CAHPS for MIPS Survey, we propose revisions to the instructions in the ''Your Care From Specialists in the Last 6 Months'' section of the CAHPS for MIPS Survey to clarify the inclusion of the provider named in Question 1 of the survey. We are considering such changes for the performance year 2021 CAHPS for MIPS Survey administration.

We refer readers to the Collection of Information Requirements section VI. of this rule for additional information.

(ii) CAHPS for MIPS Patient Assignment

Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. When furnished under the telehealth rules, these specified Medicare telehealth services are reported using the same codes used for the ''face-to-face'' services, but are furnished using audio/video, real-time, interactive communications technology instead of in person. As such, the majority of the codes for primary care services included in the additional telehealth services added in the March 31st COVID–19 IFC for purposes of the PHE for COVID–19 pandemic are already included in the definition of primary care services for purposes of the MIPS assignment methodology for the CAHPS for MIPS survey (82 FR 77168 through 77169; and 82 FR 53646 through 53647). At § 414.1305, we are proposing to codify the definition of primary care services for purposes of MIPS assignment methodology for the CAHPS for MIPS survey as follows:

- CPT codes:

++ 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by POS modifier 12); 99487, 99489, and 99490 (codes for chronic care management); and 99495 and 99496 (codes for transitional care management services); and

++ Beginning with the 2023 MIPS payment year, 99421, 99422, and 99423 (codes for online digital evaluation and management services (e-visit)); 99441, 99442, and 99443 (codes for telephone evaluation and management services); and 96160 and 96161 (codes for Administration of Health Risk Assessment).

- HCPCS codes:

++ G0402 (code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits); and

++ Beginning with the 2023 MIPS payment year, G2010 (code for remote evaluation of patient video/images); and G2012 (code for virtual check-in).

In the March 31st COVID–19 IFC, we also established flexibilities and separate payment for certain services that are furnished virtually using communication technologies, but that are not considered Medicare telehealth services such as virtual check-ins and e-visits. We also established separate payment for telephone E/M services codes during the PHE. The communications technology-based services (CTBS) and the telephone E/M services are not currently included in the MIPS assignment methodology for the CAHPS for MIPS survey.

We believe it is critical to include codes for CTBS and telephone E/M services, as identified and discussed later in this section, in the definition of primary care services to ensure these services are included in our determination of where beneficiaries receive the plurality of their primary care for purposes of beneficiary assignment. Such inclusion ensures that the assignment methodology appropriately reflects the expanded use of technology that is helping people who need routine care during the PHE for the COVID–19 pandemic and allowing vulnerable beneficiaries and beneficiaries with mild symptoms to remain in their homes, while maintaining access to the care they need. By including services provided virtually, either through telehealth or other uses of communications technology, we would ensure that this care is appropriately reflected in our consideration of the plurality of care used to assign beneficiaries to groups and virtual groups.

We have added new services to the separately billable CTBS under the Physician Fee Schedule over the past several years and a result of the PHE, we expect that the utilization of communications technology-based services will substantially increase during the PHE for the COVID–19 pandemic and thereafter. We believe that clinicians are increasingly using such services as a key component of their ongoing primary care. In an effort to address the PHE and use of telehealth, and to maintain alignment with the Shared Savings Program, we propose to integrate the same telehealth

CPT and HCPCS codes that are used for purposes of assigning beneficiaries to Shared Savings Program ACOs into the set of primary care service codes that are used for patient assignment to MIPS groups. We are proposing to revise the definition of primary care services used in the MIPS assignment methodology for the 2021 CAHPS for MIPS survey, and for any subsequent performance year, to include the following additions: (1) CPT codes: 99421, 99422, and 99423 (codes for online digital E/M services (e-visits)); 99441, 99442, and 99443 (codes for telephone E/M services); and 96160 and 96161 (codes for administration of health risk assessment); and (2) HCPCS codes: G2010 (code for remote evaluation of patient video/images) and G2012 (code for virtual check-in). It should be noted that the proposed inclusion of such codes in the MIPS assignment methodology for the CAHPS for MIPS survey aligns with the definition of primary care services used for purposes of beneficiary assignment under the Medicare Shared Savings Program, which was amended in the May 8th COVID IFC to ensure these codes would be included in determining beneficiary assignment for performance year 2020 and any subsequent performance year that starts during the PHE for the COVID–19 pandemic (85 FR 27583). We refer readers to the May 8th COVID–19 IFC (85 FR 27582 through 27586) for a detailed description of the codes that were added to the definition of primary care services under the Medicare Shared Savings Program. We also refer readers to the 2018 PFS final rule (82 FR 53007 through 53011) for a detailed description of the primary care services codes for Administration of Health Risk Assessment.

The services represented by the codes listed above are being used in place of similar E/M services, the codes for which are already included in the list of codes used for assignment. As a result, we believe these services are an important component of primary care and it is appropriate to include these codes in the definition of primary care services used for assignment for the CAHPS for MIPS survey. It should be noted that the remote evaluation of patient video/images and virtual check-in codes, and the online digital E/M service (e-visit) codes are not separately billable by a clinician if they are related to a visit within the past 7 days or lead to a visit within the following 24 hours or next available appointment. The only codes that are newly billable during the PHE for the COVID–19 pandemic pertain to the telephone E/M services.

We believe that clinicians are increasingly using communications technology-based services as a key component of their ongoing primary care. We expect that the utilization of such services will substantially increase not only during the PHE for the COVID–19 pandemic, but also thereafter. Accordingly, we propose to include virtual primary care visits and telehealth visits to determine patient assignment to groups for purposes of the CAHPS for MIPS Survey for 2021 and subsequent performance years.

(2) Cost Performance Category

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019 and CY 2020 PFS final rules (81 FR 77162 through 77177, 82 FR 53641 through 53648, 83 FR 59765 through 59776, and 84 FR 62959 through 62968, respectively) for a description of the statutory basis and existing policies pertaining to the cost performance category.

In this proposed rule, we are proposing to weight the cost performance category at 20 percent for MIPS payment year 2023 and 30 percent for MIPS payment year 2024 and all subsequent MIPS payment years.

(a) Weight in the Final Score

Under section 1848(q)(5)(E)(i)(II)(aa) of the Act, in general, 30 percent of the MIPS final score shall be based on the cost performance category. However, section 1848(q)(5)(E)(i)(II)(bb) of the Act gives the Secretary discretion with respect to the weight of the cost performance category for the first 5 years of MIPS. Specifically, under that section, for the first year for which the MIPS applies to payments (the 2019 MIPS payment year), not more than 10 percent of the MIPS final score shall be based on the cost performance category; and for each of the second, third, fourth, and fifth years for which the MIPS applies to payments (the 2020, 2021, 2022, and 2023 MIPS payment years, respectively), not less than 10 percent and not more than 30 percent of the MIPS final score shall be based on the cost performance category. Additionally, section 1848(q)(5)(E)(i)(II)(bb) of the Act states that it shall not be construed as preventing the Secretary from adopting a 30 percent weight for the second, third, fourth, or fifth year 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. The weights adopted in prior rulemaking for the cost performance category are codified under § 414.1350(d).

In the CY 2020 PFS proposed rule (84 FR 40752), we proposed to incrementally increase 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 proposed to incrementally increase the weight of the cost performance category by 5 standard increments each year through the 2024 MIPS payment year, reflecting a weight of 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 (84 FR 40752 through 40753).

As cost measures are still being developed, we recognized that clinicians may not have the same level of familiarity or understanding of cost measures as they do with the comparable quality measures. To implement a gradual and predictable approach of increasing the weight of the cost performance category each year would provide clinicians with adequate time to prepare for a 30 percent weight and enable clinicians to gain experience with the cost measures while they represent a smaller portion of the MIPS final score. We recognized that there may be greater understanding of the measures in the cost performance category as clinicians obtain more experience with the measures (84 FR 62959).

After considering the comments we received, we did not finalize our proposals, and instead established at § 414.1350(d)(3) that the weight of the cost performance category will remain at 15 percent of the MIPS final score for MIPS payment years 2021 and 2022 (84 FR 62961). We stated that we expected to propose a weight for the cost performance category for the 2023 MIPS payment year in the CY 2021 PFS proposed rule.

In developing this proposed rule, we considered a range of numerical options for the weight of the cost performance category for the 2023 MIPS payment year, with the intention of reaching a weight of 30 percent no later than the 2024 MIPS payment year as required by the statute. The first option we considered was to maintain the cost performance category weight at the status quo for an additional year, in which it would remain at 15 percent for the 2023 MIPS payment year and then increase to 30 percent beginning with the 2024 MIPS payment year, which would be a 15 percent increase in the weight from 2023 to 2024. We considered such option as a result of the

COVID–19 public health emergency in order to not increase the weight of the cost performance category during an unprecedented time. However, by maintaining the weight at 15 percent for the 2023 MIPS payment year, the weight would increase two-fold to 30 percent beginning with the 2024 MIPS payment year, which we believe would pose a significant burden to stakeholders and would eliminate any transition of an incremental increase in the cost performance category weight. We believe that the first option would be more burdensome than beneficial to clinicians as they continue to gain more experience with the cost measures and mitigate through the COVID–19 public health emergency.

The second option we considered was to increase the weight from 15 percent for MIPS payment years 2021 and 2022 to 20 percent for the 2023 MIPS payment year in order to provide a minimal transition that would enable clinicians to continue to become familiar with the cost measures and be prepared for the final increase in the weight of the cost performance category from 20 percent to 30 percent beginning with the 2024 MIPS payment year. We believe that such approach would allow us to reach the statutorily required weight of 30 percent by the 2024 MIPS payment year while providing clinicians with an eased incremental transition starting with the 2023 MIPS payment year and accounting for the consequential impact of the increased clinical costs associated with the COVID–19 public health emergency. For the 2023 MIPS payment year, we sought to identify a smaller increase in weight while enabling clinicians to gain more experience and familiarity with the cost measures amidst the mitigation of the COVID–19 public health emergency.

After considering these options, we are proposing to establish at § 414.1350(d)(4) the weight of the cost performance category to be 20 percent of the MIPS final score for the 2023 MIPS payment year and at § 414.1350(d)(5) the weight of the cost performance category to be 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year.

We solicit public comment on our proposal, the other options we considered, and any additional options for the weight of the cost performance category that commenters believe we should consider, such as a 22.5 percent weight for the 2023 MIPS payment year and a 30 percent weight beginning with the 2024 MIPS payment year (a 7.5 percent increase for each year). In general, we prefer to consider whole numbers for performance category weights, but are interested in obtaining feedback from commenters on the weighing of the cost performance category to have an increase of 7.5 percent for 2 consecutive years for the 2023 and 2024 MIPS payment years.

(b) Addition of Telehealth Services to Previously Established Measures for the Cost Performance Category Beginning With the 2021 Performance Period

For the 2021 performance period and future performance periods, we propose to add costs associated with telehealth services to the previously established cost measures. For each cost measure, the telehealth services we propose to add are directly relevant to the intent of the measure. We refer readers to Table 47 in the CY 2020 PFS final rule (84 FR 62979) for a summary list of the cost measures that have been established for the 2021 performance period and future performance periods, as well as the related discussions in the CY 2019 PFS final rule (83 FR 59767 through 83 FR 59774) and the CY 2020 PFS final rule (84 FR 62962 through 62979). Many services included on the Medicare telehealth service list are billed as telehealth services through the use of a modifier appended to the same code that is used when the service is furnished in person. These codes are already included in the cost measures; however, the additional codes we propose to add are not currently included for a few reasons. First, some codes we propose to add to the cost measures were newly included on the Medicare telehealth services list through the March 31st COVID–19 IFC (85 FR 19230) and subsequent sub-regulatory processes as established in the May 8th COVID–19 IFC (85 FR 27550). Second, some codes we propose to add were not previously considered for inclusion because they were not billed widely enough to be found in empirical claims-based data. This is because our approach for determining clinically related services to include in cost measures, which we established in the CY 2019 PFS final rule (83 PFS 59767 through 59771), relies on empirical data to examine existing practice patterns, in addition to clinical expertise. Having observed an increase in the use of these codes, including those that existed before the public health emergency, we are proposing to add them to adapt the measures to this change in practice patterns. The codes we propose to add represent service categories already captured in the measures (*e.g.,* E/M, follow up consultation following hospital discharge); thus, we do not consider their addition to alter the intent of the measures or capture a new category of costs. Updated measure specifications with the added telehealth codes are available on the CMS website at *http://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback.*

We solicit public comment on this proposal.

(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), the CY 2019 PFS final rule (83 FR 59776 through 59777), and the CY 2020 PFS final rule (84 FR 62980 through 62990). We also refer readers to § 414.1305 for the definition of improvement activities and attestation, § 414.1320(b)(2) for the performance period, § 414.1325 for the data submission requirements, § 414.1355 for the inventory and final score, § 414.1360 for the data submission criteria, § 414.1365 for the subcategories, § 414.1380 for the scoring, § 414.1380(b)(3)(i) through (iii) for weighting, § 414.1380(b)(3)(iv) and § 414.1380(b)(3)(x) for patient-centered medical home, § 414.1380(b)(3)(vii) for exceptions, and § 414.1380(b)(3)(ix) for APM.

In this proposed rule, beginning with the CY 2021 performance period and future years, we are proposing: (1) Changes to the Annual Call for Activities: An exception to the nomination period timeframe during a PHE; and a new criterion for nominating new improvement activities; (2) a process for HHS-nominated improvement activities; and (3) to modify two existing improvement activities. These proposals are discussed in more detail in this proposed rule.

(b) Improvement Activities Inventory

(i) Annual Call for Activities

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial improvement activities Inventory and took several steps to ensure it was inclusive of activities in line with statutory and program requirements. For Year 2, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive improvement activities Inventory for the Quality Payment Program Year 2 and future

years through subregulatory guidance (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf*). In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for Year 3 and future years, we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the improvement activities Inventory, including information required to submit a nomination form similar to the one we utilized for Year 2 (82 FR 53656 through 53659). It is important to note that in order to submit a request for a new activity or a modification to an existing improvement activity the stakeholder must submit a nomination form available at *www.qpp.cms.gov* during the Annual Call for Activities.

(A) Timeframe for the Annual Call for Activities

(aa) Currently Adopted Timeframe

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial improvement activities Inventory and took several steps to ensure it was inclusive of activities in line with statutory and program requirements. For Year 2, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive improvement activities Inventory for the Quality Payment Program Year 2 and future years through subregulatory guidance (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf*). In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for Year 3 and future years, we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the improvement activities Inventory, including information required to submit a nomination form similar to the one we utilized for Year 2 (82 FR 53656 through 53659). It is important to note that in order to submit a request for a new activity or a modification to an existing improvement activity the stakeholder must submit a nomination form available at *www.qpp.cms.gov* during the Annual Call for Activities.

In the CY 2019 PFS final rule (83 FR 59781 through 59782), we finalized to change the performance year for which nominations of prospective new and modified improvement activities would apply, such that beginning with the CY 2019 performance period and for future years, improvement activities nominations received in a particular year will be vetted and considered for the next year's rulemaking cycle for possible implementation in a future year. In addition, we finalized to change the submission timeframe for the Annual Call for Activities from February 1st through March 1st to February 1st through June 30th, providing approximately 4 additional months for stakeholders to submit nominations beginning with the CY 2019 performance period.

(bb) Proposed Exception During Public Health Emergencies

The COVID–19 pandemic was deemed a public health emergency (PHE) by the Secretary of the Department of Health and Human Services. Information regarding the PHE for the COVID–19 pandemic is available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.* This unprecedented PHE has brought to our attention the necessity of having the flexibility to consider nominations of new improvement activities to the Inventory outside the established Annual Call for Activities nomination period. We believe having the flexibility to consider nominations during a PHE is important because of the nature of a PHE; we want the ability to consider relevant improvement activities while the emergency is ongoing. We refer readers to the CY 2019 PFS final rule (83 FR 59779) for a complete definition of PHE and its application to inclusion criteria for new improvement activities.

Therefore, beginning with the CY 2021 performance period, we are proposing to make an exception to the established timeframe, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. Instead of only accepting nominations and modifications submitted February 1st through June 30th each year, we would accept nominations for the duration of the PHE as long as the improvement activity is still relevant. No other aspects of the Annual Call for Activities process would be affected (for example, criteria for nominating improvement activities, considerations for selection of improvement activities, or weighting policies would all still apply). We continue to believe it is important for stakeholders to be able to comment on improvement activities. Therefore, any improvement activity considered for inclusion in the Inventory would still be finalized through a future rulemaking. We invite public comments on our proposal.

(B) Criteria for Nominating New Improvement Activities

In the CY 2019 PFS final rule (83 FR 59778 through 59779), we adopted one new criterion and removed a criterion from the improvement activities nomination criteria. We also clarified our considerations in selecting improvement activities.

(aa) Currently Adopted Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77190 through 77195), we discussed guidelines for the selection of improvement activities. In the CY 2018 Quality Payment Program final rule, we formalized the Annual Call for Activities process for Year 3 and future years and added additional criteria; stakeholders should apply one or more of the below criteria when submitting nominations for improvement activities (82 FR 53660). In addition, in the CY 2019 PFS final rule (83 FR 59779) we finalized to add a ''public health emergency as determined by the Secretary'' to the criterion below.

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcomes;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family's point of view;
- Support the patient's family or personal caregiver;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes;
- Include a public health emergency as determined by the Secretary; or
- CMS is able to validate the activity.

(bb) Proposed New Criteria

In addition to the aforementioned considerations, when considering

improvement activities for possible inclusion in MIPS, we propose that beginning with the 2021 Call for Activities, MIPS improvement activities submitted should be linked to existing and related quality and cost measures, as applicable and feasible. Stakeholders that select this particular criteria would be required to provide a rationale describing how they believe their improvement activity correlates to other performance category measures as a part of the Call for Activities. We believe that when possible, it is important to establish a strong linkage between quality, cost, and improvement activities.

Therefore, we are proposing to adopt an additional criterion entitled ''Include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible'' to the criteria for nominating new improvement activities beginning with the CY 2021 performance period and future years. If our proposal to add one criterion is adopted as proposed, stakeholders should apply one or more of the below criteria when submitting nominations for improvement activities beginning with the CY 2021 performance period and future years:

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcomes;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family's point of view;
- Support the patient's family or personal caregiver;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes;
- Include a public health emergency as determined by the Secretary;
- Include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible; or
- CMS is able to validate the activity.

We invite public comment on our proposal.

(ii) HHS-Nominated Improvement Activities

(A) Background

As stated above in section IV.A.3.c.(3)(b)(i)(A)(bb) of this proposed rule titled ''Proposed Exception During Public Health Emergencies,'' this unprecedented PHE has brought to our attention the necessity of having the flexibility to consider nominations of new improvement activities to the Inventory outside the Annual Call for Activities nomination period and process.'' We also believe that we should have the flexibility to nominate activities from within HHS. The federal government is uniquely positioned to quickly address administration goals versus the public sector in pertinent areas that may have national impact to improve the health care system. For example, CMS has established the CMS Strategic Initiatives which provides 16 distinct focus areas including Patients over Paperwork. The CMS Strategic Initiatives focus areas aim to empower patients and unleash innovation while transforming the health care system. We believe that goals such as the CMS Strategic Initiatives deliver better value and results for patients through competition and innovation. To accomplish goals included in agency-wide plans, such as the CMS Strategic Initiatives, there are instances when it is necessary to accept HHS-nominated improvement activities outside of the Call to advance these type of goals in an expedited manner. We refer readers to *https://www.cms.gov/About-CMS/Story-Page/our-16-strategic-initiatives* for more information about CMS strategic initiatives and to *https://www.cms.gov/About-CMS/story-page/patients-over-paperwork* for more information about Patients over Paperwork.

(B) Proposed HHS-Nominated Improvement Activities Process

Beginning with the CY 2021 performance period and future years, we propose that we would consider HHS-nominated improvement activities all year long in order to address HHS initiatives in an expedited manner. These HHS-nominated improvement activities would be subject to the same criteria for nominating new improvement activities as discussed above in section IV.A.3.c.(3)(b)(i)(B) of this proposed rule titled ''Criteria for Nominating New Improvement Activities.'' In addition, the HHS-nominated activity would need to apply the criteria of: ''aligned with at least one of the HHS goals, when feasible and appropriate'' to the nominated activity. Further, the HHS-nominated improvement activity would be assessed for the most appropriate subcategory; we refer readers to § 414.1355(c).

We continue to believe it is important for stakeholders to be able to comment on these HHS-nominated improvement activities. Thus, we would propose any HHS-nominated improvement activities through rulemaking. In such proposal, we would specifically request comment on whether stakeholders agree the activities improve clinical practice or care delivery. We invite public comments on our proposal.

(iii) Proposed Changes to the Improvement Activities Inventory

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities 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), Tables X and G in the Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303), and Tables A, B, and C in the Appendix 2 of the CY 2020 PFS final rule (84 FR 63514 through 63538) 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 are proposing to modify two existing improvement activities for the CY 2021 performance period and future years. We refer readers to Appendix 2 of this proposed rule for further details. We are not proposing to remove any previously adopted improvement activities. We invite public comments on our proposals.

(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. 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.

(b) Promoting Interoperability Performance Category Performance Period

As finalized in the CY 2020 PFS final rule at § 414.1320(f)(1) (84 FR 62992), for purposes of the 2023 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 2023 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period within CY 2021, up to and including the full CY 2021 (January 1, 2021 through December 31, 2021).

For the 2024 MIPS payment year and each subsequent MIPS payment year, we are proposing to add § 414.1320(g)(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. This proposal aligns with the proposed EHR reporting period in CY 2022 for the Medicare Promoting Interoperability Program for eligible hospitals and CAHs (85 FR 32853). We believe this would be an appropriate performance period because it would offer stability and consistency for eligible clinicians reporting for the Promoting Interoperability performance category.

We are requesting comments on this proposal.

(c) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

(i) Proposed Changes to the Query of Prescription Drug Monitoring Program (PDMP) Measure Under the Electronic Prescribing Objective

In the CY 2020 PFS final rule (84 FR 62992 through 62994), we finalized that the Query of PDMP measure under the Electronic Prescribing objective is optional and eligible for 5 bonus points in CY 2020. However, we have continued to receive substantial feedback from health IT developers and clinicians that the flexibility currently included in the measure presents unintended challenges such as significant burden associated with IT system design and additional development needed to accommodate the measure and any future changes to it. Since publication of the CY 2020 PFS final rule, stakeholders have continued to express concern that it is still too premature to require the Query of PDMP measure and score it based on performance in CY 2021.

We agree with stakeholders that PDMPs are still maturing in their development and use. PDMPs vary among the states and are not linked at this time to one another or to a larger national system.[80]

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 recently engaged in an assessment to better understand the current state of policy and technical factors impacting PDMP integration across states. This assessment explored 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. The assessment revealed ambiguous or non-existent policies regarding PDMP placement in health IT systems, interpretation of PDMP data, and PDMP access roles. In addition, variability in standards and hubs used to facilitate interstate PMDP data exchange, as well as to store and report PDMP data, contribute to the complexity of PDMPs.

The SUPPORT for Patients and Communities Act, enacted in 2018, is an important investment in combating the opioid epidemic. Several of the provisions of the SUPPORT for Patients and Communities Act address opioid use disorder prevention, recovery, and treatment including increased access to evidence-based treatment and follow-up care, through legislative changes specific to the Medicare and Medicaid programs. Specifically, with respect to PDMPs, the SUPPORT for Patients and Communities Act included new requirements and federal funding for PDMP enhancement, integration, and interoperability, and established 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.'' Subsection (f) of section 1944 of the Act increased Medicaid FFP rates during FY 2019 and FY 2020 for certain state expenditures to design, develop, or implement a qualified PDMP (and to make subsequent connections to such program). As a condition of this enhanced FFP, states must meet the conditions described in paragraph (f)(2) regarding agreements with contiguous states. There are currently a number of states that have used or are seeking to use, this enhanced FFP.

Under section 1944(b)(1) of the Act, to be a qualified PDMP, a PDMP must facilitate access by a covered provider to the following information (at a minimum) about 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. CMS issued additional guidance to states about the enhanced FFP authorized by the SUPPORT for Patients and Communities Act, which is available at *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/faq051519.pdf.*

Additionally, we note that section 7162 of the SUPPORT for Patients and Communities Act 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 support of efforts to expand the use of PDMPs, there are currently a number of federally supported activities underway aimed at developing a more robust and standardized approach to EHR–PDMP integration. Partners

[80] *https://namsdl.org/topics/pdmp/* and *https://www.pdmpassist.org/content/pdmp-maps-and-tables.*

including CMS, CDC, ONC, and private sector stakeholders are focused on developing and refining standard-based approaches to enable effective integration into clinical workflows, exploring emerging technical solutions to enhance access and use of PDMP data, and providing technical resources to a variety of stakeholders to advance and scale the interoperability of health IT systems and PDMPs. For instance, stakeholders are working to map the NCPDP SCRIPT standard version 2017071 and the 2015 ASAP Prescription Monitoring Program Web Service standard version 2.1A to the HL7® FHIR® standard version R4.[81] These mapping efforts are currently targeting completion by the summer of 2020 after which the standard would be balloted. Moreover, a number of enhancements to PDMPs are occurring across the country, including enhancements to RxCheck which is a federally supported interstate exchange hub for PDMP data.[82] In addition, the ONC Interoperability Standards Advisory (ISA) [83] includes monitoring of current and emerging standards related to PDMP and opioid use disorder (OUD) data capture and exchange that would allow a health care provider to request a patient's medication history from a state PMDP.[84] We believe these standards and technical approaches are likely to rapidly reach maturity and support adoption across health care system stakeholders.

In addition to monitoring activities which can provide a stronger technical foundation for a measure focused on PDMP use, we also requested comments in the 2020 PFS proposed rule on alternative measures designed to advance clinical goals related to the opioid crisis (84 FR 40767 through 40769). Specifically, we sought 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 opioid quality measures endorsed by the National Quality Forum (NQF) and CDC Quality Improvement (QI) opioid measures based on CDC guidelines around prescribing practices. The latter of these includes the use of electronically specific CDS to support OUD prevention and treatment best practices and the integration of a PDMP query as a part of specific clinical workflows. We stated that these measures relate to a range of activities that hold promise in combatting the opioid epidemic as part of OUD prevention and treatment best practices, that they can be supported using CEHRT, and that they may include the use of PDMP queries as a tool within the broader clinical workflows. We continue to evaluate the comments received in response to this request, and will explore how measures such as those discussed may help participants to better understand the relationship between the measure description and the use of health IT to support the actions of the measures related to opioid use.

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 specify a single approach to EHR–PDMP integration at this time. 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 either fully develop numerator and denominator calculations for all the potential use cases and are required to change the specification at a later date. Stakeholders have noted 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 current efforts to improve the technical foundation for EHR–PDMP integration, the continued implementation of the SUPPORT for Patients and Communities Act (in particular, its provisions specific to Medicaid providers and qualified PDMPs), our ongoing review of alternative measure approaches, and stakeholder concerns as previously discussed about the current readiness across states for implementation of the existing measure, we believe that additional time is needed prior to requiring a Query of PDMP measure for performance-based scoring. While we appreciate the concerns that stakeholders have shared, we believe that this measure can play an important role in helping to address the opioid crisis. Maintaining it as an optional measure eligible for bonus points signals to the clinician and developer community that this is an important measure which addresses a current gap that can help to spur development and innovation to reduce the barriers and challenges reported to CMS.

Therefore, we are proposing for the performance period in CY 2021 to maintain the Electronic Prescribing objective's Query of PDMP measure as optional. Continuing to include the measure as optional for the performance period in CY 2021 would allow time for further progress around EHR–PDMP integration efforts minimizing the burden on MIPS eligible clinicians while still providing an opportunity for capable implementers to report on and earn bonus points for fulfilling the optional measure.

We are also proposing for the performance period in CY 2021 to increase the amount of the bonus points for the Query of PDMP measure from 5 points to 10 points to reflect the importance of this measure and to further incentivize clinicians to perform queries of PDMPs. We believe that this increase would support the President's National Drug Control Strategy [85] that is trying to increase data sharing and integration. As stated in the strategy, a PDMP is a proven means to increase accountability in opioid prescribing practices by providing information that allows for the coordination of multiple medications, as well as to prevent adverse drug interactions. PDMPs increase patient safety by assisting prescribers in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Expanding the use of PDMPs is a fundamental element of this strategy to stop opioid abuse, and ensure the safe, legal, and responsible prescribing of opioids for those who need them. We believe that improving prescribing practices by use of PDMPs will help reduce hospitalizations, Emergency Department visits, and family crises associated with the opioid epidemic. The proposed increase in bonus points for the Query of PDMP measure reflects our desire to increase the use of PDMPs.

[81] *http://hl7.org/fhir/us/meds/pdmp.html.*

[82] See *https://www.pdmpassist.org/RxCheck.*

[83] *https://www.healthit.gov/isa/.*

[84] See *https://www.healthit.gov/isa/allows-a-provider-request-a-patients-medication-history-a-state-prescription-drug-monitoring.*

[85] *https://www.whitehouse.gov/wp-content/uploads/2020/02/2020-NDCS.pdf.*

We invite comments of these proposals.

2. Health Information Exchange Objective

a. Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure

In the CY 2019 PFS final rule (83 FR 59807 through 59812), we established a new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure by combining the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure. In establishing the new measure, we did not change the specifications or actions associated with the two combined measures, which address receiving an electronic summary of care record and conducting reconciliation of the summary of care record. However, the name of the measure includes the word ''incorporating'' which is not always required to increment the numerator of the measure. Instead, clinical information reconciliation must be completed using CEHRT for the following three clinical information sets: (1) Medication; (2) Medication Allergy; and (3) Current Problem List. Thus, to better reflect specific actions required by the measure's numerator and denominator, we are proposing to replace the word ''incorporating'' with the word ''reconciling'' in the name of the measure. The new name would read: Support Electronic Referral Loops by Receiving and Reconciling Health Information measure.

We invite comment on this proposal.

b. Engagement in Bi-Directional Exchange Through Health Information Exchange (HIE)

In the CY 2020 PFS proposed rule (84 FR 40781), we discussed the concept of MIPS eligible clinicians earning credit in the Promoting Interoperability performance category by attesting to health IT or interoperability activities in lieu of reporting on specific measures. In this proposed rule, we are seeking to build on the feedback received in prior rulemaking by proposing an alternative measure for bidirectional exchange through a HIE under the Health Information Exchange objective.

HIEs allow for the sharing of health information among clinicians, hospitals, care coordinators, labs, radiology centers, and other health care providers through secure, electronic means so that healthcare providers can have the benefit of the most recent information available from other health care providers. HIEs allow for broader interoperability beyond one health system or point-to-point connections among payers, patients, and health care providers. By enabling bi-directional exchange of information between health care providers and aggregating data across providers with disparate systems, HIEs can bring together the information needed to create a true longitudinal care record and support improved care coordination by facilitating timely access to robust health information across care settings. Bi-directional exchange means that the clinician's EHR is enabled to allow for querying and sharing data by sending, receiving, and incorporating data via an HIE for every patient. Healthcare quality and public health outcomes have been shown in multiple studies to experience a beneficial effect from health information exchanges with improved medication reconciliation, improved immunization and health record completeness, and improved population level immunization rates.[86] Another study has shown that if every clinician who submits claims under Medicare Part B [87] were connected to an HIE, Medicare would have saved $63 million annually for each therapeutic procedure performed at a physician's office due to the reduction in duplicate procedures,[88] while other research has shown a decrease in emergency department utilization and improved care process when using an HIE.[89]

HIE services are available from many organizations today, which may be referred to as HIEs or health information organizations (HIOs). State and regional HIEs have a long history of connecting health care providers caring for a common patient population across a specified geographic area. These HIEs represent a significant public investment, with $564 million in federal funding provided as part of the 2009 HITECH Act, ongoing state funding and support from CMS under both 42 CFR 495.322 and 42 CFR part 433 subpart C.[90]

These state and regional HIEs typically obtain not just EHR-generated data, but a broader array of ADT (admit, discharge, transfer) feeds and lab feeds as they build on local relationships and have similar but not identical capabilities with several models of data storage and a variety of business models. In addition to these initiatives, many EHR vendors are participating in the development of national-level networks designed to ensure their customers can share information with customers of other vendors. Geographically-based exchanges have also begun to address national-level exchange, with efforts designed to link state and regional networks so that health care providers can obtain information on individual patients wherever they receive care throughout the United States.

Recent data indicate that there is wide availability of HIEs across the nation, yet gaps remain. Forthcoming analysis of a recent survey of HIEs found that 45 states, including DC, were covered by one or more operational HIOs that reported a statewide catchment area. Moreover, 81 percent (or 2,770) of health service areas (HSAs) in the United States were in the catchment area of at least one operational HIE effort and 32 percent of HSAs had more than one operational HIE effort.[91] Despite the widespread availability of HIE services; however, HIE participation data suggests there are still significant opportunities to increase health care provider engagement with HIEs. For instance, in a 2018 survey, 73 percent of hospitals reported participating in either a state, regional, or local HIE. When national HIE networks as well as state, regional, and local networks, 15 percent of hospitals reported not participating in any type of HIE.[92] While it is more difficult to assess individual clinicians' current participation in HIEs, data from the forthcoming survey noted above found that, among the HIEs surveyed, 76 percent reported that independent physician practices or practice groups contributed data to the HIE, while 89 percent reported that providers viewed data in the HIE, suggesting additional incentives may help to spur greater engagement with available HIEs.

[86] *https://academic.oup.com/jamia/article/25/9/1259/4990601:* ibid.

[87] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/Physician_FAQ.pdf.*

[88] *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2971503:* University of Connecticut School of Business Research Paper No. 17–03 ''*Do Health Information Exchanges Deter Repetition of Medical Services?*''

[89] *https://pubmed.ncbi.nlm.nih.gov/27521368/:* Journal of the American Medical Informatics Association. 2017 Apr 1;24(e1):e103–e110. doi: 10.1093/jamia/ocw116. ''*Health Information Exchange Associated With Improved Emergency Department Care Through Faster Accessing of Patient Information From Outside Organizations*''.

[90] *https://protect2.fireeye.com/url?k=d8978709-84c28e1a-d897b636-0cc47adb5650-e634c1ba410d0153&u=https://www.healthit.gov/sites/default/files/reports/finalsummativereportmarch_2016.pdf.*

[91] Forthcoming analysis of survey conducted under Contract No. HHSP233201700049C, OMB Control No: 0955–0019.

[92] ''State of Interoperability among U.S. Non-federal Acute Care Hospitals in 2018'' ONC Data Brief No. 51, March 2020. See *https://www.healthit.gov/sites/default/files/page/2020-03/State-of-Interoperability-among-US-Non-federal-Acute-Care-Hospitals-in-2018.pdf.*

We believe that incentivizing participation in HIEs that support bi-directional exchange will contribute to a longitudinal care record for the patient and facilitate enhanced care coordination across settings. The use of an HIE means that essential health information is available for care team members even in the case of referrals the clinician may not be aware of, or for instances where the clinician is contributing to the patient's record, but may not be the health care provider making the referral. In these instances, such transitions may or may not be able to be automatically identified by an EHR for inclusion in the denominators of the two existing measures associated with the HIE objective for the Promoting Interoperability performance category. For example, consider a patient who has a hospital emergency room visit in January 2020 and receives a prescription, then goes to her primary care physician appointment in March 2020 without notifying the primary care physician of the hospital visit or the new medication. The primary care physician refers the patient to a specialist and the specialist receives and reconciles the patient's data from her primary care physician records. In this scenario, the hospital may not have had access to the patient's health record from the primary care physician, and the primary care physician and the specialist may not have access to the data from the hospital including essential information like an update to current medications. We note that there was a Conditions of Participation (CoP) policy related to patient event notifications finalized in the Patient Access and Interoperability rule (85 FR 25584 through 25603). However, the new CoP would not require the hospitals to share the clinically relevant information specified in this example. The CoP requirement only specifies a minimal set of information for inclusion in a notification (patient's name, treating practitioner name, and sending institution name) and does not include the standardized clinical data that hospitals must share electronically using CEHRT in order to participate in the Promoting Interoperability program. For instance, the clinical data specified in the ''transitions of care'' criterion at 45 CFR 170.315(b)(1), which is currently the United States Core Data for Interoperability (USCDI) or Common Clinical Data Set (CCDS) (see 85 FR 25670). Moreover, if the patient were to have another emergent issue and require emergency room care, the situation becomes further compounded. For this scenario, if the hospital, primary care physician, and specialist participated in a bi-directional exchange with a health information network, each health care provider from the hospital to the specialist would have access to all of the patient's records that may be critical for patient care and safety. Under the existing measures for the HIE objective, only the known transition of care from primary care physician to specialist would be included in the denominator. However, under the proposed alternative measure for bi-directional exchange through a HIE, we would incentivize the clinician to engage in health information exchange for care coordination that includes these additional transitions and referrals as well as other potential scenarios: Where the recipient of the transition of care may be unknown; Where the eligible clinician may not be the referring health care provider; where the transition of care may happen outside the scope of the performance period; or where the patient was not seen by the eligible clinician during the performance period. In this way, the eligible clinician or group's action to engage in bi-directional exchange through an HIE would allow each health care provider to contribute to the longitudinal care record in a manner that supports a wide range of transitions and referrals beyond those currently reflected in the measure denominators. This engagement supports robust health information exchange without placing burden on the clinician or the patient to be individually accountable to facilitate exchange via multiple (and potentially unknown) point-to-point connections.

The current COVID–19 PHE has further highlighted the need to encourage interoperable HIE infrastructure and bi-directional exchange across the country that can ensure patients, health care providers, and public health authorities have the data they need to support quality care. In addition to supporting general care coordination, HIEs can specifically support the PHE response by: Enabling enhanced use of telehealth and telemedicine for obtaining and aggregating patient information including when the patient's health care provider(s) may not be known.

In response to the PHE, CMS has taken steps to significantly expand access to services via telehealth, by increasing flexibility around the use of telehealth. HIEs can support patient care by ensuring health care providers are able to access patient data in support of a telehealth encounter or subsequent in-person visit with either an established or new health care provider. Particularly for visits with a new health care provider, the HIE may provide an option for health care providers to access critical health information. In addition, HIEs can support telehealth visits for screening, evaluation, and event notification for care team members for patients that have been exposed, tested, quarantined etc. HIEs, can ensure information about testing results is available to support the immediate and longer term health and clinical needs of an individual. HIEs offer a rich source of health data to support these interactions and can be utilized by health care providers who may not have direct exchange capabilities, but operate as part of the same care team. HIEs also support these use cases in ways that direct exchange cannot, by facilitating aggregation of data from multiple sources where 'point to point' exchange may be infeasible.

- *Proposed New Measure:* In order to incentivize MIPS eligible clinicians to engage in bi-directional exchange through an HIE, we are proposing to add the following new measure under the HIE objective beginning with the performance period in 2021: Health Information Exchange (HIE) Bi-Directional Exchange measure. We propose to add this new HIE Bi-Directional Exchange measure to the HIE objective as an optional alternative to the two existing measures: 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 that clinicians either may report the two existing measures and associated exclusions OR may choose to report the new measure. We propose that the HIE Bi-Directional Exchange measure would be worth 40 points. In no case could more than 40 points be earned for the HIE objective. We are proposing the HIE Bi-Directional Exchange measure would be reported by attestation and would require a yes/no response. As we believe that fulfillment of this measure is an extremely high value action, a ''yes'' response would enable the clinician to earn the 40 points allotted to the HIE objective. We propose that clinicians would attest to the following:

++ I participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period.

++ The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and does not engage in

exclusionary behavior when determining exchange partners.

++ I use the functions of CEHRT for this measure, which may include technology certified to criteria at 45 CFR 170.315(b)(1), (b)(2), (g)(8), or (g)(10).

We believe it is appropriate for the new optional measure to serve as an alternative measure of performance on health information exchange since, in order to successfully meet the measure, an eligible clinician would be required to meet an overall standard of performance on health information exchange that is broader than the denominators and numerators of the current measures. To successfully attest to the new measure the eligible clinician or group must establish the technical capacity and workflows to engage in bi-directional exchange via an HIE for all patients seen by the eligible clinician and for any patient record stored or maintained in their EHR. This includes querying for or receiving health information for all new and existing patients seen by the eligible clinician, as well as sending or sharing information for all new and existing patients seen by the eligible clinician regardless of known referral or transition status, or the timing of any potential transition or referral. The proposed requirement to query for or receive health information for all new and existing patients is broader than the current Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, which includes only new patients and known transitions or referrals received that occur during the performance period. Similarly, the proposed requirement to send or share information for all new and existing patients represents a broader scope than the current Support Electronic Referral Loops by Sending Health Information measure which includes only known transitions of care or referrals made that occur during the performance period. In addition, such bi-directional engagement would facilitate exchange of information for patient records stored or maintained in the clinician's EHR, even when the patient does not have an encounter or is not seen by the eligible clinician during the performance period, and for which the clinician has no active transition or referral during the performance period. This proposed requirement is likewise more expansive than the denominators of either measure.

Relative to the numerators for the current measures, the new optional measure would require that bi-directional engagement occurs for all patients and for all patient records without exclusion, exception, or allowances made for partial credit. This is similar to achieving a score of 100 percent on both the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure, while additionally completing required actions for additional exchange cases not included in the existing denominators. Finally, while we believe this optional measure would establish a high performance standard with respect to information sharing, we also believe that availability of this optional measure would reduce current reporting burden associated with the program, as eligible clinicians choosing to report on the measure would not be required to report on the two existing numerator/denominator measures.

While we believe there are a significant number of HIEs across the country that would meet the standards described in the attestation statements, some HIE arrangements may not have the capacity to enable bi-directional exchange for every patient transition or referral made by a clinician, and thus would not meet the standard described in the attestation statements required to fulfill the measure. For instance, we would exclude exchange networks that only support information exchange between affiliated entities, such as health care providers that are part of a single health system, or networks that only facilitate sharing between health care providers that use the same EHR vendor.

To successfully attest to this measure, the eligible clinician must use the capabilities defined for CEHRT to engage in bi-directional exchange via the HIE, which includes exchanging the clinical data within the CCDS or USCDI. This is consistent with both of the existing measures under the Health Information Exchange objective, which require the use of CEHRT to create a C–CDA document, which includes the clinical data within the CCDS or the USCDI. We believe there are numerous certified health IT capabilities which can support bi-directional exchange with a qualifying HIE. For instance, participants may interact with an HIE by using technology certified to the criterion at § 170.315(b)(1) to transmit C–CDAs to the HIE. Participants could also utilize API technology certified to either the criterion at §§ 170.315(g)(8) or (g)(10) as recently finalized in the 21st Century Cures Act final rule (85 FR 25742), to enable an HIE to obtain data in the CCDS or USCDI from a participant's EHR. As noted in section III.M of this proposed rule, the 21st Century Cures Act final rule states that these criteria may refer to either the CCDS or USCDI for a period of 24 months following the publication of the Cures Act final rule (85 FR 25669). After this time, only technology certified to criteria referencing the USCDI would be considered certified under the ONC Certification Program. We recognize that HIEs are currently interacting with health care providers using certified health IT in a variety of ways, and believe that we should allow for substantial flexibility in how health care providers use certified health IT to exchange data using HIE.

We note that none of the actions required to attest to this measure are intended to conflict with a patient's rights or covered entities (for example, health care provider's) requirements/responsibilities under the HIPAA Privacy Rule, as set out at 45 CFR parts 160 and 164. The HIPAA Privacy Rule permits but does not require covered health care entities to get patient consent before using or disclosing PHI for treatment, payment, and health care operations. Although HIPAA does not require the health care entities offer patients a choice about the sharing of their PHI, many entities and states have adopted policies or laws that require patient consent. HIPAA is designed to work in tandem with more privacy protective policies. Moreover, we understand that different HIEs that enable exchange in the manner described may have different policies related to confidentiality of patient information based on local circumstances and requirements. Nothing in the attestation statements for this measure are intended to conflict with individual HIE policies that may exist in these areas, or prevent eligible clinicians from complying with these policies as a condition of their participation in the HIE.

We are not proposing an exclusion for this new measure as this measure would be an optional alternative measure to be reported instead of the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. The exclusions would still be available for the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure.

We invite comments on these proposals, and whether commenters believe such an optional measure would incentivize eligible clinicians to participate in HIEs while establishing a high performance standard for sharing

information with other clinicians. We are also seeking comment on the proposed attestation statements for the optional measure. For instance:

- Do these statements reflect appropriate expectations about information exchange capabilities for eligible clinicians that engage with HIEs capable of facilitating widespread exchange with other health care providers?
- How should CMS effectively identify those HIEs that can support the widespread exchange with other health care providers?
- How are eligible clinicians currently using CEHRT to exchange information with HIEs, and do the proposed attestation statements allow for different ways health care providers are connecting with HIEs utilizing certified health IT capabilities?

(d) Scoring Methodology

(1) Changes to the Scoring Methodology for the 2021 Performance Period

Table 42 reflects the Promoting Interoperability performance category objectives and measures for CY 2021 if the proposed changes discussed earlier in this section are adopted as final, including the proposed name change to the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure and the continuation of the optional Query of PDMP measure for CY 2021.

TABLE 42: Scoring Methodology for the Performance Period in CY 2021

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	10 points (*bonus*)
Health Information Exchange OR	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information *	20 points
Health Information Exchange (alternative)	HIE Bi-Directional Exchange	40 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: • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting	10 Points

Notes: The Security Risk Analysis measure is required, but will not be scored.
*Measure with a proposed name change in this proposed rule.

(e) Additional Considerations

(1) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

In 2018 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 through 2020 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.

As in past years, we intend to use data from prior performance periods to further evaluate the participation of NPs, PAs, CRNAs, and CNSs 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. Although 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 the 2017 performance period, 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. For the 2018 performance period, approximately 34percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs

submitted data individually for the Promoting Interoperability performance category. In addition, the majority of MIPS eligible clinicians reported data for the Promoting Interoperability performance category for the 2017 and 2018 performance periods using the transition measure set. This set is unavailable for the 2019 performance period, which may result in fewer MIPS eligible clinicians reporting data for Promoting Interoperability performance category. Further, due to the 2019 Novel Coronavirus (COVID–19), we anticipate that many MIPS eligible clinicians may not report data for the 2019 performance period, although we do not expect to know the full impact on reporting for the Promoting Interoperability performance category until fall 2020.

Since 2017 we have included a solicitation for new measures for the Promoting Interoperability performance category in the annual Call for Measures. We have received many suggestions for new measures. We have not received any suggestions for new measures for NPs, PAs, CRNAs, CNSs or any other non-physician practitioners, which may continue to limit their ability to successfully report for the Promoting Interoperability performance category.

For these reasons, 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 2021, and to revise § 414.1380(c)(2)(i)(A)(*5*) to reflect this proposal. We are requesting public comments on this proposal.

(2) Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologists, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition Professionals

In the CY 2020 PFS final rule (84 FR 63003 through 63004), 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 to other types of MIPS eligible clinicians who are non-physician practitioners (physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals) for the performance period in 2020. We stated that 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 IV.A.2.c.4.(b) of this proposed rule, for the performance period in 2021, 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.

(f) Future Direction of the Promoting Interoperability Performance Category

In future years of the Promoting Interoperability performance category, we will continue to consider changes which support a variety of HHS goals as previously stated (84 FR 62991 through 62992), including: Reducing administrative burden; supporting alignment with the Medicare Promoting Interoperability Program; supporting alignment with the 21st Century Cures Act; advancing interoperability and the exchange of health information; and promoting innovative uses of health IT. More specifically under the 21st Century Cures Act, we will look at and take under consideration potential areas of overlap as we continue to align, pending implementation of the statute. This may include, but is not limited to, Information Blocking, future growth of PDMP, the use of USCDI, FHIR, and updates to 2015 Edition health IT certification criteria and the ONC Health IT Certification Program. We believe maintaining our focus on promoting interoperability, alignment, and simplification will reduce health care provider burden while allowing flexibility to pursue innovative applications that improve care delivery. For more detailed information, refer to the [21st Century Cures Act final rule (85 FR 25642 through 25961)] and Interoperability and Patient Access final rule (85FR 25510 through 25640). We also refer readers to section III.M. of this proposed rule for discussion of our proposal to modify the CEHRT definition as defined for the Quality Payment Program under § 414.1305.

(5) APM Entity Groups and APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

The APM scoring standard, codified at § 414.1370, is the MIPS scoring methodology applicable for MIPS eligible clinicians 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 was designed to reduce reporting burden for participants in MIPS APMs by eliminating the need for such MIPS eligible clinicians to submit data for both MIPS and their respective APMs, and to ensure that these eligible clinicians were not assessed in multiple ways on the same performance activities. We also believed that the APM scoring standard would encourage APM participation and support the goal of encouraging APM participants to better manage care for patients within their respective APM Entities by tying their MIPS performance scores together.

As we have gained experience in implementing the APM scoring standard, we have learned that it is infeasible to fully implement it as it was originally designed, as was discussed in the CY 2020 PFS final rule (84 FR 63007). Public comments on the CY 2020 revised APM scoring standard finalized in the CY 2020 PFS final rule (84 FR 63010), and most comments in response to the request for comments on APM scoring beyond 2020, made clear that the complexity of the APM scoring standard and its inflexibility in adapting to changes in APM participation and design have resulted in confusion and unintended additional burden for APM Entities and their participant MIPS eligible clinicians.

With this insight in mind, and with the goal of better aligning MIPS reporting rules for all MIPS eligible clinicians, including those in MIPS APMs, we are proposing to terminate the APM scoring standard as described at § 414.1370, effective January 1 of the 2021 performance year, by amending that regulation accordingly.

We further propose in section III.C.3. of this proposed rule, effective January 1, 2021, to establish a MIPS APM Performance Pathway and scoring rules that would be available for MIPS reporting for MIPS eligible clinicians in MIPS APMs.

We seek comment on this proposal.

(b) APM Entity Groups

We are proposing to terminate the APM scoring standard effective January 1, 2021, however, beginning with the 2021 performance period, we propose to retain certain APM Entity group reporting policies that were established and finalized for reporting and scoring under MIPS beginning with the 2021 performance period. Therefore, we are proposing to redesignate in part the regulation that describes APM Entity group determinations, from

§ 414.1370(e) to § 414.1317, and to title that section ''APM Entity Groups.''

In addition, because we are proposing to no longer rely on quality measures reported to an APM, as is required under the existing APM scoring standard, we no longer believe that there is substantial risk of the MIPS final scores being inappropriately influenced by MIPS eligible clinicians moving into or out of APM Entities late in the performance year, which was the impetus for the full-TIN APM policy. Therefore, we are proposing to end the full-TIN APM policy currently codified at § 414.1370(e)(1), which allows for an APM Entity group to include eligible clinicians on the Participation List in a full-TIN APM on December 31 of the MIPS Performance Period only if the APM is a full-TIN APM as defined at § 414.1305. We also propose that MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of any APM Entity participating in any MIPS APM on any of the three snapshot dates (March 31, June 30, August 31), as well as December 31 during a performance period, beginning in the 2021 MIPS performance period, would be considered participants in an APM Entity group. As these proposals would eliminate the need for the term ''full TIN APM,'' we also propose to delete the defined term ''full TIN APM'' from § 414.1305.

We seek comment on this proposal.

(c) APM Entity Group Eligibility

In the absence of the APM scoring standard and mandatory reporting to MIPS through the APM Entity group, it would no longer be necessary to conduct low-volume threshold determinations at the APM Entity group level. Therefore, along with the termination of the APM scoring standard under § 414.1370, we also propose to terminate, effective January 1, 2021, the use of APM Entity level low-volume threshold determinations and remove the term APM Entity group from the definition of the low-volume threshold at § 414.1305, with corresponding changes to applicability at § 414.1310(b)(1).

Going forward, we would apply the same rules for MIPS eligibility to APM participants as to other MIPS eligible clinicians. For example, if an eligible clinician who is a participant in a MIPS APM is below the low-volume threshold he or she would not be required to report to MIPS as an individual; however, if the group TIN of which that eligible clinician is a part is MIPS eligible and does report to MIPS, that eligible clinician would be treated as a MIPS eligible clinician for purposes of MIPS scoring and payment adjustments, and would receive the higher of the group score and any available APM Entity group score. APM Entity reporting, in and of itself, would not confer MIPS eligibility to an eligible clinician who would otherwise be excluded from MIPS.

(d) APM Entity Group Scoring

Consistent with our past approach under APM scoring standard at § 414.1370(f), we are proposing at § 414.1317(b) that the MIPS final score calculated for the APM Entity would be applied to each MIPS eligible clinician in the APM Entity group. The MIPS payment adjustment would be applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity group.

Similar to our past approach under the APM scoring standard at § 414.1370(g)(4)(ii) and (iii), as originally discussed and finalized in the CY 2017 Quality Payment Program final rule (81 FR 77268), we are proposing at § 414.1317(b)(1) that in all cases where an APM Entity reports to MIPS, but a performance category's data submission cannot be made at the APM Entity level, each MIPS eligible clinician in the APM Entity group would be assigned the highest available score for that performance category (either the individual or TIN-level score), and the scores for all MIPS eligible clinicians in the APM Entity group would be averaged in order to calculate the APM Entity level performance category score. In the event that a MIPS eligible clinician in an APM Entity receives an exception from the reporting requirements, such eligible clinician would be assigned a null score when CMS calculates the APM Entity's performance category score.

Similar to our past approach under the APM scoring standard at § 414.1370(g)(1)(iv), we are proposing at § 414.1317(b)(2) that for an APM Entity for which CMS calculated a total performance category score for one or more participants in the APM Entity for the preceding MIPS performance period, CMS would calculate an improvement score for each performance category for which a previous year's total performance category score is available as specified in § 414.1380(b). Note that unlike § 414.1370(g)(1)(iv), proposed § 414.1317(b)(2) would not be limited to the quality performance category, but would apply to any performance category.

We seek comment on these proposals.

(e) Reweighting Based on Extreme and Uncontrollable Circumstances for APM Entity Groups

Section 414.1380(c)(2)(i) allows for the submission of an application to CMS to request reweighting of one or more MIPS performance categories due to extreme and uncontrollable circumstances. We are proposing that an APM Entity may submit such an application beginning with the 2020 performance period/2022 MIPS payment year, at § 414.1317(b)(3). The request for reweighting in the application would apply for all four MIPS performance categories and all MIPS eligible clinicians in the APM Entity group. If the request for reweighting is approved by CMS, this would result in MIPS eligible clinicians participating in the APM Entity being excepted from MIPS reporting requirements for the applicable performance period, and the APM Entity would receive a final score equal to the performance threshold. Such request for reweighting would be approved or denied in its entirety.

We considered allowing an APM Entity to submit an application to request reweighting for individual performance categories, but rejected this approach. We believe the amount of complexity at the intersection of the various performance category submission and scoring requirements, submitter types, and exception applications for MIPS eligible clinicians could place a burden on these clinicians and their representatives to continually invest in understanding their shifting obligations under such an approach. Furthermore, operationalizing a policy where an APM Entity would have the ability to request and receive reweighting for one or more, but not all, performance categories would be prone to error. In addition, such a piecemeal approach to addressing extreme and uncontrollable circumstances likely would cause scoring delays that could result in CMS being unable to timely provide performance feedback and payment adjustment information to all MIPS eligible clinicians.

We also are proposing at § 414.1317(b)(3)(i) that an APM Entity must demonstrate in its application to CMS that greater than 75 percent of its participant MIPS eligible clinicians would be eligible for reweighting the Promoting Interoperability performance category for the applicable performance period.

Due to the unique and complex relationship between an APM Entity and its individual participant MIPS eligible clinicians, we believe it is

appropriate to offer an APM Entity the opportunity to apply for reweighting based on extreme and uncontrollable circumstances for all performance categories, including the Promoting Interoperability performance category, rather than collecting Promoting Interoperability hardship exception applications from each MIPS eligible clinician in the APM Entity group as is currently required However, we believe that setting a 75 percent threshold for the Promoting Interoperability performance category is appropriate as a means of assuring that the request for reweighting is only granted in cases where absent the reweighting, it would be impossible to calculate a score for that performance category that is truly representative of the APM Entity group's performance. We are proposing a 75 percent threshold because such threshold is consistent with the Promoting Interoperability performance category reweighting policy for groups of hospital-based MIPS eligible clinicians and non-patient facing MIPS eligible clinicians, which similarly could face an administrative burden in attempting to secure approvals for individual reweighting requests for each MIPS eligible clinician in such groups. We recognize that as a result of the variety of participation requirements of different APMs, APM Entity groups may be composed of a wide range of health care provider types and sites of service. We believe that scoring an entire APM Entity as the result of a single MIPS eligible clinician's submission of data for the Promoting Interoperability performance category could place an extreme administrative burden on APM Entity groups, and could potentially create unintended consequences for APM participation decisions among MIPS eligible clinicians.

In addition, we propose at § 414.1317(b)(3)(ii) that if CMS approves the request for reweighting based on an APM Entity's application, and if MIPS data are submitted for the APM Entity for the applicable performance period, all four of the MIPS performance categories still would be reweighted for the APM Entity group notwithstanding the data submission. The data submission would not effectively void the request for reweighting and its approval. We are proposing this policy because we do not believe it would be appropriate or desirable for an individual MIPS eligible clinician or for a group TIN with no direct affiliation with an APM Entity to accidentally override an APM Entity's application. This could happen if the MIPS eligible clinician or group TIN reports to MIPS either out of an abundance of caution or on behalf of a MIPS eligible clinician who is not in the APM Entity, but happens to share a billing TIN with an eligible clinician who is in the APM Entity. We also recognize that there may be circumstances where an APM may require some form of quality reporting for purposes of the APM itself, such as is required for Shared Savings Program ACOs as described in section II.G. of this proposed rule, but that in complying with such requirement an APM Entity may also be submitting quality performance category data that would result in scoring for purposes of MIPS when that APM Entity group would otherwise have been excepted from MIPS reporting.

We note that under this proposal and the proposed changes to the MIPS scoring hierarchy, described in section IV.A.3.e. of this proposed rule, reporting done by a MIPS eligible clinician or group would result in a MIPS final score for only that MIPS eligible clinician or group, which may be used to determine a MIPS eligible clinician's payment adjustment.

Finally, to the extent that these proposed policies would constitute a change to the MIPS scoring or payment methodology for the 2022 MIPS payment adjustment after the start of the 2020 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 establish these policies because of the COVID–19 PHE. We believe that the intersection of the 2020 APM scoring standard rules and the extreme and uncontrollable circumstances policies being put in place by APMs themselves in response to the COVID–19 PHE, such as the changes being proposed for participants in the Shared Savings Program in section III.I.1. of this proposed rule, would make obtaining reweighting under MIPS based on extreme and uncontrollable circumstances unusually burdensome absent these proposed changes. For instance, the Shared Savings Program will continue to require the submission of quality performance data by participating ACOs, and that data would be eligible to be used for MIPS quality scoring absent this proposal, which would have the result of not allowing Shared Savings Participants the option to take advantage of extreme and uncontrollable circumstances policies that are available to other MIPS eligible clinicians. This policy change is necessary to give participants in the Shared Savings Program the opportunity to request reweighting of the MIPS performance categories in the event that they believe the data reported for purposes of the Shared Savings Program do not adequately reflect the performance of the ACO Entity for purposes of MIPS quality performance category scoring.

We seek comment on our proposals discussed above.

d. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

For the 2023 MIPS payment year, we intend to continue to build on the scoring methodology we finalized for prior years. The scoring methodology allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. We are maintaining many of our scoring policies, focusing on only making proposals to maintain stability. Specifically, we are proposing the following:

- To implement scoring flexibility for quality measures with specification or coding changes during the performance year.
- To implement benchmark and topped out scoring policies that are responsive to potential low reporting rates for the 2019 performance year due to the national public health emergency (PHE) for the COVID–19 pandemic.
- To implement scoring for all administrative claims-based measures.
- To continue policies for scoring quality measures based on achievement as well as policies for measures that do not meet case minimum, data completeness requirements, or have a benchmark.
- To continue bonuses in the quality performance category.
- To continue improvement scoring of the quality performance category comparing clinicians to a 30 percent baseline score if clinicians scored 30 percent or less.

We are not proposing changes to scoring policies for the cost, improvement activities and Promoting Interoperability performance categories.

We have maintained our approach that MIPS eligible clinicians are scored against performance standards for each performance category and receive a final score, comprised of their performance category scores, and calculated according to the final score methodology. We refer readers to § 414.1380 for general policies on scoring. We refer readers to section IV.A.3.c.(5)(a) of this proposed rule for the discussion of our proposal to remove the APM scoring standard and section IV.A.3.b of this proposed rule

for information on the APM Performance Pathway scoring.

(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 (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, and 84 FR 63011 through 63018). We are proposing to maintain many policies finalized in prior years to retain stable scoring in MIPS with minimal new proposals as we transition to MVPs.

Please refer to section IV.A.3.c.(1)(b) of this proposed rule for more information about our proposal to sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the 2021 performance period. If the proposal is finalized, scoring policies proposed for the 2021 performance period will not be applicable to CMS Web Interface as a collection type.

(i) Scoring Flexibility for Changes That Impact Quality Measures During the Performance Period

We are proposing to expand the list of reasons that a quality measure may be impacted during the performance period in addition to revising when we would allow scoring of the measure with a performance period truncation (to 9 months) or the complete suppression of the measure if 9 months of data are not available. We have previously established policies to provide scoring flexibilities in instances in which changes to measures during the performance period have impacted clinicians' ability to submit the quality measures for the entire 12-month performance period because of an ICD–10 coding change or when there are clinical guideline changes that could result in patient harm, or otherwise provide misleading results and render the measure no longer comparable to the historic benchmark. Specifically, in the CY 2018 Quality Payment Program Final rule (82 FR 53714 through 53716), we finalized that, beginning with the 2018 MIPS performance period, we will assess performance on measures considered significantly impacted by ICD–10 coding changes during the performance period based only on the first 9 months of the 12-month performance period. We believe that 9 months of data is sufficient to assess performance when 12 months of data is not available. We finalized that we would publish a list of measures requiring a 9-month assessment period on the CMS website by October 1st of the performance period if technically feasible, but no later than the beginning of the data submission period (for example, January 2, 2021 for the 2020 performance period). We refer readers to § 414.1380(b)(1)(viii) for more on our policy for scoring flexibility for ICD–10 changes.

In the CY 2019 Quality Payment final rule (83 FR 59845 through 59847),we finalized policies beginning with the 2021 MIPS payment year to reduce the total available measure achievement points from the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted by clinical guideline changes or other changes when we believe adherence to the guidelines in the existing measures could result in patient harm or otherwise no longer be comparable to a historic benchmark. We refer readers to § 414.1380(b)(1)(vii)(A) for more information on the scoring flexibility policy.

We propose beginning with the 2021 performance period, a policy to truncate the performance period or suppress a quality measure if CMS determines that revised clinical guidelines, measure specifications or codes impact clinician's ability to submit information on the measure or may lead to potentially misleading results. Based on the timing of the changes to clinical guidelines, measure specifications or codes, we would assess the measure on 9 months of data, and if 9 consecutive months of data are not available, we would suppress the measure by reducing the total available measure achievement points from the quality performance category by 10 points for each measure submitted that is impacted.

In addition to ICD–10 and clinical guideline changes, we believe that there may be instances when there are changes after the final approval of quality measures including changes to the measure specification, or updates to coding that may lead to misleading results. If there are no concerns with potential patient harm, we would like the ability to assess performance on the quality measure (not including the change) if we have sufficient data. Depending on the timing of the change during the performance period we would like to assess performance on the quality measure; we believe we can assess performance if we have 9 months of data and should suppress the measure if we have less than 9 months of data.

We will examine quality measures that are impacted by changes during the performance period to determine how the change may impact our ability to assess performance on the measure. Potential changes that may impact quality measures during the performance period include updates to clinical guidelines or measure specifications, such as revisions to medication lists, codes and clinical actions. For example, the introduction of a new drug class after the performance period began, would not be captured as numerator compliant by an existing measure specification but may meet the intent of the measure and its associated clinical actions. Assessment of clinician's performance on the measure would be hampered by the fact that the measure specification would not be able to be updated to collect information and assess performance related to use of the medication from the new drug class. As reflected at sections 1848(q)(2)(D)(1) and 1848(q)(2)(D)(1)(II)(cc) of the Act, quality measures adopted under MIPS, including substantive updates must be made through notice and comment rulemaking.

Additionally, we may examine a quality measure to determine if the change impacts the ability of clinicians to submit the measure, including the number of encounters a clinician may be able to submit, the number of clinicians who may be able to submit the measure, and the proportion of clinicians from a specialty who may be able to submit the measure. We would also assess if the change to a code would potentially lead to misleading results. For example, changes that impact the clinicians' ability to report a measure include changes to Common Procedural Technology (CPT) codes and the Healthcare Common Procedure Coding System (HCPCS) codes during the performance period, which may potentially produce misleading results. We believe that code changes that impact a clinician's ability to report a measure will be rare events, however, mid-year changes to CPT and HCPCS codes can be unanticipated when a clinician selects a quality measure and may introduce an additional burden if the clinician is unable to submit the quality measure.

When possible, we want an approach that allows us to score a quality measure even when there has been a change to the measure outside of the clinician's control during the performance period. We have finalized a policy that allows scoring on the first 9 months of data for a 12-month performance period data when there are ICD–10 code changes (82 FR 53714 through 53716). We assess performance on the first 9 months of performance data in the case of ICD–10 changes, which happen predictably in October on an annual basis, allowing us to truncate and remove the last quarter of the performance period from our assessment. However, we cannot anticipate when there will be a change to clinical guidelines, measure specifications, an inadvertent deletion, or revision of a code. These types of changes do not occur on an annual basis, and do not follow a predictable, consistent timeline. We become aware of changes to measures from feedback from clinicians, third parties and measure stewards. Updates to codes, which may not happen at a predictable time, may significantly impact how many cases a clinician can report and how a clinician performs on a measure. We want to account for instances such as coding changes during the performance period, in which scoring should be applied to the first 9 months of data from the performance period. If 9 consecutive months of data from the performance period is not available, we would have the ability to suppress the measure by reducing the total available measure achievement points from the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted.

Therefore, we propose beginning with the 2021 performance period, a policy to truncate the performance period or suppress a quality measure if CMS determines revised clinical guidelines, measure specifications or codes impact the clinician's ability to submit the measure or may lead to potentially misleading results. Under this proposal we would maintain the flexibility to assess the measure on 9 months of data when available. Under the proposal we would suppress the measure if 9 consecutive months of data are not available. We propose that we would publish a list of measures requiring a 9-month assessment period on the CMS website as soon as technically feasible, but no later than the beginning of the data submission period (for example, January 2, 2021 for the 2020 performance period).

Accordingly, we propose to consolidate § 414.1380(b)(1)(vii)(A) and (b)(1)(viii) at § 414.1380(b)(1)(vii)(A). The consolidated paragraph would provide that for each submitted measure that is impacted by significant changes that CMS determines may result in patient harm or misleading results, performance on the measure is assessed based on data for 9 consecutive months of the applicable CY performance period. If such data are not available, the total available measure achievement points are reduced by 10 points. For purposes of this paragraph § 414.1380(b)(1)(vii)(A), ''significant changes'' means changes to codes (including ICD–10, CPT, and HCPCS), clinical guidelines, or measure specifications. We will publish a list of all measures scored under this paragraph § 414.1380(b)(1)(vii)(A) on the CMS website as soon as technically feasible, but by no later than the beginning of the data submission period at § 414.1325(e)(1).

(ii) Quality Measure Benchmarks

We refer readers to the CY 2017, CY 2018, CY 2019, and CY 2020 Quality Payment Program final rules (81 FR 77277 through 77282, 82 FR 53699 through 53718, 83 FR 59841 through 59842, and 84 FR 63014 through 63016, respectively) for our previously established benchmarking policies.

In the CY 2017 QPP final rule (81 FR 77277 through 77282), we finalized that we would use performance in the baseline period to set benchmarks for the quality performance category, with the exception of new quality measures, quality measures that lack historical data, or where we do not have comparable data from the baseline period, for which we would set the benchmarks using performance in the performance period. We defined the baseline period to be the 12-month CY that is 2 years prior to the performance period for the MIPS payment year. For example, for CY 2021 performance period, the baseline period would be CY 2019 which is 2 years prior to the CY 2021 performance period (81 FR 77277). Additionally, we further clarified that CMS can establish benchmarks either by the applicable baseline or performance period in the CY 2019 final rule (83 FR 59842), where we finalized the terminology change amending § 414.1380(b)(1)(ii) to remove the mention of each individual benchmark and instead state 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.

Because of the flexibility provided to MIPS eligible clinicians to allow for no data submission for the 2019 performance period (see 85 FR 19277 through 19278), we may not have as representative of a sample of data as we would have had without the national PHE for COVID–19. Therefore, we want to revisit our benchmarking policy for the 2021 performance period. We anticipate that we may have a gap in our data due to potentially receiving fewer submissions for CY 2019 which could skew the benchmarking results, as the triggering of this policy no longer requires clinicians to submit data. We believe this gap in data could result in different distributions of scores from what we normally see, thus skewing the benchmarks when using CY 2019 baseline period for the CY 2021 performance period. As a result, we considered two benchmarking options for CY 2021 performance period.

We intend to use performance period benchmarks for the CY 2021 performance period in accordance with § 414.1380(b)(1)(ii). This would mean that benchmarks for the CY 2021 performance period are based on the actual data submitted during the CY 2021 performance period. We believe that using performance period benchmarks for the year where we are facing gaps in baseline data will allow us to ensure that we continue to have reliable and accurate data. We recognize that this methodology would not allow clinicians to know the benchmarks ahead of the performance period, but we believe that using the most current information has the potential to provide more accurate results for benchmarking purposes for CY 2021 performance period and could capture any changes in care that have occurred as a result of the national PHE for COVID–19.

We are seeking feedback on the criteria for using data from the 2019 MIPS performance period to calculate CY 2021 benchmarks. We also, as an alternative to performance period benchmarks, considered, and request stakeholder comments and feedback on, utilizing the historic benchmarks from the 2020 MIPS performance period (which are based on submissions for CY 2018 MIPS performance period) for the CY 2021 performance period. We believe that this option would allow clinicians to continue to receive advance notice for quality performance category measures so that MIPS eligible clinicians can set a clear performance goal for these measures for CY 2021 performance period. However, we remain concerned that utilizing outdated data could also potentially result in distributions of scores used for benchmarks that no longer reflect the standard of care.

(iii) Minimum Case Requirements

In the CY 2017 Quality Payment program final rule (81 FR 77287 to 77289) we finalized that we will use 20 cases as the case minimum for all quality measures, with the exception of the all-cause hospital readmission measure which has a minimum of 200 cases. As proposed in Table Group A within Appendix 1, the hospital-wide readmission measure is replacing the all-cause readmission measure and an additional administrative claims-based measure for hip/knee complications is being added to the program. In the case of the hospital-wide readmission measure, the case minimum will remain the same at 200 cases and will only apply to groups. For the new hip/knee complication measure, a case minimum of 25 is proposed and is applicable for individuals and groups. We propose to amend § 414.1380(b)(1)(i) to clarify how administrative claims measures are scored. We propose to amend § 414.1380(b)(1)(iii) to reflect that, except for administrative claims measures, the minimum case requirement is 20 cases. For each administrative claims-based measure, the minimum case requirement is specified in the annual list of MIPS measures.

(iv) Assigning Quality Measure Achievement Points

We refer readers to § 414.1380(b)(1)(i) for more details on our policies for scoring performance on quality measures (81 FR 77276 through 77307, 82 FR 53694 through 53701, 83 FR 59841 through 59856, and 84 FR 63011 through 63019).

(A) Scoring Measures Based on Achievement

We previously 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) for the 2019 through 2022 MIPS payment years. 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 we would revisit the 3-point floor in future years.

For the 2023 MIPS payment year, we propose to again apply a 3-point floor for each measure that can be reliably scored against the benchmark. As we move towards the MVP framework discussed in section IV.A.3.a.(1) of this proposed rule, we anticipate we will be able to score quality measures from 1 to 10 for measures in MVPs and as such will revisit and possibly remove the 3-point floor for traditional MIPS in future years. As a result, we will wait until there is further policy development under the MVP framework before proposing to remove the 3-point floor. Accordingly, we propose to revise § 414.1380(b)(1)(i) to remove the years 2019 through 2022 and adding in its place the years 2019 through 2023 to provide that for the 2019 through 2023 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.

(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 (84 FR 63012).

In the 2017 QPP final rule (81 FR 77288) and the 2018 QPP final rule (82 FR 53727), we identified ''classes of measures'' which were intended to characterize measures for the ease of discussion. Class 1 measures are measures that can be scored based on performance because they have a benchmark, meet the case minimum and data completeness requirements. Class 2 measures are measures that cannot be scored based on performance because they do not have a benchmark or do not meet the case minimum which is generally 20 cases. Class 3 measures are measures that do not meet the data completeness requirement. We also noted that policies for Class 2 and Class 3 measures would not apply to measures submitted with the CMS Web Interface or administrative claims-based measures.

We are not proposing to modify how we score these measures within MIPS, as we consider policies for transitioning to MVPs described in section IV.A.3.a.(3) of this proposed rule. For class 2 measures, for the 2023 MIPS payment year, we propose to again apply the special scoring policies for measures that meet the data completeness requirement but do not have a benchmark, due to fewer than 20 individual clinicians or groups adequately reporting the measure, or meet the case minimum requirement. Accordingly, we propose to revise § 414.1380(b)(1)(i)(A)(*1*) to remove the years 2019 through 2022 and add in its place the years 2019 through 2023 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 2023 MIPS payment years, MIPS eligible clinicians would 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.

A summary of the proposed policies for the CY 2021 MIPS performance period is provided in Table 43.

TABLE 43: Quality Performance Category: Proposed Scoring Policies for the CY 2021 MIPS Performance Period*

Measure type	Description	Scoring rule for Traditional MIPS
Class 1	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) Meets case minimum; and (3) Meets the data completeness standard (generally 70 percent for 2021.)**	For the 2021 MIPS performance period: 3 to 10 measure achievement 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; and (2) Meets case minimum.	For the 2021 MIPS performance period: 3 measure achievement points.
Class 3	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 points for this measure. 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.

**We refer readers to § 414.1335(a)(3) for our policy on data completeness.

(v) Assigning Measure Achievement Points for Topped Out Measures

We refer readers to § 414.1380(b)(1)(iv) for our previously finalized policies regarding the identification of topped out measures and § 414.1380(b)(1)(iv)(B) for our finalized policies regarding the scoring of topped out measures. Under § 414.1380(b)(1)(iv), we will identify topped out measures in the benchmarks published for each Quality Payment Program year. Under § 414.1380(b)(1)(iv)(B), beginning with the 2021 MIPS payment year, measure benchmarks (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years will receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out (82 FR 53726 through 53727).

As noted in section IV.A.3.d.(1)(b)(ii) of this proposed rule, we are using performance period benchmarks for the 2021 MIPS performance period, which will mean we would not be able to publish measures that are topped out prior to the 2021 MIPS performance period. That also means we would not be able to identify those that have been topped-out for 2 or more consecutive years for purposes of the topped out scoring of 7 measure achievement points. We believe it is still important to retain a topped out scoring cap of 7 measure achievement points so that clinicians have incentives to pick alternate measures that are not topped out. We also appreciate that a measure may not always be topped out and we believe that if a measure is not topped out in the 2021 performance period benchmark, then it should have the ability to achieve up to 10 measure achievement points.

Therefore, for the 2021 MIPS performance period, as an exception from the general rule at § 414.1380(b)(1)(iv)(B) we propose at § 414.1380(b)(1)(iv)(B)(1) to apply the 7 measures achievement point cap to measures that meet the following two criteria. The first criterion would be that the measures have been topped out for 2 or more periods based on the published 2020 MIPS performance period historic benchmarks (which are based on submissions for the 2018 MIPS performance period). The second criterion would be the measures remain topped out after the 2021 MIPS performance period benchmarks have been calculated. We believe these two criteria collectively would provide clinicians the information to know prior to the 2021 MIPS performance period which measures would have the topped-out scoring applied but would also account for the scenario where a measure is no longer topped out. We would not limit the number of measure achievement points for measures that have not been topped out for at least two years as published in the 2020 MIPS performance period historic benchmarks.

(vi) Incentives To Report High-Priority Measures

We refer readers to § 414.1380(b)(1)(v)(A) for our previously finalized policies regarding incentives to report high priority measures. In the CY 2017 Quality Payment Program final rule (81 FR 77293), we established the scoring policies for high priority measure bonus points to encourage the selection of additional high-priority and outcome measures that impact beneficiaries and were closely aligned to our measurement goals. In the CY 2019 PFS final rule (83 FR 59850), we discontinued awarding measure bonus points to CMS Web Interface reporters for reporting high priority measures since CMS Web Interface reporters have no choice in measures.

We stated in the CY 2019 PFS proposed and final rules (83 FR 35950, 59851) that as part of our move towards fully implementing high value measures, we believe that bonus points

for high priority measures for all collection types may no longer be needed, and as a result, we intended to consider in future rulemaking whether to modify our scoring policy to no longer offer high priority bonus points after the 2021 MIPS payment year. We noted in the CY 2019 PFS final rule (83 FR 59851) that measure bonus points were created as transition policies which were not meant to continue through the life of the program. We believe with the finalized framework for transforming MIPS through MVPs (84 FR 62948), we will find ways in the future to emphasize high priority measures without needing to incentivize with bonus points. As a result, we will wait until there is further policy development under the MVP framework before proposing to remove our policy of assigning bonus points for high priority measures.

In this proposed rule, we propose to maintain the cap on measure points for reporting high priority measures for the 2023 MIPS payment year. Accordingly, we propose to revise § 414.1380(b)(1)(v)(A)(*1*)(*ii*) to remove the years 2019 through 2022 and adding in its place the years 2019 through 2023 to provide that through the 2023 MIPS payment year, the total measure bonus points for high priority measures cannot exceed 10 percent of the total available measure achievement points.

(vii) Incentives To Use CEHRT To Support Quality Performance Category Submissions

Section 1848(q)(5)(B)(ii) of the Act requires the Secretary to encourage MIPS eligible clinicians to report on applicable quality measures through the use of CEHRT. In the CY 2017 Quality Payment Program final rule (81 FR 77297), we established the measure bonus point and bonus cap for using CEHRT for end-to-end reporting. We refer readers to § 414.1380(b)(1)(v)(B) for our previously finalized policies regarding measure bonus points for end-to-end electronic reporting. We believe with the framework for transforming MIPS through MVPs discussed in the CY 2020 PFS proposed rule (84 FR 40739) and in section IV.A.3.a.(1) of this proposed rule, we will find ways to incorporate digital measures without needing to incentivize end-to-end reporting with bonus points. In the CY 2018 Quality Payment Program final rule (82 FR 53636), we encouraged stakeholders to consider electronically specifying their quality measures as eCQMs, to encourage clinicians and groups to move towards the utilization of electronic reporting. As noted in the CY 2019 PFS final rule (83 FR 59851), bonus points were created as transition policies which were not meant to continue through the life of the program. As a result, we will wait until there is further policy development under the finalized MVP framework (84 FR 62948) before proposing to remove our policy of assigning bonus points for end-to-end electronic reporting.

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 2023 MIPS payment year. Accordingly, we propose to revise § 414.1380(b)(1)(v)(B)(*1*)(*i*) to remove the years 2019 through 2022 and add in its place the years 2019 through 2023 to provide that for the 2019 through 2023 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.

(viii) 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 through 2022 payment years, for the purpose of improvement scoring, we will assume a quality performance category achievement percent score of 30 percent in the previous year 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 improvement scoring for the 2023 MIPS payment years and to revise § 414.1380(b)(1)(vi)(C)(*4*) to remove the phrase ''2020 through 2022 MIPS payment year'' and adding in its place the phrase ''2020 through 2023 MIPS payment years'' to indicate that for each MIPS payment year through 2023, we will assume a quality performance category achievement percent score of 30 percent in the previous year 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 2023 MIPS payment year, we would compare the MIPS eligible clinician's quality performance category achievement percent score for the 2021 MIPS performance period to an assumed quality performance category achievement percent score of 30 percent if the MIPS eligible clinician earned a quality performance score less than or equal to 30 percent for the 2020 MIPS performance period.

(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 and CY 2018 Quality Payment Program final rules, and the CY 2019 and CY 2020 PFS final rules (81 FR 77319 through 77329, 82 FR 53769 through 53785, 83 FR 59868 through 59878, 84 FR 63020 through 63031, respectively). In this rule, we propose to continue the complex patient bonus for the 2023 MIPS payment year, and we also propose to modify the complex patient bonus for the 2022 MIPS payment year as established in prior rulemaking due to the national public health emergency for COVID–19. In addition, we propose performance category redistribution policies for the 2023, 2024, and future MIPS payment years. These proposals are discussed in more detail in this section of the proposed rule.

(a) Complex Patient Bonus

(i) Background

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our MIPS scoring methodology. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on an individual's 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 under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act)) (Pub. L. 113–185, enacted on October 6, 2014) and, as appropriate, other information, including information collected before completion of such studies and recommendations. In the CY 2018 Quality Payment Program final rule, under the authority in section 1848(q)(1)(G) of the Act, we established at § 414.1380(c)(3) a complex patient bonus of up to 5 points to be added to the final score for the 2020 MIPS payment year (82 FR 53771 through 53776). In subsequent rulemaking, we continued the complex patient bonus at § 414.1380(c)(3) for the 2021 and 2022 MIPS payment years (83 FR 59870 and 84 FR 63023). We refer readers to these final rules for additional details on the background, statutory authority, policy

rationale, and calculation of the complex patient bonus.

We intended for this bonus to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while we continue to work with stakeholders on methods to account for patient risk factors. The overall goal, when considering a bonus for complex patients, is two-fold: (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. We used the term ''patient complexity'' to take into account a multitude of factors that describe and have an impact on patient health outcomes; such factors include the health status and medical conditions of patients, as well as social risk factors. We believe that as the number and intensity of these factors increase for a single patient, the patient may require more services, more clinician focus, and more resources in order to achieve health outcomes that are similar to those who have fewer factors. In developing the policy for the complex patient bonus, we assessed whether there was a MIPS performance discrepancy by patient complexity using two well-established indicators in the Medicare program: 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 (82 FR 53771 through 53776).

(ii) Complex Patient Bonus for the 2023 MIPS Payment Year

We intended the complex patient bonus as a short-term solution to address the impact patient complexity may have on MIPS scoring. However, we currently do not believe we have sufficient information available to develop a long-term solution to account for patient risk factors in MIPS that we could include in this proposed rule for the 2023 MIPS payment year. In the CY 2020 PFS proposed and final rules, we considered whether newly available data from the Quality Payment Program still supported the complex patient bonus at the final score level. More specifically, within the data analysis, we did not observe a consistent linear relationship for any reporting type or complexity measure, HCC risk score or dual eligible status (84 FR 40793 through 40795 and 84 FR 63021 through 63023). However, we only have a few years of data and believe that more recent data may bring different results than the findings we explained in detail in the CY 2020 PFS final rule. We refer readers to the CY 2020 PFS final rule for further details on the methodology and findings (84 FR 63021 through 63023).

As stated previously in this proposed rule, section 1848(q)(1)(G) of the Act requires us to take into account the relevant studies conducted under section 2(d) of the IMPACT Act and, as appropriate, other information, including information collected before completion of such studies and recommendations. ASPE completed its first report 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. We also noted, in the CY 2020 PFS final rule, that a second ASPE report on social risk factors within CMS value-based purchasing programs was expected. This second report was publicly released in June 2020 which builds on the analyses included in the initial report and provides additional insight for addressing risk factors in MIPS and other value-based payment programs. As we continue to review the analyses and findings of the report, we intend to consider its recommendations, along with any updated data that would become available, for future rulemaking. Hence, based on our data analysis from the CY 2020 PFS final rule (84 FR 63022) and the lack of currently available additional data sources, for the 2021 MIPS performance period/2023 MIPS payment year, we propose to continue the complex patient bonus as finalized for the 2020 MIPS performance period/2022 MIPS payment year and to revise § 414.1380(c)(3) accordingly. We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify longer term policy solutions that achieve the goals of attaining health equity for all beneficiaries, minimizing unintended consequences, and will propose modifications to the complex patient bonus in future rulemaking as appropriate.

(iii) Complex Patient Bonus for the 2022 MIPS Payment Year

In this section of the proposed rule, we discuss our proposal to modify the complex patient bonus for the 2022 MIPS payment year in response to the national public health emergency for COVID–19. In the CY 2020 PFS final rule, we continued the complex patient bonus for the 2020 performance period/2022 MIPS payment year (84 FR 63021 through 63023). More specifically, we continued to utilize our two established complexity indicators, HCC risk scores and dual eligible status, because we believed that they continued to account for the multitude of factors that describe and have an impact on patient health outcomes. Further, risk scores are based on a beneficiary's age and sex; whether the beneficiary is eligible for Medicaid, first qualified for Medicare on the basis of disability, or lives in an institution (usually a nursing home); and the beneficiary's diagnoses from the previous year.[93] Additionally, the HCC model also accounts for the number of conditions a beneficiary has, making an adjustment as the number of diseases or conditions increases, and includes additional diagnosis codes related to mental health and substance use disorders, and chronic kidney disease.[94] However, due to the national public health emergency for COVID–19 during performance period 2020, we believe we need to re-evaluate the previously established policy for the complex patient bonus for the 2022 MIPS payment year. We acknowledge that there are direct effects of COVID–19 for those patients who have the disease and indirect effects of COVID–19 for other patients, including increased complexity and barriers such as postponing care, accessing care in a different way (for example, via telecommunications), and disruptions to lab results and medications, which are not accounted for in our existing final score calculations using these complexity indicators. We realize that the first year of the novel virus may add complexity that we have not already captured via the complex patient bonus. This complexity includes patients who have gotten sick, as well as patients who may now have complications or other factors because of delayed care or disruptions to lab services or medications due to COVID–19. Government guidelines, such as the Center for Disease Control and Prevention guidance on ''Groups at Higher Risk for Severe Illness'', indicate that COVID–19 patients who are already

[93] CMS, Medicare Fee-For-Service Provider Utilization & Payment Data Physician and Other Supplier Public Use File: A Methodological Overview'': *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/Medicare-Physician-and-Other-Supplier-PUF-Methodology.pdf.*

[94] CMS, ''Report to Congress: Risk Adjustment in Medicare Advantage'': *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf.*

high-risk due to pre-existing medical conditions are at further risks of increased COVID–19 related hospitalizations and mortality.[95] Further, literature also indicates that those patients who are already high-risk due to social factors are also at further risk of serious illness related to COVID–19.[96]

Further, during this time, hospitals reported that medical systems delayed and canceled care, resulting in reduced utilization of healthcare services and a changing care delivery system.[97] Although access to Medicare telehealth services was expanded so that beneficiaries could receive a wider range of services from clinicians without having to travel to a healthcare facility,[98] this only partially filled the gap in services from the reduction in delivery of care, as not all specialties can utilize telehealth. We recognize the increased challenges of providing care to complex patients in the context of the national public health emergency for COVID–19. Patients with comorbidities (as measured by HCC risk score) and social risk (measured by dual eligible status) are disproportionately likely to be severely affected by COVID–19.[99] [100] [101] More specifically, findings from our recently released data reinforces previous findings by the Centers for Disease Control and Prevention that older Americans and those with chronic health conditions are at the highest risk for COVID–19. The data also show that COVID–19 has disproportionately impacted lower income adults, further confirming longstanding healthcare disparities in dual eligible populations.[102] Additionally, in light of the care delivery changes, we believe clinicians may see patients in 2020, with medical or social risk factors, whose health conditions may have been exacerbated due to delayed care. Patients with comorbidities and social risk are likely to suffer adverse outcomes due to delaying or not receiving care.[103] [104] [105] Given that the limited available literature and data on COVID–19 suggests that patients with social risk factors or underlying conditions have increased complexity, we believe that our existing complexity indicators, HCC risk score and dual eligibility, could serve as a proxy for capturing increased complexity due to the pandemic.

Currently, the complex patient bonus is worth up to 5 points. However, given the anticipated increase in complexity due to the national public health emergency for COVID–19, we propose at § 414.1380(c)(3)(iv) that for the CY 2020 performance period/2022 MIPS payment year, the complex patient bonus would be calculated pursuant to the existing formulas in §§ 414.1380(c)(3)(i) and (ii), and the resulting numerical value would then be multiplied by 2, but the complex patient bonus cannot exceed 10. The doubled numerical value (subject to the 10-point cap) would be added to the final score. Additionally, we propose to revise § 414.1380(c)(3)(iii) to state that the complex patient bonus cannot exceed 5.0 except as provided in § 414.1380(c)(3)(iv). Under this proposal, clinicians could receive up to 10 complex patient bonus points added to their final score. For example, if a MIPS eligible clinician were to receive 4 complex patient bonus points under the existing formulas, the MIPS eligible clinician would receive 8 complex patient bonus points (doubling the bonus points) under our proposal for the CY 2020 performance period/2022 MIPS payment year. In instances where clinicians would have received the maximum of 5 complex patient bonus points, they would receive the maximum of 10 complex patient bonus points under our proposal for the CY 2020 performance period/2022 MIPS payment year. To the extent that this proposed change constitutes a change to the MIPS scoring or payment methodology for the 2022 MIPS payment adjustment after the start of the 2020 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 account for increased patient complexity due to the national public health emergency for COVID–19. We believe it would be contrary to the public interest if MIPS scores do not adequately recognize this increased patient complexity that could not have been accounted for during the CY 2020 rulemaking. More specifically, currently we are unable to measure the magnitude of the direct and indirect effects of the COVID–19 pandemic on MIPS scores, and we remain concerned about potentially misidentifying poor performance with regard to the care delivered in CY 2020 due to the national PHE. Hence, we believe this approach of doubling the complex patient bonus recognizes the difficulty of managing complex patients during the pandemic and lowers the risk of inaccurately identifying a clinician as a ''poor performer'' when the underlying issue is caring for increasingly complex patients due to both direct and indirect effects of COVID–19.

Due to limited data available related to the pandemic, it is difficult to gauge whether our proposal would be artificially increasing MIPS final scores or not providing enough flexibility to clinicians to account for increased patient complexity during the CY 2020 performance period. Given the challenges we assume clinicians may be facing, we believe doubling the complex patient bonus would be a reasonable and operationally feasible approach. In developing our proposal, we considered several alternatives, including maintaining the complex patient bonus as it currently is (up to 5 points) as well as whether it would be appropriate to triple (up to 15 points) the complex patient bonus. However, due to the limited data available, we decided not to propose those options as we were concerned that an approach of tripling the bonus could artificially increase final scores and maintaining the current

[95] CDC, ''Groups at Higher Risk for Severe Illness'': *https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/groups-at-higher-risk.html.*

[96] Kaiser Family Foundation, ''Low-Income and Communities of Color at Higher Risk of Serious Illness if Infected with Coronavirus'': *https://www.kff.org/coronavirus-covid-19/issue-brief/low-income-and-communities-of-color-at-higher-risk-of-serious-illness-if-infected-with-coronavirus/.*

[97] American Hospital Association, ''Hospitals and Health Systems Face Unprecedented Financial Pressures Due to COVID–19'': *https://www.aha.org/guidesreports/2020-05-05-hospitals-and-health-systems-face-unprecedented-financial-pressures-due.*

[98] CMS, ''Medicare Telemedicine Healthcare Provider Fact Sheet'': *https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet.*

[99] The Journal of the American Medical Association Network, ''Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized with COVID–19 in the New York City Area'': *https://jamanetwork.com/journals/jama/fullarticle/2765184.*

[100] Morbidity and Mortality Weekly Report/CDC COVID–19 Response Team, ''Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019—United States, February 12–March28, 2020'': *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7119513/pdf/mm6913e2.pdf.*

[101] The Commonwealth Fund, ''Assessing Underlying State Conditions and Ramp-Up Challenges for the COVID–19 Response'': *https://www.commonwealthfund.org/publications/issue-briefs/2020/mar/assessing-underlying-state-conditions-and-ramp-challenges-covid.*

[102] CMS, ''Medicare COVID–19 Data Release Blog'': *https://www.cms.gov/blog/medicare-covid-19-data-release-blog.*

[103] Kaiser Health News, ''Nearly Half of American Delayed Medical Care Due to Pandemic'': *https://khn.org/news/nearly-half-of-americans-delayed-medical-care-due-to-pandemic/.*

[104] The British Medical Journal, ''Delayed presentation of acute ischemic strokes during the COVID–19 crisis'': *https://jnis.bmj.com/content/early/2020/05/27/neurintsurg-2020-016299.*

[105] U.S. National Library of Medicine National Institutes of Health, ''Hospitalization for Ambulatory-care-sensitive Conditions in Taiwan Following the SARS Outbreak: A Population-based Interrupted Time Series Study'': *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7135451/.*

bonus (up to 5 points) may not be sufficient to account for the increased patient complexity during the CY 2020 performance period. Additionally, we believe that by doubling the complex patient bonus, clinicians whose MIPS performance may be negatively affected by the challenges of caring for a complex patient population during a pandemic will be less likely to have the maximum negative adjustment due to circumstance beyond their control.

We also considered whether we should add a new indicator of patient complexity, such as establishing a threshold for the percentage of patients with COVID–19. We were concerned about this alternative approach for two reasons. First, we do not believe the effects of COVID–19 are limited to those patients who are experiencing the illness. Second, we are uncertain of the consistency of diagnosis coding for both patients who are experiencing the illness or who are being treated for the sequelae of the illness.

We request comments on our proposal, the alternatives we considered, and any other approaches to account for patient complexity during the public health emergency that commenters believe we should consider, as well as alternative data sources for patient complexity.

(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 through CY 2018 Quality Payment Program final rules, and CY 2019 through CY 2020 PFS final rules (81 FR 77320 through 77329, 82 FR 53779 through 53785, 83 FR 59870 through 59878, and 84 FR 62950 through 84 FR 62959, respectively). In section IV.A.3.c.(2)(a) of this proposed rule, we propose that the cost performance category would make up 20 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. In section IV.A.3.c.(1) of this proposed rule, we propose the quality performance category would thus make up 40 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. Table 44 summarizes the proposed weights for each performance category.

TABLE 44: Weights by MIPS Performance Category for the 2023, 2024, and Future MIPS Payment Years

Performance Category	2023 MIPS Payment Year (Proposed)	2024 and Future MIPS Payment Years (Proposed)
Quality	40%	30%
Cost	20%	30%
Improvement Activities	15%	15%
Promoting Interoperability	25%	25%

(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 with respect to 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 generally would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Under certain circumstances, however, a MIPS eligible clinician who fails to report could be eligible for an assigned scoring weight of zero percent and a redistribution of the performance category weights. For a description of our existing policies for reweighting performance categories, please refer to § 414.1380(c)(2) and the CY 2020 PFS final rule (84 FR 63023 through 63027).

(iii) Redistributing Performance Category Weights

In the CY 2017 through CY 2018 Quality Payment Program final rules, and CY 2019 through CY 2020 PFS final rules (81 FR 77325 through 77329, 82 FR 53783 through 53785, 83 FR 59876 through 59878, and 84 FR 63027 through 63031), and at § 414.1380(c)(2)(ii), we established policies for redistributing the weights of performance categories 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. For the 2020 MIPS performance period and 2022 MIPS payment year, we did not redistribute performance category weights to improvement activities, except for the scenario where the only two performance categories being scored are improvement activities and cost (84 FR 63028). Also for that year in scenarios when the cost performance category weight is redistributed while the Promoting Interoperability performance category weight is not, we redistributed a portion of the cost performance category weight to the Promoting Interoperability performance category, as well as to the quality performance category (84 FR 63027). As stated in CY 2020 PFS final rule, we continue to believe this redistribution policy is appropriate given our 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 on December 13, 2016) to ensure seamless but secure exchange of health information for clinicians and patients and emphasize the importance of interoperability without overwhelming the contribution of the quality performance category to the final score (84 FR 63027).

In section IV.A.3.c.(2)(a) of this proposed rule, we are proposing a weight for the cost performance category of 20 percent for the 2023 MIPS payment year. For the 2023 MIPS payment year, we propose similar redistribution policies as finalized for the 2022 MIPS payment year, with minor modifications to account for the cost performance category being 20 percent. Under this proposal, we would once again only redistribute weight to the cost performance category in cases when the cost and improvement activities performance categories are the only categories scored (each of these performance categories would be 50 percent in this scenario). We do not believe it is appropriate to redistribute more weight to the cost performance category, because cost would not yet be at the maximum weight specified by the statute (30 percent), and because clinicians still have relatively limited experience being scored on and receiving feedback on cost measures compared with quality measures. Our proposed redistribution policies for the 2023 MIPS payment year, which we propose to codify at § 414.1380(c)(2)(ii)(E), are included in Table 45.

TABLE 45: 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	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%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	80%	20%	0%	0%
-No Quality and no Improvement Activities	0%	20%	0%	80%

In section IV.A.3.c.(2)(a) of this proposed rule, we are proposing to weight the cost performance category at 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year, as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act. Given that 2024 would be the first year that cost would be set at the maximum weight prescribed by the statute, we do not believe it would be prudent to begin redistributing more weight to cost for the 2024 MIPS payment year, except in cases when only the cost and improvement activities performance categories are scored. 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 continue to believe that 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. We believe this helps 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). Therefore, we continue to believe that weighting the cost and improvement activities performance categories each at 50 percent would be an appropriate balance (84 FR 63027). As for the other reweighting scenarios, we plan to revisit our redistribution policies in future rulemaking and may consider redistributing more weight to the cost performance category after clinicians have more experience with cost being weighted at 30 percent. Our proposed redistribution policies for the 2024 MIPS payment year, which we propose to codify at § 414.1380(c)(2)(ii)(F), are included in Table 46.

TABLE 46: 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	55%	30%	15%	0%
-No Quality	0%	30%	15%	55%
-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	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	70%	30%	0%	0%
-No Quality and no Improvement Activities	0%	30%	0%	70%

e. MIPS Payment Adjustments

(1) Background

For our previously established policies regarding the final score hierarchy used to determine MIPS payment adjustments, we refer readers to the CY 2020 PFS final rule (84 FR 63031 through 63045), 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 modify these policies: (1) To reflect the discontinuation of the APM scoring standard and the addition of the APM Performance Pathway (APP), both as proposed in section IV.A.2.b.(5) of this proposed rule; (2) to set the performance threshold at 50 points for the 2023 MIPS payment year, instead of 60 points as previously finalized; and (3) to potentially revisit and revise the prior estimate of the performance threshold for the 2024 MIPS payment year.

(2) Final Score Hierarchy Used in Payment Adjustment Calculation

In some cases, a TIN/NPI could have more than one final score associated with it from a performance period, if the MIPS eligible clinician submitted multiple data sets. In the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), we established the following final score hierarchy that applies as displayed in Table 47 when more than one final score is associated with a TIN/NPI.

TABLE 47: Hierarchy for Final Score When More than One Final Score Is Associated with a TIN/NPI

Example	Final Score Used to Determine Payment Adjustments
TIN/NPI has more than one APM Entity final score.	The highest of the APM Entity final scores.
TIN/NPI has an APM Entity final score and also has an individual score.	APM Entity final score.
TIN/NPI has an APM Entity final score that is not a virtual group score and also has a group final score.	APM Entity final score.
TIN/NPI has an APM Entity final score and also has a virtual group score.	APM Entity final score.
TIN/NPI has a virtual group score and an individual final score.	Virtual group score.
TIN/NPI has a group final score and an individual final score, but no APM Entity final score and is not in a virtual group.	The highest of the group or individual final score.

With the proposed discontinuation of the APM scoring standard and addition of the APP in section IV.A.2.b.(5) of this proposed rule, we are proposing to modify the existing final score hierarchy beginning with the 2021 performance period/2023 MIPS payment year. In the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), we finalized prioritizing the APM Entity final score over any other score for a TIN/NPI by using the waiver authority for Innovation Center models under section 1115A(d)(1) of the Act and the Shared Savings Program waiver authority under section 1899(f) of the Act to waive section 1848(q)(5)(I)(i)(I) and (II) of the Act so that we could use

the APM Entity final score instead of the virtual group final score for a TIN/NPI. This hierarchy was intended to incentivize APM participation; however, we are proposing to terminate the APM scoring standard in section IV.A.2.b.(5) of this proposed rule, and while we believe it is important to still encourage movement to APMs, we do not believe that prioritizing an APM Entity score over other reported MIPS data would necessarily further our goal of increasing APM participation. The proposed modifications to the final score hierarchy would include MIPS eligible clinicians who are reporting through the APP, which is designed to provide a predictable and consistent MIPS reporting standard to reduce reporting burden and encourage continued APM participation. MIPS eligible clinicians who are already participating in APMs, and therefore, have different reporting obligations than MIPS eligible clinicians who have not already taken that step, can opt to report through the APP and receive an APP final score that may be used in the MIPS payment adjustment calculation. Beginning with the 2021 performance period/2023 MIPS payment year, if a TIN/NPI has a virtual group final score associated with it, we propose to use the virtual group final score to determine the MIPS payment adjustment. If a TIN/NPI does not have a virtual group final score associated with it, we propose to use the highest available final score associated with the TIN/NPI to determine the MIPS payment adjustment. This proposal is consistent with section 1848(q)(5)(I)(i) of the Act, which requires us to prioritize a virtual group final score over other final scores such as individual and group scores (82 FR 53786). We believe that using the highest final score available regardless of how the clinician chose to submit data to MIPS would benefit all MIPS eligible clinicians. For example, we have noticed some instances where prioritizing the APM Entity final score over other final scores has resulted in some clinicians not receiving the highest final score associated with their TIN/NPI, which may have the unintended consequence of moving clinicians away from APM participation. As we seek to move more clinicians into APMs, we believe using their highest score regardless of participation method would benefit all MIPS eligible clinicians. With the establishment of MVPs, we intend to revisit policies regarding the final score hierarchy used for payment adjustment determinations in future rulemaking.

Table 48 illustrates the proposed modified final score hierarchy.

TABLE 48: Hierarchy for Final Score When More than One Final Score Is Associated with a TIN/NPI

Scenario	Final Score Used to Determine Payment Adjustments
TIN/NPI has a virtual group final score, an APM Entity final score, an APP final score, a group final score, and/or an individual final score.	Virtual group final score.
TIN/NPI has an APM Entity final score, an APP final score, a group final score, and/or an individual final score, but is not in a virtual group.	The highest of the available final scores.

(3) 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.

In the CY 2020 PFS final rule (84 FR 63031 through 63037) at § 414.1405(b)(7) and § 414.1405(b)(8), we finalized the performance thresholds for the 2022 and 2023 MIPS payment years at 45 and 60 points, respectively, an increase of 15 points each year until the 2024 MIPS payment year, where we estimated the performance threshold would be 74.01 points (based on actual year 1 performance data and estimates for the third and fourth years) as depicted in Table 49. However, we also stated that we may revisit the performance threshold for the 2023 MIPS payment year in future rulemaking, if we receive additional data that changes our estimate of the performance threshold for the 2024 MIPS payment year.

TABLE 49: Performance Thresholds for the 2019 MIPS Payment Year through 2024 MIPS Payment Year

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year	2023 MIPS Payment Year	*Estimated 2024 MIPS Payment Year
	Year 1	Year 2	Year 3	Year 4	Year 5	*Year 6
Performance Threshold	3 points	15 points	30 points	45 points	60 points	*74.01 points
Difference in PT (year n minus (year n-1))	N/A	12 points	15 points	15 points	15 points	*14.01 points

** Prior estimate for the 2024 MIPS payment year (84 FR 63031-63037). This is the estimated performance threshold for year 6 based on modeling projections and is not the finalized performance threshold for year 6.*

We believe that we should reexamine the performance threshold for year 5 (2021 performance period/2023 MIPS payment year) due to the disruptions caused by the COVID–19 Public Health Emergency (PHE). We anticipate some clinicians not having sufficient measures and activities available to participate for the fourth year (2020 performance period/2022 MIPS payment year) and opting to use flexibilities provided for MIPS participation through the extreme and uncontrollable circumstances and hardship exception policies. Furthermore, in considering the effect of the PHE on clinicians, we believe that this is enough of a disruption to revisit the performance threshold for year 5, especially for clinicians who are unable to participate in year 4 due to the PHE.

Clinicians who are unable to participate in the fourth year of MIPS due to the COVID–19 PHE, would face an abrupt and large increase in the performance threshold if they return to full participation in the fifth year, lacking the opportunity to work to improve performance. We considered a range of performance threshold values for the fifth year, from 50 to 60 points, and believe that a performance threshold above 50 could be challenging for clinicians affected by the PHE, especially those with small practices. Preliminary analysis has shown that when applying a performance threshold of 50 points to the data we received from the 2021 regulatory impact analysis described in section VIII.F.16. of this proposed rule, around 31,376 TIN/NPIs (or 5.6 percent of MIPS eligible clinicians) would have payments adjustments that go from negative to positive with a performance threshold of 50 points compared to 60 points. For example, analysis shows with the previously finalized performance threshold of 60 points, 24.4 percent of engaged small practices would receive a negative payment adjustment, whereas with a performance threshold of 50 points, 18.8 percent of engaged small practices would receive a negative payment adjustment. In analyzing the range of performance threshold values and the impact on high performers (analysis detailed in section VIII.F.16.b. of this proposed rule), we saw that in setting the performance threshold at 50 points, the maximum payment adjustment is 6.89 percent whereas when setting the performance threshold at 60 points, the maximum payment adjustment is 7.36 percent, a decrease in percentage by 0.47. To continue to incentivize high performers, we are not revisiting the additional performance threshold, which is set at 85 points for year 5. We are proposing to set the performance threshold at 50 points for the 2023 MIPS payment year, instead of 60 points as previously finalized at § 414.1405(b)(8). The performance threshold would remain at 30 points in the third year, increase to 45 points in the fourth year, and increase to 50 points in the fifth year. The increase between the third and fifth year would total 20 points. Additionally, and as discussed in more detail below in our discussion of revising the prior estimate of the performance threshold for the 2024 MIPS payment year, we are open to considering alternatives for the performance threshold for the 2023 MIPS payment year. We request comments on the proposed performance threshold of 50 points, the range of values we considered, and any alternatives that commenters believe we should consider for the performance threshold for the 2023 MIPS payment year.

Table 50 depicts the performance threshold for the 2019 MIPS payment year through 2024 MIPS payment year, including the potential change to the performance threshold for the fifth year.

TABLE 50: Performance Thresholds for the 2019 MIPS Payment Year through 2024 MIPS Payment Year

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	*2022 MIPS Payment Year	**2023 MIPS Payment Year	2024 MIPS Payment Year
	Year 1	Year 2	Year 3	*Year 4	**Year 5	Year 6
Performance Threshold	3 points	15 points	30 points	*45 points *N/A for those who do not participate in year 4	**50 points	74.01 points
Difference in PT (year n minus (year n-1))	N/A	12 points	15 points	*15 points *N/A for those who do not participate in year 4	**5 points for those who participate in year 4 **20 points for those who do not participate in year 4	24.01 points

**Assumed affected payment year due to PHE resulting in measures not being available for reporting for MIPS participants.*

*** Proposed new performance threshold for the fifth year.*

At the time of publication of this proposed rule, we do not have actual performance scores and other data for year 3 (2019 performance period/2021 MIPS payment year). In the event this information becomes available with sufficient time to inform our policy decisions for the final rule, we propose to revisit and potentially revise in the final rule our prior estimate of 74.01 points for the performance threshold for the 2024 MIPS payment year. We anticipate that the actual performance scores for the 2019 performance period/2021 MIPS payment year may be different than the estimates that we published in our regulatory impact analysis estimate (84 FR 63033) because the COVID–19 PHE occurred during the data submission period. We also expect that the 2019 performance period data may be unusual due to the PHE occurring during the submission period. We request comments on our proposal to revisit and potentially revise our prior estimate of the performance threshold for year 6. In particular, we seek comment on what indicators (for example, if the distribution of scores is skewed due to the PHE), if any, should be used to evaluate whether or not the 2019 performance period data are appropriate to use to revise our prior estimate.

Lastly, in the event that we decide to revise our prior estimate of the performance threshold for the 2024 MIPS payment year (either higher or lower) in the final rule, we propose to consider the revised estimate when we decide on an appropriate numerical value for the performance threshold for the 2023 MIPS payment year. As an example, if we believe that the estimate for the 2024 MIPS payment year performance threshold should be higher than 74.01 (say 80 or 85 points), then we anticipate the performance threshold for the 2023 MIPS payment year would be higher than 50 (likely 55 points, 60 points) to reflect the change in the estimate. We seek to ensure a gradual and incremental transition to the estimated performance threshold for the 2024 MIPS payment year, and thus, we believe that we should take into account the revised estimate when determining the performance threshold for the 2023 MIPS payment year. We request comments on our proposal to consider the revised estimate for the 2024 MIPS payment year when we select a performance threshold for the 2023 MIPS payment year.

(4) Example of Adjustment Factors

Figure A provides an illustrative 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 our proposed policies for the 2023 MIPS payment year. In Figure A, the performance threshold is set at 50 points. The applicable percentage is 9 percent for the 2023 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 2023 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 12.5 points based on the proposed performance threshold of 50 points for the 2023 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 2023 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 is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 would be greater than 9 percent.

Only those MIPS eligible clinicians with a final score equal to 50 points (which is the proposed performance threshold) would receive a neutral MIPS payment adjustment. Because the performance threshold is 50 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.

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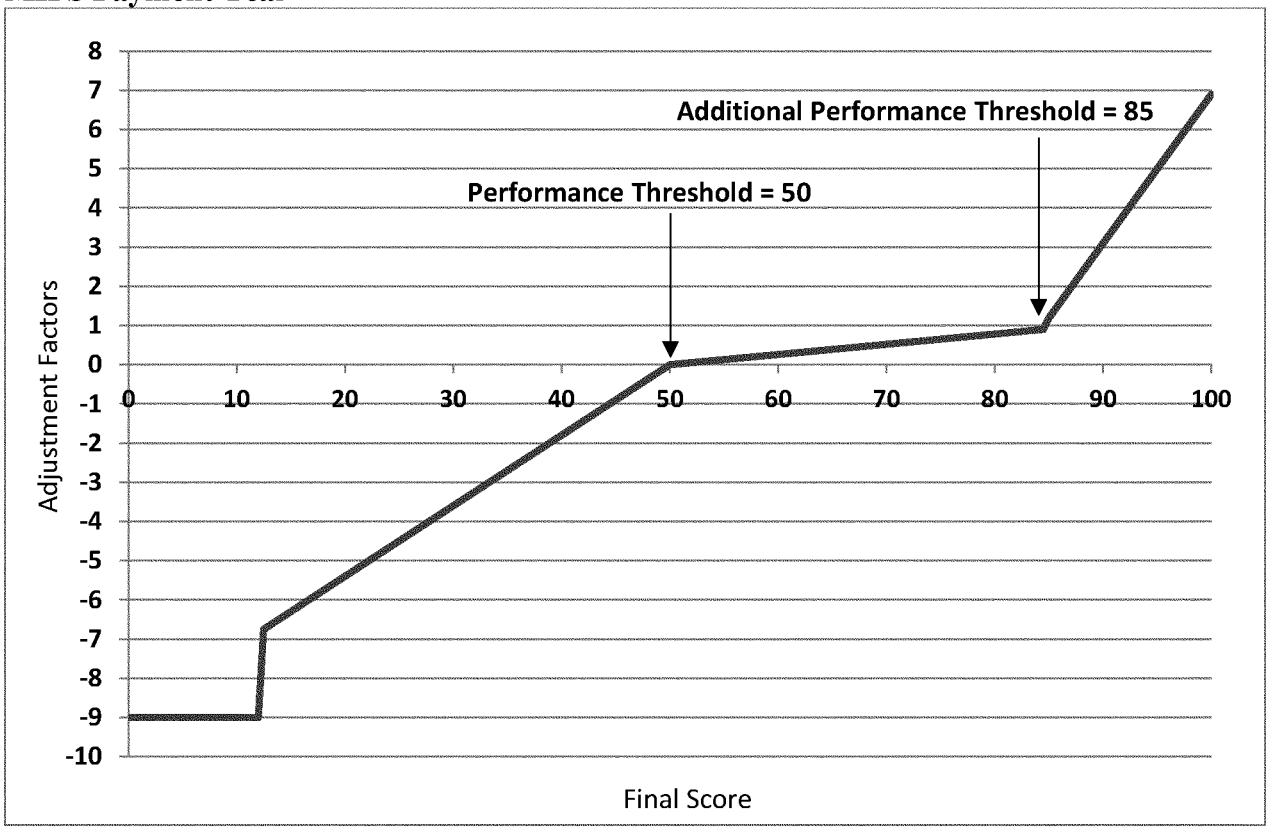
Figure A: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2023 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustartive. 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 inteded to ensure budget neutrality, but cannot be higher than 3.0. MIPS eligible clinicians with a final score of at least 85 points would also receive an additional adjustment factor for expectional performance. The additional adjustment factor starts at 0.5 percent, cannot exceed 10 percent, and is also mulitiplied by a scaling factor that is greather 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 illustartive as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 51 illustrates the changes in payment adjustment based on the final policies from the CY 2020 PFS final rule (84 FR 63031 through 63045) for the 2022 and 2023 MIPS payment year and the changes potentially modifying the performance threshold for the 2023 MIPS payment year discussed in this proposed rule, as well as the applicable percent required by section 1848(q)(6)(B) of the Act.

TABLE 51: Illustration of Point System and Associated Adjustments Comparison between the Finalized 2022 MIPS Payment Year, the finalized 2023 MIPS Payment Year, and the Proposed Policies for the 2023 MIPS Payment Year

2022 MIPS Payment Year		Previously Finalized 2023 MIPS Payment Year		New Proposed 2023 MIPS Payment Year	
Final Score Points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-11.25	Negative 9%	0.0-15.0	Negative 9%	0.0-12.5	Negative 9%
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	12.51-49.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
45.0	0% adjustment	60.0	0% adjustment	50.0	0% adjustment
45.01-84.99.	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 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	50.01-84.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 50.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality
85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final 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	85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final 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	85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final scores from 50.00 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

2022 MIPS Payment Year		Previously Finalized 2023 MIPS Payment Year		New Proposed 2023 MIPS Payment Year	
Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment	Final Score Points	MIPS Adjustment
	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.		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		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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f. Review and Correction of MIPS Final Score

(1) Feedback and Information To Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are at a minimum required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called the Promoting Interoperability) performance categories.

On July 1, 2018, we provided the first performance feedback for the Quality Payment Program. The second performance feedback was provided on July 1, 2019. However, for this year due to the Public Health Emergency (PHE) and COVID–19, we wish to inform stakeholders that we may provide performance feedback after July 1, 2020 (that is, performance feedback based on data submitted for the performance period in 2019). Although we aim to provide performance feedback on or around July 1 of each year, it is possible that the release date could be later than July 1 depending on the circumstances. At this time, we estimate that we will provide performance feedback in late July or early August, although this timeframe may be subject to change. Please refer to *qpp.cms.gov* for more information.

g. Third Party Intermediaries

We refer readers to §§ 414.1305 and 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), and the May 8th COVID–19 IFC–2 (85 FR 27594 through 27595) for our previously established policies regarding third party intermediaries.

In this proposed rule, we propose to make several changes to requirements for (1) third party intermediaries generally, (2) QCDRs, (3) qualified registries, and (4) remedial action.

(1) Generally

(a) 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 (83 FR 60088) and CY 2020 PFS final rule (84 FR 63049 through 63052) at § 414.1400(a)(2) for our current policy regarding the types of MIPS data third party intermediaries may submit. Through this proposed rule, we intend on clarifying our requirements of QCDRs, qualified registries, and health IT vendors with regards to submitting data for purposes of the MIPS program through revisions to our regulation codified at § 414.1400(a)(2), particularly for those third party intermediaries who are interested in supporting MVPs in the future. Therefore we propose to revise § 414.1400(a)(2) as follows:

Except as provided under § 414.1400(a)(2)(ii), QCDRs, qualified registries, and health IT vendors must be able to submit data for all of the following MIPS performance categories:

- Quality, except:

++ The CAHPS for MIPS survey; and

++ For qualified registries and health IT vendors, QCDR measures;

- Improvement activities; and
- Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may 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).

Health IT vendors that do not support MVPs, must be able to submit data for at least one of the MIPS performance categories described above. We request comments on these proposals.

(i) Reporting MVPs Through Third Party Intermediaries

We refer readers to section IV.A.3.a. of this proposed rule where we discuss reporting MVPs through third party intermediaries and our proposal that QCDRs, qualified registries, and health IT vendors who support the Quality, Promoting Interoperability, and Improvement Activities performance categories may also support the reporting of MVPs.

(ii) Reporting APM Performance Pathway (APP) Through Third Party Intermediaries

We refer readers to section IV.A.3.b. of this proposed rule where we discuss beginning with the CY MIPS 2023 payment year, MIPS eligible clinicians scored under the APP would be scored on the quality measure set finalized for that MIPS performance period. Three quality measures (Quality ID# 001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (≤9%), Quality ID#: 134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan, and Quality ID# 236: Controlling High Blood Pressure) are proposed to be reported using the MIPS CQM and eCQM collection types.

(b) Approval Criteria for Third Party Intermediaries

(i) Background

We refer readers to § 414.1400(a)(4), the CY 2019 PFS final rule (83 FR 59894 through 59895, 60088), the CY 2020 PFS final rule (84 FR 63052 through 63053), and the May 8th COVID–19 IFC–2 (85 FR 27594 through 27595) for previously finalized policies related to the approval criteria for third party intermediaries.

(ii) Proposed New Approval Considerations—Past Performance and Conduct

During past years of the MIPS program we have encountered third party intermediaries failing to meet program requirements and engaging in other conduct that could harm the integrity of the MIPS program. Some examples of third party intermediaries failing to meet program requirements include, but are not limited to: Failing to meet requirements to submit data for a performance category; failing to provide services throughout the entire performance period and applicable data submission period; and providing data that is not true, accurate, or complete. Additionally, we have also encountered third party intermediaries who have provided inaccurate information to the clinicians and groups they support regarding the obligation to submit data to CMS that are true, accurate and complete. For example, we are aware of third party intermediaries offering services and tools to eligible clinicians that encourage the selection of misrepresentative data, commonly referred to as ''cherry-picking,'' to maximize scores.

In preparation for future years of the program, we believe it is important to disapprove third party intermediaries that have demonstrated their failure to comply with program requirements or have provided inaccurate information regarding MIPS program requirements to clinicians. We are concerned with the potential adverse program effect of this conduct, such as delayed and erratic reporting if third party intermediaries fail to support MIPS reporting for the entire performance period and reporting period, and the possibility of inaccurate data submissions. As a result, we believe it is important to consider these factors when making determination regarding whether to approve a third party intermediary for future participation in the MIPS program.

Therefore, we are proposing to amend the current § 414.1400(a)(4) to propose a new paragraph at § 414.1400(a)(4)(ii):

The determination of whether to approve an entity as a third party intermediary for a MIPS performance period may take into account: (1) Whether the entity failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary; and (2) whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician. We intend on utilizing all available information to make these approval determinations, including without limitation, information collected through compliance audits under our existing audit authority as described in § 414.1400(g). Third party intermediaries may be selected during the performance period to be audited for a given requirement. As a part of our outreach to a selected third party intermediary, we intend on providing additional direction with regards to the timeline and information needed for the audit. The results of the audit will be reviewed to inform future approval of a third party intermediary, and if remedial action is warranted, we will utilize our existing authority as described in § 414.1400(f). We believe use of this information in approval determinations will help reduce the risk of third party intermediaries that are unreliable, thereby avoiding a possible increase in burden to clinicians who may inadvertently select an unreliable third party intermediary for purposes of reporting for the MIPS program. We request comments on our proposals; specifically, we request comments on whether there are other factors that should inform our considerations when approving third party intermediaries.

(iii) Third Party Intermediary Training and Support

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77374) and (81 FR 77384 through 77386), we established our expectation that QCDRs and qualified registries perform certain functions related to data submission. One of those expectations is participation in ongoing support conference calls hosted by CMS (approximately one call per month) and an in-person kick-off meeting (if held) at our headquarters in Baltimore, MD. (81 FR 77368) and (81 FR 77384). The purpose of these meetings is to provide approved QCDRs program updates from subject matter experts who work across the Quality Payment Program. At these meetings, CMS subject matter experts and our contractors provide approved QCDRs and qualified registries with updates, answer questions, and provide technological demonstrations. In light of the PHE for the COVID–19 pandemic and consistent with the goal of infection control, we have reevaluated our expectations and have decided to adopt a policy allowing for flexibility moving forward. With the health and safety of our stakeholders in mind, we believe virtual meetings would be sufficient when in-person meetings are not possible.

In the CY 2017 Quality Payment Program final rule (81 FR 77377 through 77382), we stated our expectations for health IT vendors that serve as third party intermediaries by obtaining data from the CEHRT of a MIPS eligible clinician and submitting such data to CMS for participation in MIPS. For further discussion of CEHRT we refer readers to sections III.M.3 and

IV.A.3.g.(1)(iv) of this proposed rule. Because the submission requirements and policies that may be added or modified from year to year have the potential to alter expectations for all third party intermediaries, we believe that mandatory meetings and training calls would also be appropriate for health IT vendors that will serve as third party intermediaries. Hosting training calls for health IT vendors would give us an opportunity to provide a review of requirements, answer questions, and explain updates to the annual submission process and other policies as applicable. Thus, we are proposing for the requirement that third party intermediaries participate in an annual meeting and training calls as deemed necessary by CMS include those third party intermediaries that are health IT vendors. We are soliciting comments on the best method to reach health IT vendors so that we can invite them to required meetings and share additional information. We are considering listserv communications through the QPP listserv but would welcome suggestions for other communication mechanisms.

We previously finalized the CMS-approved survey vendor approval criteria in § 414.1400(e) as discussed in the CY 2018 PFS final rule (83 FR 59907 through 59908). Among the approval criteria, § 414.1400(e)(3) established the requirement that the entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors. We continue to believe these previously finalized requirements are of importance to CMS-approved survey vendors, such as CAHPS for MIPS vendors. In addition, because the submission requirements and policies that may be added or modified from year to year have the potential to alter expectations for all third party intermediaries, we believe that the proposed requirement that third parties intermediaries participate in an annual meeting and training calls as deemed necessary by CMS should also be applicable to CMS-approved survey vendors.

In summary, we believe making support calls and trainings mandatory for all third-party intermediaries will provide an abundance of value to all approved third party intermediaries themselves, as well as to the MIPS program and the clinicians who rely on third party intermediaries to make complete, accurate, usable and timely data on their behalf. We believe uniformly codifying this language is appropriate to hold all third party intermediaries accountable for the training and support. Therefore, we propose to codify at § 414.1400(a)(4)(iii) that beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS. We affirm that, in addition to the obligations under this proposal, CMS-approved survey vendors must also continue to meet the requirements at § 414.1400(e)(3).

(iv) Future Safeguards for All Third Party Intermediaries

We understand our obligation to ensure the integrity of the MIPS program and we continue to assess opportunities to strengthen program safeguards. Certain safeguards apply to all third party intermediaries, including those described in § 414.1400(a), (f), and (g). As discussed in this proposed rule, we are proposing additional program safeguards in regard to data validation audit and targeted audit requirements that would apply specifically to QCDRs and qualified registries, respectively found in section IV.A.3.g.(2)(a) and section IV.A.3.g.(3) of this proposed rule. These proposals would require QCDRs and qualified registries to conduct validation on data prior to the data being submitted to CMS for purposes of the MIPS program. We have limited these proposals to QCDRs and qualified registries at this time, but as described further below we solicit feedback on expanding these requirements to all third party intermediaries through future rulemaking.

The Office of the National Coordinator for Health Information Technology's (ONC) Health IT Certification Program provides for the certification of certain health IT. The requirements for ONC certification are based on standards, implementation specifications, and certification criteria adopted by the Secretary. The Quality Payment Program has adopted a definition of certified electronic health record technology (CEHRT) at § 414.1305.

For discussion of proposed revisions to the CEHRT definition adopted for the Quality Payment Program we refer readers to section III.M. of this proposed rule.

It is important to note that a health IT vendor which acts as a third party intermediary for purposes of the MIPS program may or may not be the same entity as a health IT developer which certifies health IT products as part of the certification program. While health IT developers may act as third party intermediaries for their customers, other service providers who do not develop health IT products may also assist MIPS eligible clinicians by submitting data obtained from CEHRT on their behalf and thereby function as a health IT vendor for purposes of the MIPS program. Furthermore, the entities that are not health IT developers must only submit data on behalf of eligible clinicians that has already been captured and calculated using the functions of CEHRT. Unlike QCDRs and Qualified Registries, third party intermediaries that are health IT vendors may or may not also possess expertise related to quality improvement and analysis/validation of clinical quality data, and we do not currently require these organizations to attest that they possess these capabilities.

We are increasingly aware of data integrity issues that have impacted data submitted by health IT vendors that obtain data from MIPS eligible clinician's CEHRT and serve as a third party intermediaries to submit this data on behalf of MIPS eligible clinicians. We are aware of instances in which health IT vendors have submitted data that are inaccurate and unusable. These data issues may result in improper payments or otherwise undercut the integrity of the MIPS program. In some instances, data issues caused by health IT vendors may have downstream negative impacts to the clinicians whose data the health IT vendor is submitting, such as negative payment adjustments and inaccurate data publically posted on the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website).

Although we are not proposing to add data validation requirements for health IT vendors at this time, we are considering ways to impose such requirements in the future. We are soliciting comment on whether we should impose data validation requirements on health IT vendors as part of the third party intermediary approval process and if so, how the data validation requirements for health IT vendors should differ, if at all, from those proposed for QCDRs and Qualified Registries. We believe that potentially requiring health IT vendors to validate the data they submit to us for purposes of the MIPS program will lead to the submission of data that can be considered more reliable and accurate. Therefore, we seek comment on the future application of such requirements on health IT vendors and if there are factors unique to health IT vendors that should be considered when developing

such a policy. For instance, we are seeking to further understand where data quality issues may arise in data submitted by health IT vendors on behalf of MIPS eligible clinicians. We are also seeking comment on whether health IT vendors currently submitting data on behalf of MIPS eligible clinicians possess the capabilities to engage in the data validation processes we are proposing for QCDRs and Qualified Registries. We are also seeking comment regarding the burden on health IT vendors of adopting the data validation requirements as proposed for QCDRs and qualified registries and whether the imposition of these requirements on health IT vendors would discourage health IT vendors from serving as third party intermediaries. We also would welcome input as to whether alternative requirements for health IT vendors would impose a less burden on these third parties' intermediaries while still ensuring that the data submitted is accurate and complete. Finally, we are interested in how any future data validation processes should impact certification under the ONC Health IT Certification Program for health IT developers who also serve as a health IT vendor third party intermediary for the purposes of MIPS.

For CMS-approved survey vendors, such as CAHPS for MIPS vendors, we are also not proposing any new data validation requirements at this time. In the CY 2018 PFS final rule (83 FR 59907 through 59908) we previously finalized requirements at § 414.1400(e) that address the validity of data submitted to CMS for CMS-approved survey vendors. Specifically, we previously finalized at § 414.1400(e)(4) that as a condition of approval the entity must have submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts. We believe this previously finalized requirement at § 414.1400(e) is sufficient to address potential concerns about the accuracy of data submitted by survey vendors; however, we solicit feedback on whether the audit requirements in this proposal should be expanded to include survey vendors.

(2) Qualified Clinical Data Registries (QCDRs)

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 (ATRA) (Pub. L. 112–240, enacted January 2, 2013), 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), the CY 2020 PFS final rule (84 FR 63053 through 63058), May 8th COVID–19 IFC–2 (85 FR 27594 through 27595) and § 414.1400(a)(4) through (b) for previously finalized policies about third party intermediaries generally and QCDRs specifically. In this proposed rule, we propose a technical update to § 414.1400(b) title to rename it from ''QCDR approval criteria'' to ''QCDRs'', to better align the title with the content of the regulation. In addition, we are proposing policies related to QCDR: (1) Data validation audits and targeted audits; and (2) measure requirements. These are discussed in detail below.

(a) Data Validation Audit and Targeted Audit Requirements

In the CY 2017 Quality Payment Program final rule, we discussed our expectation that QCDRs and qualified registries would conduct validation on the data they intend on submitting for the MIPS performance period (81 FR 77366 through 77367) and provide the results of the data validation to CMS in the form of a data validation execution report by May 31st of the year following the performance period. Our intention was to establish our expectation that QCDRs would establish a process to assess whether the data are true, accurate, and complete prior to submitting them to CMS for purposes of the MIPS program. We believe it is important to establish a requirement that QCDRs conduct data validation to ensure they are actively monitoring the data they submit to CMS for purposes of a pay-for-performance program. In instances where a QCDR discovers data are inaccurate or incomplete, the entity must correct the issue prior to submitting the data to CMS in order to provide accurate certification in accordance with § 414.1400(a)(5). A QCDR that submits a false certification submits data that is inaccurate, unusable or otherwise compromised to CMS for purposes of the MIPS program may be subject to remedial action or termination under § 414.1400(f). We believe requiring QCDRs to validate the accuracy of the data they are submitting is an important safeguard to promote accurate payments under the MIPS program. Therefore, in this proposed rule, we propose to codify at § 414.1400(b)(2)(iv) and (v) requirements beginning with the 2023 MIPS payment year as condition of approval each QCDR must conduct annual data validation audits and if one or more deficiencies or data errors are identified the QCDR must also conduct targeted audits. We also propose specific obligations for those audits as discussed below.

- We propose to codify at § 414.1400(b)(2)(iv)(A), that the QCDR must conduct data validation for the payment year prior to submitting any data for that payment year to CMS for purposes of the MIPS program. We believe it is important for QCDRs to conduct validation audits to identify and fix concerns regarding data accuracy prior to submitting data to us, including potential issues related to data aggregation and calculation. Conducting the data validation prior to data submission will lead to data being more reliable and promote compliance with the requirement of data being true, accurate, and complete. In the CY 2017 Quality Payment Program final rule, we described this auditing using the term randomized audit (81 FR 77366). In this proposed rule, we are proposing instead to refer to this audit as the data validation audit in an effort to be abundantly clear regarding our expectations that the QCDR will purposefully construct a sample and conduct an audit that complies with specific regulatory requirements and also to distinguish these audits from the targeted audits discussed below and proposed at § 414.1400(b)(2)(v).
- We propose to codify at § 414.1400(b)(2)(iv)(B), the QCDR must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories. We believe that it is important that data validation be done across all performance categories for which the QCDR submits data since QCDRs must attest that data submitted to CMS is true, accurate, and complete and data for each of these performance categories can influence score calculation and payment adjustments.
- We propose to codify at § 414.1400(b)(2)(iv)(C), that the QCDR must conduct data validation on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants. We believe it is important for the data submitted to CMS be accurate for all clinicians and groups for which the QCDR intends on submitting data to the MIPS program, regardless of whether they are required to participate, have opted in, or have chosen to voluntarily participate. Therefore, we propose to require that

the data validation audits should account for all types of submitters that are utilizing the QCDR to submit data to CMS for purposes of the MIPS program. We note the importance of validating data for all submitter types regardless of its use for payment or public reporting. Even clinicians who voluntarily report to MIPS and whose data are not used for payment purposes could have their data publically posted on the Physician Compare website. We believe all data the QCDR submits, regardless of its use for payment or public reporting, should be true, accurate, and complete.

• We propose to codify at § 414.1400(b)(2)(iv)(D) that the QCDR must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed. If the data a QCDR intends to submit to CMS for purposes with the MIPS program are to demonstrate that a clinician did a particular clinical activity or achieved a particular clinical outcome, we believe meaningful validation of such data requires the QCDR to use clinical documentation to confirm that the activity occurred or was performed.

• We propose to codify at § 414.1400(b)(2)(iv)(E) that the QCDR shall conduct each data validation audit using a sampling methodology that meets the following requirements:

++ Uses a sample size of at least 3 percent of the TIN/NPIs for which the QCDR will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the QCDR must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the QCDR may use a sample size of 50 TIN/NPIs.

++ Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

We believe the aforementioned sampling methodology is appropriate for multiple reasons. First, the sampling methodology criteria are consistent with the methodology established under the legacy Physician Quality Reporting System (PQRS) program and as described in the CY 2017 Quality Payment Program final rule (81 FR 77366 through 77367). As this methodology has been used for many years under the legacy program, we believe stakeholders are well versed in executing data validation audits using this sampling methodology. Second, the proposed methodology accounts for QCDRs and qualified registries of varying sizes. Data validation requires a level of effort on the part of the QCDR to execute a data validation plan, identify a sample, and collect information for purposes of chart review; therefore, we are cognizant that requiring a larger sample size would create additional burden on QCDRs and clinicians to account for a larger volume in TIN/NPIs and medical records for review.

• We propose to codify at § 414.1400(b)(2)(iv)(F) that each QCDR data validation audit must include the following:

++ Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant. We believe that it is important for the QCDR to track the eligibility status of each clinician and group that wishes to use a third party intermediary to report, because accurate information regarding eligibility is important to ensuring payment adjustments are properly applied. Furthermore, verification of eligibility status is consistent with the requirement for QCDRs to track opt-in participants, as described at § 414.1400(a)(4)(iv) and in the context of clinicians who voluntarily report to MIPS helps ensure the accuracy of data publically posted on the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website).

++ Verification of the accuracy of Tax Identification Numbers (TINs) or National Provider Identifiers (NPIs). Correct TINs and NPIs are critical to ensure data submitted by the QCDR are attributed to the correct clinicians and groups. Inaccurate NPIs or TINs may lead to inadvertent downstream impacts to the way clinicians and groups are scored, and assigned a payment adjustment.

++ Calculation of reporting and performance rates (for example, formulas included in the quality measure specifications). QCDRs must follow the measure specifications when calculating reporting and performance rates. Calculations that deviate the formulas included in the quality measure specifications undercut efforts to ensure data are consistent, reliable, and have been calculated in a uniform manner.

++ Verification that only MIPS quality measures and QCDR measures that are relevant to the performance period will be utilized for MIPS submission. Measure specifications for the MIPS quality measures and QCDR measures go through maintenance on an annual basis. Use of outdated measure specifications would likely result in the QCDR submitting inaccurate or compromised data for the clinicians and groups they support. While not all measures go through substantive changes on an annual basis, there are changes to codes that do occur annually that should be accounted for when programing measures. Therefore, we believe it is important that QCDRs are utilizing the most current version of the measure specification, relevant to the performance period in which they are participating.

• We propose to codify at § 414.1400(b)(2)(iv)(G), that in a form and manner and by a deadline specified by CMS, the QCDR must report the results of each data validation audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. We believe it is important that the results of the data validation be shared with us in order for us to understand the types of issues the QCDRs have encountered and what resolutions were executed to fix the issues. The information provided will help us track frequently occurring issues which may be identified as an area to provide further education. It is our belief that the report will be largely comprised of issues that were identified and resolved. However, if an issue has been identified and could not be resolved, we would want to understand what the issue is and why it could not be resolved. We emphasize that all data submitted to CMS by a QCDR on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge as described in § 414.1400(a)(5). If a QCDR submits a false certification or data that are data that are inaccurate, unusable, or otherwise compromised, the QCDR may be subject to remedial action or termination as described at § 414.1400(f).

• We propose to codify at § 414.1400(b)(2)(v)(A), that if a data validation audit under § 414.1400(b)(2)(iv) identifies one or more deficiency or data error, the QCDR must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year. We believe targeted audits are important to further evaluate the impact of deficiencies or data errors to the cohort of clinicians and groups that the QCDR intends to submit data for, and for QCDRs to determine the

reason the deficiency or data error occurred.

• We propose to codify at § 414.1400(b)(2)(v)(B), that the QCDR must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year. To promote the accuracy of the data submitted to the MIPS program for the payment year and to reduce the risk that the agency initiates payment calculations in reliance on inaccurate data, it is important for the QCDR to conduct required targeted audits and correct any deficiencies and data errors identified through those audits prior to submitting the data to CMS.

• We propose to codify at § 414.1400(b)(2)(v)(C), the QCDR must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (b)(2)(iv)(E). The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

We believe the sampling methodology we are proposing for data validation audits is equally appropriate for the conduct of targeted audits. We believe that adopting the same methodology for both audit types would be less burdensome on QCDRs than requiring these entities to apply a separate sampling methodology for their targeted audits. Provided that data in the sample for the targeted audit does not overlap with the data that was reviewed in the data validation audit, we believe the targeted audit would provide the QCDR with a reasonable perspective into impact and root cause of deficiencies and data errors across the data to be submitted without imposing the burden that would result from maintaining a separate sampling methodology for targeted audits.

• We propose to codify at § 414.1400(b)(2)(v)(D), in a form and manner and by a deadline specified by CMS, the QCDR must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected. As is the case with the results of data validation audits, we believe it is important that the results of the targeted audits be shared with us in order for us to understand the types of issues the QCDRs have encountered and what resolutions were executed to fix the issues. The information provided will help us track frequently occurring issues which may be identified as an area to provide further education.

We request comments on the aforementioned proposals, including whether stakeholders are concerned with implementing these policies for the 2023 MIPS payment year, and if so, what barriers do they believe they would face in implementing these requirements.

(b) QCDR Measures

We refer readers to § 414.1400(b), 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), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), and the May 8th COVID–19 IFC–2 (85 FR 27594 through 27595) for where we previously finalized standards and criteria for QCDR measures. In this proposed rule, we are proposing modifications to previously finalized QCDR measure requirements. While we understand the level of time and work needed to meet these requirements, we would not be grandfathering in previously approved QCDR measures.

(i) QCDR Measure Considerations and Requirements for Approval or Rejection

We refer readers to § 414.1400(b)(3), the CY 2020 PFS final rule (84 FR 63059 through 63073) for our previously finalized policies related to the 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 in this proposed rule will help to refocus measures to those most meaningful to a clinician's scope of practice.

In this proposed rule, we are proposing to modify a few QCDR measure requirements: Measures in MVPs; measure testing; duplicative QCDR measures; and collection of data. These proposals are discussed in detail below.

(A) QCDR Measures in MVPs

We refer readers to section IV.A.3.a. of this proposed rule, where we discuss the inclusion of QCDR measures in MVPs, at CMS discretion, beginning with the 2024 MIPS payment year. While we acknowledge and appreciate the level of innovation that QCDRs have put forward as they have developed and implemented QCDR measures, we note the differences between the QCDR measures utilized in the existing MIPS reporting method versus that of MVP reporting. In the current MIPS program, clinicians and groups may select to report on measures from a large library of what is available through the MIPS quality measure inventory and that of the QCDR measures available, if they choose to report through a QCDR. In our gradual transition to MVPs, we move to subsets of measures and activities, where clinicians may have a more focused selection of items to report on.

For that reason, it is important that the measures included in an MVP are reliable, feasible, and valid as to not inadvertently cause a clinician or group an issue with submission, calculation, and scoring of a given measure. We refer readers to our discussion below about measure testing requirements for QCDR measures in MVPs.

(B) Measure Testing Requirements

In the CMS Blueprint,[106] measure testing enables a measure developer to assess the suitability of the quality measure's technical specifications and acquire empirical evidence to help assess the strengths and weaknesses of a measure with respect to the NQF Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement. Information gathered through measure testing is part of full measure development, and this information can be used in conjunction with expert judgment to evaluate a measure. For Blueprint purposes, measure testing refers to testing quality measures, including the components of the quality measures, such as the data elements, the instruments, and the performance score.

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 criterion for a QCDR measure to be considered for MIPS in future rulemaking (83 FR 59901 through 59902). After consideration of the previous 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 finalized a requirement to require all QCDR measures to be fully developed and tested, with complete testing results at the clinician level, beginning with the CY 2023 payment year in the CY 2020 PFS final rule (84 FR 40816). Subsequently, due to the

[106] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

PHE for the COVID–19 pandemic, we delayed this requirement by 1 year in the May 8th COVID–19 IFC–2 (85 FR 27594 through 27595). In the May 8th COVID–19 IFC–2 (85 FR 27594 through 27595), we finalized at § 414.1400(b)(3)(v)(C) beginning with the CY 2024 MIPS payment year, 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. However, based on subsequent stakeholder feedback on the level of burden, the limited amount of time, and costs associated with measure testing after the CY 2020 PFS final rule published, we are proposing to both further modify our QCDR measure testing policy generally and add testing policies for QCDR measures that are being considered for inclusion in MVPs.

We continue to believe that reliable, valid measures with robust testing with empirical data should be used in quality evaluation and payment programs. However, we want to balance those interests with stakeholders' concerns. Therefore, we propose a gradual approach to have fully tested QCDR measures within the MIPS program. We want to emphasize that we still believe that all QCDR measures should be fully tested, particularly as we rely on the data from these measures to score clinicians which impact their final score and associated MIPS payment adjustments, and as we seek to utilize QCDR measures in MVPs, as described in section IV.A.3.a and below of this proposed rule. We propose at § 414.1400(b)(3)(v)(C)(1) that, generally, to be approved for the 2024 MIPS payment year, a QCDR measure must be face valid. To be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved. Therefore, we propose to revise § 414.1400(b)(3)(v)(C) to account for an incremental approach to require fully tested QCDR measures. We discuss requirements for QCDR measures considered for inclusion in an MVP separately. This is discussed in more detail below.

(i) Proposed Requirements for Existing Measures

We propose that QCDR measures that were previously approved for the CY 2022 MIPS payment year, would be required to, at a minimum, be face valid prior to being self-nominated for the CY 2024 MIPS payment year. Face validity is defined in the CMS Measures Blueprint [107] as the following: The extent to which a test appears to cover the concept it purports to measure ''at face value.'' It is a subjective assessment by experts of whether the measure reflects the quality of care (for example, the utilization of a current clinical guideline to frame the measure, such as using the blood pressure guideline of <140/90 is a marker of quality).

In addition, we propose that these measures, which were approved for the preceding MIPS performance year with face validity (that is, CY 2024 MIPS payment year), would be required to be fully tested prior to being self-nominated for any subsequent performance periods (that is, CY 2025 MIPS payment year and beyond) in order to be considered for inclusion in the MIPS program.

In the CY 2019 PFS final rule, we referred readers to 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*) for a definition of ''fully developed with completed testing results at the clinician level'' (84 FR 40817). Our Blueprint discusses both alpha and beta testing (Blueprint 15.0 September 2019 Page 207–208). To avoid any potential confusion, we are clarifying in this proposed rule that for purposes of QCDR measures, we would expect QCDR measures to complete beta testing to be considered fully tested. Beta testing is defined in the CMS Measures Blueprint [108] as the following: Beta testing (that is, field testing) generally occurs after initial technical specifications have been developed and is usually larger in scope than alpha testing. In addition to gathering further information about feasibility, beta tests serve as the primary means to assess scientific acceptability and usability of a measure. For example, beta testing allows for an enhanced evaluation of a measure's importance, including evaluation of performance thresholds, disparities analysis, and outcome variation. It helps in looking for opportunities for improvement in the population, which aids in measuring the QCDR measure's importance for reasons that include evidence collection to measure variability among comparison groups, to demonstrate the measure is not topped-out where most groups achieve similarly high performance levels approaching the measure's maximum possible value. We refer readers to the CMS Blueprint for the CMS Measures Management System at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf* for additional details regarding beta testing.

(ii) Proposed Requirements for New QCDR Measures

We propose that for a new QCDR measure to be approved for the 2024 MIPS payment year, a QCDR measure must be face valid; to be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved.

For example, for the CY 2026 MIPS payment year (the 2024 performance period), the self-nomination application period would open on July 1, 2023 and close on September 1, 2023. A QCDR that self-nominates a new QCDR measure by September 1, 2023 would need to complete face validity measure testing prior to submission in order for the measure to be considered for the CY 2026 MIPS payment year. If that new QCDR measure is approved for the CY 2026 MIPS payment year, it would need to be fully tested by the next self-nomination date for the CY 2027 MIPS payment year (by no later than September 1, 2024 for the 2025 performance period). QCDR measures that are not fully tested by the second year of the measure's life in MIPS (that is, second self-nomination date), would not be considered for approval for the second year.

We recognize that not all QCDR measures currently approved would continue in the program due to business decisions by each QCDR. We acknowledge that there is a cost involved with full testing of quality measures (see 84 FR 63173); however, we believe it is important that all measures used within the MIPS program are fully tested and reliable. We believe this incremental approach in testing would allow QCDRs time to plan appropriately to complete measure testing in a timely, efficient, and effective manner. However, we do encourage QCDRs to submit fully-tested QCDR measures to the extent possible, as we have a strong preference for QCDR measures that are fully tested versus those that have only completed face validity testing.

[107] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

[108] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

(iii) Proposed Requirements for QCDR Measures Considered for MVP

As an additional layer, we are also proposing § 414.1400(b)(3)(v)(c)(2) that in order for a QCDR measure to be considered for inclusion in an MVP for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested. We believe it is imperative to ensure that QCDR measures are fully tested before being included in an MVP. Unlike traditional MIPS, where clinicians and groups may choose from a large inventory of measures to report on for purposes of the quality performance category, the MVPs seek to create a focused selection of measures and activities relevant to a specific clinical topic. Since clinicians and groups who choose to report on MVPs will be reporting on a subset of measures and activities, there will be heavy reliance on the QCDR measures being reliable, valid, and feasible for reporting purposes.

We request comments on our proposals.

(C) Duplicative QCDR Measures

Throughout previous rulemaking cycles, we have communicated our desire to eliminate duplicative QCDR measures in the MIPS program, as it is counterintuitive to the Meaningful Measure Initiative (84 FR 63068). One of the methods we previously suggested to address duplicative measures is measure harmonization, as discussed in the CY 2020 PFS final rule (84 FR 63068 through 63070). We have received comments and questions from stakeholders, requesting clarification for us to define what we mean by measure harmonization.

In this rule, we intend on clarifying that to mean measures for which previously identified areas of duplication with other approved QCDR measures or MIPS quality measures have been addressed. To be clear with our intent, we are proposing to revise previously codified policies that refer to measure harmonization with this updated terminology.

Therefore, we propose to revise § 414.1400(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 or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure.

In addition, we propose to revise § 414.1400(b)(3)(vi) to state, beginning with the 2023 MIPS payment year, 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 a QCDR measure's second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

Furthermore, we propose to remove two previously codified policies that we have identified as areas of redundancy. We propose to remove § 414.1400(b)(3)(vii)(H), which states whether the previously identified areas of duplication have been addressed as requested, and to remove § 414.1400(b)(3)(vii)(L), which states 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. We believe the previously finalized regulatory text under § 414.1400(b)(3)(vii)(A), which states QCDR measures that are duplicative, or identical to other QCDR measures or MIPS quality measures currently in the program will address instances where areas of duplication amongst QCDR measures are not addressed or where a QCDR measure approved for a previous year is duplicative with a QCDR measure approved for the current year.

As a result of the proposed removals of two previously codified policies, as stated in the above paragraph, we are proposing technical updates to re-number the regulation text to reflect these removals. Therefore, in § 414.1400(b)(3)(vii), we propose to redesignate paragraphs (I), (J), (K), (M), and (N) as paragraphs (H), (I), (J), (K) and (L), respectively.

(D) Collection of Data on QCDR Measure

In the CY 2020 PFS final rule (84 FR 63067 through 63068), we finalized at § 414.1400(b)(3)(v)(D) that 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. For reasons discussed in the May 8th COVID–19 IFC–2 (85 FR 27594 through 27595), we delayed implementation of this policy by 1 year, as described at § 414.1400(b)(3)(v)(D), beginning with the CY 2022 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. We are not proposing any changes in this proposed rule.

(3) Qualified Registries

We refer readers to §§ 414.1305 and 414.1400, the CY 2018 Quality Payment Program final rule (82 FR 53815 through 53818), CY 2019 PFS final rule proposed rule (83 FR 59906), and the CY 2020 PFS final rule (84 FR 40819 through 40820) for our previously finalized policies regarding qualified registries. In this proposed rule, we propose a technical update to the title at § 414.1400(c) to rename it from ''qualified registry approval criteria'' to ''qualified registries'', to better align the title with the content of the regulation. In addition, in this proposed rule, we propose requirements related to data validation audits and targeted audits.

In the CY 2017 Quality Payment Program final rule, we discussed our expectation related to QCDRs and qualified registries would conduct validation on the data they intend on submitting for the MIPS performance period (81 FR 77384 through 77386) and provide the results of the data validation to CMS in the form of a data validation execution report by May 31st of the year following the performance period. Our intention was to establish our expectation that qualified registries would establish a process to assess whether the data are true, accurate, and complete prior to submitting them to CMS for purposes of the MIPS program. We believe it is important to establish a requirement that qualified registries conduct data validation to ensure they are actively monitoring the data they submit to CMS for purposes of a pay-for-performance program. In instances where a qualified registry discovers data are inaccurate or incomplete, the entity must correct the issue prior to submitting the data to CMS in order to provide accurate certification in accordance with § 414.1400(a)(5). A qualified registry that submits a false certification submits data that is inaccurate, unusable or otherwise compromised to CMS for purposes of the MIPS program may be subject to remedial action or termination under § 414.1400(f). We believe requiring qualified registries to validate the accuracy of the data they are submitting is an important safeguard to promote accurate payments under the MIPS program. Therefore, in this proposed rule, we propose at § 414.1400(c)(2)(iii)

and (iv) requirements beginning with the 2023 MIPS payment year as condition of approval each qualified registry must conduct annual data validation audits and if one or more deficiencies or data errors are identified the qualified registry must also conduct targeted audits. We also propose specific obligations for those audits as discussed below.

- We propose to codify at § 414.1400(c)(2)(iii)(A), the qualified registry must conduct their data validation audits prior to submitting any data to CMS for purposes of the MIPS program. We believe it is important for qualified registries to conduct validation audits to identify and fix concerns regarding data accuracy prior to submitting data to us, including potential issues related to data aggregation and calculation. Conducting the data validation prior to data submission will lead to data being more reliable and promote compliance with the requirement of data being true, accurate, and complete. In the CY 2017 Quality Payment Program final rule, we described this auditing using the term randomized audit (81 FR 77384). In this proposed rule, we are proposing instead to refer to this audit as the data validation audit in an effort to be abundantly clear regarding our expectations that the qualified registry will purposefully construct a sample and conduct and audit that complies with specific regulatory requirements and also to distinguish these audits from the targeted audits discussed below and proposed at § 414.1400(c)(2)(v).
- We propose to codify at § 414.1400(c)(2)(iii)(B), the qualified registry must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories. We believe that it is important that data validation be done across all performance categories for which the qualified registry submits data since qualified registries must attest that data submitted to CMS is true, accurate, and complete and data for each of these performance categories can influence score calculation and payment adjustments.
- We propose to codify at § 414.1400(c)(2)(iii)(C), that the qualified registry must conduct data validation on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants. We believe it is important for the data submitted to CMS be accurate for all clinicians and groups for which the qualified registry intends on submitting data to the MIPS program, regardless of whether they are required to participate, have opted in, or have chosen to voluntarily participate. Therefore, we propose to require that the data validation audits should account for all types of submitters that are utilizing the qualified registry to submit data to CMS for purposes of the MIPS program. We note the importance of validating data for all submitter types regardless of its use for payment or public reporting. Even clinicians who voluntarily report to MIPS and whose data are not used for payment purposes could have their data publically posted on the Physician Compare website. We believe all data the qualified registry submits, regardless of its use for payment or public reporting, should be true, accurate, and complete.
- We propose to codify at § 414.1400(c)(2)(iii)(D) that the qualified registry must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed. If the data a qualified registry intends to submit to CMS for purposes with the MIPS program are to demonstrate that a clinician did a particular clinical activity or achieved a particular clinical outcome, we believe meaningful validation of such data requires the qualified registry to use clinical documentation to confirm that the activity occurred or was performed.
- We propose to codify at § 414.1400(c)(2)(iii)(E), the qualified registry shall conduct each data validation audit using a sampling methodology that meets the following requirements:

++ Uses a sample size of at least 3 percent of the TIN/NPIs for which the qualified registry will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the qualified registry must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the qualified registry may use a sample size of 50 TIN/NPIs.

++ Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

We believe the aforementioned sampling methodology is appropriate for multiple reasons. First, the sampling methodology criteria are consistent with the methodology established under the legacy Physician Quality Reporting System (PQRS) program and as described in the CY 2017 Quality Payment Program final rule (81 FR 77366 through 77367). As this methodology has been used for many years under the legacy program, we believe stakeholders are well versed in executing data validation audits using this sampling methodology. Second, the proposed methodology accounts for QCDRs and qualified registries of varying sizes. Data validation requires a level of effort on the part of the qualified registry to execute a data validation plan, identify a sample, and collect information for purposes of chart review; therefore, we are cognizant that requiring a larger sample size would create additional burden on qualified registries and clinicians to account for a larger volume in TIN/NPIs and medical records for review.

- We propose to codify at § 414.1400(c)(2)(iii)(F) that each qualified registry data validation audit must include the following:

++ Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant. We believe that it is important for the qualified registry to track the eligibility status of each clinician and group that wishes to use a third party intermediary to report, because accurate information regarding eligibility is important to ensuring payment adjustments are properly applied. Furthermore, verification of eligibility status is consistent with the requirement for qualified registries to track opt-in participants, as described at § 414.1400(a)(4)(iv) and in the context of clinicians who voluntarily report to MIPS helps ensure the accuracy of data publically posted on the Physician Compare website (or a successor website) of the CMS website.

++ Verification of the accuracy of Tax Identification Numbers (TINs) or National Provider Identifiers (NPIs). Correct TINs and NPIs are critical to ensure data submitted by the qualified registry are attributed to the correct clinicians and groups. Inaccurate NPIs or TINs may lead to inadvertent downstream impacts to the way clinicians and groups are scored, and assigned a payment adjustment.

++ Calculation of reporting and performance rates (for example, formulas included in the quality measure specifications). Qualified registries must follow the measure specifications when calculating reporting and performance rates. Calculations that deviate the formulas included in the quality measure specifications undercut efforts to ensure

data are consistent, reliable, and have been calculated in a uniform manner.

++ Verification that only MIPS quality measures and qualified registry measures that are relevant to the performance period will be utilized for MIPS submission. Measure specifications for the MIPS quality measures and qualified registry measures go through maintenance on an annual basis. Use of outdated measure specifications would likely result in the qualified registry submitting inaccurate or compromised data for the clinicians and groups they support. While not all measures go through substantive changes on an annual basis, there are changes to codes that do occur annually that should be accounted for when programing measures. Therefore, we believe it is important that qualified registries are utilizing the most current version of the measure specification, relevant to the performance period in which they are participating.

- We propose to codify at § 414.1400(c)(2)(iii)(G), that in a form and manner and by a deadline specified by CMS, the qualified registry must report data validation results, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. We believe it is important that the results of the data validation be shared with us in order for us to understand the types of issues the qualified registries have encountered and what resolutions were executed to fix the issues. The information provided will help us track frequently occurring issues which may be identified as an area to provide further education. It is our belief that the report will be largely comprised of issues that were identified and resolved. However, if an issue has been identified and could not be resolved, we would want to understand what the issue is and why it could not be resolved. We emphasize that all data submitted to CMS by a qualified registry on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge as described in § 414.1400(a)(5). If a qualified registry submits a false certification or data that are data that are inaccurate, unusable, or otherwise compromised, the qualified registry may be subject to remedial action or termination as described at § 414.1400(f).
- We propose to codify at § 414.1400(c)(2)(iv)(A) that if a data validation audit under § 414.1400(c)(2)(iii) identifies one or more deficiency or data error, the qualified registry must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year. We believe targeted audits are important to further evaluate the impact of deficiencies or data errors to the cohort of clinicians and groups that the qualified registry intends to submit data for, and for qualified registries to determine the reason the deficiency or data error occurred.
- We propose to codify at § 414.1400(c)(2)(iv)(B), that the qualified registry must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year. To promote the accuracy of the data submitted to the MIPS program for the payment year and to reduce the risk that the agency initiates payment calculations in reliance on inaccurate data, it is important for the qualified registry to conduct required targeted audits and correct any deficiencies and data errors identified through those audits prior to submitting the data to CMS.
- We propose to codify at § 414.1400(c)(2)(iv)(C), the qualified registry must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (c)(2)(iii)(E). The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified. We believe the sampling methodology we are proposing for data validation audits is equally appropriate for the conduct of targeted audits. We believe that adopting the same methodology for both audit types would be less burdensome on qualified registries than requiring these entities to apply a separate sampling methodology for their targeted audits. Provided that data in the sample for the targeted audit does not overlap with the data that was reviewed in the data validation audit, we believe the targeted audit would provide the qualified registry with a reasonable perspective into impact and root cause of deficiencies and data errors across the data to be submitted without imposing the burden that would result from maintaining a separate sampling methodology for targeted audits.
- We propose to codify at § 414.1400(c)(2)(iv)(D), in a form and manner and by a deadline specified by CMS, the qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each error type was corrected. As is the case with the results of data validation audits, we believe it is important that the results of the targeted audits be shared with us in order for us to understand the types of issues the qualified registries have encountered and what resolutions were executed to fix the issues. The information provided will help us track frequently occurring issues which may be identified as an area to provide further education.

We request comments on the aforementioned proposals, including whether stakeholders are concerned with implementing these policies for the 2023 MIPS payment year, and if so, what barriers do they believe they would face in implementing these requirements.

(4) 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), CY 2019 PFS final rule (83 FR 59908 through 59910), and the CY 2020 PFS final rule (84 FR 63077 through 63080) for previously finalized policies for remedial action and termination of third party intermediaries.

As described in § 414.1400(f)(1)(i), the remedial actions CMS may take against a third party intermediary including requiring the third party intermediary to submit to CMS by a date specified by the agency a corrective action plan (CAP) to address the identified deficiencies or data issue, including that actions it will take to prevent the deficiencies or data issues from recurring. To clarify expectations and create consistency in the content of the CAPs provide by third party intermediaries, we are proposing to revise and elaborate on the obligations for a CAP. Specifically, we propose to modify § 414.1400(f)(1)(i) such that, unless different or additional information is specified by CMS, the CAP submitted by the third party intermediary must address four issues: (1) The issues that contributed to the non-compliance; (2) the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program; (3) the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved will not

recur in the future and (4) the detailed timeline for achieving compliance with the applicable requirements.

We believe these four elements are generally warranted in each instance in which a CAP is required. First, any meaningful efforts at corrective action necessitate an understanding of what needs to be corrected. Therefore, we propose at § 414.1400(f)(1)(i)(A) to require that each third party intermediary be required to articulate the issues that contributed to the non-compliance. The third party intermediary must articulate what factors cause it to fail in its obligation to meet program requirements. For example, a survey vendor subject to remedial action for not completing vendor trainings would be required to explain what factors lead to its failure to complete training. We believe this analysis will allow third party intermediary to improve their processes to better meet existing requirements and will allow CMS to better understand what operational and other challenges third party intermediaries face in meeting program requirements. Second, depending on the circumstances, non-compliance by a third party intermediary may affect an uncertain number of clinicians and groups and has the potential to implicate substantial program dollars. Accordingly, we propose at § 414.1400(f)(1)(i)(B) to require that a third party intermediary subject to a CAP disclose to CMS the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program. We believe this information regarding the scope of harms is necessary for the agency to assess the full program impact of the non-compliance. Furthermore, we believe it is important for the CAP to include this impact information regardless of the clinician's participation status, because non-compliance may have programmatic implications even if it does not affect payment, such as for data posted on the Physician Compare website. Third, meaningful remedial action requires the identification of specific action steps both to address prior harm but to protect against future harms. Therefore, we propose at § 414.1400(f)(1)(i)(C) that a third party intermediary subject to a CAP must address the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future. The third party intermediary will be expected to follow through with the implementation of the corrective actions and to see that the issue has been corrected permanently. It is important for us to understand in detail what actions the third party intermediary will take to resolve the issue and to evaluate the effectiveness of the proposed solution for long-term sustainability. Fourth, non-compliance must be resolved methodically and timely. Therefore, we propose at § 414.1400(f)(1)(i)(D) that each CAP must include the detailed timeline for achieving compliance with the applicable requirements. We invite public comments on these proposed revisions to our requirements for correction action plans.

h. Public Reporting on Physician Compare

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), the CY 2020 PFS final rule (84 FR 63080 through 63083), and the Physician Compare Initiative website at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/.*

(1) Definitions & Proposed Regulation Text Changes

Physician Compare (*http://www.medicare.gov/physiciancompare*) draws its operating authority from section 10331(a)(1) of the Affordable Care Act, which defines the term ''Physician Compare'' to mean the internet website developed under this section of the statute. Physician Compare has continued to pursue a phased approach to public reporting under the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. Section 104(f)(2) of the MACRA defines the term ''Physician Compare'' to mean the Physician Compare internet website on the CMS (or a successor) website. To more completely and accurately reference the website for which CMS will post information available for public reporting, in accordance with section 104(f)(2) of the MACRA, we propose to define Physician Compare at § 414.1305 to mean the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website). We seek comment on this proposal. For ease of reference, we will use the term ''Physician Compare'' in this proposed rule.

4. APM Incentive Payment

(a) Overview

Under the Quality Payment Program, Qualifying APM Participants (QPs) receive a 5 percent APM Incentive Payment in payment years 2019 through 2024. In the CY 2017 Quality Payment Program final rule (81 FR 77480 through 77489), we finalized at § 414.1450(d) that this payment is made based on the clinician's QP status in the QP Performance Period that is 2 years prior (for example, the 2021 payment will correspond to the 2019 performance year), and at § 414.1450(b)(1) that the payment is equal to 2 percent of the estimated aggregate amount of payments for covered professional services in the base period (the year between the QP performance and payment years). We finalized at § 414.1450(c)(1) that the APM Incentive Payment amount is made to the TIN associated with the Advanced APM Entity through which an eligible clinician becomes a QP during the QP Performance Period. Under § 414.1450(c)(3), if an eligible clinician becomes a QP through participation in multiple Advanced APMs, CMS divides the APM Incentive Payment proportionally between the TINs associated with the QP's participation in each Advanced APM based on payments for covered professional services during the QP Performance Period. In addition, under § 414.1450(c)(2), we finalized that if the QP is no longer affiliated with the TIN associated with the QP's participation in the APM Entity, the APM Incentive Payment is made to the TIN listed on the NPI's CMS–588 Electronic Funds Transfer (EFT).

In our first year making the APM Incentive Payment, we experienced operational limitations that made it difficult in certain cases to distribute the payment to a current billing organization associated with the QP according to the current regulations. In particular, we encountered challenges when QPs are no longer affiliated with the TIN associated with the QP's participation in the APM Entity through which they attained QP status, and when we were unable to make the APM Incentive Payment to the TIN listed on the eligible clinician's CMS–588 EFT Application form. In certain circumstances, it has been challenging to locate accurate billing organizations for some QPs 2 years after they earned QP status. For example, we have encountered situations such as inaccurate or missing billing

associations for the QP because the QP has changed their primary billing TIN between the performance and the payment year, or the billing TIN through which the QP attained QP status is not the TIN through which CMS payments are processed, and so it is not possible for CMS to know that the two are in fact connected.

(b) APM Incentive Payment Amount

In the first Quality Payment Program final rule (81 FR 77480), we finalized at § 414.1450(b)(1) through (3) how we calculate the amount of the APM Incentive Payment. Specifically, we finalized that: (1) The amount of the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the incentive payment base period (that is, the calendar year immediately preceding the payment year); (2) the estimated aggregate payment amount for covered professional services includes all such payments to the QP (NPI) via any and all of their TIN/NPI combinations; and (3) in calculating the estimated aggregate payment for a QP, CMS uses claims submitted for covered professional services with dates of service from January 1 through December 31 of the incentive payment base period.

In this proposed rule, we are clarifying that the APM Incentive Payment amount is calculated based on the paid amount of the applicable claims for covered professional services that are subsequently aggregated to calculate the estimated aggregate payments. We are proposing to amend our regulation at § 414.1450(b)(1) to reflect that clarification.

Section 1833(z)(1)(A) of the Act specifies that the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3) of the Act. Because the APM Incentive Payment is a percentage of the estimated aggregate payments made, it would not be appropriate to calculate the APM Incentive Payment based on amounts that were allowed, but not actually paid by Medicare, for such covered professional services.

We also note that, as provided in § 414.1450(b)(4) and (5), we exclude certain payments and adjustments, including the MIPS payment adjustments, when calculating the APM Incentive Payment amount.

We seek comment on this proposal.

(c) APM Incentive Payment Recipient

Under our current policy as finalized at § 414.1450(c), CMS first seeks to disburse the APM Incentive Payment to the TIN associated with the QP's participation with the APM Entity in the Advanced APM through which they earned QP status. If the QP is no longer affiliated with that TIN, we seek to disburse the APM Incentive Payment to the TIN listed on the eligible clinician's CMS–588 EFT form on the date that we make the payment. And if the eligible clinician becomes a QP through participation in multiple Advanced APMs, we seek to divide the APM Incentive Payment proportionally, based on payments for covered professional services during the QP Performance Period, and to make proportional payment to each of the TINs associated with the QP's participation with the APM Entity or APM Entities in the Advanced APMs.

It is still our intention to reward achievement of QP status through participation in Advanced APMs by seeking to disburse APM Incentive Payments to TINs that are affiliated with an APM Entity through which the QP has achieved QP status, as is described in the CY 2017 Quality Payment Program final rule (81 FR 77847). However, after our first year of making APM Incentive Payments, we have learned that the amount of time between when an eligible clinician earns QP status and when APM Incentive Payments are made makes it difficult to ensure that payments can be made for these QPs in a routine and efficient manner. For example, in the space of 2 years between making QP determinations and APM Incentive Payments, eligible clinicians may change TINs, join new TINs, join new APM Entities, remain in the same APM Entity under a new billing TIN, leave Medicare altogether, or make other potential changes impacting their relationship with the Medicare program. CMS receives updated records of these changes when APM participants update their payment information through the internet based Provider Enrollment, Chain and Ownership system (PECOS) or a CMS–588 EFT Application, and subsequent updates to APM Participation Lists and Affiliated Practitioner Lists, although we note that such updates are not consistently and timely made across APM participants, as we originally believed, and therefore such lists have variable reliability. Further, on our own end, if we limit our initial search for the party or parties to which we should make the APM Incentive Payment to only the TIN or TINs through which the eligible clinician earned QP status, as is specified in our regulations at § 414.1450(c)(1) and (3), when the QP has made changes to their TIN affiliations, we might limit our opportunities to make the APM Incentive Payment to a more current TIN with which the QP is affiliated at the time we make the APM Incentive Payment. If we limit the TINs to which we will make the APM Incentive Payment to only those through which a QP was billing at the time they achieved QP status, we might be unable to identify any TIN to which we would make a payment for that QP during the payment year, or payments may be significantly delayed as a result, even in cases where a current payee TIN is available.

Therefore, we are proposing to establish in our regulation at § 414.1450(c) a revised approach to identifying the TIN(s) to which we make the APM Incentive Payment. This approach would involve looking at a QP's relationship with their TIN(s) over time, as well as considering the relationship the TIN(s) have with the APM Entity or Entities through which the eligible clinician earned QP status, or other APM Entities the QP may have joined in the interim. We believe that this revised approach will enable CMS to more accurately identify TINs with which QPs are currently receiving other Medicare payments, and through which they would likely anticipate receiving their APM Incentive Payment. This approach would also prioritize, when the QP is no longer affiliated with the original TIN through which they achieved QP status, identifying and paying TINs with which QPs are affiliated at the time the APM Incentive Payment is made, thereby reducing the potential burden on payee TINs to find QPs no longer affiliated with them in order to disburse the APM Incentive Payment amount, as well as reducing uncertainty and delays for the QPs themselves as they anticipate their APM Incentive Payment.

We are also proposing to introduce a cutoff date of November 1 of each payment year, or 60 days from the day on which we make the initial round of APM Incentive Payments, whichever is later, as a point in time after which CMS will no longer accept new helpdesk requests from QPs or their representatives who have not received their payments. There may be scenarios where we are unable to identify any appropriate TIN to which the APM Incentive Payment should be made, such as when the QP is no longer participating in Medicare, the QP has

recently reassigned his or her billing rights, or where a payment TIN may be undergoing business transformations such that payment information changes during the payment year. In these cases, it is our goal to make correct payments for the relevant QPs as soon as feasible. In order to do so, it is necessary to establish a date after which we will not consider additional inquiries or additional information from QPs or their representatives for purposes of disbursing remaining APM Incentive Payments for the payment year.

In order to improve and expand the ways we identify the TIN(s) to which we would make the APM Incentive Payment for a QP in a more timely and efficient manner, we propose to sequentially apply the hierarchy in the following paragraph and to amend § 414.1450(c) of our regulations to reflect such hierarchy. We propose to begin at the first step in the hierarchy, and if we are unable to identify one or more TINs with which the QP has a current affiliation at this step, we move to the next and successive steps of the hierarchy until we do identify one or more TINs with which the QP is currently affiliated at the time we are distributing APM Incentive Payments. When we identify one or more TINs with which the QP is affiliated at a step, we would make the APM Incentive Payment to those TINs. We further propose that if we identify more than one TIN at the applicable step in the hierarchy, we will divide the APM Incentive Payment proportionally between such TINs based on the relative paid amount for Part B covered professional services that are billed through each such TINs. We propose the hierarchy to be:

(1) Any TIN associated with the QP that, during the QP Performance Period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(2) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(3) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity participating in an Advanced APM through which the eligible clinician had achieved QP status;

(4) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated in an APM Entity in an Advanced APM;

(5) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in any track of the APM through which the eligible clinician achieved QP status;

(6) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in an APM other than an Advanced APM;

(7) Any TIN associated with the QP that submitted a claim for covered professional services furnished by the QP during the APM Incentive Payment base period, even if such TIN has no relationship to any APM Entity or APM; then

(8) If we have not identified any TIN associated with the QP to which we can make the APM Incentive Payment, we will attempt to contact the QP via a public notice to request their Medicare payment information. The QPs identified in the public notice, or any other eligible clinicians who believe that they are entitled to an APM Incentive Payment must then notify CMS of their claim as directed in the public notice by November 1 of the payment year, or 60 days after CMS announces that initial payments for the year have been made, whichever is later. After that time, any claims by a QP to an APM Incentive Payment will be forfeited for such payment year.

We seek comment on these proposals.

(d) Eligible Clinicians With No Covered Professional Services in the Incentive Payment Base Period

In our experience calculating the APM Incentive Payments, it has come to our attention that there is a cohort of eligible clinicians who have been determined to be QPs for a year, and for whom an APM Incentive Payment has been calculated and in some cases paid, despite the fact that these eligible clinicians did not bill for any Part B covered professional services during the incentive payment base period. This situation arises in cases where an APM Entity is paid under the terms of the APM for supplemental services on behalf of an eligible clinician who is on their Participation List. This can occur because, for purposes of calculating the APM Incentive Payment, such supplemental service payments as described in § 414.1450(b)(7) of our regulations are considered covered professional services for purposes of calculating the APM Incentive Payment.

This scenario creates difficulty when CMS attempts to make the APM Incentive Payment for the QP because there are no relevant claims in our database indicating a TIN to which we should make the APM Incentive Payment. We believe this situation is largely the result of clerical errors or delays, either in updates to the APM's Participation List that is submitted to CMS by APM participants, or through more general processes used to update an eligible clinician's Medicare enrollment information. We remind our enrolled physicians, practitioners, group practices and other suppliers that it is their responsibility, in accordance with their APM participation and their Medicare enrollment agreement, to routinely update their APM participation lists that they submit directly to their APMs, as well as their lists of enrolled providers assigned to their organization and associated TINs, either through the internet-based PECOS or using a CMS–855F Form. Any payments resulting from a failure to make such updates may be considered fraud, waste, or abuse.

However, in the event that a QP's APM Incentive Payment was calculated based solely on supplemental services payments and no Medicare claims for covered professional services furnished by the QP were submitted during the incentive payment base period, we would categorically assign these QPs to the list of QPs that will be given public notice requesting updated payment information within 90 days, as described in the proposed regulation at § 414.1450(c)(8). We believe that in many if not most of these cases, such individuals have retired or otherwise ceased participation in Medicare; however, we recognize that there may be scenarios under which such individuals remain active, and our proposal is meant to provide an opportunity for such clinicians to identify their current billing affiliation(s) or otherwise identify a TIN to which the APM Incentive Payment should be made.

We seek comment on this proposal.

d. Qualifying APM Participant (QP) and Partial QP Determinations

(1) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77450), we finalized policies relating to QP and Partial QP determinations. In the CY 2019 PFS final rule (83 FR 59923 through 59925), we finalized additional policies relating to QP determinations and the Partial QP election to report to MIPS.

In this proposed rule, we are proposing to:

- Update the methodology for addressing prospectively aligned beneficiaries for Threshold Score calculations and QP determinations.
- Establish a Targeted Review process for QP Determinations.

Additionally, we are clarifying our policies on Advanced APM

determinations and QP determinations in light of questions that may arise based on the effects of the COVID–19 PHE.

Finally, we are soliciting comment on whether to allow an APM Entity to make the Partial QP election on behalf of all of the APM Entity's participating eligible clinicians.

(2) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77440), we finalized that QP determinations would first be made at the APM Entity level, after which we would make further QP determinations at the individual level for eligible clinicians who are either: (1) Participating in multiple Advanced APM Entities, none of which meet the QP threshold as a group; or (2) on an Affiliated Practitioner List that is the list used for the QP determination when there are no eligible clinicians on a Participation List for the APM Entity (81 FR 77439 through 77443). As such, the QP determination at the APM Entity level generally applies to all the individual eligible clinicians who are on a Participation List of the Advanced APM. The QP determination Threshold Score calculations are aggregated using data for all eligible clinicians participating in the APM Entity on each snapshot date (March 31, June 30, August 31) during the QP Performance Period. If the 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 at the NPI level, for the relevant performance year (PY).

(3) Attribution of Prospectively Attributed Beneficiaries in QP Threshold Score Calculations

When making QP determinations, we include information for all attribution-eligible beneficiaries in the denominator of the patient count and payment amount methods used to calculate QP Threshold Scores as set forth in § 414.1435. ''Attribution-eligible beneficiary'' is a term defined in our regulation at § 414.1305, and the definition is generally based on the attribution methodology and rules for the particular Advanced APM. We have specified at § 414.1435(b)(3) that a beneficiary may be counted only once in the numerator and denominator for a single APM Entity group, and at § 414.1435(b)(4) that a beneficiary may be counted multiple times in the numerator and denominator for multiple different APM Entity groups.

When making QP determinations, at the APM Entity or individual eligible clinician level, we begin by calculating Threshold Scores which are the ratio of the payment amounts or patient counts for ''attributed beneficiaries'' to the payment amounts or patient counts for ''attribution eligible beneficiaries.'' If this ratio (the Threshold Score) for the eligible clinician or APM Entity level, as applicable, meets or exceeds the relevant QP thresholds described at § 414.1430(a), the relevant eligible clinicians will have attained QP status for a year. It has come to our attention that under our current methodology for calculating Threshold Scores, we include attribution-eligible beneficiaries in the denominator of the calculation for some APM Entities for whom those same beneficiaries could never be included in the numerator. This may happen in a scenario where a beneficiary is prospectively attributed to an APM Entity and as a result is precluded by the applicable rules for one or more APMs from attribution to other APM Entities in certain other APMs.

For example, the Shared Savings Program offers the option for ACOs to select prospective beneficiary assignment, and prospective beneficiary alignment is also used in the Direct Contracting Model and Next Generation ACO Model. When beneficiaries are prospectively attributed to an ACO in one of these APMs, under the rules of precedence within the APMs themselves, those beneficiaries are generally not available for attribution to participants in some other APMs, including other ACOs with retrospective attribution methodologies. However, the population of attribution-eligible beneficiaries for APM Entities in these other APMs still includes those prospectively aligned beneficiaries. This could have the effect of disadvantaging the APM Entities to which the beneficiaries may never be attributed, because their ratio of attributed beneficiaries to attribution-eligible beneficiaries will be lower, for reasons entirely outside the control of the relevant eligible clinicians and APM Entities.

Therefore, we propose to amend § 414.1435(c)(1) of our regulations and add a new paragraph § 414.1435(c)(1)(i) to specify that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list. The effect of this proposed policy would be to remove such prospectively attributed beneficiaries from the denominators when calculating Threshold Scores for APM Entities or individual eligible clinicians in Advanced APMs that align beneficiaries retrospectively, thereby preventing dilution of the Threshold Score for the APM Entity or individual eligible clinician in an Advanced APM that uses retrospective attribution.

We seek comment on these proposals.

(3) Targeted Review of QP Determinations

(i) Overview

We are proposing at § 414.1455(b) to establish a targeted review process for limited circumstances surrounding QP determinations. This targeted review process would provide a systematic opportunity for eligible clinicians to bring to our attention potential clerical errors we may have made, and for us to review and make corrections if warranted. We also propose that, after the conclusion of the time period for targeted review, there would be no further review of our QP determination with respect to an eligible clinician for the QP Performance Period.

We note that, consistent with section 1833(z)(4) of the Act and under § 414.1455(a) of our regulations, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise, of the determination that an eligible clinician is a QP or Partial QP under § 414.1425, that an APM Entity is an Advanced APM Entity under § 414.1410, or of the determination of the amount of the APM Incentive Payment under § 414.1450.

(ii) Scope of Targeted Review

We propose at § 414.1455(b)(1) that an eligible clinician or APM Entity may request targeted review of a QP or Partial QP determination only if they believe in good faith that, due to a CMS clerical error, an eligible clinician was omitted from a Participation List used for purposes of QP determinations. If we determine that we made such a clerical error, we believe that it would be appropriate, and we are proposing to assign to the erroneously omitted eligible clinician the most favorable QP status that was determined at the APM Entity level on any snapshot dates for the relevant QP Performance Period on which the eligible clinician participated in the APM Entity. We believe that this policy is appropriate in these circumstances because, as a result of a CMS clerical error, the eligible clinician was not provided the opportunity to become a QP based on the level of payment amounts or patient counts

through an Advanced APM for an APM Entity with which they were associated.

Alternatively, if we were to instead recalculate an APM Entity's Threshold Scores for one or more of the snapshot dates in the relevant QP Performance Period, and the Threshold Scores no longer met the applicable QP threshold(s), that outcome could affect all of the eligible clinicians in the APM Entity group, removing their QP status. However, the affected eligible clinicians in the APM Entity group are likely to have acted in accordance with our CMS's notification of their prior QP determination, and not have prepared for or reported to MIPS. In correcting our own clerical error with respect to some eligible clinicians, we do not believe it would be appropriate to revisit our prior QP determinations for a broader set of eligible clinicians, thereby potentially disadvantaging those eligible clinicians in MIPS scoring through no fault of their own.

We are proposing to not conduct targeted review of potential omissions from Affiliated Practitioner Lists, as QP determinations for eligible clinicians on an Affiliated Practitioner List are made at the individual eligible clinician level for each of the QP Performance Period snapshots. As such, we would not have completed a QP determination for the QP Performance Period in question for the individual eligible clinician who has been identified prior to the targeted review if that eligible clinician was indeed omitted due to CMS clerical error. We recognize that this circumstance may occur, however, we believe this to be an infrequent occurrence. Additionally, such calculations would not be operationally feasible in order to make the APM Incentive Payment in a timely manner.

We note that we are not proposing to accept targeted review requests to correct omissions from Participation Lists of Other Payer Advanced APMs, as those lists are provided to us directly by eligible clinicians and Other Payer Advanced APMs. As such, any clerical error would not be the fault of CMS.

(iii) Targeted Review Process

In general, we propose to align this targeted review process with the MIPS targeted review process as codified at § 414.1385. We believe that this general alignment is appropriate and will reduce the likelihood of confusion and burden on eligible clinicians and APM Entities. We propose to revise § 414.1455 of our regulations by redesignating the current preclusion of administrative or judicial review under § 414.1455(a) and (b) to § 414.1455(a)(1) and (2) and to codify our targeted review policy at § 414.1455(b).

We propose to specify at § 414.1455(b) that either an eligible clinician or APM Entity may submit a request for targeted review. We also propose 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 as described at § 414.1385(a)(2) of our regulations. The targeted review request submission period may be extended as specified by CMS. We also propose that all requests for targeted review must be submitted in accordance with the form and manner specified by CMS.

We propose that a request for targeted review may be denied if the request is duplicative of another request for a targeted review; the request for targeted review is not submitted during the targeted review request submission period; or the request is outside the scope of the targeted review, as specified in § 414.1455(b)(1). If the targeted review request is denied, there will be no change to either the QP or Partial QP determination. If the targeted review request is approved, we would assign the most favorable Threshold Score and corresponding QP status of the APM Entity in which such eligible clinician participates.

We propose that we will respond to each request for targeted review timely submitted and determine whether a targeted review is warranted.

We propose that a request for targeted review may include additional information in support of the request at the time it is submitted. If CMS requests additional information from requests additional information from the eligible clinician or the APM Entity group that is the subject of a request for targeted review, it must be provided and received by CMS within 30 days of CMS's request. Non-responsiveness to CMS' request for additional information may result in a final decision based on the information available, although another non-duplicative request for a targeted review may be submitted before the end of the targeted review request submission period.

We propose that if targeted review requests reveal a pattern of CMS error with impacts that extend beyond the eligible clinician or clinicians who submitted such targeted review requests, we would correct any additional errors that we identify regardless of whether a targeted review was submitted for the other eligible clinicians affected.

We propose that decisions based on the targeted review are final, and there is no further administrative review or appeal or judicial review.

We seek comment on these proposals.

(4) COVID–19 Public Health Emergency (PHE) Advanced APM determination and QP Determinations

(i) Advanced APM Determinations

We anticipate that the COVID–19 PHE, as defined in 42 CFR 400.200, may result in CMS making changes to aspects of some APMs. For example, CMS may publish regulations or amend APM Participation Agreements to address issues that arise as a result of the COVID–19 PHE.

Due to the COVID–19 PHE and the urgent need to address changes to certain APMs during CY 2020 to respond to the extreme shifts in the healthcare delivery system, CMS is exercising its enforcement discretion in connection with Advanced APM determinations. Specifically, CMS will not reconsider the Advanced APM determinations of APMs which have already been evaluated and determined to meet the Advanced APM criteria for CY 2020, even in the event that the APMs make changes to their governing documents or operations in such a way that, if there were a redetermination, they would no longer meet the criteria to be an Advanced APM. Furthermore, we will evaluate all APMs in future years with the understanding that any provisions of the Participation Agreement or governing regulation designed in response to the COVID–19 PHE will not be considered to the extent they would prevent the APM from meeting the Advanced APM criteria for a year.

We note that the following APMs are considered Advanced APMs for 2020:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- Comprehensive Primary Care Plus Model;
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two Sided Risk Arrangement);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Track 2, Track 3, Basic Track Level E, and the ENHANCED Track);
- Medicare Accountable Care Organization (ACO) Track 1+ Model;
- Next Generation ACO Model;
- Oncology Care Model (Two-Sided Risk Arrangements);

• Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

(ii) QP Determinations

We also understand that the COVID–19 PHE may lead the adoption of an earlier end date for certain APMs based on amendments to the APM's governing documentation, such as a Participation Agreement. For example, an Advanced APM governed by a Participation Agreement was originally scheduled to end on December 31, 2020, and the amended Participation Agreement may revise the ending date to July 1, 2020. In the event that such changes are made to a Participation Agreement to modify the end date of an Advanced APM in response to the COVID–19 PHE, we would not consider this to be a termination from an Advanced APM under § 414.1425(c)(5) or (6) of our regulations. As such, we would not revoke the QP status of eligible clinician participants in the Advanced APM on that basis.

We are aware that circumstances resulting from the COVID–19 PHE could affect the results of QP and Partial QP determinations for the 2020 QP Performance Period, as compared to what those determinations would otherwise be in absence of the COVID–19 PHE.

However, after considering whether changes in our methodology to address the PHE were warranted, we determined that any change to the QP determination methodology could have unintended negative consequences for Advanced APM participants as practice patterns have shifted even in areas with a low volume of COVID–19 cases. We note that with the duration, scope, and severity of the PHE being unknown, it is impossible to predict the potential impact both in terms of scale and which providers may be most likely to be affected. As such, we are concerned that making changes to the QP determination methodology would be more likely to inadvertently pick winners (those who would benefit from the change in methodology by achieving higher scores) and losers (those who would score better under our normal methodology than under a changed one) than it would be to generate relief from the PHE across the board. We also anticipate that there would be significant challenges resulting from modifying QP calculations with so many unknown variables at play, and are concerned that any changes to our methodology could result in delays in the timing of our announcing QP status.

We also believe Advanced APM participants benefit from timely and predictable QP determinations. With all of these considerations in mind, we are clarifying that, apart from the exercise of enforcement discretion explained above, we will continue to perform QP determinations as established in our regulations at §§ 414.1305, 414.1425, 414.1430, 414.1435, and 414.1440 for the 2020 QP Performance Period, without modifications to address the COVID–19 PHE.

(5) Partial QP Election To Report MIPS

We anticipate there may be an increase in the number of eligible clinicians who are determined to be Partial QPs in the 2021 QP Performance Period in comparison to the 2020 QP Performance Period, due to the increase in the QP thresholds. Beginning in the CY 2021 QP Performance Period, as provided at § 414.1430(a) of our regulations for the Medicare option, the QP payment amount threshold increases from 50 percent to 75 percent, while the QP patient count threshold increases from 35 percent to 50 percent. While the Partial QP thresholds for the Medicare option also increase, based on historical performance we expect a greater number of Partial QPs based on performance in the CY 2021 QP Performance Period than for the prior QP Performance Period. As provided in § 414.1310(b)(2), Partial QPs who do not elect to participate in MIPS as a MIPS eligible clinician are excluded from MIPS, and thus, not subject to the MIPS reporting requirements or payment adjustments. To date our method of contacting Partial QPs has been to send a letter to the APM Entity's contact listed with the APM. As such, we are considering options to make the Partial QP election process less burdensome.

We are requesting comment on whether to allow an APM Entity to make the Partial QP election on behalf of all of the individual eligible clinicians associated with such APM Entity. We believe that allowing an APM Entity to make a single election on behalf of all of its eligible clinicians may help to simplify such elections, particularly for those eligible clinicians who will be Partial QPs for the first time because of the increasing QP thresholds in 2021. We also believe that allowing an APM Entity to make the Partial QP election for its eligible clinicians could reduce burden for individual eligible clinicians and allow APM Entities to have a centralized source of feedback as to the statuses of their individual eligible clinician participants.

However, we acknowledge that allowing APM Entities to make elections on behalf of eligible clinicians would create the possibility that we could receive conflicting election responses from different parties. Specifically, we are interested in receiving comments, feedback, and recommendations for how to address: (1) Conflicting responses either from an APM Entity and an individual or from two or more different APM Entities (eligible clinicians often participate with more than one APM Entity); and (2) situations where the eligible clinician is participating in more than one APM Entity and we do not receive elections from all parties.

In the case where an APM Entity election conflicts with that of an individual eligible clinician, we believe it would be most appropriate to follow the individual eligible clinician's election, as that election would apply at the NPI level across all of their TIN/NPI combinations, and in recognition that the eligible clinician has taken the opportunity to express their preference. Similarly, if we were to receive an election for an eligible clinician from one APM Entity in which the eligible clinician participates but not all such APM Entities, and the individual clinician does not make an election, we believe it would be appropriate to apply the election we received for the eligible clinician across all their TIN/NPI combinations. However, if multiple APM Entities make elections that are not in agreement, and the individual eligible clinician does not make an election, there is no clearly appropriate course of action as to which election to follow, and therefore we solicit comments detailing how we might go about applying conflicting Partial QP elections for an eligible clinician made by more than one APM Entity.

We seek public comment on whether to allow Partial QP elections to be made by APM Entities on behalf of all eligible clinicians within the APM Entity, and how to handle potentially conflicting elections.

V. Planned 30-Day Delayed Effective Date for the Final Rule

We are committed to ensuring that we fulfill our statutory obligation to update the PFS as required by law and are working diligently in that regard. We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued in accord with the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)). However, 5 U.S.C. 808(2) provides that, if an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the rule shall take effect at such time as the agency determines.

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has

now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named ''SARS CoV 2'' and the disease it causes has been named ''coronavirus disease 2019'' (abbreviated ''COVID 19'').

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of International Concern'' (PHEIC). On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation's healthcare community in responding to COVID–19. On March 11, 2020, the WHO publicly characterized COVID–19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID–19 outbreak a national emergency.

Due to CMS prioritizing efforts in support of containing and combatting the COVID–19 PHE, and devoting significant resources to that end, the work needed on the PFS payment rule will not be completed in accordance with our usual schedule for this rulemaking, which aims for a publication date of at least 60 days before the start of the fiscal year to which it applies. Up to an additional 30 days may be needed to complete the work needed on this payment rule. The PFS payment rule is necessary to annually review and update the payment systems, and it is critical to ensure that the payment policies for these systems are effective on the first day of the fiscal year to which they are intended to apply.

Therefore, due to CMS prioritizing efforts in support of containing and combatting the COVID–19 PHE, and devoting significant resources to that end, we expect that we will determine, pursuant to 5 U.S.C. 808(2), that the PFS final rule will be effective 30 days after publication; it would be impracticable and contrary to the public interest for CMS to do otherwise. Accordingly, we also do expect to provide a 30-day delay in the effective date of the final rule in accordance with the Administrative Procedure Act (5 U.S.C. 553(d)), which ordinarily requires a 30-day delay in the effective date of a final rule from the date of its public availability in the **Federal Register**, and section 1871(e)(1)(B)(i) of the Act, which generally prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date of its public availability.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), 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 OMB'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.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 52 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 52: National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Anesthesiologists	29-1211	125.83	125.83	251.66
Billing and Posting Clerks	43-3021	19.53	19.53	39.06
Computer Systems Analyst	15-1211	46.23	46.23	92.46
Family Medicine Physicians	29-1215	102.53	102.53	205.06
General Internal Medicine Physicians	29-1216	96.85	96.85	193.70
Health Diagnosing and Treating Practitioners	29-1000	49.26	49.26	98.52
Licensed Practical Nurse (LPN)	29-2061	23.32	23.32	46.64
Medical and Health Services Managers	11-9111	55.37	55.37	110.74
Medical Secretary	43-6013	18.31	18.31	36.62
Obstetricians and Gynecologists	29-1218	112.31	112.31	224.62
Pediatricians, General	29-1221	88.66	88.66	177.32
Physicians, All Other; and Ophthalmologists, Except Pediatric	29-1228	97.81	97.81	195.62
Psychiatrists	29-1223	105.98	105.98	211.96
Surgeons, Except Ophthalmologists	29-1248	121.17	121.17	242.34

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.

For the CY 2019 and CY 2020 PFS final rules, we used the BLS wage rate for ''Physicians and Surgeons'' (occupation code 29–1060) to estimate the burden for Physicians. In BLS' most recent set of occupational wage rates dated May 2019, they have discontinued this occupation in their wage data. As a result, in order to estimate the burden for Physicians, we are using a rate of $212.78/hr which is the average of the mean wage rates for Anesthesiologists; Family Medicine Physicians; General Internal Medicine Physicians; Obstetricians and Gynecologists; Pediatricians, General; Physicians, All Other; and Ophthalmologists, Except Pediatric; Psychiatrists; and Surgeons, Except Ophthalmologists [($251.66/hr + $205.06/hr + $193.70/hr + $224.62/hr + $177.32/hr + $195.62/hr + $211.96/hr + $242.34/hr) ÷ 8].

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Modifications to OTP Enrollment Process (§ 424.67)

The following proposed requirement and burden changes will be submitted to OMB for approval under control numbers 0938–0685 and 0938–1377 (respectively, CMS–855A and CMS–855B).

a. Form CMS–855B Completion—Estimates in November 15, 2019 Final Rule

In the aforementioned November 15, 2019 final rule (84 FR 62568), we prepared estimates of the hour and cost burdens to OTPs in completing the Form CMS–855B (Medicare Enrollment Application Clinics/Group Practices and Certain Other Suppliers). We are restating them in the current proposed rule to help stakeholders better understand the burdens associated with our proposed changes to § 424.67.

Based on SAMHSA statistics and our internal data, we estimated in the November 15, 2019 final rule, that: (1) About 1,700 certified and accredited OTPs were eligible for Medicare enrollment; and (2) 200 OTPs would become certified by SAMHSA in the next 3 years (or roughly 67 per year). This brought the total number of OTPs eligible to enroll during this 3-year period to approximately 1,900.

We projected that it would take each OTP an average of 3 hours to obtain and furnish the required information on the Form CMS–855B and a new supplement thereto designed to capture data unique to OTPs. Per our experience, we believed that the OTP's medical secretary would secure and report the data on the Form CMS–855B and supplement. We estimated that this task would take approximately 2.5 hours, of which about 30 minutes would involve completion of the supplement. In addition, a health diagnosing and treating practitioner of the OTP would review and sign the form, a process we estimated would take 30 minutes.

Using BLS' May 2018 wage estimates, we consequently projected a first-year burden of 5,301 hours (1,767 entities × 3 hr) at a cost of $244,146 [1,767 entities ((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 $9,257 [67 entities × ((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 $9,119 (66 entities × ((2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr))]. In aggregate, we estimated a total 3-year burden of 5,700 hours (5,301 hr + 201 hr + 198 hr) at a cost of $262,522 ($244,146 + $9,257 + $9,119). When averaged over the typical 3-year OMB approval period, we estimated an annual burden of 1,900 hours (5,700 hr/3) at a cost of $87,507 ($262,522/3).

b. Proposed Revisions to § 424.67

(1) Completion of Form CMS–855A

We foresee three main implications associated with our proposed changes to § 424.67. First, newly enrolling OTPs would be able to complete and submit a Form CMS–855A (Medicare Enrollment Application—Institutional Providers) instead of a Form CMS–855B. Second, we anticipate that numerous OTPs that are currently enrolled via the Form CMS–855B would terminate the latter enrollments and complete/submit a Form CMS–855A application in order to bill for OTP services via the 837I. (As stated in proposed/revised § 424.67(c), an OTP cannot be enrolled via both the Form CMS–855A and Form CMS–855B; it must choose one of these two enrollment mechanisms.) Third, it is possible that some OTPs that enroll using the Form CMS–855A (pursuant to revised § 424.67(b)) would later change their enrollment to a Form CMS–855B.

In preparing the following OTP enrollment estimates, we: (1) Reviewed internal PECOS and billing data concerning existing OTP Form CMS–855 enrollments and claim submissions; and (2) considered feedback recently received from the OTP community regarding potential billing and enrollment options. Based on this, we project that over the first 3 years of our proposed changes to § 424.67:

- Roughly one-half (or 33) of the previously estimated 67 annually enrolling OTPs (that is, in Years 2 and 3 and beyond) would elect to complete a Form CMS–855A rather than a Form CMS–855B.
- Approximately 300 currently enrolled OTPs would change their enrollment from a Form CMS–855B to a Form CMS–855A.
- About 10 OTPs that enroll using the Form CMS–855A would later change their enrollment to a Form CMS–855B.

(a) New OTPs Enrolling via the Form CMS–855A

We estimate that it would take each OTP approximately 4 hours to secure and provide the relevant data on the Form CMS–855A and the new supplement thereto (which would capture OTP-specific information). Consistent with our experience, the OTP's medical secretary would obtain and report information on the Form CMS–855A and supplement, a task that would take roughly 3.5 hours (about 30 minutes of which would involve completion of the supplement). A health diagnosing and treating practitioner of the OTP would spend 30 minutes reviewing and signing the form.

Given the preceding data, we project an annual burden for new OTPs seeking to complete a Form CMS–855A of 132 hours (4 hr × 33 OTPs) at a cost of $5,855 (33 OTPs × ((3.5 hr × $36.62/hr) + (0.5 hr × $98.52/hr)). Since these OTPs would not be completing the Form CMS–855B as originally anticipated in the November 15, 2019 final rule and approved by OMB in that rule's collection of information request, we must revise the Form CMS–855B estimates identified therein. Using the hour and wage burdens from that rule, we project a Form CMS–855B annual burden reduction of 99 hours (33 OTPs × 3 hr) at a cost of $4,560 (33 OTPs × (2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr)).

(b) Enrolled OTPs Transitioning to Form CMS–855A or Form CMS–855B Enrollment

As already mentioned, we believe that roughly:

++ 300 currently enrolled OTPs would change their enrollment from a Form CMS–855B to a Form CMS–855A.

++ 10 OTPs that enroll using the Form CMS–855A would later change their enrollment to a Form CMS–855B.

This would involve the OTP's: (1) Completion of a Form CMS–855A or Form CMS–855B application as a new enrollment; and (2) reporting the voluntary termination of its existing Form CMS–855 enrollment via the latter form (*i.e.,* if the OTP is ceasing its Form CMS–855B enrollment, it would report this via a Form CMS–855B voluntary termination submission).

(i) Transition to Form CMS–855A Enrollment

Under our previously mentioned Form CMS–855A hour and wage estimates, we project a total burden for new Form CMS–855A enrollments pursuant to revised § 424.67(b) of 1,200 hours (300 OTPs × 4 hr) at a cost of $53,229 (300 OTPs × ((3.5 hr × $36.62/hr) + (0.5 hr × $98.52/hr)). Regarding voluntary terminations (and consistent with previous ICR estimates for reporting this type of Form CMS–855B transaction), the typical burden is 15 minutes. Of this time period, a medical secretary spends 12 minutes completing the relevant sections of the Form CMS–855 while a health diagnosing and treating practitioner takes 3 minutes to review and sign the form. This would result in a total burden of 75 hours (300 OTPs × 0.25 hr) at a cost of $3,675 (300 OTPs × ((0.2 hr × $36.62/hr) + (0.05 hr × $98.52/hr)).

We believe that the burden described in the previous paragraph would be incurred exclusively in the first year following our proposed changes; it is very likely these OTPs would wish to pursue Form CMS–855A enrollment as soon as possible in order to bill via the 837I. Accordingly, the average annual burden in the first 3 years would be as follows:

- Form CMS–855A—400 hours (1,200 hr/3) at a cost of $17,743 ($53,229/3).
- Form CMS–855B—25 hours (75 hr/3) at a cost of $1,225 ($3,675/3).

(ii) Transition to Form CMS–855B Enrollment

In line with our hour and wage estimates previously referenced in this section IV.B.1, we project a total burden for new Form CMS–855B enrollments under § 424.67(c)(2) of 30 hours (10 OTPs × 3 hr) at a cost of $1,480 (10 OTPs × ((2.5 hr × $36.62/hr) + (0.5 hr × $98.52/hr)). Concerning Form CMS–855A voluntary terminations (and using the time burdens identified earlier), we estimate a total burden of 2.5 hours (10 OTPs × 0.25 hr) at a cost of $123 (10 OTPs × ((0.2 hr × $36.62/hr) + (0.05 hr × $98.52/hr)).

We anticipate that changes to a Form CMS–855B would occur in the second and third years following the effective date of our revisions. This is because Year 1 would mostly involve these new OTPs enrolling for the first time via the Form-855A; only in the succeeding two years would they switch to a Form CMS–855B enrollment. We thus project that the average annual burden in the first 3 years would be as follows:

- Form CMS–855B—10 hours (30 hr/3) at a cost of $469 ($1,408/3).
- Form CMS–855A—0.8 hours (2.5 hr/3) at a cost of $41 ($123/3).

(2) Total Annual Burden

In light of foregoing estimates, and when averaged over the typical 3-year OMB approval period, we estimate the following:

- Form CMS–855A—The total annual increased burden would be 533 hours (132 hr + 400 hr + 0.8 hr) at a cost of $23,639 ($5,855 + $17,743 + $41).
- Form CMS–855B—We project a reduction in annual burden of −64 hours (−99 hr − 25 hr − 10 hr) and $2,866 (−$4,560 − $1,225 − $469).

(3) Application Fee

Under § 424.67(b)(2), an enrolling OTP must comply with the application fee requirements in § 424.514. This means, in short, that an OTP must pay the required application fee as part of the enrollment process. 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 did not set out such burden under this section of the

preamble, the cost is included under the Regulatory Impact Analysis section.

(4) Fingerprinting

We discussed in section III.B. of this proposed rule that certain OTPs are subject to the high-risk level of categorical screening under § 424.518. Said screening includes the submission of a set of fingerprints (via FBI Applicant Fingerprint Card FD–258) 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. In the November 15, 2019 final rule, we calculated the hour and cost burden associated with this activity, basing our estimates on an anticipated 1,900 total OTP enrollees over the 3-year period following publication of that rule.

We do not believe our proposed revisions to § 424.67 would involve any additional or reduced fingerprinting burden for two reasons. First, we are proposing in revised § 424.67(b)(3)(ii) that, in effect, Form CMS–855B-enrolled OTPs that are changing to a Form CMS–855A enrollment need only undergo the limited level of categorical screening (§ 424.518) if they have (as part of their Form CMS–855 enrollment) already successfully completed the moderate or high level of categorical screening under that same regulatory section. Since completion of moderate or high level screening (as applicable) would have been required for Form CMS–855B OTP enrollment, these OTPs (previously estimated at 300 total) would not have to again undergo fingerprinting as part of their Form CMS–855A enrollment. Second, and with the exception of the 300 new enrollments mentioned in the previous sentence, we do not foresee additional enrolling OTPs beyond: (1) The 1,900 which we estimated in the November 15, 2019 final rule; and (2) the roughly 67 newly enrolling OTPs in Year 2 and Year 3 and annually thereafter. In other words, the only change we project would be in the type of Form CMS–855 application these OTPs may complete, not the number of anticipated enrollees. As such, the total fingerprinting burden would not change.

2. 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.C., 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 sections VIII.H.7. and VIII.H.8. of this proposed rule for a discussion of the impacts associated with this rule's proposed changes to the Shared Savings Program's quality reporting requirements.

3. ICRs Regarding the Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan § 423.160(a)

The following requirements and burden will be submitted to OMB for approval under control number 0938–0763 (CMS–R–262).

We are proposing to implement section 2003 of the SUPPORT for Patients and Communities Act, which requires that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. We are proposing that prescribers be required to use the NCPDP SCRIPT 2017071 standard for Electronic Prescription for Controlled Substances (EPCS) prescription transmissions.

Based on internal 2019 CMS data, the transaction costs for the current process is approximately $2,855,390.85 [560,430 authorizations * 0.5 (accounting for one transaction since manual authorization takes 2 transactions) * $10.19 per manual authorization]) per year. Should we finalize this requirement after reviewing comments received in response to this proposed rule and the Request for Information entitled ''Medicare Program: Electronic Prescribing for Controlled Substances; Request for Information,'' the total annual cost for conducting the process electronically using the standard that we propose is $526,804.20($1.88 * 0.5 * 560,430 authorizations). This amounts to an annual savings of $2,328,586.65 ($2,855,390.85 − $526,804.20).

In the first year of implementation, we expect that prescribers would have to revise their policies and procedures and-train staff on this new requirement. Based on our conversations with the industry, we understand that because electronic prescribing is so widespread and vendors train the staff directly and set-up their systems, we estimate that this transition could be completed with a one-time burden of 5 hours at $36.62/hr by an Administrative Assistant or Medical Secretary. However, we seek comment on this assumption.

Based on internal CMS data, there are 425,000 Part D prescribing practices. Based on the increasing rate of doctors conducting e-prescribing thus far and the benefits of e-prescribing, in light of the current social distancing guidelines, we estimate that by January 1 2022, 65 percent of Part D prescribers will have electronic prescribing capabilities absent the requirement. Therefore, the one-time burden to implement this provision is 743,750 hours (148,750 prescribers * 5 hr) at a cost of $27,236,125 (743,750 hr * $36.62/hr). Based on the modeling that we have seen, we have found that EHR companies provide the initial set-up of e-prescribing software free of charge, provided the prescribers pay the per transaction cost of $1.88 mentioned previously. However, we seek comment on this assumption and all other assumption in this burden estimate.

Therefore, the total costs of the existing ePA activity is $2,855,390.85 per year as compared to $526,804.20 for using the standard. This amounts to an annual savings of $2,328,586.65 in prescriber expenses with the first year resulting in an added cost of $24,907,538.35 ($27,236,125 − $2,328,586.65)

4. ICRs Regarding the Medicare Diabetes Prevention Program (MDPP) Expanded Model

In section III.P. of this proposed rule, we propose policies necessary to allow certain flexibilities for Medicare enrolled MDPP suppliers and eligible beneficiaries in the MDPP Expanded Model during a public health emergency. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model, from the provisions of the PRA.

5. The Quality Payment Program (42 CFR Part 414 and Section IV. of this Proposed Rule)

The following QPP-specific ICRs reflect this rule's proposed policy changes and policies that have been finalized in our CY 2017 and 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), and our CY 2019 and CY 2020 PFS final rules (83 FR 59452 and 84 FR 62568, respectively).

a. Background

(1) ICRs Associated With MIPS and Advanced APMs

The Quality Payment Program is comprised of a series of ICRs associated with MIPS and Advanced APMs. The MIPS ICRs consist of: Registration for virtual groups (see section VI.B.5.b of this proposed rule); QCDR self-nomination applications and other requirements (see section VI.B.5.c.(2) of this proposed rule); qualified registry self-nomination applications and other

requirements (see section VI.B.5.c.(3) of this proposed rule); CAHPS survey vendor applications (see section VI.B.5.c.(4) of this proposed rule); Open Authorization credentialing and token request process (see section VI.B.5.d of this proposed rule); Quality Payment Program Identity Management Application Process (see section VI.B.5.e.(3) of this proposed rule); quality performance category data submission by Medicare Part B claims collection type (see section VI.B.5.e.(4) of this proposed rule), QCDR and MIPS CQM collection type (see section VI.B.5.e.(5) of this proposed rule), and eCQM collection type (see section VI.B.5.e.(6) of this proposed rule); CAHPS for MIPS survey beneficiary participation (see section VI.B.5.e.(7) of this proposed rule); group registration for CAHPS for MIPS survey (see section VI.B.5.e.(8) of this proposed rule); call for quality measures (see section VI.B.5.f of this proposed rule); reweighting applications for Promoting Interoperability and other performance categories (see section VI.B.5.g.(2) of this proposed rule); Promoting Interoperability performance category data submission (see section VI.B.5.g.(3) of this proposed rule); call for Promoting Interoperability measures (see section VI.B.5.h of this proposed rule); improvement activities performance category data submission (see section VI.B.5.i of this proposed rule); nomination of improvement activities (see section VI.B.5.j of this proposed rule); nomination of MVPs (see section VI.B.5.k of this proposed rule); and opt-out of Physician Compare for voluntary participants (see section VI.B.5.o of this proposed rule).

The ICRs for Advanced APMs consist of: Partial Qualifying APM Participant (QP) election (section VI.B.5.m of this proposed rule); Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes (sections VI.B.5.n.(1) and (2) of this proposed rule); and submission of data for QP determinations under the All-Payer Combination Option (section VI.B.5.n.(3) of this proposed rule).

(2) Summary of Quality Payment Program Changes: MIPS

Two of our currently approved MIPS ICRs [(1) quality performance category data submission by CMS Web Interface collection type and (2) group registration for the CMS Web Interface] are being removed while five MIPS ICRs [(1) quality performance category data submission by QCDR and MIPS CQM collection type, (2) quality performance category data submission by eCQM collection type, (3) CAHPS for MIPS survey beneficiary participation, (4) nomination of improvement activities, and (5) reweighting applications for Promoting Interoperability and other performance categories] show changes in burden due to proposed policies. In aggregate, we estimate the proposed policies will result in a net decrease in burden of −5,488 hours and −$488,115. The proposal discussed in section IV.A.3.c.(1)(c) of this proposed rule to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 performance period will result in removal of the quality performance category data submission by CMS Web Interface collection type and group registration for the CMS Web Interface ICRs. The same proposal will increase the number of respondents for both the MIPS CQM and QCDR and eCQM collection types for the quality performance category as we assume respondents who previously submitted via the CMS Web Interface collection type will alternatively utilize one of these collection types to submit quality data. The proposal discussed in section IV.A.3.c.(1)(e)(i) of this proposed rule to add a survey-based measure on telehealth that assesses patient-reported usage of telehealth services to the CAHPS for MIPS Survey will increase the time required for beneficiaries to respond to the survey by 0.2 minutes (0.0033 hours) per beneficiary. The proposal discussed in section IV.A.3.c.(3)(b)(i)(B)(bb) of this proposed rule to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible will increase the time by 1 hour per improvement activity nominated. Finally, the proposal discussed in section IV.A.3.c.(5)(e) of this proposed rule to allow APM Entities the ability to submit an extreme and uncontrollable circumstances exception application will increase our estimated number of respondents by 7 APM Entities. The remaining changes to our currently approved burden estimates are adjustments due to the use of updated data sources available at the time of publication of this proposed rule.

We have also added two new ICRs (Open Authorization (OAuth) Credentialing and Token Request Process (see section VI.B.5.d, below) and the Nomination of MVPs (see section VI.B.5.k, below). The Open Authorization (OAuth) Credentialing and Token Request Process ICR reflects the burden associated with the availability of a new process for all submitter types to request approval to submit data via direct upload to CMS. The Nomination of MVPs reflects the burden associated with a new process available for all stakeholders to nominate MVPs for inclusion in the Quality Payment Program.

We are not making any changes or adjustments to the following ICRs: Registration for virtual groups, CAHPS survey vendor applications, Quality Payment Program Identity Management Application Process, group registration for CAHPS for MIPS survey; call for MIPS quality measures; and call for Promoting Interoperability measures. See section VI.B.5. 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 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 are unable to predict with 100 percent certainty who will be a QP. New eligible clinician participants in Advanced APMs who become QPs would be excluded from MIPS reporting requirements and payment adjustments, and as such, unlikely to report under MIPS; while some current Advanced APM participants may end participation such that the APM Entity's eligible clinicians would not be QPs for a year based on § 414.1425(c)(5), and thus be required to report under MIPS. Second, it is difficult to predict what Partial QPs, who can elect whether to report to MIPS, will do in the 2021 MIPS performance period compared to the 2018 MIPS performance period, and therefore, the actual number of Advanced APM 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

For these ICRs (identified above under, ''ICRs Associated with MIPS and Advanced APMs''), the changes to currently approved burden estimates are adjustments based on updated projections for the 2021 MIPS performance period. We are not making any changes to the Other Payer Advanced APM identification: Eligible Clinician Initiated Process and submission of Data for QP determinations under the All-Payer Combination Option ICRs.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 53 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 53, 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 53.

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. As discussed in section IV.A.3.b. of this proposed rule, for clinicians in APM Entities, the APM Performance Pathway is available for both ACO and non ACOs to submit quality data. Due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period, we assume ACO APM Entities will submit data through the APM Performance Pathway and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity.

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.

Eligible clinicians who attain Partial QP status 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).

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TABLE 53: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician*

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
MIPS Eligible Clinicians and Other Eligible Clinicians Voluntarily Submitting MIPS Data, Participating in Shared Savings Program, and other MIPS APMs that use the APM Performance Pathway for model measures	As virtual group, group, individual clinicians, or APM Entity.[a]	As virtual group, group, individual clinicians, or APM Entity. Certain MIPS eligible clinicians are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category (please refer to the CY 2020 PFS final rule for a summary of the finalized criteria (84 FR 63111)). Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting. 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].[b]	As virtual group, group, or individual clinicians. MIPS APMs do not submit information. 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.[c]	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. MIPS APMs electing the APM Performance Pathway. APM Entities will make Partial QP election for participating eligible clinicians. Virtual groups must register via email.[d]

* 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] 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. 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.

[b] 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.

[c] 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 activity score. 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.

[d] Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, the CY 2019 and CY 2020 PFS final rules, and continued in this proposed rule create some additional data collection requirements not listed in Table 53. These additional data collections, some of which are currently 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 ICRs Related to MIPS Third-Party Intermediaries (See Section VI.B.5.c)

- 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).
- Open Authorization Credentialing and Token Request Process (New) (OMB 0938–1314) (see section VI.B.5.d).

Additional ICRs Related to the Data Submission and the Quality Performance Category (See Section VI.B.5.e)

- 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 (See Section VI.B.5.g)

- 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 (See Sections VI.B.5.f, VI.B.5.h, VI.B.5.j. and VI.B.5.k)

- 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 MIPS quality measures (83 FR 60010 through 60011) (OMB 0938–1314).
- Nomination of MVPs (OMB 0938–1314)

Additional ICRs Related to MIPS (See Section VI.B.5.o)

- 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 (See Sections VI.B.5.m and VI.B.5.n)

- 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 is not proposing 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)

In section IV.A.3.g. of this rule, we proposed multiple changes to the third party intermediary regulations at § 414.1400. Specifically, we are proposing to: (1) Amend current requirements for approval of third party intermediaries to take into account past performance and provision of inaccurate information regarding MIPS program requirements to eligible clinicians; (2) require attendance by all third party intermediaries for training and support sessions; (3) require that QCDRs and qualified registries must conduct an annual data validation audit and if one or more deficiencies or data errors are identified also conduct targeted audits; (4) incrementally increase requirements for QCDR measure testing and clarify what is meant by full testing; and (5) require third party intermediaries to submit a CAP to address identified deficiencies and data issues as well as actions to prevent recurrence. The collection of information burdens associated with each of these topics are discussed separately below for qualified registries, QCDRs, and survey vendors.

(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 either one quality performance category measure, or towards 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.[109] 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 nominate QCDR measures for approval for the reporting of quality performance category data. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval.

(2) QCDR Self-Nomination Applications

This rule is not proposing any new or revised collection of information requirements or burden related solely to QCDRs. For simplicity and due to limitations in data available, the changes in burden associated with QCDRs due to this rule's proposals have been incorporated into the discussion of burden for qualified registries. We assume no additional changes in burden due to other proposals discussed in this section. The requirements and burden for QCDRs are currently approved by OMB under control number 0938–1314 (CMS–10652). Consequently, we are not making any changes under that control number other than those discussed in the context of qualified registries.

(a) Self-Nomination Process and Other Requirements

We refer readers to § 414.1400(a)(4) 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. We also refer readers to § 414.1400(b) and the CY 2017 Quality Payment Program final rule (81 FR 77507 through 77508), CY 2018 Quality Payment Program final

[109] As stated in the CY 2019 PFS final rule (83 FR 53998), health IT vendors are not included in the burden estimates for MIPS.

rule (82 FR 53906 through 53908), CY 2019 PFS final rule (83 FR 59998 through 60000), and the CY 2020 PFS final rule (84 FR 63116 through 63121) for our previously finalized requirements and burden for self-nomination of QCDRs and nomination of QCDR measures. In sections VI.A.3.g.(2)(a) of this rule, we are proposing to codify that beginning with the 2023 payment year as a condition of approval each QCDR must conduct an annual data validation audit that conforms to the requirements in § 414.1400(b)(2)(iv), including specific obligations discussed in detail in those sections, and if one or more deficiencies or data errors are identified the QCDR must also conduct targeted audits that conform to the § 414.1400(b)(2)(v) including specific obligations discussed in detail in those sections. In particular, we propose to codify at § 414.1400(b)(2)(iv)(G), that in a form and manner and by a deadline specified by CMS, the QCDR must report the results of each data validation audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. In addition, we propose to codify at § 414.1400(b)(2)(v)(D), that in a form and manner and by a deadline specified by CMS, the QCDR must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected. We are not revising our burden estimates as a result of the proposal to codify that QCDRs must conduct particular data validation audits and report data validation results because we believe the burdens of the proposed data validation requirements are not greater than existing expectations for which we have already accounted the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999) and previously submitted to OMB for approval under control number 0938–1314 (CMS–10621). With regard to the proposal to require QCDRs to conduct targeted audits if one or more data errors are identified during data validation audits, we are unable to estimate the number of targeted audits which may occur or the time and costs associated with submitting results which could vary substantially depending on the nature of the data error and the amount of data to be audited. We seek comment on the burdens associated with the proposed requirements for data validation audits and targeted audits, including expected frequency of targeted audits and the anticipated scope of effort related to submitting results to assist in estimating the burden associated with this proposal. We also discuss additional impacts of this proposal in section VIII.F.16.d.(4)(d) of the Regulatory Impact Analysis.

In sections VI.A.3.g.(1)(b)(iii) of this rule, we are proposing to codify that beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner and at the times specified by CMS. Due to the nature of the information provided during these calls and because the proposed training requirements as applied to qualified registries and QDCRs are similar to existing expectations for these entities, we are not revising our burden estimates as a result of these proposals. However, we refer readers to section VIII.F.16.d.(4)(d) of this proposed rule for discussion of our estimates of overall impact.

In section VI.A.3.g.(1)(b)(ii) of this rule, we are proposing that the determination of whether to approve as entity as a third party intermediary for a MIPS performance period may take into account: (1) Whether the entity failed to comply with requirements of third party intermediaries for any prior MIPS payment year for which it was approved as third party intermediary; and (2) whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician. Because this proposal does not require any additional effort for affected entities but instead allows CMS to utilize already available information to make approval decisions, collection of information burden is unaffected for all entities. In addition, we do not anticipate this proposal will result in any QCDRs electing not to self-nominate during the 2021 MIPS performance period, but believe it is possible this may occur. However, we have neither any data nor knowledge of intent from previously approved QCDRs with which to support making any changes to our burden estimates as a result of this proposal. We are soliciting public feedback to help us determine if there are any burden implications.

(b) QCDR Measure Requirements

Previously, we finalized a requirement to require all QCDR measures to be fully developed and tested, with complete testing results at the clinician level, beginning with the CY 2021 performance period in the CY 2020 PFS final rule (84 FR 40816). In the May 8th COVID–19 IFC–2 (85 FR 27594 through 27595), we delayed this requirement such that beginning with the CY 2022 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. In section VI.A.3.g.(2)(b)(i)(A)(aa) of this rule, we are proposing an incremental approach to require fully tested QCDR measures. Specifically, we propose at § 414.1400(b)(3)(v)(C)(1) that, generally, QCDR measures that were previously approved for the CY 2020 performance period, would be required to, at a minimum, be face valid prior to being self-nominated for the CY 2022 performance period/CY 2024 payment year. To be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved. In order for the QCDR measure to be considered for approval, testing must be completed at the clinician level by the time the measure is self-nominated. However, to be included in an MVP for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested. QCDR measures that were previously approved for the 2020 performance period, will be required to, at a minimum, be face valid prior to being self-nominated for the CY 2022 performance period, and would be required to be fully tested prior to being self-nominated for any subsequent performance periods in order to be considered for inclusion in the MIPS program. Because these proposals are not modifying the final testing requirements for QCDR measures but are instead proposing modifications to the phasing and timeline for implementation of previously finalized requirements for QCDR measures other than those which will be included in an MVP, we are not making any changes to our currently approved burden estimates; however, we refer readers to section VIII.F.16.d.(4)(d) of this proposed rule for discussion of impacts associated with this proposal. Such burden estimates and requirements are currently approved by OMB under control number 0938–1314 (CMS–10621). We seek comment on our burden estimates and assumptions

associated with these proposals regarding the testing of QCDR measures including those which will be included in an MVP.

(3) Qualified Registry Self-Nomination Process and Other Requirements

The requirements and burden associated with this rule's proposed data submission changes related to qualified registries and QCDRs will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to § 414.1400(a)(4) which states 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. We also refer readers to § 414.1400 (c) and the CY 2017 Quality Payment Program final rule (81 FR 77507 through 77508), CY 2018 Quality Payment Program final rule (82 FR 53906 through 53908), CY 2019 PFS final rule (83 FR 59997 through 59998), and the CY 2020 PFS final rule (84 FR 63114 through 63116) for our previously finalized requirements and burden for self-nomination of qualified registries.

In sections IV.A.3.g.(3)(a) of this rule, we are proposing to codify that beginning with the 2023 payment year as a condition of approval each qualified registry must conduct an annual data validation audit that conforms to the requirements in § 414.1400(b)(2)(iv), including specific obligations discussed in detail in those sections and if one or more deficiencies or data errors are identified the qualified registry must also conduct targeted audits that conform to the § 414.1400(b)(2)(v) including specific obligations discussed in detail in those sections. In particular, we propose to codify at § 414.1400(c)(2)(iii)(G), that in a form and manner and by a deadline specified by CMS, the qualified registry must report data validation results, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. In addition, we propose to codify at § 414.1400(c)(2)(iv)(D), in a form and manner and by a deadline specified by CMS, the qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each error type was corrected. We are not revising our burden estimates as a result of the proposal to codify that qualified registries must conduct particular data validation audits and report data validation results because we believe the burdens of the proposed data validation requirements are not greater than existing expectations for which we have already accounted for the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999) and previously submitted to OMB for approval under control number 0938–1314 (CMS–10621). With regard to the proposal to require qualified registries conduct targeted audits if one or more data errors are identified during data validation audits, we are unable to estimate the number of targeted audits which may occur or the time and costs associated with submitting results which could vary substantially depending on the nature of the data error and the amount of data to be audited. We seek comment on the burdens associated with the proposed requirements for data validation audits and targeted audits, including expected frequency of targeted audits and the anticipated scope of effort related to submitting results to assist in estimating the burden associated with this proposal. We also discuss additional impacts of this proposal in section VIII.F.16.d.(4)(d) of the Regulatory Impact Analysis.

In sections VI.A.3.g.(1)(b)(iii) of this rule, we are proposing to codify that beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner and at the times specified by CMS. Due to the nature of the information provided during these calls and because the proposed training requirements as applied to qualified registries and QDCRs are similar to existing expectations for these entities, we are not revising our burden estimates as a result of these proposals. However, we do refer readers to section VIII.F.16.d.(4)(d) of this proposed rule for discussion of our estimates of the overall impact of this proposal for all third party intermediaries.

In section VI.A.3.g.(1)(b)(ii) of this rule, we are proposing that the determination of whether to approve an entity as a third party intermediary for a MIPS performance period may take into account: (1) Whether the entity failed to comply with requirements of third party intermediaries for any prior MIPS payment year for which it was approved as third party intermediary; and (2) whether the entity provided inaccurate information regarding the requirements of the subpart to any eligible clinician. Because this proposal does not require any additional effort for affected entities but instead allows CMS to utilize already available information to make approval decisions, collection of information burden is unaffected for all entities. We also do not anticipate this proposal will result in any qualified registries or other third party intermediaries electing not to self-nominate during the 2021 MIPS performance period, but believe it is possible this may occur. However, we have neither any data nor knowledge of intent from previously approved qualified registries or other third party intermediaries with which to support making any changes to our burden estimates as a result of this proposal. We are soliciting public feedback to help us determine if there are any burden implications.

In section VI.A.3.g.(4) of this proposed rule, we are proposing to modify the existing requirement at § 1400(f)(1)(i) requiring third party intermediaries to submit to CMS by a date specified by the agency a Corrective Action Plan (CAP) to address the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring. While the requirement for third party intermediaries to submit a CAP was finalized in our CY 2017 Quality Payment Program final rule (81 FR 77389), we did not specify the information that must be included to be included in the CAP and neglected to identify the burden associated with the required information. We are correcting that oversight in this proposed rule. In addition, to clarify expectations and create consistency in the content of the CAPs provide by third party intermediaries, we are proposing to revise and elaborate on the obligations for a CAP in this proposed rule. Specifically, we propose to modify § 414.1400(f)(1)(i) such that, unless different or additional information is specified by CMS, the CAP submitted by the third party intermediary must address four issues: (1) The issues that contributed to the non-compliance; (2) the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program; (3) the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved will not

recur in the future and (4) the detailed timeline for achieving compliance with the applicable requirements. Specifically, we propose at § 414.1400(f)(1)(i)(A) to require that each third party intermediary be required to articulate the issues that contributed to the non-compliance. The third party intermediary must articulate what factors cause it to fail in its obligation to meet program requirements. We also propose at § 414.1400(f)(1)(i)(B) to require that a third party intermediary subject to a CAP disclose to CMS the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program. In addition, we propose at § 414.1400(f)(1)(i)(C) that a third party intermediary subject to a CAP must address the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future. Furthermore, we propose at § 414.1400(f)(1)(i)(D) that each CAP must include the detailed timeline for achieving compliance with the applicable requirements. We have historically received a total of 34 CAPs over the 3-year period of CY 2017–2019 (an average of 11.3 per year). As third party intermediaries become increasingly effective at identifying data issues and discrepancies prior to submitting data to CMS and accounting for the estimated decrease in number of QCDRs and qualified registries self-nominating in the 2020 MIPS performance period compared to the 2019 MIPS performance period (from 350 to 229), we anticipate the annual number of CAPs received to decrease to fewer than 10 per year (83 FR 59997 through 60000 and 84 FR 63114 through 63121). The effort involved in developing a CAP including the detail specified in this proposed rule and submitting it to CMS is likely to be no more than 3 hours for a computer systems analyst at a rate of $92.46/hr. In aggregate we estimate an annual burden of no more than 30 hours (3 hr × 10 CAPs) at a cost of $2,774 (30 hr × $92.46/hr) for third party intermediaries to develop and submit a CAP.

In the CY 2020 PFS final rule, we estimated 153 qualified registries would self-nominate (84 FR 63116). Using updated wage rates, the currently approved burden associated with these qualified registries is 459 hours (153 respondents × 3 hr/respondent) at a cost of $42,439 (459 hr × $92.46/hr). Because we are unable to predict how many of the estimated 10 third party intermediaries submitting CAPs will be qualified registries, QCDRs, survey vendors, or health IT vendors; for simplicity we are adding the burden to the currently approved burden for qualified registries for a total of 489 hours (459 hr + 30 hr) at a cost of $45,213 ($42,439 + $2,774).

(4) Survey Vendor Requirements

This rule is not proposing 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.

(5) Health IT Vendors

This rule is not proposing any new or revised collection of information requirements or burden related to health IT vendors and we do not anticipate any changes to the CEHRT process as a result of proposals promulgated in this proposed rule. Consequently, we are not setting out burden or making any changes under the 0938–1314 (CMS–10621) control number.

d. Open Authorization (OAuth) Credentialing and Token Request Process

In the CY 2017 Quality Payment Program final rule (81 FR 77035), we finalized the initial MIPS data submission terminology at § 414.1305 and requirements at § 414.1325, as well as the associated burden estimates. As discussed in the CY 2019 PFS final rule (83 FR 59747 through 59748), it subsequently came to our attention that the way we had previously described data submission did not precisely reflect the experience users have when submitting data to us. To ensure clarity and precision for all users, we amended the terminology at § 414.1305 to more precisely reflect this experience and made conforming amendments to § 414.1325 and other MIPS regulations. Among the newly defined terms was ''submission type'', which we defined at § 414.1305 as the mechanism by which a submitter type submits data to CMS, including, as applicable: Direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web Interface. We stated in the CY 2019 PFS final rule that the direct submission type allows users to transmit data through a computer-to-computer interaction, such as an Application Programming Interface (API).

Beginning in the 2021 MIPS performance period, CMS will offer the Open Authorization (OAuth) Credentialing and Token Request Process. This process utilizes an API to allow users to transmit data through a computer-to-computer interaction. As such, it is an alternate means of operationalizing the previously established direct submission type. The process first requires software developers to apply for production OAuth credentials to the submissions API by registering their application so that it can interact with the system providing OAuth capabilities. Next, the developer must request a meeting with the Quality Payment Program development team. During this meeting, the requesting organization will demonstrate their application's use of OAuth to successfully submit data in the Submissions API test environment. The requesting organization will also provide documentation about their terms of service, privacy policy, and related information for review by the Quality Payment Program team. If further clarification is required about any of the documentation or application, the Quality Payment Program team will follow up with the requesting organization. Once approved, the Quality Payment Program development team will issue production OAuth credentials to the requesting organization's point of contact. Detailed instructions for the authentication process and application for organizations to request OAuth credentials are available at *https://cmsgov.github.io/qpp-submissions-docs/*.

The following burden estimates are associated with the first year of data collection for the OAuth Credentialing and Token Request Process. This process is available to all submitter types to be approved to submit data via the direct submission type. However, we assume the only parties that will elect to undergo the process will be health IT vendors or other third party intermediaries, as we believe these are the most likely parties to be developing applications. The burden associated with this ICR belongs only to the application developer; QPP participants will not be required to do anything additional to submit their data. For third party intermediaries, OAuth Credentialing will allow QPP participants to use their own QPP credentials to login through the third party intermediary's application to submit their data and view performance feedback from QPP. The proposed burden associated with the OAuth

Credentialing and Token Request Process will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). 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 and CY 2020 PFS final rules at § 414.1400(a)(2) (83 FR 60088 and 84 FR 63052) for our current policy regarding the types of MIPS data third party intermediaries may submit.

As stated in the CY 2020 PFS final rule (84 FR 63049) we are aware of stakeholders' desire to have a more cohesive participation experience across all performance categories under MIPS. We are offering this process in support of our current requirements for QCDRs and qualified registries to be able to submit data for all MIPS performance categories and health IT vendors to be able to submit data for at least one MIPS performance category (84 FR 63052 and 84 FR 63076) as well as our desire to further reduce administrative burden for clinicians to participate in MIPS. As we discuss in sections VI.B.5.e.(5), VI.B.5.e.(6), VI.B.5.g, and VI.B.5.i of this proposed rule individual clinicians or groups may submit their quality measures using the direct submission type via the MIPS CQM and QCDR or eCQM collection types as well as their Promoting Interoperability measures and improvement activities through the same direct submission type. Entities that receive approval for their applications through this process will be able to provide QPP participants a more comprehensive and less administratively burdensome experience using the direct submission type.

We estimate it would take approximately 1 hour at $92.46/hr for a computer systems analyst (or their equivalent) to provide documentation and any follow-up communication via email. We estimate that for during the 2021 MIPS performance period, 15 submitter types, consisting of third party intermediaries will complete this process to be approved for the CY 2022 submission period. We expect health IT vendors to adopt this method initially, with limited further adoption by QCDRs and Qualified Registries in future years. As shown in Table 54, we estimate it would take 1 hour at $92.46/hr for a computer systems analyst (or their equivalent) to complete the process. We estimate an annual burden of 15 hours (15 vendors × 1 hr) at a cost of $1,387 (15 hr × $92.46/hr) or $92.46 per organization ($1,387/15 vendors).

TABLE 54: Estimated Burden for the OAuth Credentialing and Token Request Process

	Burden Estimate
# of Organizations (a)	15
Total Annual Hours Per Organization to Submit (b)	1
Total Annual Hours (c) = (a)*(b)	**15**
Cost Per Organization (@ computer systems analyst's labor rate of $92.46/hr.) (d)	$92.46/hr
Total Annual Cost (e) = (a)*(d)	$1,387

e. ICRs Regarding Quality Data Submission (§§ 414.1325 and 414.1335)

(1) Background

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77502 through 77503), CY 2018 Quality Payment Program final rule (82 FR 53908 through 53912), CY 2019 PFS final rule (83 FR 60000 through 60003), and the CY 2020 PFS final rule (84 FR 63121 through 63124) for our previously finalized requirements for data submission for the quality performance category.

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 subject to MIPS payment adjustments. Clinicians are ineligible for MIPS payment adjustments 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.

(2) Changes and Adjustments to Quality Performance Category Respondents

To determine which QPs should be excluded from MIPS, we used the QP List for the 2019 third snapshot that contains participation in Advanced APMs as of August 31, 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 (QP) definition at § 414.1305 for the 2021 QP Performance Period. We assumed that all Partial QPs will 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 2021 QP Performance Period (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the number of respondents.

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). In the CY 2020 PFS final rule, we provided a set of assumptions and an approach to account for the clinicians not in small practices for whom the Medicare Part B claims collection type will no longer be available as an option for collecting and reporting quality data (84 FR 63121 through 63122). As in the CY 2020 PFS final rule, we are using 2018 MIPS performance period data to estimate the number of respondents, so we use the same methodology for this proposed rule; however, because of changes in the number of QPs and APM participation, the application of this methodology results in a slightly different adjustment to our estimates of respondents. In the CY 2020 PFS final rule, this approach resulted in a 103,103 decrease in the estimated number of clinicians who will submit quality data via Medicare Part B claims and a 12,931 increase in the number of clinicians who will submit via the QCDR/MIPS CQM collection type (84 FR 63122). For this rule, our assumptions result in a 101,390 decrease (from 195,977 to 94,587 in the estimated number of clinicians who will

submit quality data via Medicare Part B claims and a 12,496 increase (from 92,340 to 104,836 in the number of clinicians who will submit via the MIPS CQM and QCDR collection type.

In section IV.A.3.c.(1)(c) of this rule, we are proposing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 performance period. If this proposal is finalized, it will result in groups of 25 or more clinicians that previously submitted quality performance data via the CMS Web Interface being required to use an alternate collection type, which will have to be either the MIPS CQM and QCDR or eCQM collection type. While we know that 111 groups submitted quality performance data via the CMS Web Interface in the 2019 MIPS performance period, we are not able to ascertain what alternative collection type(s) the groups would elect. In order to estimate the number of groups that will select each of these collection types, we first clustered the number of groups which submitted data via the CMS Web Interface collection type during the 2018 MIPS performance period by practice size (between 25 and 49 clinicians, between 50 and 99 clinicians, etc.). Then, for each cluster, we allocated these groups to each of the MIPS CQM and QCDR and eCQM collection types based on the percent of TINs that submitted MIPS data via these two collection types. For example, of the 1,335 TINs with a practice size of 25 to 49 clinicians which submitted data for the 2018 MIPS performance period, 974 (73 percent) submitted data via the MIPS CQM and QCDR collection type and 361 (27 percent) submitted data via the eCQM collection type. We applied these percentages to the 11 TINs with a practice size of 25 to 49 clinicians which submitted data via the CMS Web Interface collection type for the 2018 MIPS performance period to estimate that 8 (11 TINs $\times$ 0.73) would elect to submit data via the MIPS CQM and QCDR collection type and the remaining 3 (11 TINs $\times$ 0.27) would elect to submit data via the eCQM collection type. In total, we estimate that 50 of the 111 groups that submitted data via the CMS Web Interface collection type for the 2018 MIPS performance period will now submit quality data via the MIPS CQM and QCDR collection type and 61 groups will now submit quality data via the eCQM collection type. Note that the 111 groups is an increase of 7 from our currently approved estimate of 104 groups due to updated data (84 FR 63123) (111 groups $-$ 104 groups). We also performed this analysis to determine the number of clinicians that would be affected and would need to submit quality data via an alternate collection type. In total, of the estimated 39,318 individual clinicians affected by this proposal, we estimate that 11,448 would submit quality data as part of a group via the MIPS CQM and QCDR collection type and 27,870 would submit quality data as part of a group via the eCQM collection type. These estimates are reflected in Tables 55 and 57 and the associated changes in burden are reflected in Tables 61, 63, and 85. In aggregate, as discussed in sections VI.B.5.e.(5), (6), and (9) of this proposed rule, we estimate the proposal to sunset the CMS Web Interface measures as a collection type/submission type will result in a net decrease in quality performance data reporting burden while acknowledging the additional financial impacts on clinicians as discussed in section VIII.F.16.d.(4)(b)(i) of the Regulatory Impact Analysis. We assume that 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional reporting for ACO APM entities, consistent with assumptions used in the CY 2019 and CY 2020 PFS final rules (83 FR 60000 through 60001 and 84 FR 63122), we include all quality data voluntarily submitted by MIPS APM participants made at the individual or TIN-level in our respondent estimates. As stated in section VI.4.a.(4) of this proposed rule, we assume non-ACO APM Entities will participate through traditional MIPS and submit as an individual or group rather than as an entity. To estimate who will be a MIPS APM participant in the 2021 MIPS performance period, we used the latest QP List for the third snapshot data of the 2019 QP performance period and supplemented with clinicians who are in an APM in 2018 but not in the 2019 snapshot. 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 2018 MIPS performance period.

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.[110] Tables 55, 56 and 57 explain our 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 55 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the 2021 MIPS performance period based on data from the 2018 MIPS performance period.

For the 2021 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. We estimate the burden for collecting data via collection type: Claims, QCDR and MIPS CQMs, and eCQMs. 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.

As shown in Table 55, using participation data from the 2018 MIPS performance period combined with the estimate of QPs for the 2021 performance period, we estimate a total of 792,061 clinicians will submit quality data as individuals or groups in the 2021 MIPS performance period, an increase of 11,456 clinicians when compared to our estimate of 780,605 clinicians in the CY 2020 PFS final rule (84 FR 63122). We estimate 94,587 clinicians will submit data as individuals for the Medicare Part B claims collection type; 410,518 clinicians will submit data as individuals or as part of groups for the MIPS CQM and QCDR collection type; and 286,956 clinicians will submit data as individuals or as part of groups via eCQM collection types.

Table 55 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

[110] 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.

expected number of clinicians to submit as individuals or part of groups.

TABLE 55: Estimated Number of Clinicians Submitting Quality Performance Category Data by Collection Type (as Individual Clinicians or as Part of Groups)

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2021 MIPS performance period (excludes QPs) (a)	94,587	410,518	286,956	0	792,061
* 2020 MIPS performance period (excludes QPs) (b)	94,846	391,430	247,856	46,473	780,605
Difference (c)=(a)-(b)	-259	+19,088	+39,100	-46,473	+11,456

*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 2018 MIPS performance period.

Table 56 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 2021 MIPS performance period. We estimate that approximately 94,587 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 104,836 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 41,477 clinicians will submit data as individuals using eCQMs collection type.

TABLE 56: 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
2021 MIPS Performance Period (excludes QPs) (a)	94,587	104,836	41,477	0	240,900
* 2020 MIPS Performance Period (excludes QPs) (b)	94,846	100,269	38,935	0	234,050
Difference (c)=(a)-(b)	-259	+4,567	+2,542	0	+6,850

*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 56 are not mutually exclusive.

Table 57 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the 2021 MIPS performance period. We assume that groups that submitted quality data as groups in the 2018 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 2021 MIPS performance period. Specifically, we estimate that 11,071 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type on behalf of 305,682 clinicians; and 4,474 groups and virtual groups will submit for eCQM collection types on behalf of 245,479 eligible clinicians. In section IV.A.3.(b) of this rule, we are proposing the APM Performance Pathway for clinicians in APM Entities. The APM Performance Pathway is available for both ACO and non ACOs. However, due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism, we assume non-ACO APM Entities would participate through traditional MIPS and base our estimates on submissions received in the 2018 MIPS performance period.

TABLE 57: 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
2021 MIPS performance period (excludes QPs) (a)	0	11,071	4,474	0	15,545
*2020 MIPS performance period (b)	0	10,949	4,398	104	15,451
Difference (c)=(a)-(b)	0	+122	+76	-104	+94

*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 2021 MIPS performance period, the total number of quality measures will be 206. The new MIPS quality measures proposed for inclusion in MIPS for the 2021 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 58 as well as counts of new, removed, and substantively changed measures.

TABLE 58: Summary of Quality Measures for the 2021 MIPS Performance Period

Collection Type	# Measures Proposed as New	# Measures Proposed for Removal	# Measures Proposed with a Substantive Change	# Measures Remaining for CY 2021*
Medicare Part B Claims Specifications	0	-10	23	45
MIPS CQMs Specifications	0	-14	81	182
eCQM Specifications	0	0	35	47
Survey – CSV	0	0	0	1
CMS Web Interface Measure Specifications	0	-10	0	0
Administrative Claims	+2	-1	0	2
Total	+2	-14	92	206

*A measure may be specified under multiple collection types but will only be counted once in the total.

For the 2021 MIPS performance period, there is a net reduction of 12 quality measures across all collection types compared to the 218 measures finalized for the 2020 MIPS performance period (84 FR 63124). Specifically, as discussed in section IV.A.3.c.(1)(d), we are proposing to add 2 new administrative claims outcome measures, remove 14 quality measures, and make substantive updates to 92 quality measures where the changes will require the removal of an existing benchmark. 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.

(3) Quality Payment Program Identity Management Application Process

This rule is not proposing 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.

(4) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

This rule is not proposing 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 adjusting our currently approved burden estimates based on more recent data. The following proposed burden

will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77501 through 77504), CY 2018 Quality Payment Program final rule (82 FR 53912), CY 2019 PFS final rule (83 FR 60004 through 60005), and the CY 2020 PFS final rule (84 FR 63124 through 63126) for our previously finalized requirements and burden for quality data submission via the Medicare Part B claims collection type.

As noted in Table 55, based on 2018 MIPS performance period data, we assume that 94,587 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. This rule is proposing to adjust the number of Medicare Part B claims respondents from 94,846 to 94,587 (a decrease of 259) based on more recent data and our methodology of accounting only for clinicians in small practices who submitted such claims data in the 2018 MIPS performance period rather than all clinicians who submitted quality data codes to us for the Medicare Part B claims collection type.

As shown in Table 59, consistent with our currently approved per response time figures, we estimate that the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) at a cost of $13.87 (0.15 hr × $92.46/hr) to 7.2 hours at a cost of $665.71 (7.2 hr × $92.46/hr). The burden will involve becoming familiar with MIPS quality measure specifications. We believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $110.74/hr for a medical and health services manager, 1 hour at $212.78/hr for a physician, 1 hour at $46.64/hr for an LPN, 1 hour at $92.46/hr for a computer systems analyst, and 1 hour at $39.06/hr for a billing and posting clerk. We are not revising our currently approved per response time estimates.

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 676,297 hours (7.15 hr × 94,587 clinicians) to 1,343,135 hours (14.2 hr × 94,587 clinicians). The estimated annual cost (per clinician) ranges from $737.03 [(0.15 hr × $92.46/hr) + (3 hr × $110.74/hr) + (1 hr × $92.46/hr) + (1 hr × $46.64/hr) + (1 hr × $39.06/hr) + (1 hr × $212.78/hr)] to a maximum of $1,388.87 [(7.2 hr × $92.46/hr) + (3 hr × $110.74/hr) + (1 hr × $92.46/hr) + (1 hr × $46.64/hr) + (1 hr × $39.06/hr) + (1 hr × $212.78/hr)]. The total annual cost ranges from a minimum of $69,713,362 (94,587 clinicians × $737.03) to a maximum of $131,369,236 (94,587 clinicians × $1,388.87).

Table 59 summarizes the range of total annual burden associated with clinicians submitting quality data via Medicare Part B claims.

TABLE 59: Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

	Minimum Burden	Median Burden	Maximum Burden
# of Clinicians (a)	94,587	94,587	94,587
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Medical and Health Services Manager 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 Physician 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)	**676,297**	**761,425**	**1,343,135**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $92.46/hr @ varying times) (j)	$13.87	$97.08	$665.71
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $110.74/hr @ 3 hr) (k)	$332.22	$332.22	$332.22
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $92.46/hr @ 1 hr) (l)	$92.46	$92.46	$92.46
Cost to Review Measure Specifications (@ LPN's labor rate of $46.64/hr @1 hr) (m)	$46.64	$46.64	$46.64
Cost to Review Measure Specifications (@ billing clerk's labor rate of $39.06/hr @ 1 hr) (n)	$39.06	$39.06	$39.06
Cost to Review Measure Specifications (@ physician's labor rate of $212.78/hr @ 1 hr) (o)	$212.78	$212.78	$212.78
Total Annual Cost Per Clinician (p) = (j)+(k)+(l)+(m)+(n)+(o)	$737.03	$820.24	$1,388.87
Total Annual Cost (q) = (a)*(p)	**$69,713,362**	**$77,584,325**	**$131,369,236**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 60, using the unchanged currently approved per respondent burden estimates which range from $737.03 to $1,388.87, the decrease in number of respondents from 94,846 to 94,587 results in a total adjustment of between −1,852 hours (−259 respondents × 7.15 hr/respondent) at a cost of −$190,891 (−259 respondents × $737.03/respondent) and −3,678 hours (−259 respondents × 14.2 hr/respondent) at a cost of −$359,718 (−259 respondents × $1,388.87/respondent). For purposes of calculating total burden associated with the proposed rule as shown in Table 60, only the maximum burden is used.

TABLE 60: Adjusted 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 2020 Final Rule (a)	678,149	763,510	1,346,813
Total Annual Hours for Respondents in CY 2021 Proposed Rule (b)	676,297	761,425	1,343,135
Difference (c) = (b)-(a)	**-1,852**	**-2,085**	**-3,678**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$69,904,253	$77,796,768	$131,728,954
Total Annual Cost for Respondents in CY 2021 Proposed Rule (e)	$69,713,362	$77,584,325	$131,369,236
Difference (f) = (e)-(d)	**-$190,891**	**-$212,443**	**-$359,718**

(5) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

The following proposed requirement and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77504 through 77505), CY 2018 Quality Payment Program final rule (82 FR 53912 through 53914), CY 2019 PFS final rule (83 FR 60005 through 60006), and the CY 2020 PFS final rule (84 FR 63127 through 63128) for our previously finalized requirements and burden for quality data submission via the MIPS CQM and QCDR collection types.

As discussed in section IV.A.3.c.(1)(c) of this rule, we are proposing to sunset the CMS Web Interface measures as a collection type and submission type starting with the 2021 performance period. Using the methodology discussed in section VI.B.5.e.(1) of this proposed rule, we estimate 50 groups which previously submitted quality data via the CMS Web Interface collection type will now submit quality data via the MIPS CQM and QCDR collection type.

As noted in Tables 55, 56, and 57, and based on 2018 MIPS performance period data, we assume that 410,518 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types; 104,836 clinicians will submit as individuals and the remaining 305,682 clinicians will submit as members of 11,071 groups and virtual groups. 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 quality measure specifications 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 $891.13. This consists of 3 hours at $92.46/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $110.74/hr for a medical and health services manager, 1 hour at $92.46/hr for a computer systems analyst, 1 hour at $46.64/hr for a LPN, 1 hour at $39.06/hr for a billing clerk, and 1 hour at $212.78/hr for a physician 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) at $92.46/hr for a computer systems analyst at a cost of $7.70 (0.083 hr × $92.46/hr). Overall we estimate a cost of $897.47/response [(3 hr × $92.46/hr) + (2 hr × $110.74/hr) + (1 hr × $212.78/hr) + (1 hr × $92.46/hr) + (1 hr × $46.64/hr) + (1 hr × $39.06/hr) + (0.083 hr × $92.46/hr)].

In aggregate, we estimate an annual burden of 1,052,783 hours [9.083 hr/response × (104,836 clinicians submitting as individuals + 11,071 groups submitting via QCDR or MIPS CQM on behalf of individual clinicians or 115,907 responses)] at a cost of $ 104,023,540 (115,907 responses × $897.47/response). Based on these assumptions, we have estimated in Table 61 the burden for these submissions.

TABLE 61: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

	Burden Estimate
# of clinicians submitting as individuals (a)	104,836
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	11,071
# of Respondents (groups plus clinicians submitting as individuals) (c)=(a)+(b)	115,907
Hours Per Respondent to Report Quality Data (d)	3
# of Hours Medical and Health Services Manager 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 Physician Review Measure Specifications (i)	1
# 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)	**1,052,783**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $92.46/hr) (m)	$277.38
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $110.74/hr) (n)	$221.48
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $92.46/hr) (o)	$92.46
Cost LPN Review Measure Specifications (@ LPN's labor rate of $46.64/hr) (p)	$46.64
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $39.06/hr) (q)	$39.06
Cost Physician Review Measure Specifications (@ physician's labor rate of $212.78/hr) (r)	$212.78
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $92.46/hr) (s)	$7.70
Total Annual Cost Per Respondent (t) = (m)+(n)+(o)+(p)+(q)+(r)+(s)	$897.47
Total Annual Cost (u) = (c)*(t)	**$104,023,540**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 62, using the unchanged currently approved per respondent burden estimate, the increase of 4,689 respondents from 111,218 to 115,907 results in an increase of 42,590 hours (4,689 respondents × 9.083 hr/respondent) and $4,208,256 (4,689 respondents × $897.47/respondent).

TABLE 62: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	1,010,193
Total Annual Hours for Respondents in CY 2021 Proposed Rule (b)	1,052,783
Difference (c) = (b)-(a)	**+42,590**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$99,815,283
Total Annual Cost for Respondents in CY 2021 Proposed Rule (e)	$104,023,540
Difference (f) = (e)-(d)	**+$4,208,256**

(6) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

The following proposed requirement and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77505 through 77506), CY 2018 Quality Payment Program final rule (82 FR 53914 through 53915), CY 2019 PFS final rule (83 FR 60006 through 60007), and the CY 2020 PFS final rule (84 FR 63128 through 63130) for our previously finalized requirements and burden for quality data submission via the eCQM collection types.

In section IV.A.3.c.(1)(c) of this rule, we are proposing to sunset the CMS Web Interface measures as a collection type and submission type starting with the 2021 performance period. Using the methodology discussed in section VI.B.5.e.(1) of this proposed rule, we estimate 61 groups which previously submitted quality data via the CMS Web Interface collection type will now submit quality data via the eCQM collection type.

Based on 2018 MIPS performance period data, we assume that 286,956 clinicians will elect to use the eCQM collection type; 41,477 clinicians are expected to submit eCQMs as individuals; and 4,474 groups and virtual groups are expected to submit eCQMs on behalf of the remaining 245,479 clinicians. 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. For this collection of information request, we estimate 45,951 respondents (41,477 clinicians who are expected to submit eCQMs as individuals + 4,474 groups and virtual groups who are expected to submit eCQMs) an increase of 2,618 respondents (45,951 proposed respondents − 43,333 active respondents).

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 a QCDR/qualified registry 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 a QCDR/qualified registry.

We estimate that it will take no more than 2 hours at $92.46/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS quality measure specifications. 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 $110.74/hr for a medical and health services manager, 1 hour at $212.78/hr for a physician, 1 hour at $92.46/hr for a computer systems analyst, 1 hour at $46.64/hr for an LPN, and 1 hour at $39.06/hr for a billing clerk. Overall we estimate a cost of $797.34/response [(2 hr × $92.46/hr) + (2 hr × $110.74/hr) + (1 hr × $212.78/hr) + (1 hr × $92.46/hr) + (1 hr × $46.64/hr) + (1 hr × $39.06/hr)].

In aggregate we estimate an annual burden of 367,608 hours (8 hr × 45,951 groups and clinicians submitting as individuals) at a cost of $36,638,570 (45,951 responses × $797.34/response). Based on these assumptions, we have estimated in Table 63 the burden for these submissions.

TABLE 63: 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)	41,477
# of Groups submitting via EHR on behalf of individual clinicians (b)	4,474
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	45,951
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2
# of Hours Medical and Health Services Manager 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 Physicians Review Measure Specifications (i)	1
Annual Hours Per Respondent (j)=(d)+(e)+(f)+(g)+(h)+(i)	8
Total Annual Hours (k)=(c)*(j)	**367,608**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $92.46/hr) (l)	$184.92
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $110.74/hr) (m)	$221.48
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $92.46/hr) (n)	$92.46
Cost to Review Measure Specifications (@ LPN's labor rate of $46.64/hr) (o)	$46.64
Cost to Review Measure Specifications (@ clerk's labor rate of $39.06/hr) (p)	$39.06
Cost to D21Review Measure Specifications (@ physician's labor rate of $212.78/hr) (q)	$212.78
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$797.34
Total Annual Cost (s) = (c)*(r)	**$36,638,570**

As shown in Table 64, using the unchanged currently approved per respondent burden estimate, the increase of 2,618 respondents from 43,333 to 45,951 results in a total difference of 20,944 hours (2,618 respondents × 8 hr/respondent) at a cost of $2,087,436 (2,618 respondents × $797.34/respondent).

TABLE 64: 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 2020 Final Rule (a)	346,664
Total Annual Hours for Respondents in CY 2021 Proposed Rule (b)	367,608
Difference (c) = (b)-(a)	**+20,944**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$34,551,134
Total Annual Cost for Respondents in CY 2021 Proposed Rule (e)	$36,638,570
Difference (f) = (e)-(d)	**+$2,087,436**

(7) Beneficiary Responses to CAHPS for MIPS Survey

In this proposed rule, we are proposing changes to requirements for the CAHPS for MIPS survey which, if finalized, will result in updates to the CAHPS for MIPS survey instrument which is currently approved by OMB under control number 0938–1222 (CMS–10450). The survey instrument is not ready at this time, therefore we will make the updated survey instrument and burden available for public review through a stand-alone non-rule **Federal Register** notice that is expected to publish in early CY 2021.

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77509), CY 2018 Quality Payment Program final rule (82 FR 53916 through 53917), and CY 2019 PFS final rule (83 FR 60009 through 60010 for our previously finalized requirements and burden for beneficiary responses to the CAHPS for MIPS survey.

In section IV.A.3.c.(1)(e)(ii), we are proposing to (1) revise and codify at

§ 414.1305 the definition of primary care services used in the MIPS assignment methodology to include virtual primary care visits and telehealth visits to determine patient assignment to groups starting in the 2021 CAHPS for MIPS survey; and (2) revise the CAHPS for MIPS Survey cover page to include a reference to care received in telehealth settings. We do not believe any of these proposals will impact the number of groups electing to have the CAHPS for MIPS survey administered on their behalf, the number of beneficiaries who complete the survey, or the time required for a beneficiary to complete the survey. In the future, if additional data becomes available, we may revise our assumptions at that time.

Additionally, we are also proposing in IV.A.2.c.(1)(e)(i) to add a survey-based measure on telehealth that assesses patient-reported usage of telehealth services to the performance year 2021 CAHPS for MIPS Survey. Currently, the CAHPS for MIPS survey instrument contains 58 questions and we estimate it requires a beneficiary 12.9 minutes on average to complete it, or approximately 0.2 minutes per question. We assume this proposal will result in 1 additional question being added to the survey which would result in the total time to complete the survey increasing from 12.9 minutes (0.215 hr) to 13.1 minutes (0.2183 hr) per beneficiary, or an increase of 0.2 minutes (0.0033 hr).

Based on the number of beneficiaries who completely or partially responded to the survey in the 2019 MIPS performance period, we assume that 29,915 beneficiaries will respond to the survey during the 2021 MIPS performance period. This is a decrease of 9,124 from our currently approved estimate of 39,039 beneficiaries. Using this updated number of respondents and our revised estimate of burden per respondent, we estimate an annual burden of 6,531 hours (29,915 respondents × 0.2183 hr/respondent) at a cost of $167,989 (6,531 hr × $25.72/hr). Table 66 shows the estimated annual burden for beneficiaries to participate in the CAHPS for MIPS Survey.

TABLE 65: Estimated Burden for Beneficiary Responses to CAHPS for MIPS Survey

	Burden Estimate
Number of beneficiaries who will respond to the survey (a)	29,915
Number of hours per beneficiary respondent (b)	0.2183
Total Annual Hours (c) = (a)*(b)	**6,531**
Labor rate for a beneficiary (d)	$25.72/hr
Total Annual Cost (e) = (a)*(d)	**$167,989**

*Due to burden being estimated in fractions of minutes and hours, totals may reflect impact of rounding.

Independent of the change in burden per respondent, the decrease of −9,124 respondents from 39,039 to 29,915 results in a difference of −1,962 hours (−9,124 respondents × 0.215 hr/respondent) at a cost of −$50,454 (−9,124 hrs × $25.72/hr). Accounting for the change in number of respondents, the increase in burden per respondent from 0.215 hours to 0.2183 hours results in a difference of 100 hours (29,915 respondents × 0.0033 hr/respondent) at a cost of $2,565 (100 hrs × $25.72/hr). As shown in Table 66, the aggregate change in burden is −1,862 hours (100 hours − 1,962 hours) at a cost of −$47,889 ($2,565 − $50,454).

TABLE 66: Change in Estimated Burden for Beneficiary Responses to CAHPS for MIPS Survey

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	8,393
Total Annual Hours for Respondents in CY 2021 Proposed Rule (b)	6,531
Difference (c) = (b)-(a)	**-1,862**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$215,878
Total Annual Cost for Respondents in CY 2021 Proposed Rule (e)	$167,989
Difference (f) = (e)-(d)	**-$47,889**

The revised survey and burden will be released to the public via the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

(8) Group Registration for CAHPS for MIPS Survey

This rule is not proposing 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, we are not making any changes to burden for CAHPS for MIPS survey group registration under that control number.

(9) Removal of Quality Data Submission by Clinicians and Groups: CMS Web Interface Collection Type and Group Registration for CMS Web Interface ICRs

The following proposed changes will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As discussed in section IV.A.3.c.(1)(c) we are proposing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 performance period. If this proposal is finalized, it will result in removal of the CMS Web Interface collection type and group registration for CMS Web Interface ICRs as they will no longer be necessary. In the CY 2020 PFS final rule, we estimated the time associated with quality data submissions via the CMS Web Interface to be 6,414 hours (104 responses × 61.67 hr per response) (84 FR 63130). Using more recent BLS wage estimates, we estimate a cost of $593,038 (6,414 hr × $92.46/hr). We had also estimated the time associated with group registration for the CMS Web Interface to be 17.25 hours (69 responses × 0.25 hr per response) (84 FR 63131). Using more recent BLS wage estimates, we estimate a cost of $1,595 (17.25 hr × $92.46/hr). In this regard, this rule proposes a reduction of 6,431 hours (6,414 hr + 17.25 hr) and $594,633 ($593,038 + $1,595) (see Table 85).

f. ICRs Regarding the Call for MIPS Quality Measures

This rule is not proposing any new or revised collection of information requirements or burden related to the call for MIPS quality measures. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any call for MIPS quality measure changes under that control number.

g. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the 2021 MIPS performance period, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. 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. 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

The requirements and burden associated with this rule's proposed data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53918 through 53919), CY 2019 PFS final rule (83 FR 60011 through 60012), and the CY 2020 PFS final rule (84 FR 63134 through 63135) for our previously finalized requirements and burden for reweighting applications for Promoting Interoperability and other performance categories.

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, quality, cost, and/or improvement activities performance categories under specific circumstances (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785). Respondents who apply for a reweighting for the quality, cost, and/or improvement activities 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.

Table 67 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 by December 31, 2019 for the 2019 MIPS performance period, we assume 51,098 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 and an additional 994 respondents will submit a request to reweight one or more of the quality, cost, Promoting Interoperability, or improvement activity performance categories due to an extreme or uncontrollable circumstance, for a total of 52,092 reweighting applications submitted. This is an increase of 21,472 respondents compared to our currently approved estimate of 30,620 respondents (84 FR 63134). Similar to the data used to estimate the number of respondents in the CY 2020 PFS final rule, our respondent estimate includes a significant number of applications submitted as a result of a data issue CMS was made aware of and is specific to a single third-party intermediary. While we do not anticipate similar data issues to occur in each performance period, we do believe future similar incidents may occur and are electing to use this data without adjustment to reflect this belief. Our respondent estimate is also based on data that does not include applications submitted during the extended period ending April 30, 2020 due to the 2019 Coronavirus Disease (COVID–19) pandemic, as we do not believe it would be an accurate basis for future estimates of application submissions. Of our total respondent estimate of 52,092, we estimate that 35,986 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 16,106 respondents will submit a request for reweighting the Promoting Interoperability performance category to zero percent as a small practice experiencing a significant hardship.

In section IV.A.3.c.(5)(e), we are proposing that, beginning with the 2022 MIPS payment year (2020 performance year), APM Entities may submit an extreme and uncontrollable circumstances exception application for all four performance categories and applicable to all MIPS eligible clinicians in the APM Entity group. As previously discussed in section VI.B.5.a.(4), due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period,

we assume ACO APM Entities will submit data through the APM Performance Pathway and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. Therefore, we limited our analysis to ACOs that were eligible for an exception due to extreme and uncontrollable circumstances during the 2019 MIPS performance period and elected not to report quality data. Based on this data, we estimate 7 APM Entities will submit an extreme and uncontrollable circumstances exception application for the 2021 MIPS performance period. Combined with our aforementioned estimate of 52,092 eligible clinicians and groups, the total estimated number of respondents for the 2021 MIPS performance period is 52,099.

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 continue to estimate it will take 0.25 hours at $92.46/hr for a computer system analyst to complete and submit the application. As shown in Table 67, we estimate an annual burden of 13,025 hours (52,099 applications × 0.25 hr/application) and $1,204,268 (13,025 hr × $92.46/hr).

TABLE 67: 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 or Extreme and Uncontrollable Circumstances (a)	35,986
# of Eligible Clinicians or Groups Applying Due to Significant Hardship for Small Practice (b)	16,106
# APM Entities requesting Extreme and Uncontrollable Circumstances exception	7
Total Applications Submitted (c)	52,099
Hours Per Applicant per Application Submission (d)	0.25
Total Annual Hours (e)=(a)*(c)	**13,025**
Labor Rate for a computer systems analyst (f)	$92.46/hr
Total Annual Cost (g)=(a)*(f)	**$1,204,268**

As shown in Table 68, using our unchanged currently approved per respondent burden estimate, the increased number of respondents results in a total adjustment of 5,370 hours (21,479 respondents × 0.25 hr/respondent) and $496,487 (5,370 hr × $92.46/hr).

TABLE 68: Adjusted Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	7,655
Total Annual Hours for Respondents in CY 2021 Proposed Rule (b)	13,025
Difference (c) = (b)-(a)	**+5,370**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$707,781
Total Annual Cost for Respondents in CY 2021 Proposed Rule (e)	$1,204,268
Difference (f) = (e)-(d)	**+$496,487**

(3) Submitting Promoting Interoperability Data

This rule is not proposing any new or revised collection of information requirements related to the submission of data for the Promoting Interoperability performance category. However, we are adjusting our currently approved burden estimates based on more recent data. The proposed burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77509 through 77511), CY 2018 Quality Payment Program final rule (82 FR 53919 through 53920), CY 2019 PFS final rule (83 FR 60013 through 60014), and the CY 2020 PFS final rule (84 FR 63135 through 63137) for our previously finalized requirements and burden for submission of data for the Promoting Interoperability performance category.

In this proposed rule, we are not proposing any changes to our current criteria for automatic reweighting of the

Promoting Interoperability performance category for certain MIPS eligible clinicians or MIPS eligible clinicians who have experienced a significant hardship or decertification of an EHR.

In section IV.A.3.c.(4)(b) of this rule, we are proposing to add § 414.1320(g)(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. Because this does not change the number of required Promoting Interoperability measures that must be reported, we are not making any changes to our burden assumptions.

In section IV.3.c.(4)(c)(2)(b) we are proposing to add the HIE bi-directional exchange measure for the 2021 performance period and subsequent years as an optional alternative to the two existing measures: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. This proposal provides clinicians the option of either reporting the new measure or the two existing measures. Because the new HIE measure is an optional alternative instead of a new requirement and the proposal does not change the number of required Promoting Interoperability measures that must be reported, we are not making any changes to our burden assumptions.

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. Because we are not making changes at § 414.1375 to the scoring for APM entities as a result of our proposal in section IV.A.3.(b) of this proposed rule to establish an APM Performance Pathway, our reporting assumptions for clinician in MIPS APMs remains unchanged.

As shown in Table 69, based on data from the 2018 MIPS performance period, we estimate that a total of 77,499 respondents consisting of 62,746 individual MIPS eligible clinicians and 14,753 groups and virtual groups will submit Promoting Interoperability data. Since our CY 2020 final rule estimated 74,281 respondents, this represents an increase of 3,218 respondents (77,499 proposed respondents − 74,281 active respondents).

We assume that MIPS eligible clinicians previously scored under the APM scoring standard, as described in the CY 2020 PFS final rule, will continue to submit Promoting Interoperability data (84 FR 63006) in a similar way through the APM Performance Pathway. As a result, we do not anticipate any change in burden. Each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. 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. However, 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 through 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 TINs 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 69: Estimated Number of Respondents to Submit Promoting Interoperability Performance Data on Behalf of Clinicians

	# of Respondents
Number of individual clinicians to submit Promoting Interoperability (a)	62,746
Number of groups to submit Promoting Interoperability (b)	14,753
Total Respondents in 2021 MIPS performance period (CY 2021 Proposed Rule) (c) = (a) + (b)	77,499
*Total Respondents in 2020 MIPS performance period (CY 2020 Final Rule) (d)	74,281
Difference (e) = (c) – (d)	+3,218

We continue to estimate the time required for an individual or group to submit Promoting Interoperability data to be 2.67 hours. As shown in Table 70, the total burden estimate for submitting data on the specified Promoting Interoperability objectives and measures is estimated to be 206,664 hours (77,499 respondents × 2.67 incremental hours for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $19,108,153 (206,664 hr × $92.46/hr)).

TABLE 70: Estimated Burden for Promoting Interoperability Performance Category Data Submission

	Burden Estimate
Number of individual clinicians to submit Promoting Interoperability (a)	62,746
Number of groups to submit Promoting Interoperability (b)	14,753
Total (c) = (a) + (b)	77,499
Total Annual Hours Per Respondent (b)	2.67
Total Annual Hours (c) = (a)*(b)	**206,664**
Labor rate for a computer systems analyst to submit Promoting Interoperability data (d)	$92.46/hr
Total Annual Cost (e) = (a)*(d)	**$19,108,153**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 71, using our unchanged currently approved per respondent burden estimate, the decrease in number of respondents results in a total adjustment of +8,581 hours (3,218 respondents × 2.67 hr/respondent) at a cost of +$793,430 (8,581 hr × $92.46/hr).

TABLE 71: Adjusted Burden for Promoting Interoperability Performance Category Data Submission

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	198,083
Total Annual Hours for Respondents in CY 2021 Proposed Rule (b)	206,664
Difference (c) = (b)-(a)	**+8,581**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$18,314,723
Total Annual Cost for Respondents in CY 2021 Proposed Rule (e)	$19,108,153
Difference (f) = (e)-(d)	**+$793,430**

h. ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule is not proposing any new or revised collection of information requirements or burden related to the nomination of Promoting Interoperability measures. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes under that control number.

i. ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

We are adjusting our currently approved burden estimates based on more recent data. The proposed adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77511 through 77512), CY 2018 Quality Payment Program final rule (82 FR 53920 through 53922), CY 2019 PFS final rule (83 FR 60015 through 60017), and the CY 2020 PFS final rule (84 FR 63138 through 63140) for our previously finalized requirements and burden for submission of data for the Improvement Activities performance category.

In this proposed rule, we are not proposing any changes to our requirements associated with criteria for attesting to specific improvement activities.

As discussed in section IV.A.3.c.(3)(b)(iii) of this rule, we are proposing for the CY 2021 performance period and future years to modify 2 existing improvement activities. We refer readers to Appendix 2 of this proposed rule for further details. Because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform, we do not expect these proposals to affect our currently approved information collection burden estimates.

In section IV.A.3.(b).(3)(c) of this rule, we propose how we would assign a score for the Improvement Activities performance category for MIPS APMs. We would assign Improvement Activities scores to APM participants in the APP based on the requirements of participation in APMs. To develop the Improvement Activities score for MIPS APMs, we would compare requirements of the APM with the list of Improvement Activities measures for the applicable year, and score those measures as they would otherwise be scored according to § 414.1355. In the event a MIPS APM participant does not actually perform an activity for which Improvement Activities credit would otherwise be assigned under this proposal, the MIPS APM participant would not receive credit for the associated Improvement Activity. In the event that the assigned score does not represent the maximum improvement activities score, we propose that MIPS eligible clinicians reporting through the APP would have the opportunity to report additional improvement activities that then would be applied towards their scores. Our burden estimates assume there will be no improvement activities burden for MIPS APM participants electing the APP. We will assign the improvement

activities performance category score at the APM Entity level.

A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. 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. Similar to our assumption in the CY 2018 Quality Payment Program final rule, our burden estimates assume that the MIPS APM models for the 2021 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. (82 FR 53921 through 53922).

As represented in Table 72, based on 2018 MIPS performance period data, we estimate that a total of 102,474 respondents consisting of 85,760 individual clinicians and 16,714 groups will submit improvement activities during the 2021 MIPS performance period. Since our currently approved burden sets out 103,813 respondents, this represents a decrease of −1,339 respondents (102,474 proposed respondents − 103,813 active respondents).

As discussed in sections VI.B.5.e.(2) and VI.B.5.g.(3) of this proposed rule 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 ACO in the 2018 MIPS performance period but will be in the 2021 MIPS performance period, and will therefore not be required to submit improvement activities data.

TABLE 72: Estimated Number 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 2021 MIPS performance period (a)	85,760
# of Groups to submit improvement activities on behalf of clinicians during the 2021 MIPS performance period (b)	16,714
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 2021 Proposed Rule) (c) = (a) + (b)	102,474
*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 2020 Final Rule) (d)	103,813
Difference (e)=(c)-(d)	**-1,339**

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

Consistent with the CY 2020 PFS final rule, we continue to estimate that the per response time required per individual or group is 5 minutes 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 (84 FR 63140).

As shown in Table 73, we estimate an annual burden of 8,540 hours (102,474 responses × 5 minutes/60) and $789,562 (8,540 hr × $92.46/hr)).

TABLE 73: 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)	102,474
Total Annual Hours Per Respondent (b)	5 minutes
Total Annual Hours (c) = (a)*(b)	**8,540**
Labor rate for a computer systems analyst to submit improvement activities (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$789,562**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 74, using our unchanged currently approved per respondent burden estimate, the decrease in the number of respondents results in an adjustment of −111 hours (−1,339 responses × 5 minutes/60) at a cost of −$10,317 (−111 hr × $92.46/hr).

TABLE 74: Adjusted Burden for Improvement Activities Submission

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	8,651
Total Annual Hours for Respondents in CY 2021 Proposed Rule (b)	8,540
Difference (c) = (b)-(a)	**-111**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$799,879
Total Annual Cost for Respondents in CY 2021 Proposed Rule (e)	$789,562
Difference (f) = (e)-(d)	**-$10,317**

j. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

The requirements and burden associated with this rule's proposed data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53922), CY 2019 PFS final rule (83 FR 60017 through 60018), and the CY 2020 PFS final rule (84 FR 63141) for our previously finalized requirements and information collection burden for the nomination of improvement activities.

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). In section IV.A.3.c.(3)(b)(i)(B)(bb) of this rule, we are proposing to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible. Similar to the burden assumptions finalized in the CY 2020 PFS final rule for the nomination of quality measures, we believe this will require approximately 0.6 hours at $110.74/hr for a medical and health services manager and 0.4 hours at $212.78/hr for a physician to research existing measures and provide a rationale for the linkage (84 FR 63132). We previously estimated it would require 1.2 hours for a medical and health services manager or equivalent and 0.8 hours for a physician to nominate an improvement activity (84 FR 63141). Combined with our currently approved burden estimate, we now estimate 1.8 hours at $110.74/hr for a medical and health services manager or equivalent and 1.2 hours at $212.78/hr for a physician to nominate an improvement activity. This represents a change of +0.6 hours (1.8 hr − 1.2 hr) for a medical and health services manager or equivalent and +0.4 hours (1.2 hr − 0.8 hr) for a physician and an overall increase of 1 hour.

In section IV.A.3.c.(3)(b)(i)(A)(bb), we are proposing to make an exception to the established timeframe for nomination of improvement activities, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. Instead of only accepting nominations and modifications submitted February 1st through June 30th each year, we would accept nominations for the duration of the PHE as long as the improvement activity is still relevant. No other aspects of the Annual Call for Activities process would be affected (for example, criteria for nominating improvement activities, considerations for selection of improvement activities, or weighting policies would all still apply). While we expect additional nominations may be received as a result of this proposal, we do not have any data with which to estimate what the additional number may be. As a result, our burden estimate remains unchanged due to this proposal. Additionally, in section IV.A.3.c.(3)(b)(ii)(B), we are proposing, beginning with the CY 2021 performance period and future years, to consider agency-nominated improvement activities. Because these nominations would be submitted by federal agencies, the associated time is exempt from the PRA and therefore not included in our estimates. We also refer readers to section VIII.F.16.d.(4)(c) where we discuss our impact analysis.

The 2020 Annual Call for Activities will end on July 1, 2020. Therefore, we continue to use our currently approved assumption that we will receive 31 nominations of new or modified activities which will be evaluated for the Improvement Activities Under Consideration (IAUC) list for possible inclusion in the CY 2022 Improvement Activities Inventory.

As shown in Table 75, we estimate an annual information collection burden of 93 hours (31 nominations × 3 hr/nomination) at a cost of $14,095 (31 × [(1.8 hr × $110.74/hr) + (1.2 hr × $212.78/hr)]).

TABLE 75: Estimated Burden for Nomination of Improvement Activities

	Burden Estimate
# of Nominations of New Improvement Activities (a)	31
# of Hours Per Medical and Health Services Manager to Identify and Propose Activity (b)	1.8
# of Hours Per Physician to Identify Activity (c)	1.2
Annual Hours Per Respondent (d)= (b) + (c)	3.0
Total Annual Hours (e) = (a)*(d)	**93**
Cost to Identify and Submit Activity (@ medical and health services manager's labor rate of $110.74/hr) (f)	$199.33
Cost to Identify Improvement Activity (@ physician's labor rate of $212.78/hr) (g)	$255.34
Total Annual Cost Per Respondent (h)=(f)+(g)	$454.67
Total Annual Cost (i)=(a)*(h)	**$14,095**

As shown in Table 76, using our unchanged estimate of the number of activities nominated, the increase in the burden per nomination results in a change of 31 hours (31 nominations × 1 hr/nomination) at a cost of $4,698 (31 activities × [(0.6 hr × $110.74/hr) + (0.4 hr × $212.78/hr)]).

TABLE 76: Change in Estimated Burden for Nomination of Improvement Activities

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	62
Total Annual Hours for Respondents in CY 2021 Proposed Rule (b)	93
Difference (c) = (b)-(a)	**+31**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$9,396
Total Annual Cost for Respondents in CY 2021 Proposed Rule (e)	$14,095
Difference (f) = (e)-(d)	**+$4,698**

k. Nomination of MVPs

The following reflects the burden associated with the first year of data collection associated with a new process available for all clinicians/third party intermediaries to nominate MVPs for inclusion in the Quality Payment Program. The proposed requirements and burden associated with the Nomination of MVPs will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Beginning with the 2022 performance period, we are proposing at that stakeholders should formally submit their MVP candidates utilizing a standardized template, which will be published in the QPP resource library four our consideration for future implementation. Stakeholders should submit all information including a description of how their MVP abides by the MVP development criteria as described in section IV.A.3.a.(2)(a)(i) of this proposed rule, and provide rationales as to why specific measures and activities were chosen to construct the MVP. As MVP candidates are received, they will be reviewed, vetted, and evaluated by CMS and our contractors to determine if the MVP is feasible and ready for inclusion in the upcoming performance period. For the 2021 MIPS performance period, we assume 25 MVP nominations will be received and the estimated time required to submit all required information is 12 hours per nomination. We seek comment on our estimate of the time required to nominate an MVP.

Similar to the call for quality measures, nomination of Promoting Interoperability measures, and the nomination of improvement activities, we assume MVP nomination will be performed by both practice administration staff or their equivalents and clinicians. We estimate 7.2 hours at $110.74/hr for a medical and health services manager or equivalent and 4.8 hours at $212.78/hr for a physician to nominate an MVP. As shown in Table 77, we estimate an annual burden of 300 hours (25 nominations × 12 hr/nomination) at a cost of $45,467 (25 × [(7.2 hr × $110.74/hr) + (4.8 hr × $212.78/hr)]).

TABLE 77: Estimated Burden for Nomination of MVPs

	Burden Estimate
# of Nominations of New Improvement Activities (a)	25
# of Hours Per Medical and Health Services Manager (b)	7.2
# of Hours Per Physician (c)	4.8
Annual Hours Per Respondent (d)= (b) + (c)	12
Total Annual Hours (e) = (a)*(d)	**300**
Cost to Nominate an MVP (@ medical and health services manager's labor rate of $110.74/hr) (f)	$797.33
Cost to Nominate an MVP (@ physician's labor rate of $212.78/hr) (g)	$1,021.34
Total Annual Cost Per Respondent (h)=(f)+(g)	$1,818.67
Total Annual Cost (i)=(a)*(h)	**$45,467**

l. 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. Moreover, the provisions of this proposed rule do not result in the need to add or revise or delete any claims data fields. Consequently, we are not setting out burden or making any changes under the 0938–1197 control number.

m. ICRs Regarding Partial QP Elections (§§ 414.1310(b)(ii) and 414.1430)

This rule is not proposing 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 are adjusting our currently approved burden estimates based on updated projections for the 2021 MIPS performance period. The proposed burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As shown in Table 78, based on our predictive QP analysis for the 2021 QP performance period, which accounts for historical response rates in performance year 2019, we estimate that 100 APM Entities and 200 eligible clinicians (representing approximately 2,500 Partial QPs) will make the election to participate as a Partial QP in MIPS, a total of 300 elections which is a decrease of 1,722 from the 2,022 elections that are currently approved by OMB under the aforementioned control number. We continue to 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 75 hours (300 respondents × 0.25 hr/election) and $6,935 (75 hr × $92.46/hr).

TABLE 78: Estimated Burden for Partial QP Election

	Burden Estimate
# of respondents making Partial QP election (100 APM Entities, 200 eligible clinicians) (a)	300
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25
Total Annual Hours (c) = (a)*(b)	**75**
Labor rate for computer systems analyst (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$6,935**

As shown in Table 79, using our unchanged currently approved per respondent burden estimate, the decrease in the number of Partial QP elections results in an adjustment of −430.5 hours (−1,722 elections × 0.25 hr) from our currently approved burden of 505.5 hours at a cost of −$39,804 (−430.5 hr × $92.46/hr) (84 FR 63142).

TABLE 79: Adjusted Burden for Partial QP Election

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	505.5
Total Annual Hours for Respondents in CY 2021 Proposed Rule (b)	75
Difference (c) = (b)-(a)	**-430.5**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$46,739
Total Annual Cost for Respondents in CY 2021 Proposed Rule (e)	$6,935
Difference (f) = (e)-(d)	**-$39,804**

n. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1445) and Eligible Clinician Initiated Process (§ 414.1445)

The following proposed burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

(1) Payer Initiated Process (§ 414.1445)

This rule is not proposing any new or revised collection of information requirements related to the Payer-Initiated Process. However, we are adjusting our currently approved burden estimates based on updated projections for the 2021 MIPS performance period. As mentioned above, the adjusted burden will be submitted to OMB for approval.

As shown in Table 80, based on the actual number of requests received in the 2019 QP performance period, we estimate that in CY 2021 for the 2022 QP performance period 80 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (10 Medicaid payers, 50 Medicare Advantage Organizations, and 20 remaining other payers), a decrease of 30 from the 110 total requests currently approved by OMB under the aforementioned control number. We continue to estimate it will take 10 hours for a computer system analyst per arrangement submission. We estimate an annual burden of 800 hours (80 submissions × 10 hr/submission) and $73,968 (800 hr × $92.46/hr).

TABLE 80: Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

	Burden Estimate
# of other payer payment arrangements (10 Medicaid, 50 Medicare Advantage Organizations, 20 remaining other payers) (a)	80
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a)*(b)	**800**
Labor rate for a computer systems analyst (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$73,968**

As shown in Table 81, using our unchanged currently approved per respondent burden estimate, the decrease in the number of payer-initiated requests from 110 to 80 results in an adjustment of −300 hours (−30 requests × 10 hr) from our currently approved burden of 1,100 hours at a cost of −$27,738 (−300 hr × $92.46/hr) (84 FR 63143).

TABLE 81: Adjusted Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	1,100
Total Annual Hours for Respondents in CY 2021 Proposed Rule (b)	800
Difference (c) = (b)-(a)	**-300**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$101,706
Total Annual Cost for Respondents in CY 2021 Proposed Rule (e)	$73,968
Difference (f) = (e)-(d)	**-$27,738**

(2) Eligible Clinician Initiated Process (§ 414.1445)

This rule is not proposing 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 making any changes to the eligible clinician initiated process under that control number.

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

This rule is not proposing any new or revised collection of information requirements related to the Submission of Data for QP Determinations under the All-Payer Combination Option. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the QP Determinations under the All-Payer Combination Option under that control number.

o. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Physician Compare (§ 414.1395)

This rule is not proposing 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 are adjusting our currently approved burden estimates based on data from the 2018 MIPS performance period. The proposed burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53924 through 53925), CY 2019 PFS final rule (83 FR 60022), and the CY 2020 PFS final rule (84 FR 63145 through 63146) for our previously finalized requirements and burden for voluntary participants to opt-out of public reporting on Physician Compare.

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 9,904 (0.10 × 99,042 voluntary MIPS participants) clinicians and groups, a decrease of 138 from the currently approved estimate of 10,042. 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 RIA 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).

Table 82 shows that for these voluntary participants, we continue to estimate it will take 0.25 hours for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 2,476 hours (9,904 requests × 0.25 hr/request) and $228,931 (2,476 hr × $92.46/hr).

TABLE 82: 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)	9,904
Total Annual Hours Per Opt-out Requester (b)	0.25
Total Annual Hours (c) = (a)*(b)	**2,476**
Labor rate for a computer systems analyst (d)	$92.46/hr
Total Annual Cost (e) = (a)*(d)	**$228,931**

As shown in Table 83, using our unchanged currently approved per respondent burden estimate, the decrease of −138 opt outs by voluntary participants results in an adjustment of −34.5 hours (−138 requests × 0.25 hr) from our currently approved burden of 2,510.5 hours at a cost of −$3,190 (−34.5 hr × $92.46/hr) (84 FR 63145).

TABLE 83: Adjusted Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	2,510.5
Total Annual Hours for Respondents in CY 2021 Proposed Rule (b)	2,476
Difference (c) = (b)-(a)	**-34.5**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$232,121
Total Annual Cost for Respondents in CY 2021 Proposed Rule (e)	$228,931
Difference (f) = (e)-(d)	**-$3,190**

p. Summary of Annual Quality Payment Program Burden Estimates

Table 85 summarizes this proposed rule's burden estimates for the Quality Payment Program. In the CY 2020 PFS final rule, the total estimated burden was 2,932,649 hours at a cost of $279,550,490 ($279,573,747 − $23,257) (84 FR 63146). Accounting for updated wage rates and the subset of all Quality Payment Program ICRs discussed in this rule compared to the CY 2020 PFS final rule, the total estimated burden of continuing policies and information set forth in the CY 2020 PFS final rule into the 2021 MIPS performance period is 2,937,520 hours at a cost of $287,160,638; an increase of 4,871 hours and $7,610,148. To understand the burden implications of the policies proposed in this rule, we provide an estimate of the total burden associated with continuing the policies and information collections set forth in the CY 2020 PFS final rule into the 2021 MIPS performance period. This burden estimate of 3,008,022 hours at a cost of $293,717,313 reflects the availability of more accurate data to account for all potential respondents and submissions across all the performance categories and more accurately reflect the exclusion of QPs from all MIPS performance categories, a difference of 70,502 hours and $7,044,791. This burden estimate is higher than the burden approved for information collection related to the CY 2020 PFS final rule due to updated data and assumptions as well as the addition of the Open Authorization Credentialing and Token Request Process information collection, which is not a result of any new or revised policies proposed in this rule or finalized in any previous final rule, but rather an operational improvement. The difference of −5,488 hours (70,502 hours − 66,876 hours + 1,862 hours) and −$488,115 ($7,044,791 − $6,604,565 + $47,889) between this estimate and the total burden shown in Table 87 is the reduction in burden associated with impacts of the proposed policy to sunset the CMS Web Interface measures as a collection type/submission type; partially offset by an increase in burden due to a new information collection for nomination of MVPs, the proposed policy to add a survey-based measure on telehealth that assesses patient-reported usage of telehealth services to the CAHPS for MIPS Survey, the proposal to allow APM Entities to submit an extreme and uncontrollable circumstances exception application, and the proposed policy to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible. We have included Table 84 to assist in understanding these differences.

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TABLE 84: Summary of Changes in Burden from CY 2020 PFS Final Rule

Burden Estimate Description	Burden Hours	Burden Cost
CY 2020 PFS Final Rule (a)	2,932,649	$279,550,490
CY 2021 PFS Proposed Rule w/ updated wage rates and ICRs (b)	2,937,520	$287,160,638
CY 2021 PFS Proposed Rule w/ updated data and assumptions (c)	3,008,022	$294,205,428
Change in burden due to updated data and assumptions (d) = (c) – (b)	**70,502**	**$7,044,791**
CY 2021 PFS Proposed Rule Total Burden (e)	3,002,534	$293,717,313
Total change in burden (as shown in Table 87) (f) = (e) – (b)	**65,014**	**$6,556,676**
Change in burden associated with proposed policies (g) = (f) – (d)	**-5,488**	**-$488,115**

TABLE 85: Summary of 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 (see section VI.B.5.c.(3))	153	163	+10	459	489	+30
Open Authorization Credentialing and Token Request Process (see section VI.B.5.d)	0	15	+15	0	15	+15
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see section VI.B.5.e.(4))	94,846	94,587	-259	1,346,813	1,343,135	-3,678
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see section VI.B.5.e.(5))	111,218	115,907	+4,689	1,010,193	1,052,783	+42,590
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see section VI.B.5.e.(6))	43,333	45,951	+2,618	346,664	367,608	+20,944
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface collection type (see section VI.B.5.e.(9))	104	0	-104	6,414	0	-6,414
§§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface (see section VI.B.5.e.(9))	69	0	-69	17.25	0	-17.25
§ 414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see section VI.B.5.g.(2))	30,620	52,099	+21,479	7,655	13,025	+5,370
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission (see section VI.B.5.g.(3))	74,281	77,499	+3,218	198,083	206,664	+8,581
§ 414.1360 (Improvement Activities Performance Category) Data Submission (see section VI.B.5.i	103,813	102,474	-1,339	8,651	8,540	-111
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities (see section VI.B.5.j	31	31	0	62	93	+31
Nomination of MVPs (see section VI.B.5.k)	0	25	+25	0	300	+300
§ 414.1430 Partial Qualifying APM Participant (QP) Election (see section VI.B.5.m)	2,022	300	-1,722	505.5	75	-430.5
§ 414.1440 Other Payer Advanced APM Identification: Payer Initiated Process (see section VI.B.5.n(1)	110	80	-30	1,100	800	-300
§ 414.1395 (Physician Compare) Opt Out for Voluntary Participants (see section VI.B.5.o	10,042	9,904	-138	2,510.5	2,476	-34.5
SUBTOTAL OMB 0938-1314 (CMS-10621)	**470,642**	**499,035**	**+28,393**	**2,929,127**	**2,996,003**	**+66,876**
§§ 414.1325 and 414.1335 Beneficiary Responses to CAHPS for MIPS Survey (see section VI.B.5.e.(7))	39,039	29,915	-9,124	8,393	6,531	-1,862
SUBTOTAL OMB 0938-1222 (CMS-10450)	**39,039**	**29,915**	**-9,124**	**8,393**	**6,531**	**-1,862**
TOTAL	**509,681**	**528,950**	**+19,269**	**2,937,520**	**3,002,534**	**+65,014**

Table 86 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 4 policies that reflect updated data and revised methods.

TABLE 86: Reasons for Change in Burden Compared to the Currently Approved CY 2020 Information Collection Burden

Quality Payment Program Table	Changes in burden due to CY 2021 Proposed Rule policies	Adjustments in burden from continued CY 2020 Final Rule policies due to revised methods or updated data
Section VI.B.5.c.(3): Qualified Registry Self-Nomination and other Requirements	Increase in number of responses (+10) and burden (+ 3 hrs per response) due to current policies not previously having a burden estimate as well as proposal to require additional information in Corrective Action Plans.	None.
Section VI.B.5.d: Open Authorization Credentialing and Token Request Process	New information collection request.	Not applicable.
Section VI.B.5.e.(4): Quality Performance Category Medicare Part B Claims Collection Type	None.	Decrease in number of respondents due to use of updated data from the 2018 MIPS performance period and updated QP projections for the 2021 MIPS performance period.
Section VI.B.5.e.(5): Quality Performance Category QCDR/ MIPS CQM Collection Type	Increase in number of respondents (+7) due to proposal to sunset the CMS Web Interface measures as a collection type/submission type.	Increase in number of respondents due to increased number of data submissions received by APM participants and updated QP projections for the 2021 MIPS performance period reflecting updated QP threshold. This is offset by decrease in number of non-APM respondents in updated 2018 MIPS performance period data.
Section VI.B.5.e.(6): Quality Performance Category eCQM Collection Type	Increase in number of respondents due to proposal to sunset the CMS Web Interface measures as a collection type/submission type.	Increase in number of respondents due to increased number of data submissions received by APM participants and updated QP projections for the 2021 MIPS performance period reflecting updated QP threshold. This is offset by decrease in number of non-APM respondents in updated 2018 MIPS performance period data.
Section VI.B.5.e.(7): Beneficiary Responses to CAHPS for MIPS Survey	Increase in per response burden (+ 0.2 hrs) due to proposal to add a survey-based measure on telehealth.	Decrease in number of respondents due to updated data from 2019 MIPS performance period.
Section VI.B.5.e.(9): Quality Performance Category CMS Web Interface Collection Type	Removal of information collection due to proposal to sunset the CMS Web Interface measures as a collection type/submission type.	None.
Section VI.B.5.e.(9): Registration for CMS Web Interface	Removal of information collection due to proposal to sunset the CMS Web Interface measures as a collection type/submission type.	None.
Section VI.B.5.g.(2): Reweighting Applications for Promoting Interoperability and Other Performance Categories	Increase in number of respondents due to proposal to allow APM Entities to submit an extreme and uncontrollable circumstances exception application.	Increase in number of applications submitted due to updated data from the 2019 MIPS performance period.
Section VI.B.5.g.(3): Promoting Interoperability Performance Category Data Submission	None.	Increase in number of non-APM individual respondents and number of data submissions received by APM participants offset by decrease in number of non-APM group submissions due to use of updated data from the 2018 MIPS performance period.
Section VI.B.5.i: Improvement Activities Submission	None.	Decrease in number of respondents due to use of updated data from the 2018 MIPS performance period.

Quality Payment Program Table	Changes in burden due to CY 2021 Proposed Rule policies	Adjustments in burden from continued CY 2020 Final Rule policies due to revised methods or updated data
Section VI.B.5.j: Nomination of Improvement Activities	Increase in per response burden (+1 hour) due to proposal to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible.	None.
Section VI.B.5.k: Nomination of MVPs	New information collection request.	Not applicable.
Section VI.B.5.m: Partial QP Election	None	Decrease in number of respondents due to updated projections for the 2021 MIPS performance period.
Section VI.B.5.n.(1): Other Payer Advanced APM Identification: Other Payer Initiated Process	None.	Decrease in number of respondents due to updated projections for the 2021 MIPS performance period.
Section VI.B.5.o: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare	None.	Decrease in the number of respondents due to use of updated data from the 2018 MIPS performance period.

C. Summary of Annual Burden Estimates for Proposed Requirements

TABLE 87: Annual Requirements and Burden

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number	Respondents	Total Annual Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§ 424.67 (Conditions for Payment, Form CMS-855A)	0938-0685	136	136	varies	533	varies	23,639
§ 424.67 (Conditions for Payment, Form CMS-855B)	0938-1377	70	70	varies	-64	varies	-2,866
§ 423.160(a) (Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan)	0938-0763	148,750	560,430	5	743,750	36.62	27,236,125
§§ 414.1325 and 414.1335, 414.1360, 414.1375, 414.1380, 414.1395, 414.1400, 414.1430, and 414.1440 (Quality Payment Program)	0938-1314	346,317	28,393	varies	66,876	varies	6,604,565
§§ 414.1325 and 414.1335 (Quality Payment Program)	0938-1222	29,915	-9,124	0.22	-1,862	25.72	-47,889
	TOTAL	525,188	579,905	varies	809,233	varies	33,813,574

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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–1734–P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

VII. 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.

VIII. Regulatory Impact Analysis

A. Statement of Need

This proposed rule would make 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 would also make 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 nonphysician practitioners (NPPs) 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 will 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 2020, that threshold is approximately $156 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. This proposed rule, if finalized, is expected to be an E.O. 13771 regulatory action. We estimate the rule generates $1.34 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 proposed 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 2020 with payment rates for CY 2021 using CY 2019 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 2021, as required by section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments.

To calculate the CY 2021 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 estimate the CY 2021 PFS CF to be 32.2605 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)(19) of the Act. We estimate the CY 2021 anesthesia CF to be 19.9631 which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 88: Calculation of the CY 2021 PFS Conversion Factor

CY 2021 Conversion Factor		36.0896
Statutory Update Factor	0.00 percent (1.0000)	
CY 2021 RVU Budget Neutrality Adjustment	-10.61 percent (0.8939)	
CY 2021 Conversion Factor		**32.2605**

TABLE 89: Calculation of the CY 2021 Anesthesia Conversion Factor

CY 2021 National Average Anesthesia Conversion Factor		22.2016
Statutory Update Factor	0.00 percent (1.0000)	
CY 2021 RVU Budget Neutrality Adjustment	-10.61 percent (0.8939)	
CY 2021 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.59 percent (1.0059)	
CY 2021 Conversion Factor		**19.9631**

Table 90 shows the payment impact on PFS services of the policies contained 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 will be different from those shown in Table 90 (CY 2021 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 90.

- *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 2019 utilization and CY 2020 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 2021 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 2021 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 2021 impact on total allowed charges of the changes in the MP RVUs.

- *Column F (Combined Impact):* This column shows the estimated CY 2021 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 90: CY 2021 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	$246	5%	4%	0%	9%
Anesthesiology	$2,011	-7%	-1%	0%	-8%
Audiologist	$74	-4%	-2%	0%	-7%
Cardiac Surgery	$264	-6%	-2%	-1%	-9%
Cardiology	$6,849	1%	0%	0%	1%
Chiropractor	$759	-7%	-3%	0%	-10%
Clinical Psychologist	$824	-1%	1%	0%	0%
Clinical Social Worker	$851	-1%	1%	0%	0%
Colon And Rectal Surgery	$168	-4%	-1%	0%	-5%
Critical Care	$376	-6%	-2%	0%	-8%
Dermatology	$3,758	-1%	-1%	0%	-2%
Diagnostic Testing Facility	$813	-1%	-5%	0%	-6%
Emergency Medicine	$3,065	-5%	-1%	0%	-6%
Endocrinology	$506	11%	6%	1%	17%
Family Practice	$5,982	9%	4%	1%	13%
Gastroenterology	$1,749	-3%	-1%	0%	-5%
General Practice	$405	5%	2%	0%	8%
General Surgery	$2,041	-4%	-2%	0%	-7%
Geriatrics	$190	2%	2%	0%	4%
Hand Surgery	$245	-2%	-1%	0%	-3%
Hematology/Oncology	$1,702	9%	5%	1%	14%
Independent Laboratory	$639	-3%	-2%	0%	-5%
Infectious Disease	$653	-4%	-1%	0%	-4%
Internal Medicine	$10,654	2%	2%	0%	4%
Interventional Pain Mgmt	$932	4%	3%	0%	7%
Interventional Radiology	$497	-3%	-5%	0%	-9%
Multispecialty Clinic/Other Phys	$152	-3%	-1%	0%	-4%
Nephrology	$2,213	4%	2%	0%	6%
Neurology	$1,513	3%	2%	0%	6%
Neurosurgery	$806	-4%	-2%	-1%	-7%
Nuclear Medicine	$56	-5%	-3%	0%	-8%
Nurse Anes / Anes Asst	$1,316	-9%	-1%	0%	-11%
Nurse Practitioner	$5,069	5%	3%	0%	8%
Obstetrics/Gynecology	$633	4%	3%	0%	8%
Ophthalmology	$5,328	-4%	-2%	0%	-6%
Optometry	$1,349	-2%	-2%	0%	-5%
Oral/Maxillofacial Surgery	$78	-2%	-3%	0%	-5%
Orthopedic Surgery	$3,796	-3%	-1%	0%	-5%
Other	$47	-3%	-2%	0%	-5%
Otolarngology	$1,264	4%	3%	0%	7%
Pathology	$1,257	-6%	-4%	0%	-9%
Pediatrics	$66	4%	2%	0%	6%
Physical Medicine	$1,157	-3%	0%	0%	-3%
Physical/Occupational Therapy	$4,946	-5%	-5%	0%	-9%
Physician Assistant	$2,888	5%	3%	0%	8%
Plastic Surgery	$378	-4%	-3%	0%	-7%
Podiatry	$2,111	-1%	0%	0%	-1%
Portable X-Ray Supplier	$94	-2%	-4%	0%	-6%
Psychiatry	$1,099	4%	3%	0%	8%
Pulmonary Disease	$1,647	0%	0%	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
Radiation Oncology And Radiation Therapy Centers	$1,803	-3%	-3%	0%	-6%
Radiology	$5,253	-6%	-5%	0%	-11%
Rheumatology	$546	10%	6%	1%	16%
Thoracic Surgery	$350	-5%	-2%	-1%	-8%
Urology	$1,803	4%	4%	0%	8%
Vascular Surgery	$1,287	-2%	-5%	0%	-7%
TOTAL	**$96,557**	**0%**	**0%**	**0%**	**0%**

* Column F may not equal the sum of columns C, D, and E due to rounding.

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2. CY 2021 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 endocrinology, rheumatology, family practice, and hematology/oncology reflect increases relative to other physician specialties. These increases can largely be attributed to previously finalized policies for increases in valuation for office/outpatient E/M visits which constitute nearly 20 percent of total spending under the PFS. These increases are also due to proposed increases in value for particular services following the recommendations from the American Medical Association (AMA)'s Relative Value Scale Update Committee (RUC) 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. For nephrologists, our proposal to increase the valuations of the ESRD monthly capitation payments that have office/outpatient E/M visits explicitly included in their valuations result in estimated impacts of +5 percent. For clinical social workers and clinical psychologists, our proposals to increase the valuations for certain behavioral health services that are analogous to office/outpatient E/M visits result in estimated impacts of 0 percent.

The estimated impacts for several specialties, including radiology, nurse anesthetists, pathology, and cardiac surgery reflect decreases in payments relative to payment to other physician specialties which are largely the result of the redistributive effects of previously finalized changes to the office/outpatient E/M visits taking effect in 2021. These decreases are also due to the revaluation of individual procedures reviewed by the AMA's RUC and CMS, as well as 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 the physical/occupational therapy specialty, estimated impacts of −8 percent reflect proposed increased valuations for therapy evaluation services that are analogous to office/outpatient E/M visits. However, therapy evaluation services do not account for a large portion of allowed charges for these specialties.

For emergency medicine practitioners, estimated impacts of −6 percent reflect a 3 percent gain as a result of proposed increased valuations to emergency department visits using specialty society recommendations to maintain relativity with office/outpatient E/M visits. However, the magnitude of the office/outpatient E/M visit valuations are dampening the effect of increased valuations for the emergency department visits. 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 5 percent decrease for CY 2021 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 90), 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 90 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 90 displays the estimated CY 2021 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 2021 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/*.

D. Effect of Changes Related to Telehealth Services

As discussed in section II.F. of this proposed rule, we are proposing to add eight new codes, HCPCS code GPC1X and CPT codes 99XXX, 96121, 99483, 99334, 99335, 99347, and 99348, to the list of Medicare telehealth services list for CY 2021. We are also proposing to add the following services provisionally on a category 3 basis: CPT codes 96130,

96131, 96132, 96133, 96136, 96137, 96138, 96139, 99281, 99282, 99283, 99315, 99316, 99336, 99337, 99349, and 99350. 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 additions, we estimate there will only be a negligible impact on PFS expenditures from these additions. For example, services already on the list are furnished via telehealth, on average, less than 0.1 percent of the time they are reported overall. The restrictions placed on Medicare telehealth services by section 1834(m) of the statute limit increases in utilization; however, we believe there is value in allowing physicians to furnish these additional services via Medicare Telehealth, and for patients to receive broader access to this care through telehealth. Additionally, for services added to the Medicare telehealth list on a Category 3 basis, outside of the circumstances of the PHE, all of the statutory restrictions will also apply to these services. Even with the addition of the category 3 services for an additional year, we would not anticipate any significant uptick in utilization.

E. Effect of Proposed Changes Related to Scopes of Practice

As discussed in section II.G. Scopes of Practice for PFS Services, of this proposed rule, we proposed to allow certain nonphysician practitioners to supervise diagnostic tests, which would authorize NPs, CNSs, PAs, and CNMs to provide the appropriate level of supervision assigned to diagnostic tests, to the extent authorized under State law and scope of practice. As for all services they furnish, in accordance with statute, the NP, CNS or PA necessarily would be working either under physician supervision or in collaboration with a physician. This flexibility may increase the capacity and availability of practitioners who can supervise diagnostic tests, which would alleviate some of the demand on physicians as the only source to perform this particular function. However, we have not located information indicating the degree to which NPP scope of practice includes supervision of auxiliary staff, especially for the subset of services that are diagnostic tests. There is a wide range of diagnostic tests, from a simple strep throat swab to more sophisticated and/or invasive tests such as X-rays and cardiology procedures. We would need to understand the scope of practice for many types of auxiliary staff (some of whom are not licensed) who could potentially provide these tests under the supervision of an NPP, including RNs, LPNs, medical assistants, radiologic technicians, and many others. To the extent practice patterns change, there could be induced utilization that would increase costs, but this might be offset by reduced payment rates because direct payment to NPPs is at a lower rate than payment to physicians.

An alternative in the case of this proposal concerning supervision of diagnostic tests is to maintain the status quo. That is, we could maintain the basic rule under § 410.32(b)(1) that allows only physicians as defined under Medicare law to supervise the performance of diagnostic tests. In that case, the pool of practitioners who could supervise diagnostic tests would remain at current levels and certain NPPs would be limited under Medicare from practicing to the full extent allowed by their state license and scope of practice.

Also, we are proposing to allow a physical therapist (PT) or occupational therapist (OT)—whether they are an enrolled private practice PT or OT or a therapist working for an institutional provider—who establishes a therapy maintenance program to assign the duties to a PTA or OTA, as clinically appropriate, to perform maintenance therapy services. We added this as a flexibility under the May 8th COVID–19 IFC for the duration of the PHE based on respondents feedback on scope of practice following the President's Executive Order 13890. Our current requirements for maintenance therapy services restrict a PT's/OT's ability to delegate the performance of maintenance therapy services to PTAs and OTAs which is counter to the therapist's ability to use PTAs/OTAs in furnishing rehabilitative outpatient physical or occupational therapy services. Our proposal would allow PTs/OTs to oversee and delegate to a PTA or OTA the performance of physical and occupational therapy services in the same way, whether the therapy services are part of a plan of care geared toward rehabilitative or maintenance therapy. While therapy services furnished by PTs/OTs and their PTAs/OTAs are separately payable when they occur in different time slots (that is, if the PT/PTA or OT/OTA work together at the same time in furnishing a service to the patient, only one service is payable), we do not believe that there would be an increase in utilization since it is of no consequence whether the PTA/OTA is furnishing the service as rehabilitative or maintenance therapy. Additionally, we note that beginning January 1, 2022, payment for services furnished in whole or in part by a PTA/OTA (when the part by the PTA/OTA separate from the part of furnished by the PT/OT exceeds 10 percent of the service) will be paid at a lower rate (85 percent of the PFS fee schedule amount) which could offset any nominal increase in service volume. The alternative option—maintaining the status quo to require the PT/OT to personally furnish all maintenance therapy services, would not address the mandates established in Executive Order 13890. Currently, in SNF and home health settings when payment for therapy is made under Part A, maintenance therapy can be furnished by a PT/OT or delegated to be performed by a PTA/OTA, and our proposal would permit this to occur in all settings when therapy is paid under Part B.

In summary, we expect that these proposed policies regarding scope of practice would result in increased administrative and clinical flexibility for the specified professionals, but we cannot determine the specific impact our proposed policies would have on practice business plans and demand for certain types of clinicians. This is especially true due to the wide variation in diagnostic tests as well as variation in state law and facility policies.

F. Effect of Proposed Changes to Bundled Payments Under the PFS for Substance Use Disorders (HCPCS Codes G2086, G2087, and G2088)

As discussed in section II.H. Valuation of Specific Codes, of this proposed rule, we are proposing to expand the bundled payments described by HCPCS codes G2086, G2087, and G2088, finalized in the CY 2020 PFS final rule (84 FR 62673) to be inclusive of all SUDs. As noted in the CY 2020 PFS final rule (84 FR 62673), if a patient's treatment involves MAT, this 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. We note that payment for the proposed codes would be budget neutral under the PFS and therefore have no cost impact on PFS spending; however, this policy may have impacts on billing practices and services provided.

Currently, the codes most frequently used when billing for treatment of SUD include the E/M visit codes, psychotherapy codes, SBIRT codes, and potentially the Behavioral Health Integration codes. HCPCS codes G2086–G2088 offer a bundled payment that would allow a more streamlined approach to billing in cases where all of the services described in the code descriptors are furnished. In our

previous response, we sought to clarify that these codes provide an option for billing, but are not required; therefore, in cases where only select services are being furnished, practitioners may continue to bill for the code that most accurately describes the service that was furnished, which could be, for example, just an E/M visit code.

G. Effect of Proposed Modifications to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Section 2005 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit for OUD treatment services furnished by OTPs on or after January 1, 2020. As part of CY 2020 PFS rulemaking, we implemented coverage requirements, created new coding to describe bundled episodes of care for the treatment of OUD, and established payment methodologies to determine the payment amounts for the drug and non-drug components of an episode of care.

For CY 2021, we are proposing to create two new add-on codes, one add-on code for nasal naloxone and another add-on code for auto-injector naloxone. We are proposing to price nasal naloxone based upon the methodology set forth in section 1847A of the Act, except that the payment amount shall be ASP + 0. We are proposing to price the auto-injector using the lowest pricing available (the lower of ASP + 0, WAC + 0, or NADAC). Under this methodology, the proposed price for nasal naloxone would be $89.63 per 2-pack and the proposed price for the naloxone auto-injector would be $178 per 2-pack. We are proposing to limit Medicare payment to OTPs for naloxone to one add-on code (HCPCS code GOTP1 or GOTP2) every 30 days to the extent that it is medically reasonable and necessary.

We estimate the cost impact of the recommended naloxone add-on codes will be approximately $2.28 million in CY 2021. This estimate is based on a maximum impact of approximately $23 million, scaled down using the percentage of beneficiaries on MAT who received naloxone under Medicare Part D in 2018 (9.91 percent). The maximum total annual cost was calculated using the proposed payment rate for the more expensive of the two codes, and we assumed every Medicare beneficiary receiving treatment at an OTP would receive the maximum allowed number of doses ($178 × 12 months) under the proposed frequency limit. However, we note that some patients would receive the less expensive nasal formulation and we believe that many patients would not require doses each month, if no need arises for opioid overdose reversal. This estimate uses the assumption from CY 2020 rulemaking that roughly 10,600 beneficiaries would utilize the OTP benefit in the first year. This estimate also assumes that there is no beneficiary cost-sharing and makes no assumptions for ramp-up.

We believe that the benefits associated with establishing payment for naloxone in the OTP setting justify the cost of this proposal. As noted in section II.I. of this proposed rule, Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs), U.S. Surgeon General Jerome M. Adams, M.D., M.P.H. has released a public health advisory stating that, ''Research shows that when naloxone and overdose education are available to community members, overdose deaths decrease in those communities. Therefore, increasing the availability and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths and, when combined with the availability of effective treatment, to ending the opioid epidemic.'' [111] We are proposing to add naloxone to the definition of OUD treatment services in order to increase access to this important emergency treatment and to allow OTPs to be paid under Medicare for dispensing naloxone to Medicare beneficiaries who are receiving other OUD treatment services from the OTP. Under this proposal, beneficiaries receiving OUD treatment services from the OTP would be able to receive two doses of naloxone from the OTP every 30 days under the OUD treatment services benefit, to the extent it is medically reasonable and necessary as part of their OUD treatment. We believe allowing beneficiaries to access this important emergency treatment at the OTP may help decrease barriers to access because there are no copayments for services furnished by OTPs and beneficiaries would not need to visit a separate provider to access naloxone.

H. Other Provisions of the Regulation

1. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions

In section III.A. of this proposed rule, we discuss statutory revisions to the data reporting period and phase-in of payment reductions. In accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we are proposing to make certain conforming changes to the data reporting and payment requirements in our regulations at 42 CFR part 414, subpart G. Specifically, for clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs), we are revising § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every 3 years beginning January 2022. This revision delays the next data reporting period under the CLFS by 2 years, that is, it will require the next data reporting during the period of January 1, 2022 through March 31, 2022. Subsequently, the next private payor rate-based CLFS update will be effective January 1, 2023 instead of January 1, 2021. In addition, we are proposing to make conforming changes to our requirements for the phase-in of payment reductions to reflect the CARES Act amendments. Specifically, we are proposing to revise § 414.507(d) to indicate that for CY 2021, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2020, and for CYs 2022 through 2024, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We recognize that private payor rates for CDLTs paid on the CLFS and the volumes paid at each rate for each test, which are used to determine the weighted medians of private payor rates, have changed since the first data collection period (January 1, 2016 through June 30, 2016) and data reporting period (January 1, 2017 through March 31, 2017). In addition, as discussed in section III.A. of this proposed rule, in the CY 2019 PFS final rule (83 FR 59671 through 59676), we amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill. As such, the conforming regulatory changes to the data reporting period would delay using updated private payor rate data and data reported by hospital outreach laboratories to set revised CLFS payment rates.

Due to the unforeseen changes in private payor rates, inclusion of hospital outreach laboratory data, and unpredictable nature of test volumes and their impact on calculating updated weighted medians private payor rates, we are uncertain as to whether the delay in data reporting would result in a measurable budgetary impact. In other

[111] *https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html.*

words, in order to comprehend the impact of delayed reporting and subsequent implementation of updated CLFS rates, we would need to calculate weighted medians of private payor rates based on new data and compare the revised rates to the current rates. As such, we believe that we will only know the impact of the delay in data reporting after collecting actual updated applicable information from applicable laboratories, including the collection of private payor rate data from applicable hospital outreach laboratories, and calculate the updated weighted medians of private payor rates.

With regard to the conforming changes to our requirements for the phase-in of payment reductions, we note that this revision shifts the 15 percent limitation on payment reductions from CYs 2021 through 2023, to CYs 2022 through 2024. Therefore, we believe this conforming regulatory amendment to the phase-in of payment reductions in § 414.507(d) is budget neutral for scoring purposes.

2. OTP Provider Enrollment Regulation Updates for Institutional Claim Submissions

We stated in section III.B. of this proposed rule that:

- Section 424.67(b)(2) requires newly enrolling OTPs to pay an application fee at the time of enrollment under § 424.514.
- 300 currently enrolled OTPs would change their enrollment from a Form CMS–855B to a Form CMS–855A.
- 10 OTPs that enroll using the Form CMS–855A would later change their enrollment to a Form CMS–855B.

These 310 OTPs would be required to pay an application fee because said change to a Form CMS–855A enrollment would constitute a new/initial enrollment.

The application fees for each of the past 3 calendar years (CY) were or are $569 (CY 2018), $586, (CY 2019), and $595 (CY 2020). Consistent with § 424.514, the differing fee amounts are 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. Although we cannot predict future changes to the CPI, the fee amounts between 2018 and 2020 increased by an average of $13 per year. We believe this is a reasonable barometer with which to estimate (strictly for purposes of this proposed rule) the fee amount in CY 2021, the year in which we believe all of the above-referenced 310 OTPs would change their enrollments. Accordingly, we project a fee amount of $608 in 2021, resulting in a total application fee cost of $188,480 (310 × $608).

3. Payment for Principal Care Management (PCM) Services in Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs)

After reviewing the PFS, FQHC, and RHC historical spending, including the first quarter of calendar year 2020 spending for the new principal care management codes under the PFS, we estimate the addition of these codes (G2064 and G2065) to G0511 would have a negligible impact on Medicare spending.

4. Changes to the Federally Qualified Health Center Prospective Payment System (FQHC PPS) for CY 2021: Proposed Rebasing and Revising of the FQHC Market Basket

Since the proposed FQHC market basket and multi-factor productivity adjustment are the same under the current 2013-based market basket and the proposed 2017-based market basket (1.9 percent), we estimate no economic impact from rebasing and revising of the FQHC market basket for CY 2021.

5. Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention That Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

We are proposing to implement section 2002 of the Support Act by adding regulatory language to the existing Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) regulations to explicitly include elements regarding screening for potential substance use disorders and a review of current opioid prescriptions. We expect the new regulatory elements to add minimal burden since review of medical and social history, risk factor identification, education, counseling, and referrals are already fundamental parts of the IPPE and AWV. Standard documentation in the medical record that these services were furnished would not change based on these new requirements. We note that in section VIII.C.2.a. of this RIA, we discuss the increase in payment for E/M visits in general. Accordingly, the increase in payment for E/M visits applies to the IPPE and AWV and the impact to 2021 expenditures is included in section VIII.C.2.a. of this RIA.

6. 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 2021 with those available for MIPS eligible clinicians for the CY 2021 performance period. We anticipate that this alignment 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 2021. 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 proposed policy would have only a minimal impact on states, by requiring minor adjustments to state systems for 2021 to maintain current eCQM lists and specifications. Based on a sampling of funding requests, each state typically spends, on average, approximately $670,000 per year to operate its Medicaid Promoting Interoperability Program attestation system for EPs. Only a small fraction of those costs is typically attributable to updating eCQM specifications. We estimate that the costs for updating eCQM specifications under this proposal would be approximately $100,000 per state. State expenditures to make any systems changes that would be required as a result of this proposal would most likely be eligible for 90 percent Federal financial participation.

For 2021, 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 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 proposal 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 2020 and we believe it will not create new burden for EPs or states.

7. Medicare Shared Savings Program

In section III.G.1.c. of this proposed rule, we propose changes to the Shared Savings Program quality performance standard. The quality performance standard is the minimum performance level ACOs must achieve in order to share in any savings earned, avoid maximum losses under certain payment tracks, and avoid quality-related compliance actions. We are proposing to increase the quality performance standard for all ACOs to achievement of a quality performance score equivalent to the 40th percentile or above across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. Please refer to section III.G.1.c. of this proposed rule for a detailed discussion of the data simulation used to inform the impacts for the proposed change to the quality performance standard.

Our analysis of quality performance data reported by ACOs for performance year 2018 indicates that the proposed methodological changes in ACO quality scoring will reduce the mean ACO quality score by roughly 10 to 15 percentage points relative to recent historical performance years where ACO quality performance scores have averaged 90 percent or more. Despite an expectation for a decreasing score for most ACOs and an increase in the fraction of ACOs failing to achieve the minimum threshold for qualifying for potential shared savings, the proposal is estimated to marginally increase overall shared savings payments to ACOs because under the proposed approach we would no longer prorate the savings sharing rate for ACOs that do meet or exceed the threshold. Our best estimate is that shared savings payments to ACOs would increase by $38 million for the 2021 performance year because of these proposed changes, representing an increase in shared savings payments of only about 2 percent of projected total gross measured savings for ACOs earning shared savings that year. We also recognize that this impact could differ if the 40th percentile across all MIPS Quality performance category scores improves relative to ACOs' quality performance scores, or alternatively if ACOs, particularly ACOs at risk of failing, respond to the methodology change by boosting their performance. Taking into account such possibilities indicates the impact of the proposed changes to the quality performance standard could range from $15 million in lower total shared savings payments to ACOs to $154 million in additional shared savings payments to ACOs (reflecting the respective extreme scenarios assumed above). However, it is important to note that under all scenarios, the program continues to achieve significant net savings after sharing savings with ACOs.

We do not anticipate a material aggregate impact for the other proposed changes related to the Shared Savings Program, specifically the changes related to repayment mechanism requirements (section III.G.3. of this proposed rule) and the assignment methodology (section III.G.2. of this proposed rule); however, the latter proposal may have differing effects on a subset of participating ACOs, for example by changing which competing ACO ultimately achieves the assignment for a small subset of beneficiaries.

8. Modifications to Medicare Shared Savings Program Quality Reporting Requirements for Performance Year 2020

We are proposing to waive the CAHPS for ACOs reporting requirement for performance year 2020 and will assign automatic full credit to all ACOs for the CAHPS for ACOs survey measures. Based on recent ACO performance on CAHPS measures, we estimate moving to a 100 percent score for the CAHPS measures would increase the final quality score for the group of all non-new ACOs by roughly 2 percentage points. This would translate to an estimated increase in total shared savings payments to ACOs of approximately $20 million.

9. Proposal To Remove Selected National Coverage Determinations

We are proposing to remove nine older NCDs that no longer contain clinically pertinent and current information or that involve items or services that are used infrequently by beneficiaries. Generally, proactively removing obsolete or unnecessary NCDs removes barriers to innovation and reduces burden for stakeholders and CMS. The nine NCDs fall into two impact categories. First, eliminating an NCD for items and services that were previously covered means that the item or service will no longer be automatically covered by Medicare. Instead, the coverage determinations for those items and services will be made by Medicare Administrative Contractors (MACs). Second, if the previous national coverage determination barred coverage for an item or service under title XVIII, MACs would now be able to cover the item or service if the MAC determines that such action is appropriate under the statute. We believe that allowing local contractor flexibility in these cases better serves the needs of the Medicare program and its beneficiaries since we believe the future utilization for items and services within these policies will be limited, each affecting less than one percent of the Medicare FFS population.

For the six NCDs where we are proposing to go from limited coverage to MAC discretion, claims data from 2019 show that less than one percent of the Medicare population are affected. Specifically, CMS provides limited coverage for specific conditions under NCD 20.5, Extracorporeal Immunoadsorption (ECI) using Protein A Columns, where CMS paid 1,918 Medicare FFS claims for 118 beneficiaries for a total expenditure of $3,757,178.36. Under NCD 100.9, Implantation of Gastroesophageal Reflux Device, CMS received no claims in 2019. For NCD 110.14, Apheresis (Therapeutic Pheresis), CMS paid 84,539 Medicare FFS claims for 10,641 beneficiaries for a total expenditure of $77,486,916.37. CMS provides coverage for FDA approved labeled indications under NCD 110.19, Abarelix, and no claims were submitted in 2019 because the device is no longer marketed. Under NCD 190.1, Histocompatability Testing, CMS paid 4,986 Medicare FFS claims for 2,525 beneficiaries for a total expenditure of $206,085.04. For NCD 190.3, Cytogenetic Studies, CMS paid 163,522 Medicare FFS claims for 145,212 beneficiaries for a total expenditure of $18,997,807.17. If under MAC discretion, these items and services continue to be covered, we estimate there will be de minimis change to 2021 expenditures, compared to 2019. However, we note that MAC discretion may result in the MACs determining that in particular instances of these items and services, a noncoverage decision may be appropriate for the patient, which could result in a decrease in 2021 expenditures, compared to 2019.

For the three non-covered NCDs proposed to be eliminated, we would not expect to find historical claims data. CMS broadly noncovers both Electrosleep Therapy (NCD 30.4) and Magnetic Resonance Imaging (NCD 220.2.1) for all indications. CMS noncovers FDG PET (NCD 220.6.16) for three specific conditions. The FDG PET NCD as written is silent on covered conditions, thereby allowing MACs to determine coverage for all other conditions not specifically noncovered. Because these NCDs provide for noncoverage, we do not have accurate claims data to estimate total impact. However, based on the diagnoses and services, we expect future claims to affect less than one percent of Medicare

FFS beneficiaries. Furthermore, removing a national noncoverage NCD may reduce burden for stakeholders and CMS. It may also remove barriers to innovations and increase patient access to technologies that may now be beneficial for some uses.

10. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

This provision does not have any cost to stakeholders other than what is reflected in the Collection of Information section of this proposed rule, including cost to Medicare.

11. Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act

We believe that if finalized, our proposal to continue assigning certain section 505(b)(2) drug products to existing multiple source drug codes, as described in section III.L. of this proposed rule, would result in continued savings by preventing excessive payments for some drug products that are labeled and used in a manner that is similar to generic versions of existing products that are paid under multiple source drug codes. Finalizing this proposal would result in the continuation of what we have characterized as longstanding policy. We believe that savings would continue based on differences in Medicare payment allowances between codes that contain only section 505(b)(2) drug products (with labeling and uses that are similar to multiple source drug codes) and multiple source drug codes that include generic drugs with the same active ingredient(s). In these cases, recent payment limits determined under section 1847A of the Act for the 505(b)(2) drugs were roughly 10 times higher than the payments for multiple source drug codes that included the generic drug products. The multiple source drug code payment limits used in the comparisons consisted of a weighted average of generic and branded drug products.

We are not able to provide a detailed estimate of the potential continued savings for the following reasons. First, we cannot estimate how many section 505(b)(2) drug products will be approved over the next few years. Second, we cannot estimate how many of these drug products will be paid under Part B. Third, we cannot estimate what share of Part B drug claims relative to similar (and potentially lower priced) multiple source drug codes the section 505(b)(2) drug products will capture. Fourth, we cannot estimate the price or payment difference between the yet to be approved section 505(b)(2) drug products and items priced in multiple source drug codes. We also note that the proposed approach will not prevent the separate payment of all section 505(b)(2) drug products. If an approved section 505(b)(2) drug product does not meet the definition of a multiple source drug as discussed in section III.L. of this proposed rule and is separately payable under Part B, that section 505(b)(2) drug product would be paid separately, for example it would be assigned to a single source drug code.

However, we can provide a very rough estimate of the effect on spending that this policy has. Based on 2018 data on the Part B Drug Spending Dashboard (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB*), a 50 percent uptake of two recently approved section 505(b)(2) drug products relative to the corresponding multiple source drug code, and payment allowance estimates derived from the July 2020 ASP Drug Pricing files (or WAC from pricing compendia if ASP was not yet available), we estimate that payment under separate single source drug codes could result in $15 million to $33 million more spending per code each year for each section 505(b)(2) drug product that is assigned to a separate code. Even if a small number of section 505(b)(2) drug products were paid under separate codes, for example 5 to 10 each year, this could result in $75 million to $330 million in additional spending per year (just for each year's 5 to 10 new section 505(b)(2) drug products). Over 10 years, the combined total for paying for 5 to 10 more additional section 505(b)(2) drug products each year using separate codes could result in over $1 billion in additional Part B spending if this proposal is not finalized and these section 505(b)(2) drug products are treated as single source drugs.

We also note that as discussed in section III.L. of this rule, the proposed approach will not prevent the separate payment of all section 505(b)(2) drug products.

12. Updates To Certified Electronic Health Record Technology Due to the 21st Century Cures Act

In section III.M. of this proposed rule, we propose to update the definitions of CEHRT for the Promoting Interoperability Programs and for MIPS. Under this proposal, the technology must be certified under the Certification Program to the current 2015 Edition certification criteria or the certification criteria in the 2015 Edition Cures Update, for the period of 24 months, as described in timelines finalized in the 21st Century Cures Act final rule (85 FR 25670). After that time, when ONC only allows certification under the 2015 Edition Cures Update, the technology must be certified to the 2015 Edition Cures Update. We also propose flexibility such that participants in the Hospital IQR Program may use either the 2015 Edition certification criteria or the 2015 Edition Cures update for CEHRT beginning in the CY 2020 reporting period.

If these proposals are finalized, eligible hospitals and clinicians would be required to update their EHR technology to meet the CEHRT definition under the 2015 Edition Cures Update. It is important to note that the regulatory impacts of the ONC 21st Century Cures Act final rule accounts for the quantified and unquantified costs and benefits to hospitals and clinicians associated with acquiring technology certified to the 2015 Edition Cures Update (85 FR 25905 through 25938). Specifically, ONC based their analysis regarding the number of hospitals and health care providers that would be impacted by their regulatory action on the number of hospitals and health care providers that have historically participated in the CMS EHR Incentive Programs (now Promoting Interoperability (PI) Programs (85 FR 25908). Because we expect that the eligibility criteria proposed under this rule will be a subset of those who participated in the EHR Incentive Programs (for example the MIPS program has eligibility criteria for low-volume that the EHR Incentive program did not have), this regulatory impact analysis assumes that the cost to program participants to acquire the upgraded technology has been accounted for under the ONC 21st Century Cures Act. However, we acknowledge ambiguity in attributing impacts across that earlier rule and this proposal, and request comment that would help with identification of effects that are dependent on these new regulatory provisions. (We further note that if the ambiguity is ultimately resolved such that all the costs are attributed to the ONC 21st Century Cure Rule, leaving no costs associated with this proposed rule's certified EHR provisions, then these provisions would also yield no benefits.)

13. Proposal To Establish New Code Categories

In section III.N. of this proposed rule, we are proposing to create 15 new Level

II HCPCS codes to identify the current array of buprenorphine/naloxone products available on the U.S. market. This code series is intended to replace and more specifically identify the series of four existing codes (J0572 through and including J0575). Even though this would result in a greater number of codes than previously available, the net result of this modification is simply a more complete set of codes, updated to reflect the current market, available for health care providers and coders to identify and report on claims. Therefore these changes place no additional burden on coders, health care providers.

14. Medicare Diabetes Prevention Program Expanded Model Emergency Policy

a. Effects on Beneficiaries

In section III.O. of this proposed rule, we are proposing certain Medicare Diabetes Prevention Program (MDPP) expanded model policies to allow CMS to remove the once per life time benefit for some MDPP beneficiaries, increase the number of virtual sessions, allow MDPP suppliers to start new cohorts, and allow certain MDPP suppliers to deliver time-limited virtual MDPP sessions in the event of extreme and uncontrollable circumstances that would adversely affect access to MDPP services. These proposed changes would apply during the COVID–19 Public Health Emergency (PHE) and any future PHE, in the emergency area during the emergency period, as defined under section 1135 (g) of the Act, when the Secretary has authorized waivers under section 1135 for such emergency area and period.

Throughout the rulemaking for the MDPP expanded model, we sought to ensure that the set of MDPP services would be delivered in-person, in a classroom-based setting, within an established interval timeline. At the time, the priority was placed on establishing a structured service that, when delivered within the confines of the rule, would create the least risk of fraud and abuse, increase the likelihood of success, and maintain the integrity of the data collected for evaluation purposes. However, circumstances such as the COVID–19 PHE have led CMS to make changes to the MDPP expanded model, and now to propose an Emergency Policy for MDPP that allows for temporary flexibilities and that prioritizes availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by 1135 waiver events.

In the March 31st COVID–19 IFC, we sought to ensure that the set of MDPP services that had already started when the COVID–19 PHE began could continue given the guidance from CDC that Medicare age beneficiaries stay home. The priority was to allow for temporary flexibilities that prioritize availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by the COVID–19 PHE. Given the extended duration of the COVID–19 PHE, we are proposing to finalize the regulations in the March 31st COVID–19 IFC, amend the MDPP expanded model to revise certain MDPP policies during the COVID–19 PHE and any future 1135 waiver event where such 1135 waiver event may cause a disruption to in-person MDPP services. These proposed temporary flexibilities allow beneficiaries to either continue to have access to set of MDPP services through virtual sessions, pause in-person set of MDPP services and resume with the most recent attendance session of record, or restart MDPP from the beginning in accordance with the March 31st COVID–19 IFC (85 FR 19230). Under the current MDPP regulations, as implemented in the IFC, and for future 1135 events, should MDPP suppliers deliver set of MDPP services virtually and beneficiaries opt to continue with the set of MDPP services virtually during the 1135 waiver event, those beneficiaries are not eligible to restart the set of MDPP services at a later date.

Beneficiaries who are eligible to restart the set of MDPP services, as proposed in § 410.79(e)(4)(vi), would be currently enrolled in the first 12 months of the set of MDPP services, as demonstrated by the effective date of the first core session.

b. Effects on the Market

At this point, we cannot make clear estimates of the true costs of the MDPP Emergency Policy costs given the current Medicare enrollment. For an example, as part of the COVID–19 flexibilities, we are using authority under section 1135 of the Act to waive the supplier enrollment application fee for any applications submitted on or after March 1, 2020 in response to COVID–19. This, along with CDC's promotion of the temporary application fee waiver to its DPRP registered organizations, have led to an increase in MDPP supplier enrollment applications and approved suppliers. Currently, more than 250 organizations nationally are enrolled as MDPP suppliers, representing 938 locations across the US and its territories.

For the current COVID–19 PHE, we anticipated in the March 31st COVID–19 IFC that of the 1,818 beneficiaries identified through our monitoring data and the CDC's Diabetes Prevention Recognition Program (DPRP) data, 1,358 beneficiaries may be impacted by allowing both the once-per-lifetime benefit and the minimum weight loss requirement to be waived for those beneficiaries in the first 12 months of MDPP. Of those, we assumed that roughly half of the beneficiaries will want to restart their set of MDPP services after the PHE ends, with a $279,748 cost impact of our waiving the once-per-lifetime benefit as part of the COVID–19 flexibilities, assuming that the estimated cost of year 1 of MDPP is $412.

For this MDPP Emergency Policy, we propose to update our assumptions, based on subsequent data from the CDC regarding DPRP organizations' plans for managing their existing cohorts during the PHE, which include either continuing with their cohorts virtually, pausing set of MDPP services and restarting them virtually, or restarting at a later date after the emergency event ends. Based on these data, we assume that 20 percent of MDPP suppliers and 20 percent of beneficiaries will want to restart the set of MDPP services at the first core session after the emergency event ends, taking advantage of the once-per-lifetime requirement removal. We assume that future emergencies will be more geographic-specific, resulting from a natural disaster versus the national-level COVID–19 PHE. For future emergencies, we assume that 2,500 beneficiaries will be enrolled in MDPP in the impacted geographic region. We note that this number is currently an overestimate, and over time, it will likely be an underestimate. We also note that these assumptions are incorrect in cases where a geographic region suffers widespread damage, including to electrical and/or telecommunications systems. In this scenario, we assume there would be no virtual or physical access to set of MDPP services for some time, and the supplier will need to either pause or restart classes altogether until such infrastructure systems are back in place. We also assume that beneficiaries who opt to continue with the set of MDPP services virtually are within the first 12 months of the MDPP core service period, and will not be eligible to take advantage of the waived once-per-lifetime limit; and beneficiaries who are in year 2 of the set of MDPP services, as demonstrated by the effective date of the first core session, are not eligible to restart MDPP at the beginning. The cost per impacted geographic area of the removal of the once-per-lifetime limit is estimated to be $209,000. This assumes

that MDPP suppliers are paid an estimated $418 due to beneficiaries reaching the following performance milestones: Beneficiary attended 9 sessions, and reached the 5 percent weight loss during interval 2 of the core maintenance session, and attended the required core maintenance sessions.

TABLE 91: Cost of MDPP Emergency Policy per Geographic Area Impacted by the Emergency

Recommended Waivers	Cost impact
Adjust the limit to the # Virtual sessions	$ 0
Remove the once per lifetime requirement	$ 209
Remove the MDPP services time periods and intervals	$ 0
Average Y1 MDPP Payments (Y1) with no action	$ 0
Total cost of MDPP Emergency Policy per PHE	$ 209

Units of Measurement in thousands

Assumptions: Estimated MDPP payments in Year 1: $418, assuming that beneficiaries attended 9 sessions, and reached the 5 percent weight loss during interval 2 of the core maintenance session. For future emergencies we assume that 2,500 beneficiaries in any geographic area will be impacted by a public health emergency, or 500 beneficiaries per geographic area.

15. Changes Due to Updates to the Quality Payment Program

In section IV.A. of this proposed rule, we included our 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 2021 MIPS performance period based on various proposed policies to modify the MIPS final score and the performance threshold proposed in section IV.A.3.e.(3) of this rule and additional performance threshold finalized in the CY 2020 PFS final rule (84 FR 63040).

The measure submissions for the 2019 MIPS performance period were not available in time to incorporate into this CY 2021 PFS proposed rule regulatory impact analysis. As a result, this analysis uses the 2018 MIPS performance period submissions that were used for the CY 2020 PFS final rule (84 FR 63164), with some updates of supplementary 2019 datasets used to better reflect trends in APM participation and QP status since the 2018 MIPS performance period. Furthermore, due to the application of the extreme and uncontrollable circumstances policy for the 2019 MIPS performance period, not all clinicians submitted measure data for the 2019 performance period. We will evaluate for the final rule as to whether it will be appropriate to use the 2019 performance period data.

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. 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 allows eligible clinicians to become QPs by meeting the QP payment amount or patient count threshold 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 payments for covered professional services furnished by an eligible clinician during that year. Eligible clinicians who become QPs for a year are not subject to MIPS reporting requirements and payment adjustments. 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 are not eligible to receive the APM Incentive Payment. For the 2021 QP Performance Period, as set forth in § 414.1430(a)(2), Partial QPs are eligible clinicians in Advanced APMs who have at least 50 percent, but less than 75 percent, of their payments for Part B covered professional services through an APM Entity, or furnish Part B covered professional services to at least 35 percent, but less than 50 percent, of their Medicare beneficiaries through an APM Entity. This MIPS payment 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, the Conversion Factor (CF) used to calculate 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 the CF used to calculate 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 fifth payment year (2023 payment year) of the Quality Payment Program.

Overall, we estimate that for the 2021 QP Performance Period between 196,000 and 252,000 eligible clinicians will become QPs, therefore be excluded from MIPS, and qualify for the lump sum APM incentive payment in Payment Year 2023 based on 5 percent of their Part B paid amounts for covered professional services in the preceding year. These paid amounts for QPs are estimated to be between approximately $14,012 million and $18,015 million in total for the 2021 performance year. The analysis for this proposed rule used the 2019 third snapshot participation file. We based APM Incentive Payment Amounts on paid amounts with service states of January 1, through September 30, 2019. We multiplied the calculated amounts by 1.5 to approximate payment amounts for the full calendar year. We estimate that the total lump sum APM Incentive Payments will be approximately $700–900 million for the 2023 Quality Payment Program payment year.

In section IV.F.10.b. of this proposed rule, 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 2021 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2021 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that would attain QP status through the All-Payer Combination Option. We note that the Next Generation ACO Model, previously scheduled to conclude December 2020, the Comprehensive Care for Joint Replacement Payment Model (CEHRT Track), currently scheduled to conclude March 31, 2021, and the Radiation Oncology Model as proposed, have been included in our analysis as we anticipate that they will be Advanced APMs in 2021. The following APMs are expected to be Advanced APMs for the 2021 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track), if extended;
- Comprehensive Primary Care Plus (CPC+) Model;
- Direct Contracting Model;
- Kidney Care Choices Model;
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Track 2, Track 3, Basic Track Level E, and the ENHANCED Track);
- Medicare ACO Track 1+ Model;
- Next Generation ACO Model, if extended;
- Oncology Care Model (Two-Sided Risk Arrangements);
- Primary Care First (PCF) Model;
- Radiation Oncology Model (RO), if finalized; and
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

We used the Participation 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 the number of QPs, total Part B paid amounts for covered professional services, and the aggregate total of APM Incentive Payments for the 2021 QP Performance Period. We examined the extent to which Advanced APM participants would meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

b. Impact for the 2022 MIPS Payment Year

In section IV.A.3.d.(2)(a) of this proposed rule, we proposed to double the total points available for the complex patient bonus to up to 10 points. If this proposal is finalized, we expect the median bonus to increase by 3 points, thus increasing MIPS final scores at the median by 3 points. We do not know the effects of the COVID–19 PHE and its effect on MIPS performance in 2020, so we did not recreate the analysis and payment distributions with the updated bonus for the 2020 MIPS performance period. We expect the higher MIPS final scores would result in smaller payment adjustments for two reasons. First, we expect reductions to the budget neutral pool due to the higher scores. Second, for clinicians above the performance threshold or additional performance threshold, an increased score would mean more clinicians sharing the budget neutral pool and additional $500 million for exceptional performance and potentially lowering the scaling factor that is applied to the MIPS payment adjustment and additional payment adjustment.

c. Estimated Number of Clinicians Eligible for MIPS Eligibility for the 2023 MIPS Payment Year

(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 2021 MIPS performance period in this proposed rule, our scoring model used a combination of the first determination period from the 2019 MIPS performance period (from October 1, 2017 to September 30, 2018) and data from the end of calendar year 2018 (from October 1, 2018 to December 31, 2018). The first determination period from the 2019 MIPS performance period eligibility file was selected as it includes the several eligibility file changes that affect the Quality Payment Program moving forward. The rationale for including the data from the end of CY 2018 was to create a 15-month window for assigning MIPS eligible clinicians, as finalized in the CY 2019 PFS final rule (83 FR 59727 through 59730). We included 1.6 million clinicians (*see* Table 92) who had PFS claims from October 1, 2017 to December 31, 2018. We excluded from our analysis individual clinicians who were affected by the automatic extreme and uncontrollable policy finalized for the 2018 MIPS performance period/2020 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. We also excluded from our analysis submissions from clinicians that are CPC+ practitioners due to data limitations and an inability to model their behavior within the APM Performance Pathway. Finally, submitters with one or more categories identified as being suppressed as a result of bad data were also excluded.

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 the estimate of clinicians eligible for MIPS.

For the estimated MIPS eligible population for the 2023 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 clinicians in the initial population of 1.6 million should be excluded as QPs, we used Advanced APM payment and patient percentages from the APM Participant List for the final snapshot date for the 2019 QP performance period, supplemented by the most recent 2018 performance period APM participation data for those clinicians not on the 2019 first snapshot list. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2021 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 115,936. Due to data limitations, we could not identify specific clinicians who may become QPs in the 2021 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 enrollment date from the 2018 Quality Payment Program performance period data.

(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) levels based on how data are submitted or at the APM Entity level if the clinician is part of an APM Entity in a MIPS APM (hereafter, a MIPS APM Entity) that elects to submit to MIPS. 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. Our method of modeling opt-in participation is described later in this section.

Table 92 presents the estimated MIPS eligibility status and the associated PFS allowed charges of clinicians in the initial population of 1.6 million clinicians in the analysis of the 2021 MIPS performance period after using 2018 MIPS performance period data and applying the proposed policies for the 2021 MIPS performance period.

To apply the low-volume threshold, we need to understand whether clinicians participate as a group, virtual group, APM entity, or as individuals. For the purposes of this regulatory impact analysis, we made assumptions as to which clinicians would elect group reporting, virtual group or APM Entity reporting. One extreme and unlikely assumption is that no practices elect group reporting, virtual group reporting, or participate in an APM Entity that elects MIPS reporting and the low-volume threshold is applied at the individual level. Although we believe a scenario in which clinicians would only 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 approximately 230,000 clinicians [112] would be MIPS eligible because they exceed the low volume threshold as individuals and are not otherwise excluded. In Table 92, we identify these clinicians as having ''required eligibility.''

For this RIA, we assume the following participation requirements for virtual groups and MIPS APM Entities that elect to participate in MIPS. We assume that TINs that registered as a virtual group for the CY 2018 MIPS performance period will continue to do so for the CY 2021 MIPS performance period. Due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period, our model assumes ACO APM Entities would elect to submit data to MIPS through the APM Performance Pathway and that participants in non-ACO APM Entities would participate in MIPS as an individual or group rather than as an APM Entity. We included those who are in MIPS APM ACOs in the 2018 performance period as well as the additional clinicians in the final snapshot date of the 2019 QP performance period.

Finally, we assume that groups that submitted to MIPS as a group will continue to do so for the CY 2021 MIPS performance period. Using CY 2018 MIPS performance period data, we can identify group reporting through the submission of improvement activities, Promoting Interoperability, or quality performance category data. Using these assumptions, we identified 680,253 MIPS eligible clinicians who are eligible because they had the low-volume threshold applied to an identified group, APM entity, or virtual groups. In Table 92, we identify these clinicians who do not meet the low-volume threshold individually but are assumed to submit to MIPS as a group, virtual group or MIPS APM as having ''group eligibility.''

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 2018 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 33 percent opt-in participation assumption 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 92 as ''Opt-In eligibility''. In this proposed rule analysis, we estimate an additional 20,059 clinicians would be eligible through this ''opt-in'' policy for a total MIPS eligible clinician population of approximately 930,000. The leads to an associated $72 billion allowed PFS charges estimated to be included in the 2021 MIPS performance period.

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[112] The count of 230,738 MIPS eligible clinicians for required eligibility includes those who participated in MIPS (212,973 MIPS eligible clinicians), as well as those who did not participate (17,765 MIPS eligible clinicians).

TABLE 92: Description of MIPS Eligibility Status for CY 2023 MIPS Payment Year Using the CY 2021 PFS Proposed Rule Assumptions**

		CY 2021 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	212,973	$50,561
	Do not participate in MIPS	17,765	$3,948
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	680,253	$16,606
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	20,059	$992
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**931,050***	**72,106**
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	368,961	$8,903
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	80,454	$437
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	220,305	$7,623
Total Number of Clinicians Not MIPS Eligible		**669,720**	**16,964**
Total Number of Clinicians (MIPS and Not MIPS Eligible)		**1,600,770**	**89,070**

* Estimated MIPS Eligible Clinician Population

** Table 92 does not include clinicians impacted by the automatic extreme and uncontrollable policy (approximately 20,000 clinicians and $1,643 million in PFS allowed charges). It also does not include excluded eligible clinicians in CPC+ APMs who otherwise would have been MIPS eligible and submitters with one or more categories identified as being suppressed as a result of bad data

*** Allowed charges estimated using 2017 and 2018 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

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There are an estimated 368,961 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 the MIPS eligible clinician population could be as high as 1.3 million clinicians.

Finally, there are some clinicians who would not be MIPS eligible either because they and their group are below the low-volume threshold on all three criteria (approximately 80,000) or because they are excluded for other reasons (approximately 220,000).

Since eligibility among many clinicians is contingent on submission to MIPS as a group, virtual group, APM participation in a MIPS APM Entity that elects to report to MIPS, or election to opt-in, we will not know the number of MIPS eligible clinicians until the

submission period for the 2021 MIPS performance period is closed. For this impact analysis, we used the estimated population of 931,050 MIPS eligible clinicians described above.

d. Estimated Impacts on Payments to MIPS Eligible Clinicians for the 2023 MIPS Payment Year

(1) Summary of Approach

In sections IV.A.3.c., IV.A.3.d. and IV.A.3.e. of this proposed rule, we present several provisions 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 VIII.H.15.c.(2) of this RIA as we describe our methodology to estimate MIPS payments for the 2023 MIPS payment year. We note that some of the MIPS policies in the CY 2020 PFS final rule were only defined for the 2020 MIPS performance period and 2022 MIPS payment year and did not continue to future years, such as the quality and cost performance category weights. Because we did not have category weights for the 2021 MIPS performance period, we could not calculate a final score for the 2021 MIPS performance period and 2023 MIPS payment year. Therefore, we could not create a baseline for the 2021 performance period that would allow us to fully distinguish between the impact of the previously finalized policies for the 2021 performance period and the proposed policies for the 2021 performance period. Our impact analysis looks at the total effect of the previously finalized and newly proposed MIPS policies on the MIPS final score and payment adjustment for the CY 2021 MIPS performance period/CY 2023 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 (as an individual, group, virtual group, or APM Entity) in the four MIPS performance categories: Quality, cost, improvement activities, and Promoting Interoperability. As discussed in section VIII.H.15.c.(2) of this proposed rule, we generally used the most recently available data from the Quality Payment Program which is data submitted for the 2018 MIPS performance period.

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 2021 Quality Payment Program for this proposed rule, we generally used 2018 MIPS performance period data. Our scoring model included the 931,050 estimated MIPS eligible clinicians as described in section VIII.H.15.b.(1)(b) of this RIA.

To estimate the impact of MIPS policies on MIPS eligible clinicians, we generally used the 2018 MIPS performance period data, including data submitted for the quality, improvement activities, and Promoting Interoperability 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.[113] We calculated a hypothetical final score for the 2021 MIPS performance period/2023 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.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a similar methodology described in the CY 2020 PFS final rule (84 FR 63168 through 63169) with the following modifications that reflect the newly proposed policies for the 2021 MIPS performance period. As discussed in section IV.A.3.c.(1)(c) of this proposed rule, we proposed to replace the All-Cause Readmission measure with the Hospital Wide Readmission measure and add the hip-knee complications measure for those for whom it is applicable. We used testing data for these new administrative claims measures.

As discussed in section IV.A.3.d.(1)(b) of this proposed rule, we proposed to use a performance period benchmark as opposed to a historical benchmark. Because the performance data for this analysis came primarily from the 2018 MIPS performance period, we elected to continue using the 2018 MIPS performance period benchmarks. We did not believe using performance period benchmarks for 2018 performance period submissions would appropriately simulate the data issues that might occur with historic benchmarks for the 2019 MIPS performance period. The one exception to using the 2018 MIPS performance benchmarks is we identified measures subject to the topped out scoring cap that was finalized (82 FR 53721 through 53727) using the 2020 MIPS performance period benchmark file.

As discussed in section IV.A.3.c.(1)(b) of this proposed rule, we proposed the removal of Web Interface as a collection type for the 2021 MIPS performance period. As discussed in section IV.A.3.c.(1) of this proposed rule, we proposed a quality performance category weight of 40 percent for the 2021 MIPS performance period.

To estimate a quality performance category score for clinicians in groups who previously used Web Interface as a collection type in 2018, we assumed these groups would use the other two other collection types (MIPS CQMs and eCQMs) available in the 2021 MIPS performance period. To estimate the effect of this change, we used the measures submitted through Web Interface in 2018 and estimated a 2021 quality performance category score by multiplying their computed 2021 quality performance category score using Web Interface by an adjustment factor. The assumption is that the adjustment factor would reflect how clinicians who previously used Web Interface in the 2018 MIPS performance period would perform in the 2021 MIPS performance period in the absence of Web Interface when using the other two collection types available in the 2021 MIPS performance period. The computed adjustment factor accounts for the distribution of clinicians using MIPS CQMs and eCQMs in 2018 and the associated average quality performance category score by practice size categories (25–49 clinicians, 50–99 clinicians, 100–199 clinicians, 200–499 clinicians, 500–999 clinicians, and 1000 or more clinicians). The adjustment factor was calculated in two steps within each practice size category: In

[113] Data submitted to MIPS for the 2017 MIPS performance period 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.

step one, the average quality performance category score for each collection type was weighted by the proportion of MIPS eligible clinicians using each collection type. In step two, the weighted average quality performance category score for the other collection types was divided by the average quality performance score for Web Interface, which yields the adjustment factor for each practice size category.

Finally, our model applied the APM Performance Pathway policies proposed in section IV.A.3.b. of this proposed rule for clinicians in APM Entities. The APM Performance Pathway is available for both ACO and non ACOs. However, due to data limitations, our analysis only applied the APM Performance Pathway scoring policies to ACO APM Entities. For ACOs, quality performance under the proposed APM performance pathway was modeled using data from the 2018 Shared Savings Program and Next Generation ACO Model public use files.[114] We simulated scores for the Hospital Wide Readmission measure proposed in section IV.A.3.c.(1)(c). Data does not exist for APM performance pathway or MIPS quality measures for non-ACO APM Entities, so we assumed these non-ACO APM entities would not participate in the APP. For the purposes of modeling, we assumed that their participating clinicians (or their groups) would participate in regular MIPS, and scored those clinicians using the available MIPS submissions of the clinician or its group. Therefore, because of data limitations our results may overestimate or underestimate the number of APM Entities that elect to participate in MIPS as an APM Entity and how they elect to participate.

(b) Methodology To Estimate the Cost Performance Category Score

In section IV.A.3.c.(2) of this proposed rule, we proposed a cost performance category weight of 20 percent for the 2021 MIPS performance period. We estimated the cost performance category score using the methodology described in the CY 2020 PFS final rule (84 FR 63169)

(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 estimated the facility-based score using the scoring policies finalized in the CY2018 Quality Payment Program final rule (82 FR 53763) and the methodology described in the CY 2020 PFS final rule (84 FR 63169).

(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 2020 PFS final rule (84 FR 63169 through 84 FR 63170)).

In section IV.2.c.(4)(c)(ii)(B) we are proposing to add the HIE bi-directional exchange measure for the 2021 performance period and subsequent years as an optional alternative to the two existing measures: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. This proposal provides clinicians the option of either reporting the new measure or the two existing measures. Because we lack data on who would adopt these new measures and how they would score, we have used past reporting on existing measures to estimate future PI performance, and do not otherwise model the impact of these HIE measures.

In our model, for the APM participants that we modeled as participating in APP (that is, those in ACO entities), 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.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

We modeled the improvement activities performance category score based on CY 2018 MIPS performance period data and APM participation identified in section VIII.H.15.b.(1)(b) of this proposed rule. We continued to apply the methodology described in the CY 2020 PFS final rule (84 FR 63170) to assign an improvement activities performance category score. For the APM participants identified in section IV.A.3.b.(2) of this proposed rule, as there was no APM performance pathway score in the previous final rule, we assigned an improvement activity performance category score of 100 percent.

(f) Methodology To Estimate the Complex Patient Bonus

In section IV.A.3.d.(2)(a) of this proposed rule, we proposed to continue the complex patient bonus for the 2021 MIPS performance period. 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.

(g) Methodology To Estimate the Final Score

As discussed in sections IV.A.3.c.(1)(b), IV.A.3.c.(2)(a), and summarized in section IV.A.3.d.(2)(b) of this proposed rule, our model assigned 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 any performance category, we redistributed the weights according to section IV.A.3.d.(2)(b)(iii) of this proposed rule.

(h) Methodology To Estimate the MIPS Payment Adjustment

As described in section IV.A.3.e.(2) of this proposed rule we applied the proposed 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.

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 the performance threshold of 50 points which was proposed in section IV.A.3.e.(3) of this rule and the previously finalized additional performance threshold of 85 points (84 FR 63039 through 63040). In the alternatives considered discussed in section VIII.I.2. of this rule, we include the key statistics if the performance threshold was 60 as finalized in the CY 2020 PFS final rule (84 FR 63037). We used these resulting parameters to estimate the positive or negative MIPS

[114] The public use files for the 2018 Medicare Shared Savings Program can be accessed here: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-data.*

payment adjustment based on the estimated final score and the paid amount for covered professional services furnished by the MIPS eligible clinician.

(3) Impact of Payments by Practice Size

Using the assumptions provided above, our model estimates that $442 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 mean final score is 76.75 and the median is 81.32.

The model further estimates that the maximum positive payment adjustments are 6.9 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In the alternatives considered discussed in section VIII.I.2. of this rule, we include the details of the model in which the performance threshold was set to 60, which had been finalized in the 2020 PFS final rule. In this alternate model, $520 million would be redistributed through budget neutrality and the maximum positive payment adjustments would be 7.4 percent.

Table 93 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. Table 93 also shows that 90.7 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 2018 MIPS performance period submissions data to simulate a 2021 MIPS performance period final score, and it is likely that there will be changes that we cannot account for at this time, including services and payments disrupted by the PHE or clinicians changing behavior because of the performance thresholds increased for the 2021 MIPS performance period to avoid a negative payment adjustment.

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 some MIPS eligible clinicians that do not submit data to MIPS receive a non-zero score for 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, 89 percent are in small practices (15,748 out of 17,780 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 2018 performance period, which is associated with the 2020 MIPS payment year and had a performance threshold of 15 points, and that participation may change for the 2021 performance period when the performance threshold is proposed at 50 points.

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TABLE 93: MIPS Estimated Payment Year 2023 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	144,570	81.2%	29.9%	18.8%	1.2%
2) 16-24	43,225	86.9%	33.9%	13.1%	1.4%
3) 25-99	199,156	90.9%	36.0%	9.1%	1.4%
4) 100+	526,319	96.6%	34.4%	3.4%	1.4%
Overall	**913,270**	**92.5%**	**34.0%**	**7.5%**	**1.3%**
Among those not submitting data					
1) 1-15	15,748	0.0%	0.0%	100.0%	-8.4%
2) 16-24	644	0.0%	0.0%	100.0%	-8.5%
3) 25-99	940	0.0%	0.0%	100.0%	-8.6%
4) 100+	448	0.0%	0.0%	100.0%	-8.8%
Overall	**17,780**	**0.0%**	**0.0%**	**100.0%**	**-8.4%**

*Practice size is the total number of TIN/NPIs in a TIN.

** 2018 data used to estimate 2021 performance period payment adjustments. Payments estimated using 2018 dollars trended to 2023. 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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(4) Additional Impacts From Outside Payment Adjustments

(a) Burden Overall

In addition to the payment adjustments, we propose several policies that have an impact on burden. In section VI.B.4 of this proposed rule, we outline the costs of data collection that includes both policy updates and adjustments due to the use of updated data sources. For each proposal included in this regulation which impacts our estimate of collection burden, the incremental burden for each is summarized in Table 94. We also provide additional burden discussions that we are not able to quantify.

TABLE 94: Incremental Burden from Associated Proposals

Burden Description and associated proposal	Burden Hours	Burden Dollars
Total burden associated with continuing the policies and ICRs set forth in the CY 2020 PFS final rule into the 2021 MIPS performance period (as discussed in section VI.B.4.o)	3,008,022	$ 294,205,428
Burden change due to proposal to sunset of the CMS Web Interface measures as a collection type/submission type*	-5,920	-$ 541,006
Burden change due to new ICR for Nomination of MVPs	300	$ 45,467
Burden change due to proposal to add a survey-based measure on telehealth to the CAHPS for MIPS Survey	100	$ 2,565
Burden change due to proposal to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible	31	$ 4,698
Total change in burden due to policy	**-5,488**	**-$ 488,115**
Total burden set forth in the CY 2021 PFS proposed rule	**3,002,534**	**$ 293,717,313**

* The total change in burden due to this policy includes a decrease in burden due to elimination of the "Quality Data Submission: CMS Web Interface collection type" and "Group Registration for CMS Web Interface" ICRs and an increase in burden for the "Quality Data Submission: MIPS CQM and QCDR collection type" and "Quality Data Submission: eCQM collection type" ICRs associated with respondents who previously submitted via the CMS Web Interface submitting data via an alternate collection type." See section VI.B.4.

(b) Additional Impacts to Clinicians

(i) Web Interface

As discussed in section IV.A.3.c.(1)(b) of this proposed rule, we are proposing to sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the 2021 performance period. We recognize that the sunset of the CMS Web Interface for groups and virtual groups may be burdensome to current groups and virtual groups submitting quality data on CMS Web Interface measures. Such groups and virtual groups would need to select a different collection type/submission type and redesign their systems to be able to interact with the new collection type/submission type. Given that the Medicare Part B claims collection type is limited to small practices, the alternatives for these groups and virtual groups would be either the MIPS CQM, QCDR or eCQM collection types. Given the size of the affected groups and virtual groups, we believe the majority are likely to already be using a QCDR, qualified registry, or EHR as part of their practice workflow. Of the 2,932 TINs comprised of 25 or more clinicians who submitted MIPS data via a collection type other than the CMS Web Interface, 62 percent reported via the MIP CQM and QCDR collection type and 38 percent reported via the eCQM collection type. For groups converting from Web Interface, there will be some non-recurring costs associated with modifying clinical and MIPS data reporting workflows to utilize an alternate collection type. For any remaining groups and virtual groups there will also be registry fees paid to a QCDR or qualified registry or the financial expense of purchasing/licensing and deploying an EHR system. Because we are unable to assess either the existing workflows of each individual group and virtual group or the decisions each group and virtual group will make in response to this proposal, we cannot quantify the resulting economic impact. While there may be an initial increase in burden for current groups and virtual groups utilizing the CMS Web Interface measures having to transition to the utilization of a different collection type/submission type, we recognize that we would also be reducing reporting requirements. Groups and virtual groups would no longer have to completely report on all pre-determined CMS Web Interface measures and would be able to select their own measures (at least 6) to report.

Groups and virtual groups account for less than 20 percent of organizations utilizing the CMS Web Interface measures while ACOs participating in the Medicare Shared Savings Program and Next Generation ACO Model account for more than 80 percent. With an 80 percent reduction and a continued decrease interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures, it is not fiscally viable, feasible, or sustainable for MIPS to continue to make available the CMS Web Interface measures as a collection type/submission type. There would be proportionally higher costs associated with the operationalization and maintenance of the CMS Web Interface with a significantly smaller number of groups and virtual groups utilizing the CMS Web Interface. In assessing the utilization of the CMS Web Interface by groups and virtual groups, there has been a substantial decrease in participation each year since the inception of MIPS in the 2017 performance period. From 2017 to 2019, the number of groups eligible to report quality measures via the CMS Web Interface (groups registered to utilize the CMS Web Interface) decreased by approximately 45 percent. Similarly, the number of groups utilizing the CMS

Web Interface as a collection type decreased by approximately 40 percent from 2017 to 2019. In our cost analysis, operating and maintaining the CMS Web Interface for significantly smaller number of groups and virtual groups would not be cost-effective. To operate and maintain the CMS Web Interface measures solely for groups and virtual groups, there would be an increase in cost and needed resources under MIPS associated with the items such as the establishment and maintenance of CMS Web Interface benchmarks, assignment and sampling, technical support, and education and outreach; thus, there would be proportionally higher costs associated with the operationalization and maintenance of the CMS Web Interface with a significantly smaller number of groups and virtual groups utilizing the CMS Web Interface measures as a collection type/submission type.

(ii) Administrative Claims Measure

As discussed in section IV.A.3.c.(1)(c), we are proposing to add two new administrative claims measures beginning in the 2021 MIPS performance period and for future performance periods. We acknowledge there are administrative burdens and related financial costs associated with each administrative claims measure that clinicians, groups, and organizations may choose to monitor. However, because these costs can vary significantly due to organizational size, number of administrative claims measures being reported, volume of clinicians reporting each measure, and the specific methods employed to improve performance, we are unable to provide an estimate of the financial impact each clinician, group, or organization may experience. In summary, we are acknowledging that while there is no data submission requirements per § 414.1325(a)(2)(i) for administrative claim measures, there may be associated costs for clinicians and group practices to monitor new administrative claim measures; however, we are unable to quantify that impact.

(iii) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.3.c.(3)(b)(ii) of this rule, we are proposing for the CY 2021 performance period and future years to modify two existing improvement activities. We refer readers to Appendix 2 of this proposed rule for further details. We do not believe these proposals would impact time or financial burden on stakeholders because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform. We do not expect this proposal to affect our currently approved information collection burden estimates in terms of neither the number of estimated respondents nor the burden per response. We 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 rulemaking (82 FR 54175). Most of the improvement activities in the Inventory remain unchanged for the 2020 MIPS performance period.

(c) Stakeholders Nominating Improvement Activities

In section IV.A.3.c.(3)(b)(i)(A)(aa) of this rule, we are proposing to make an exception to the established timeframe for nomination of improvement activities, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. While we expect additional nominations may be received as a result of this proposal, we do not have any data with which to estimate what the additional number may be but we assume the additional costs associated with nominating new improvement activities are unchanged. Additionally, in section IV.A.2.c.(3)(b)(ii)(B) of this rule, we are proposing, beginning with the CY 2021 performance period and future years, to consider agency-nominated improvement activities. We are unable to estimate the number of improvement activity nominations we will receive, but similar to the per respondent estimate we have provided in section VI.B.5.i. of this proposed rule, we assume it will require 3 hours at $55.75/hr for a GS–13 Step 5 to nominate an improvement activity for a total cost of $167.25 (3 hrs × $55.75/hr) per activity.

(d) Impact on Third Party Intermediaries

In section IV.A.3.g. of this rule, we proposed multiple changes to the third party intermediary regulations at § 414.1400. Specifically, we are proposing to: (1) Amend current requirements for approval of third party intermediaries to take into account past performance and provision of inaccurate information regarding MIPS program requirements to eligible clinicians; (2) require attendance by all third party intermediaries for training and support sessions; (3) require that QCDRs and qualified registries must conduct an annual data validation audit and if one or more deficiencies or data errors are identified also conduct targeted audits; (4) incrementally increase requirements for QCDR measure testing and clarify what is meant by full testing; and (5) require third party intermediaries to submit a CAP to address identified deficiencies and data issues as well as actions to prevent recurrence.

With regard to the proposal to amend current requirements for approval of third party intermediaries, we do not anticipate this to require any additional effort for affected entities as the proposal is to allow CMS to utilize already available information to make approval decisions.

The proposed requirement for attendance at training and support sessions and the associated burdens on third parties closely aligns to expectations previously established in the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77374) and (81 FR 77384 through 77386). With regard to survey vendors, we previously finalized the CMS-approved survey vendor approval criteria in § 414.1400(e) as discussed in the CY 2018 PFS final rule (83 FR 59907 through 59908). Among the approval criteria, § 414.1400(e)(3) established the requirement that the entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors. Therefore, we assume no additional impact for survey vendors as a result of this proposal. We do not have data on the number of health IT vendors that missed training and support sessions, but the most recent data cites 684 health IT developers through program year 2016 of the Medicare EHR Incentive Program.[115] In CY 2019, 16 total training and support sessions were missed by 14 QCDRs and 33 total sessions were missed by 27 qualified registries. Based on historical frequency and duration, we expect future training and support sessions to continue occurring monthly for approximately 2 hours each. For QCDRs and qualified registries, we estimate an impact of 98 hours [(16 sessions by QCDRs + 33 sessions by qualified registries) × 2 hours]. We lack insight into the exact occupation of session attendees, but for estimating purposes we assume a Physician labor rate of $212.78/hr and

[115] *https://dashboard.healthit.gov/quickstats/pages/FIG-Vendors-of-EHRs-to-Participating-Professionals.php.*

estimate a total burden of $20,852 ($212.78/hr × 98 hours).

We do not anticipate a significant impact to QCDRs and qualified registries resulting from proposal to require QCDRs and qualified registries to conduct an annual data validation audit and if one or more deficiencies or data errors are identified also conduct targeted audits. First, we are not revising our burden estimates because the proposed data validation requirements are similar to existing expectations which we have already accounted for the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999). Second, we believe that the proposed requirements for conduct of the data validation audits are aligned with methods and procedures which stakeholders currently utilize.

With regard to the proposal to require QCDRs and qualified registries to conduct targeted audits if one or more data errors are identified during data validation audits, we are unable to estimate the number of audits which may occur or the time and costs associated with their conduct which could vary substantially depending on the nature of the data error and the amount of data to be audited. We seek comment on the expected frequency of targeted audits and the anticipated scope of effort.

Because the proposal to incrementally increase requirements for QCDR measure testing is not changing the requirements for fully testing measures, but is instead proposing an incremental approach to achieve previously finalized requirements, we do not anticipate any additional impact as a result of the proposal.

As discussed in section VI.B.5.c.(2) of this rule, we estimate the total burden impact associated with the proposal to require CAPs to be 30 hours (10 respondents × 3 hr/respondent) at a cost of $2,774 for all respondents (10 respondents × $277.38/respondent).

f. Assumptions & Limitations

We note several limitations to our estimates of clinicians' MIPS eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the 2023 MIPS payment year. Due to the PHE, we are aware that there may be changes in health care delivery and billing patterns that will impact results for the 2023 MIPS payment year that we were not able to model with our historic data sources. We based our analyses on the data prepared to support the 2019 performance period initial determination of clinician and special status eligibility (available via the NPI lookup on *qpp.cms.gov*),[116] APM Participant List for the final snapshot date for the 2019 QP performance period, CY 2018 Quality Payment Program Year 2 data, 2018 ACO Public Use File for MSSP and Next Gen and CAHPS for ACOs. The scoring model results presented in this proposed rule assume that CY 2018 Quality Payment Program data submissions and performance are representative of CY 2021 Quality Payment Program data submissions and performance. The estimated performance for CY 2021 MIPS performance period using CY 2018 Quality Payment Program data may be underestimated because the performance threshold to avoid a negative payment adjustment for the 2018 MIPS performance period/2020 MIPS payment year was significantly lower (15 out of 100 points) than the performance threshold for the 2021 MIPS performance period/2023 MIPS payment year (60 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 2018 Quality Payment Program 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) 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 93; and (2) our cost data does not overlap with CY 2018 so we may not be capturing performance for all clinicians. Due to the limitations described, there is considerable uncertainty around our estimates that is difficult to quantify.

I. 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 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.

1. Alternatives Considered for the MDPP Expanded Model Emergency Policy

For the MDPP Expanded Model Emergency Policy, no alternatives were considered. If we do not take action it will have an extremely negative impact to MDPP supplier and beneficiaries; which would threaten the success of the entire expanded model; as beneficiaries would become ineligible and not be able to finish the program, MDPP suppliers would not be paid for services rendered, and no new cohorts of set of MDPP services could be started, effectively ending the expanded model test.

2. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold as a critical factor affecting the distribution of payment adjustments. We ran a separate model with a performance threshold of 60 which was previously finalized in the CY 2020 final rule (84 FR 63037) as an alternative to the proposed performance threshold of 50. For reference, our model of proposed policies has a mean final score of 76.75 and median final score of 81.32. The model with a performance threshold of 60, has a mean final score of 76.75 and a median final score of 81.32. We estimate that $520 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 7.36 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 10.4 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data.

In addition, we view the cost performance category weight as a critical factor affecting final scores. We ran two separate models with cost performance category weights of 15 and 30, with corresponding quality performance category weights of 45 and 30, respectively (as an alternative to the proposed cost performance category weight of 20 and quality performance category weight of 40) to estimate the impact of keeping the weights consistent with the CY 2020 PFS final rule and a more aggressive increase in the cost performance category weight.

[116] The time period for this eligibility file (September 1, 2017 to August 31, 2018) maximizes the overlap with the performance data in our model.

The model with a cost performance category weight of 15 has a mean score of 82.14 and a median score of 77.31. The model with a cost performance category weight of 30 has a mean score of 75.85 and a median score 80.06. We refer readers to section IV.A.2.c.(2)(a) for additional rationale on the selection of the cost performance category weight.

3. Alternatives Considered for Changes Related to Scopes of Practice

With regard to the proposal concerning supervision of diagnostic tests by certain NPPs, an alternative would be to maintain the status quo. That is, we could maintain the basic rule under § 410.32(b)(1) that allows only physicians as defined under Medicare law to supervise the performance of diagnostic tests. In that case, the pool of practitioners who could supervise diagnostic tests would remain at current levels and certain NPPs would be limited under Medicare from practicing to the full extent allowed by their state license and scope of practice. However, this alternative would fail to address the mandates established in E.O. 13890.

With regard to the proposal to allow a PTA/OTA to furnish maintenance therapy services, an alternative would be maintaining the status quo to require the PT/OT to personally furnish all maintenance therapy services. However, this alternative would not address the mandates established in E.O. 13890. It would also be inconsistent with our policy in SNF and home health settings when payment for therapy is made under Part A, maintenance therapy can be furnished by a PT/OT or delegated to be performed by a PTA/OTA.

J. Impact on Beneficiaries

We do not believe our proposals will have a negative impact on beneficiaries given overall PFS budget neutrality.

1. Medicare Diabetes Prevention Program Expanded Model Emergency Policy

This change would have a positive impact on affected MDPP beneficiaries, as it would allow them to maintain eligibility for the program, and request virtual sessions if needed for successful completion of attendance and weight loss milestones. It would also allow them to start set of MDPP services virtually, allowing remote digital technology to capture body weight measurement or self-reported weight measurements from a participant's personal home digital scale. Finally, if continuing with set of MDPP services is not an option for beneficiaries during the PHE, the proposed Emergency Policy allows beneficiaries to restart their set of MDPP services, maximizing beneficiary options and access to MDPP both during the PHE and after it ends.

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 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.

K. 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 this year's proposed 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 $110.74 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 $885.92 (8.0 hours × $110.74). Therefore, we estimated that the total cost of reviewing this regulation is $38,477,277.44 ($885.92 × 43,432 reviewers on last year's proposed rule).

L. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 95 and 96 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2020 to CY 2021 based on the FY 2021 President's Budget baseline.

TABLE 95: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2021 Annualized Monetized Transfers	Estimated increase in expenditures of $0.0 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 96: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2021 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.0 billion
From Whom to Whom?	Beneficiaries to Federal Government.

M. 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 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

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 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, 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 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 2. Section 410.15 is amended in paragraph (a)—

■ a. By adding a definition for ''A review of any current opioid prescriptions'' in alphabetical order;

■ b. In the definition of ''First annual wellness visit providing personalized prevention plan services'' by revising paragraph (xi) and adding paragraphs (xii) and (xiii);

■ c. In the definition of ''Subsequent annual wellness visit providing personalized prevention plan services'' by revising paragraph (ix) and adding paragraphs (x) and (xi).

The additions and revisions read as follows:

§ 410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.

(a) * * *

A review of any current opioid prescriptions means, with respect to the individual determined to have a current prescription for opioids, all of the following:

(i) A review of the potential risk factors to the individual for opioid use disorder;

(ii) An evaluation of the individual's severity of pain and current treatment plan;

(iii) The provision of information on non-opioid treatment options; and

(iv) A referral to a specialist, as appropriate.

* * * * *

First annual wellness visit providing personalized prevention plan services * * *

(xi) Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

(xii) Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(xiii) Any other element determined appropriate through the national coverage determination process.

* * * * *

Subsequent annual wellness visit providing personalized prevention plan services * * *

(ix) Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

(x) Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(xi) Any other element determined appropriate through the national coverage determination process.

* * * * *

■ 2. Section 410.16 is amended in paragraph (a)—

■ a. By adding the definition for ''A review of any current opioid prescriptions'' in alphabetical order;

■ b. In the definition of ''Initial preventive physical examination'' by revising paragraphs (6) and (7) and adding paragraphs (8) and (9).

The addition and revisions read as follows:

§ 410.16 Initial preventive physical examination: Conditions for and limitations on coverage.

(a) * * *

A review of any current opioid prescriptions means, with respect to the individual determined to have a current prescription for opioids, all of the following:

(i) A review of the potential risk factors to the individual for opioid use disorder;

(ii) An evaluation of the individual's severity of pain and current treatment plan;

(iii) The provision of information on non-opioid treatment options; and

(iv) A referral to a specialist, as appropriate.

* * * * *

Initial preventive physical examination * * *

(6) A review of any current opioid prescriptions as defined in this section.

(7) Screening for potential substance use disorders to include a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(8) Education, counseling, and referral, as deemed appropriate by the physician or qualified nonphysician practitioner, based on the results of the review and evaluation services described in this section.

(9) Education, counseling, and referral, including a brief written plan such as a checklist provided to the individual for obtaining an electrocardiogram, as appropriate, and the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in sections 1861(s)(10), (jj), (nn), (oo), (pp), (qq)(1), (rr), (uu), (vv), (xx)(1), (yy), (bbb), and (ddd) of the Act.

* * * * *

■ 3. Section 410.32 is amended by—

■ a. Revising paragraphs (b)(1) and (b)(2)(iii)(B),

■ b. Adding paragraph (b)(2)(ix), and

■ c. Revising paragraph (b)(3)(ii).

The revisions and addition read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(1) *Basic rule.* Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, physician assistant or a certified nurse-midwife. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(2) * * *

(iii) * * *

(B) Furnished under the general supervision of a physician or clinical psychologist; or under the general supervision of a nurse practitioner, clinical nurse specialist, physician assistant, or certified nurse-midwife, to the extent they are authorized to perform the tests under their scope of practice and applicable State laws.

* * * * *

(ix) Diagnostic tests performed by a physician assistant authorized to perform the tests under their scope of practice and applicable State laws.

(3) * * *

(ii) *Direct supervision* in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician (or other supervising practitioner) must be present in the room when the procedure is performed. Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or, December 31, 2021, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

* * * * *

■ 4. Section 410.33 is amended by adding paragraph (j) to read as follows:

§ 410.33 Independent diagnostic testing facility.

* * * * *

(j) *Exception for IDTFs with no beneficiary interaction.* An IDTF supplier that has no beneficiary interaction, treatment, or testing at its practice location must not be subject to the requirements at:

(1) Paragraph (c) of this section.

(2) Paragraph (e)(1)(i) of this section.

(i) The requirement that the IDTF maintain documentation that its technicians are licensed and certified in each of the States in which the IDTF operates does not apply to IDTFs that are excepted in this paragraph (j). The requirement that the IDTF maintain documentation that its supervising physicians are licensed and certified in each of the States in which the IDTF operates does apply to IDTFs that are excepted in this paragraph.

(ii) [Reserved]

(3) Paragraph (e)(1)(ii) of this section.

(4) Paragraph (g)(1) of this section.

(5) Paragraph (g)(6) of this section.

(6) Paragraph (g)(8) of this section.

(7) Paragraph (g)(9) of this section.

(8) Paragraph (g)(11) of this section.

(9) Paragraph (g)(12) of this section.

* * * * *

■ 5. Section 410.67 is amended—

■ a. By revising paragraph (7) and adding paragraph (8) in the definition of ''Opioid use disorder treatment service'';

■ b. By revising paragraph (d)(2)(i)(A); and

■ c. By adding paragraph (d)(4)(i)(E).

The additions and revision read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

Opioid use disorder treatment service * * *

(7) Periodic assessment services required under § 8.12(f)(4) of this title, that are furnished during a face-to-face encounter, including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During the Public Health Emergency, as defined in § 400.200 of this chapter, in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

(8) Opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for the emergency treatment of known or suspected opioid overdose.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(A) For implantable and injectable medications, the payment is determined using the methodology set forth in section 1847A of the Act, except that the payment amount must be 100 percent of the ASP, if ASP is used; and the payment must be 100 percent of the wholesale acquisition cost (WAC), if WAC is used.

* * * * *

(4) * * *

(i) * * *

(E) Take-home supply of opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal, Food, Drug and Cosmetic Act for the emergency treatment of known or suspected opioid overdose an adjustment will be made when these medications are dispensed. This adjustment will be limited to once every 30 days to the extent that it is medically reasonable and necessary. The amount of the adjustment will be determined using the methodology in paragraph (d)(2)(i) of this section, except the payment for auto-injector naloxone will be determined using the lowest pricing available (the lower of 100 percent of the ASP, 100 percent of WAC, or the National Average Drug Acquisition Cost).

* * * * *

■ 6. Section 410.78 is amended by revising paragraph (a)(3) and (f) to read as follows:

§ 410.78 Telehealth services.

(a) * * *

(3) *Interactive telecommunications system* means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

* * * * *

(f) *Process for adding or deleting services.* Except as otherwise provided in this paragraph (f), changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process. During the Public Health Emergency, as defined in § 400.200 of this chapter, we will use a subregulatory process to modify the services included on the Medicare telehealth list during the Public Health Emergency taking into consideration infection control, patient safety, and other public health concerns resulting from the emergency. CMS maintains the list of services that are Medicare telehealth services under this section, including the current HCPCS codes that describe the services on the CMS website.

■ 7. Section 410.79 is amended by revising paragraphs (c)(3)(i) and (ii) and (e) to read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(c) * * *

(3) * * *

(i) Except as set forth in paragraph (c)(3)(ii) of this section—

(A) The MDPP services period ends upon completion of the core services period described in paragraph (c)(2)(i) of this section, unless the MDPP beneficiary qualifies for the first ongoing maintenance session interval, in accordance with paragraph (c)(1)(ii) of this section.

(B) If the MDPP beneficiary qualifies for the first ongoing maintenance session interval as described in paragraph (c)(1)(ii) of this section, the MDPP services period ends upon completion of that maintenance session interval, unless the MDPP beneficiary qualifies for a subsequent ongoing maintenance session interval, in accordance with paragraph (c)(1)(iii) of this section, in which case the MDPP service period ends upon completion of the last ongoing maintenance session interval for which the beneficiary qualified.

(ii) In the case of an applicable 1135 waiver event as defined in paragraph (e) of this section, the MDPP services period may be suspended and resumed or restarted in accordance with paragraph (e) of this section.

* * * * *

(e) *MDPP expanded model Emergency Policy.* (1) Notwithstanding paragraphs (a) through (d) of this section, the policies described in this paragraph (e) apply during the Public Health Emergency (PHE) as defined in § 400.200 of this chapter and during any future 1135 waiver event that CMS determines may disrupts in-person MDPP services (an ''applicable 1135 waiver event''). For purposes of this paragraph (e), ''1135 waiver event'' means an emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, for which the Secretary has authorized one of more waivers under section 1135 of the Act.

(2)(i) CMS determines that an 1135 waiver event may disrupt in-person MDPP services if MDPP suppliers would likely be unable to conduct classes in-person, or MDPP beneficiaries would likely be unable to attend in-person classes, for reasons related to health, safety, or site availability or suitability. Health and safety reasons may include, but are not limited to, the avoidance of transmission of contagious diseases, compliance with laws and regulations during an 1135 waiver event, or the physical safety of MDPP beneficiaries and MDPP coaches, as defined in § 424.205(a), during an 1135 waiver event.

(ii) If CMS determines that an 1135 event may disrupt in-person MDPP services, CMS will communicate such determination for policies described in this paragraph (e), to all impacted MDPP suppliers.

(3) The following changes apply under this paragraph (e), when CMS has determined that an 1135 waiver event may disrupt in-person MDPP services:

(i) The in-person attendance requirements of paragraphs (c)(1)(ii)(A) and (c)(1)(iii)(A) of this section do not apply.

(ii) MDPP suppliers may start new cohorts during the PHE as defined in § 400.200 of this chapter or an applicable 1135 waiver event only if a baseline weight measurement can be obtained as described in paragraph (e)(4)(iii) of this section.

(iii) MDPP suppliers can obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss based performance achievement goals in the following manner:

(A) In-person, when the weight measurement can be obtained safely and in compliance with all applicable laws and regulations;

(B) Via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or

(C) Self-reported weight measurements from the at-home digital scale of the MDPP beneficiary. Self-reported weights must be submitted via video, by the MDPP beneficiary to the MDPP supplier. The video must clearly document the weight of the MDPP beneficiary as it appears on his/her digital scale on the date associated with the billable MDPP session.

(iv) The virtual session limits described in paragraphs (d)(2), (d)(3)(i) and (ii) of this section do not apply, and MDPP suppliers may provide all MDPP sessions virtually during the PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event so long as the provision of virtual services complies with all of the following requirements:

(A) The curriculum furnished during the virtual session must address the

same CDC-approved DPP curriculum topic as the regularly scheduled session;

(B) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one virtual make-up session on the same day as a regularly scheduled session;

(C) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one virtual make-up session per week;

(D) Virtual sessions must be furnished in a manner consistent with the DPRP standards for virtual sessions;

(E) An MDPP supplier can offer virtual sessions only upon an individual MDPP beneficiary's request or agreement to receive services virtually;

(F) An MDPP supplier can offer to an MDPP beneficiary:

(*1*) No more than 16 virtual sessions offered weekly during the core session period, months 1 through 6 of the MDPP services period;

(*2*) No more than 6 virtual sessions offered monthly during the core maintenance session interval periods, months 7 through 12 of the MDPP services period; and

(*3*) No more than 12 virtual sessions offered monthly during the ongoing maintenance session intervals, months 13 through 24.

(v) MDPP suppliers may suspend the in-person delivery of the set of MDPP services, when necessary due to the 1135 waiver event, and subsequently resume services either upon the effective end date of the 1135 waiver event or upon an effective date specified by CMS. Upon resumption of the set of MDPP services, the MDPP services must be furnished in compliance with the requirements in accordance with the following paragraphs (the once per lifetime requirement as described in paragraph (c)(1)(i)(B) of this section does not apply):

(A) Beneficiaries who were receiving MDPP services as of March 1, 2020 may elect to restart the set of MDPP services at the beginning or resume with the most recent attendance session of record.

(B) Beneficiaries who begin the set of MDPP services on or after January 1, 2021 and who are in the first 12 months of the set of MDPP services as of the start of an applicable 1135 waiver event, and whose sessions are suspended due to the applicable 1135 waiver event, may elect to restart the set of MDPP services at the beginning, or may resume with the most recent attendance session of record.

(C) Beneficiaries who began the set of MDPP services on or after January 1, 2021 and who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event are eligible to restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event or may resume with the most recent attendance session of record;

(D) Beneficiaries who elected to continue with MDPP services virtually, as described in paragraph (c)(iii) of this section, are not eligible to restart or resume the set of MDPP services at a later date.

(E) Beneficiaries who elect to suspend the set of MDPP services at the start of an applicable 1135 waiver event may choose to restart the set of MDPP services at the beginning, or may resume with the most recent attendance session of record, only one time per 1135 waiver event.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 8. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 9. Section 414.502 is amended by revising the definitions of ''Data collection period'' and ''Data reporting period'' to read as follows:

§ 414.502 Definitions.

* * * * *

Data collection period is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period, except that for the data reporting period of January 1, 2022 through March 31, 2022, the data collection period is January 1, 2019 through June 30, 2019.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period, except that for the data collection period of January 1, 2019 through June 30, 2019, the data reporting period is January 1, 2022 through March 31, 2022.

* * * * *

■ 10. Section 414.504 is amended by revising paragraph (a)(1) to read as follows:

§ 414.504 Data reporting requirements.

(a) * * *

(1) For CDLTs that are not ADLTs, initially January 1, 2017 and every 3 years beginning January 1, 2022.

* * * * *

■ 11. Section 414.507 is amended by revising paragraphs (d) introductory text and (d)(4) and adding paragraph (d)(7) to read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

* * * * *

(d) *Phase-in of payment reductions.* For years 2018 through 2024, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

* * * * *

(4) 2021—0.0 percent of the payment rate established in 2020.

* * * * *

(7) 2024—15 percent of the payment rate established in 2023.

* * * * *

■ 12. Section 414.902 is amended by revising the definition of ''Multiple source drug'' to read as follows:

§ 414.902 Definitions.

* * * * *

Multiple source drug means a drug described by section 1847A(c)(6)(C) of the Act, including drug products approved through the pathway established under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that are described in § 414.904(k).

* * * * *

■ 13. Section 414.904 is amended by adding paragraph (k) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(k) *Assigning drug products approved through the pathway established under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act to a multiple source drug code.* (1) Drug products approved through the pathway established under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act are assigned to multiple source drug billing and payment codes based on—

(i) The existence of a multiple source drug billing code described by section 1847A(c)(6)(C) of the Act.

(ii) A determination of whether an existing multiple source drug code's descriptor describes the drug product approved through the pathway established under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act based on factors including—

(A) The active ingredient(s), drug name, and the drug description.

(B) Information in drug labeling.

(C) Prescribing and clinical use of the drug.

(2) [Reserved]

■ 14. Section 414.1305 is amended—

■ a. By revising the definition of ''Attestation'';

■ b. In the definition of ''Certified Electronic Health Record Technology

(CEHRT)'' by revising paragraphs (1)(ii)(D) and (2)(ii) introductory text;
■ c. By revising the definition of ''Collection type'';
■ d. By removing the definition of ''Full TIN APM;
■ e. By revising the definitions of ''Low volume threshold'', ''Meaningful EHR user for MIPS'', and ''MIPS APM'';
■ f. By adding definitions for ''Physician Compare'' and ''Primary care services'' in alphabetical order; and
■ g. By revising the definitions of ''Submission type'' and ''Submitter type''.

The revisions and addition read as follows:

§ 414.1305 Definitions.

* * * * *

Attestation means a secure mechanism, specified by CMS, with respect to a particular performance period, whereby a MIPS eligible clinician or group may submit the required data for the Promoting Interoperability or the improvement activities performance categories of MIPS in a manner specified by CMS.

* * * * *

Certified Electronic Health Record Technology (CEHRT) * * *

(1) * * *

(ii) * * *

(D) The certification criteria that are necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) or 45 CFR 170.315(g)(1) or (2) for all certification criteria that support an objective with a percentage-based measure.

* * * * *

(2) * * *

(ii) Necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category including the following:

* * * * *

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: electronic clinical quality measures (eCQMs); MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; for the 2019 through 2022 MIPS payment years, CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures.

* * * * *

Low-volume threshold means:

(1) For the 2019 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has Medicare Part B allowed charges less than or equal to $30,000 or provides care for 100 or fewer Medicare Part B-enrolled individuals.

(2) For the 2020 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has allowed charges for covered professional services less than or equal to $90,000 or furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals.

(3) For the 2021 and 2022 MIPS payment years, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

(4) For the 2019 and 2020 MIPS payment years, the low-volume threshold determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding to the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the low-volume threshold determination period includes a 60-day claims run out. For the 2020 MIPS payment year, each segment of the low-volume threshold determination period includes a 30-day claims run out.

(5) Beginning with the 2023 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, or group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

Meaningful EHR user for MIPS means a MIPS eligible clinician who possesses CEHRT, uses the functionality of CEHRT, and reports on applicable objectives and measures specified for the Promoting Interoperability performance category for a performance period in the form and manner specified by CMS, supports information exchange and the prevention of health information blocking, and engages in activities related to supporting providers with the performance of CEHRT.

* * * * *

MIPS APM means:

(1) For the 2019 through 2022 MIPS payment years, an APM that meets the criteria specified under § 414.1370(b).

(2) Beginning with the 2023 MIPS payment year, an APM that meets the criteria as set forth in § 414.1367(b).

* * * * *

Physician Compare means the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website).

Primary care services for purposes of CAHPS for MIPS survey beneficiary assignment means the set of services identified by the following:

(1) CPT codes:

(i) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by POS modifier 12); 99487, 99489, and 99490 (codes for chronic care management); and 99495 and 99496 (codes for transitional care management services); and

(ii) Beginning with the 2023 MIPS payment year, 99421, 99422, and 99423 (codes for online digital evaluation and management services (e-visit)); 99441, 99442, and 99443 (codes for telephone evaluation and management services); and 96160 and 96161 (codes for administration of health risk assessment).

(2) HCPCS codes:

(i) G0402 (code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits); and

(ii) Beginning with the 2023 MIPS payment year, G2010 (code for remote evaluation of patient video/images); and G2012 (code for virtual check-in).

* * * * *

Submission type means the mechanism by which the submitter type submits data to CMS, including, but not limited to:

(1) Direct;

(2) Log in and upload;

(3) Log in and attest;

(4) Medicare Part B claims; and

(5) For the 2019 through 2022 MIPS payment years, the CMS Web Interface.

Submitter type means the MIPS eligible clinician, group, Virtual Group, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, Virtual Group, or APM Entity, as applicable, that submits data on measures and activities under MIPS.

* * * * *

■ 15. Section 414.1310 is amended by revising paragraphs (b)(1)(iii) and (e)(1) to read as follows:

§ 414.1310 Applicability.

* * * * *

(b) * * *

(1) * * *

(iii) Does not exceed the low volume threshold.

(A) Beginning with the 2021 MIPS payment year, if an individual eligible clinician or group exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the individual eligible clinician or group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such solo practitioners and groups that elect to participate in MIPS as a virtual group (except for APM Entity groups in MIPS APMs), the virtual group election under § 414.1315 constitutes an election under this paragraph and results in the solo practitioners and groups being treated as MIPS eligible clinicians for the applicable MIPS payment year.

(B) For the 2021 and 2022 MIPS payment years, if an APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such APM Entity groups in MIPS APMs, only the APM Entity group election can result in the APM Entity group being treated as MIPS eligible clinicians for the applicable MIPS payment year.

* * * * *

(e) * * *

(1) Except as provided under §§ 414.1317(b) and 414.1370(f)(2), each MIPS eligible clinician in the group will receive a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) based on the group's combined performance assessment.

* * * * *

■ 16. Section 414.1317 is added to read as follows:

§ 414.1317 APM Entity groups.

(a) *APM entity group determination.* The APM Entity group will be determined according to the requirements set forth in § 414.1425(b)(1).

(1) In addition to the dates set forth in § 414.1425(b)(1), for purposes of MIPS, the APM Entity group includes an eligible clinician who is on a Participation List on December 31 of the MIPS performance period.

(2) For purposes of MIPS scoring, the APM Entity group will be comprised only of those eligible clinicians within the APM Entity group who are determined to be MIPS eligible at the individual or group level.

(3) For purposes of calculating the APM Entity group score, MIPS scores submitted by virtual groups will not be included.

(b) *APM Entity group scoring.* The MIPS final score calculated for the APM Entity is applied to each MIPS eligible clinician in the APM Entity group. The MIPS payment adjustment is applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity group.

(1) *Determination of performance category score for each MIPS eligible clinician in an APM Entity.* For APM Entities, where a performance category is not reported by the APM Entity, CMS uses one score for each MIPS eligible clinician in an APM Entity group to derive a single average APM Entity score for the performance category. The applicable score for each MIPS eligible clinician is the higher of either:

(i) A group score based on the measure data for the performance category reported by a TIN for the MIPS eligible clinician according to MIPS submission and reporting requirements for groups.

(ii) An individual score based on the measure data for the performance category reported by the MIPS eligible clinician according to MIPS submission and reporting requirements for individuals.

(iii) In the event that a MIPS eligible clinician in an APM Entity receives an exception from the reporting requirements, such eligible clinician will be assigned a null score when CMS calculates the APM Entity's performance category score.

(2) *Improvement scoring for APM Entity groups.* For an APM Entity for which CMS calculated a total performance category score for one or more participants in the APM Entity for the preceding MIPS performance period, CMS calculates an improvement score for each performance category for which a previous year's total performance category score is available as specified in § 414.1380(b).

(3) *Extreme and uncontrollable circumstances.* Beginning with the 2022 MIPS payment year, an APM Entity may submit to CMS an application described at § 414.1380(c)(2)(i)(A)(*6*) and § 414.1380(c)(2)(i)(C)(2) requesting reweighting of all four MIPS performance categories and for all MIPS eligible clinicians in the APM Entity group, based on extreme and uncontrollable circumstances.

(i) An APM Entity must demonstrate in its application to CMS that greater than 75 percent of its participant MIPS eligible clinicians would be eligible for reweighting the Promoting Interoperability performance category for the applicable performance period.

(ii) If CMS approves the request for reweighting based on an APM Entity's application, and if MIPS data are submitted for the APM Entity for the applicable performance period, all four of the MIPS performance categories will be reweighted for the APM Entity group notwithstanding the data submission.

■ 17. Section 414.1320 is amended by revising paragraphs (d) introductory text and (d)(1) and adding paragraph (g) to read as follows:

§ 414.1320 MIPS performance period.

* * * * *

(d) Beginning with the 2023 MIPS payment year, the performance period for:

(1) The quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1).

* * * * *

(g) For purposes of the 2024 MIPS payment year and each subsequent 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]

■ 18. Section 414.1325 is amended by revising paragraph (c)(1) to read as follows:

§ 414.1325 Data submission requirements.

* * * * *

(c) * * *

(1) For the quality performance category, the direct; login and upload; Medicare Part B claims (beginning with the 2021 MIPS payment year, for small practices only); and for the 2019 through 2022 MIPS payment years, CMS Web Interface (for groups consisting of 25 or more eligible clinicians or a third party intermediary submitting on behalf of a group) submission types.

* * * * *

■ 19. Section 414.1330 is amended by adding paragraphs (b)(4) and (5) to read as follows:

§ 414.1330 Quality performance category.

* * * * *

(b) * * *

(4) 40 percent of a MIPS eligible clinician's final score for the MIPS payment year 2023.

(5) 30 percent of a MIPS eligible clinician's final score for the MIPS payment year 2024 and future years.

■ 20. Section 414.1350 is amended by adding paragraphs (d)(4) and (5) to read as follows:

§ 414.1350 Cost performance category.

* * * * *

(d) * * *

(4) 20 percent of the MIPS final score for MIPS payment year 2023.

(5) 30 percent of the MIPS final score for MIPS payment year 2024 and each subsequent MIPS payment year.

■ 21. Section 414.1367 is added to read as follows:

§ 414.1367 APM performance pathway.

(a) *General.* Beginning with the 2023 MIPS payment year, the APM Performance Pathway is a MIPS scoring methodology available to MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM.

(b) *Criteria for MIPS APMs.* MIPS APMs are those in which:

(1) APM Entities participate in the APM under an agreement with CMS or through a law or regulation; and

(2) The APM bases payment on quality measures and cost/utilization.

(c) *MIPS performance category scoring in the APM Performance Pathway.*

(1) *Quality.* Except as provided in paragraphs (c)(1)(i) and (ii) of this section, the quality performance category score is calculated for a MIPS eligible clinician, group, or APM Entity group in accordance with § 414.1380(b)(1) based on the APM Performance Pathway quality measure set established by CMS through rulemaking for a MIPS payment year.

(i) Each submitted measure that does not have a benchmark or meet the case minimum requirement is excluded from the MIPS eligible clinician, group, or APM Entity group's total measure achievement points and total available measure achievement points.

(ii) Any measure that is identified as topped out is not subject to the scoring cap described at § 414.1380(b)(1)(iv).

(2) *Cost.* The cost performance category weight is zero percent for MIPS eligible clinicians who are scored through the APM Performance Pathway.

(3) *Improvement activities.* The improvement activities performance category score is calculated for a MIPS eligible clinician, group, or APM Entity group in accordance with § 414.1380(b)(3) based on the activities required by the MIPS APM that are included in the MIPS final inventory of improvement activities described in § 414.1355(a) (excluding any such activities that the MIPS eligible clinician, group, or APM Entity group does not perform. MIPS eligible clinicians, groups, or APM Entities may report additional improvement activities in accordance with § 414.1360.

(4) *Promoting interoperability.* The promoting interoperability performance category will be scored for the MIPS eligible clinician, group, or APM Entity as described in § 414.1375.

(d) *APM Performance Pathway performance category weights*—(1) *Performance category weights.* Subject to paragraph (d)(2) of this section, the performance category weights used to calculate the final score for a MIPS eligible clinician, group, or APM Entity reporting through the APM performance Pathway are:

(i) Quality: 50 percent.

(ii) Cost: 0 percent.

(iii) Improvement Activities: 20 percent.

(iv) Promoting Interoperability: 30 percent.

(2) *Reweighting MIPS performance categories.* If CMS determines, in accordance with § 414.1380(c)(2), that a different scoring weight should be assigned to the quality or promoting interoperability performance category, CMS will redistribute the performance category weights as follows:

(i) If CMS reweights the quality performance category to 0 percent: Promoting Interoperability performance category is reweighted to 75 percent, and Improvement Activities performance category is reweighted to 25 percent.

(ii) If CMS reweights the Promoting Interoperability performance category to 0 percent: Quality performance category is reweighted to 75 percent, and Improvement Activities performance category is reweighted to 25 percent.

(e) *Final score.* The final score is calculated for a MIPS eligible clinician, group, or APM Entity in accordance with § 414.1380(c).

■ 22. Section 414.1370 is amended by revising paragraph (a) to read as follows:

§ 414.1370 APM scoring standard under MIPS.

(a) *General.* For the 2019 through 2022 MIPS payment years, the APM scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified on the Participation List for the performance period of an APM Entity participating in a MIPS APM.

* * * * *

■ 23. Section 414.1380 is amended—

■ a. By revising paragraph (b)(1)(i) introductory text;

■ b. In paragraph (b)(1)(i)(A)(*1*) by removing ''for the 2019 through 2022 MIPS payment years'' and adding in its place ''for the 2019 through 2023 MIPS payment years'';

■ c. By revising paragraphs (b)(1)(iii) and (b)(1)(iv)(B);

■ d. In paragraph (b)(1)(v)(A)(*1*)(*ii*) by removing ''For the 2019 through 2022 MIPS payment years'' and adding in its place ''For the 2019 through 2023 MIPS payments years'';

■ e. In paragraph (b)(1)(v)(B)(*1*)(*i*) by removing ''For the 2019 through 2022 MIPS payment years'' and adding in its place ''For the 2019 through 2023 MIPS payment years'';

■ f. In paragraph (b)(1)(vi)(C)(*4*) by removing ''For the 2020 through 2022 MIPS payment years'' and adding in its place ''For the 2020 through 2023 MIPS payment years'';

■ g. By revising paragraph (b)(1)(vii)(A);

■ h. By removing paragraph (b)(1)(viii);

■ i. By revising paragraphs (c)(2)(i)(A)(*4*) and (*5*);

■ j. By adding paragraphs (c)(2)(ii)(E) and (F);

■ k. By revising paragraph (c)(3) introductory text and (c)(3)(iii); and

■ l. By adding paragraph (c)(3)(iv).

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(i) Measure achievement points. For the 2019 through 2023 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 and for each administrative claims-based measure that has a benchmark at paragraph (b)(1)(ii) of this section and meets the case minimum requirement at paragraph (b)(1)(iii) of this section. The number of measure achievement points received for each such 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.

* * * * *

(iii) *Minimum case requirements.* Except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1), the minimum case requirement is 20 cases.

(iv) * * *

(B) Except as provided in paragraph (b)(1)(iv)(B)(*1*) of this section, beginning with the 2021 MIPS payment year, each measure (except for measures in the CMS Web Interface) for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years receives no more than 7 measure achievement points in the second consecutive year it is identified as topped out, and beyond.

(*1*) For the 2023 MIPS payment year, a measure is topped out if it is identified as such in the baseline period benchmarks for the 2020 MIPS performance period and in the performance period benchmarks for the 2021 MIPS performance period.

(*2*) [Reserved]

* * * * *

(vii) * * *

(A) For each submitted measure that is impacted by significant changes that CMS determines may result in patient harm or misleading results, performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. For purposes of this paragraph (b)(1)(vii)(A), ''significant changes'' means changes to codes (including, but not limited to, ICD–10, CPT, and HCPCS codes), clinical guidelines, or measure specifications. CMS will publish on the CMS website a list of all measures scored under this paragraph (b)(1)(vii)(A) as soon as technically feasible, but by no later than the beginning of the data submission period at § 414.1325(e)(1).

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*4*) For the Promoting Interoperability performance category for the 2021, 2022 and 2023 MIPS payment years, the MIPS eligible clinician is a physical therapist, occupational therapist, clinical psychologist, qualified audiologist, qualified speech-language pathologist, or a registered dietitian or nutrition professional. 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.

(*5*) For the Promoting Interoperability performance category for the 2019, 2020, 2021, 2022, and 2023 MIPS payment years, the MIPS eligible clinician is a nurse practitioner, physician assistant, clinical nurse specialist, or certified registered nurse anesthetist. 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.

* * * * *

(ii) * * *

(E) For the 2023 MIPS payment year:

Reweighting scenario	Quality (%)	Cost (%)	Improvement Activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	40%	20%	15%	25%
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%
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%	50%	50%	0%
No Promoting Interoperability and no Improvement Activities	80%	20%	0%	0%
No Quality and no Improvement Activities	0%	20%	0%	80%

(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%
No Cost	55%	0%	15%	30%
No Promoting Interoperability	55%	30%	15%	0%
No Quality	0%	30%	15%	55%
No Improvement Activities	45%	30%	0%	25%
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%	50%	50%	0%
No Promoting Interoperability and no Improvement Activities	70%	30%	0%	0%
No Quality and no Improvement Activities	0%	30%	0%	70%

* * * * *

(3) *Complex patient bonus.* For the 2020, 2021, 2022, and 2023 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:

* * * * *

(iii) The complex patient bonus cannot exceed 5.0 except as provided in paragraph (c)(3)(iv) of this section.

(iv) For the 2022 MIPS payment year, the complex patient bonus is calculated pursuant to paragraphs (c)(3)(i) and (ii), and the resulting numerical value is then multiplied by 2.0. The complex patient bonus cannot exceed 10.0.

* * * * *

■ 24. Section 414.1400 is amended—

■ a. By revising paragraphs (a)(2)(i) and (ii) and (a)(4);

■ b. By revising the paragraph (b) subject heading and paragraph (b)(2) introductory text;

■ c. By adding paragraphs (b)(2)(iv) and (v);

■ d. By adding paragraphs (b)(3)(v)(C)(*1*) and (*2*);

■ e. By revising paragraphs (b)(3)(v)(E) and (b)(3)(vi);

■ f. By removing paragraphs (b)(3)(vii)(H) and (L);

■ g. By redesignating paragraphs (b)(3)(vii)(I), (J), (K), (M), and (N) as paragraphs (b)(3)(vii)(H), (I), (J), (K), and (L), respectively;

■ h. By revising the paragraph (c) subject heading;

■ i. By adding paragraphs (c)(2)(iii) and (iv); and

■ j. By revising paragraph (f)(1)(i).

The additions and revisions read as follows:

§ 414.1400 Third party intermediaries.

(a) * * *

(2) * * *

(i) Except as provided under paragraph (a)(2)(ii) of this section, QCDRs, qualified registries, and Health IT vendors must be able to submit data for all of the following MIPS performance categories:

(A) Quality, except:

(*1*) The CAHPS for MIPS survey; and

(*2*) For qualified registries and Health IT vendors, QCDR measures;

(B) Improvement activities; and

(C) Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may 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*).

(ii) Health IT vendors that do not support MIPS Value Pathways must be able to submit data for at least one of the MIPS performance categories described in paragraphs (a)(2)(i)(A) through (C) of this section.

* * * * *

(4) Third party intermediary approval criteria—

(i) To be approved as a third party intermediary, an entity must agree to meet the applicable requirements of this section, including, but not limited to, the following:

(A) A third party intermediary's principle place of business and retention of any data must be based in the U.S.

(B) If the data is derived from CEHRT, a QCDR, qualified registry, or health IT vendor must be able to indicate its data source.

(C) All data must be submitted in the form and manner specified by CMS.

(D) If the clinician chooses to opt-in in accordance with § 414.1310, the third party intermediary must be able to transmit that decision to CMS.

(E) The third party intermediary must provide services throughout the entire performance period and applicable data submission period.

(F) 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 third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved a transition plan.

(ii) The determination of whether to approve an entity as a third party intermediary for a MIPS payment year may take into account:

(A) Whether the entity failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary; and

(B) Whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician.

(iii) Beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS.

* * * * *

(b) *QCDRs.*

* * * * *

(2) *QCDR conditions for approval.* In addition to the other requirements in this section, the criteria for an entity to be approved as a QCDR include the following:

* * * * *

(iv) Beginning with the 2023 payment year, the QCDR must conduct annual data validation audits in accordance with this paragraph (b)(2)(iv).

(A) The QCDR must conduct data validation for the payment year prior to submitting any data for that payment year to CMS for purposes of the MIPS program.

(B) The QCDR must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories.

(C) The QCDR must conduct data validation on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants.

(D) The QCDR must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.

(E) The QCDR shall conduct each data validation audit using a sampling methodology that meets the following requirements:

(*1*) Uses a sample size of at least 3 percent of the TIN/NPIs for which the QCDR will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the QCDR must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the QCDR may use a sample size of 50 TIN/NPIs.

(*2*) Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

(F) Each QCDR data validation audit must include the following:

(*1*) Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant.

(*2*) Verification of the accuracy of TINs and NPIs.

(*3*) Calculation of reporting and performance rates.

(*4*) Verification that only the MIPS quality measures and QCDR measures, as applicable, that are relevant to the performance period will be used for MIPS submission.

(G) In a form and manner and by a deadline specified by CMS, the QCDR must report the results of each data validation audit, including the overall data deficiencies or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or error, and, how and when each deficiency or data error type was corrected.

(v) Beginning with the 2023 MIPS payment year, the QCDR must conduct targeted audits in accordance with this this paragraph (b)(2)(v).

(A) If a data validation audit under § 414.1400(b)(2)(iv) identifies one or more deficiency or data error, the QCDR must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year.

(B) The QCDR must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year.

(C) The QCDR must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (b)(2)(iv)(E) of this section. The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

(D) In a form and manner and by a deadline specified by CMS, the QCDR must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected.

(3) * * *

(v) * * *

(C) * * *

(*1*) To be approved for the 2024 MIPS payment year, a QCDR measure must be face valid. To be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved.

(*2*) To be included in an MIPS Value Pathway for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested.

* * * * *

(E) 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 or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure.

(vi) Beginning with the 2023 MIPS payment year, 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 a QCDR measure's second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

* * * * *

(c) *Qualified registries.*

(2) * * *

(iii) Beginning with the 2023 payment year, the qualified registry must conduct annual data validation audits in accordance with this paragraph (c)(2)(iii).

(A) The qualified registry must conduct their data validation audits prior to submitting any data to CMS for purposes of the MIPS program.

(B) The qualified registry must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories.

(C) The qualified registry must conduct data validation on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants.

(D) The qualified registry must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.

(E) The qualified registry shall conduct each data validation audit using a sampling methodology that meets the following:

(*1*) Uses a sample size of at least 3 percent of the TIN/NPIs for which the qualified registry will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the qualified registry must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the qualified registry may use a sample size of 50 TIN/NPIs.

(*2*) Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

(F) Each qualified registry data validation audit must include the following:

(*1*) Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant.

(*2*) Verification of the accuracy of TINs and NPIs.

(*3*) Calculation of reporting and performance rates.

(*4*) Verification that only MIPS quality measures and qualified registry measures that are relevant to the performance period will be utilized for MIPS submission.

(G) In a form and manner and by a deadline specified by CMS, the qualified registry must report data validation results, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, how and when each deficiency or data error type was corrected.

(iv) Beginning with the 2023 MIPS payment year, the qualified registry must conduct targeted audits in accordance with this paragraph (c)(2)(iv).

(A) If a data validation audit under § 414.1400(c)(2)(iii) identifies one or more deficiency or data error, the qualified registry must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year.

(B) The qualified registry must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year.

(C) The qualified registry must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (c)(2)(iii)(E)(*1*) and (*2*) of this section. The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

(D) In a form and manner and by a deadline specified by CMS, the qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, how and when each deficiency or data error type was corrected.

* * * * *

(f) * * *

(1) * * *

(i) Require the third party intermediary to submit a corrective action plan (CAP) by a date specified by CMS. The CAP must address the following issues, unless different or additional information is specified by CMS:

(A) The issues that contributed to the non-compliance.

(B) The impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program.

(C) The corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future.

(D) The detailed timeline for achieving compliance with the applicable requirements.

* * * * *

■ 25. Section 414.1405 is amended by revising paragraph (b)(8) to read as follows:

§ 414.1405 Payment.

* * * * *

(b) * * *

(8) The performance threshold for the 2023 MIPS payment year is 50 points.

* * * * *

■ 26. Section 414.1435 is amended by revising paragraph (c)(1) to read as follows:

§ 414.1435 Qualifying APM Participant determination: Medicare option.

* * * * *

(c) * * *

(1) Attributed beneficiaries are determined from each Advanced APM Entity's attributed beneficiary lists generated by each Advanced APM's specific attribution methodology except as set forth below.

(i) Beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list.

(ii) [Reserved]

* * * * *

■ 27. Section 414.1450 is amended by revising paragraphs (b)(1) and (c) to read as follows:

§ 414.1450 APM incentive payment.

* * * * *

(b) * * *

(1) The amount of the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. CMS uses the paid amounts on claims for covered professional services to calculate the estimated aggregate payments on which CMS will calculate the APM Incentive Payment.

* * * * *

(c) *APM Incentive Payment recipient.* CMS will pay the APM Incentive Payment amount for a payment year to the TIN or TINs associated with the QP identified at a specific step in the following hierarchy. If no TIN or TINs with which the QP has an association can be identified at a step, CMS will move to the next and successive steps listed below until CMS identifies a TIN or TINs with which the QP is associated, and to which CMS will make the APM Incentive Payment.

(1) Any TIN associated with the QP that, during the QP Performance Period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(2) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(3) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity participating in an Advanced APM through which the eligible clinician had achieved QP status;

(4) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated in an APM Entity in an Advanced APM;

(5) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in any track of the APM through which the eligible clinician achieved QP status;

(6) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in an APM other than an Advanced APM;

(7) Any TIN associated with the QP that submitted a claim for covered professional services furnished by the QP during the APM Incentive Payment base period, even if such TIN has no relationship to any APM Entity or APM; then

(8) If we have not identified any TIN associated with the QP to which we can make the APM Incentive Payment, we will attempt to contact the QP via a public notice to request their Medicare payment information. The QPs identified in the public notice, or any other eligible clinicians who believe that they are entitled to an APM Incentive Payment must then notify CMS of their claim as directed in the public notice by November 1 of the payment year, or 60 days after CMS announces that initial payments for the year have been made, whichever is later. After that time, any claims by a QP to an APM Incentive Payment will be forfeited for such payment year.

* * * * *

■ 28. Section 414.1455 is revised to read as follows:

§ 414.1455 Limitation on review.

(a) There is no right to administrative or judicial review under sections 1869, 1878, or otherwise, of the Act of the following:

(1) The determination that an eligible clinician is a QP or Partial QP under § 414.1425.

(2) The determination of the amount of the APM Incentive Payment under § 414.1450, including any estimation as part of such determination.

(b) *Targeted review.* (1) An eligible clinician or APM Entity may request targeted review of a QP or Partial QP determination only if they believe in good faith that, due to a CMS clerical error, an eligible clinician was omitted from a Participation List.

(2) If CMS determines that there was such a clerical error, if the QP determination for the eligible clinician would have been made at the APM Entity level under § 414.1425(b)(1), CMS will assign to the eligible clinician the most favorable QP status that was determined at the APM Entity level on any snapshot dates for the relevant QP Performance Period on which the eligible clinician participated in the APM Entity.

(3) The process for targeted review is as follows:

(i) An eligible clinician or APM Entity may submit a request for targeted review.

(ii) All requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins with the publication of MIPS performance feedback as described at § 414.1385(a)(2). The targeted review request submission period may be extended as specified by CMS.

(iii) All requests for targeted review must be submitted in accordance with the form and manner specified by CMS.

(iv) A request for 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 the scope of targeted review specified in this section. If the targeted review request is denied, CMS will make no changes to the QP status of the eligible clinician for whom targeted review was requested.

(iv) CMS will respond to each timely submitted request for targeted review.

(v) A request for targeted review may include additional information in support of the request at the time it is submitted. CMS may also request additional information from the requestor. If CMS requests additional information relating to the eligible clinician or the APM Entity group that is the subject of a request for targeted review, responsive information must be provided and received by CMS within 30 days of the request. If CMS does not receive a timely response to a request for additional information, CMS may make a final decision on the targeted review request based on the information available.

(vi) If targeted review requests reveal a pattern of CMS error with impacts that extend beyond the scope of eligible clinicians or APM Entities that submitted such targeted review requests, CMS may adjust the QP status of other affected eligible clinicians as provided in paragraph (b)(2) of this section.

(vi) Decisions on a targeted review request are final, and not subject to any further administrative or judicial review in accordance with paragraph (a) of this section.

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 29. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 30. Section 415.184 is revised to read as follows:

§ 415.184 Psychiatric services.

Physician fee schedule payment is made for psychiatric services furnished under an approved GME program if the requirements of §§ 415.170 and 415.172 are met, including documentation, except that the requirement for the presence of the teaching physician during the service in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device. During the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, the requirement for the presence of the teaching physician during the service in which a resident is involved may be met by audio/video real-time communications technology.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 31. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–01 through 1395w–152, and 1395hh.

■ 32. Section 423.160 is amended by adding paragraph (a)(5) to read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(5) On or after January 1, 2022, prescribers must, except in circumstances in which the Secretary waives the requirement, conduct all prescribing for all Schedule II, III, IV, and V controlled substances electronically using the applicable standards in paragraph (b) of this section.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 33. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 34. Section 424.67 is amended by—

■ a. Revising paragraphs (b)(1) introductory text, (b)(1)(ii), (b)(2) and (3), and (b)(5) introductory text;

■ b. Redesignating paragraphs (c) through (f) as paragraphs (d) through (g), respectively;

■ c. Adding new paragraph (c); and

■ d. Revising newly redesignated paragraph (e)(2)(i).

The revisions and additions read as follows:

§ 424.67 Enrollment requirements for opioid treatment programs (OTP).

* * * * *

(b) * * *

(1) Fully complete and submit, as applicable, the Form CMS–855A or Form CMS–855B application (or their successor applications) and any applicable supplement or attachment thereto to its applicable Medicare contractor. This includes, but is not limited to, the following:

* * * * *

(ii) Certifying via the Form CMS–855A or Form CMS–855B (as applicable) 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 (e) of this section.

(2) Comply with the application fee requirements in § 424.514. (This includes OTPs enrolling under the circumstances described in paragraph (c)(2) of this section.)

(3)(i) Except as stated in paragraph (b)(3)(ii) of this section, successfully complete the assigned categorical risk level screening required under, as applicable, § 424.518(b) and (c).

(ii) For currently enrolled OTPs that are changing their OTP enrollment from a Form CMS–855B enrollment to a Form CMS–855A enrollment, or vice versa, successfully complete the limited level of categorical screening under § 424.518(a) if the OTP has already completed, as applicable, the moderate or high level of categorical screening under § 424.518(b) or (c), respectively.

* * * * *

(5) Report on the Form CMS–855A or Form CMS–855B (as applicable) and/or any applicable supplement all OTP staff who meet the definition of ''managing employee'' in § 424.502. Such individuals include, but are not limited to, the following:

* * * * *

(c) *Clarification of required enrollment forms.* (1) An OTP may only be enrolled as an OTP via the Form CMS–855A or Form CMS–855B but not both.

(2) If a currently enrolled OTP is changing its OTP enrollment from a Form CMS–855B enrollment to a Form CMS–855A enrollment, or vice versa, the effective date of billing that was established for the OTP's prior enrollment under §§ 424.520(d) and 424.521(a) of this chapter is applied to the OTP's new enrollment.

* * * * *

(e) * * *

(2) * * *

(i) 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 or standard in this section, including, but not limited to, the OTP standards in paragraphs (b)(6) and (e)(1) of this section.

* * * * *

■ 35. Section 424.210 is amended by revising paragraph (a) and adding paragraph (b)(9) to read as follows:

§ 424.210 Beneficiary engagement incentives under the Medicare Diabetes Prevention Program expanded model.

(a) *Definitions.* In addition to the definitions specified at § 410.79(b) and § 424.205(a) of this chapter, the following definitions apply to this section:

1135 waiver event means an emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, for which the Secretary has authorized waivers under section 1135 of the Act.

COVID–19 Public Health Emergency means the emergency period and emergency area, as such terms are defined in section 1135(g) of the Social Security Act, related to the COVID–19 pandemic and declared by the Secretary on January 27, 2020.

Engagement incentive period means the period of time during which an MDPP supplier may furnish in-kind beneficiary engagement incentives to a given MDPP beneficiary to whom the MDPP supplier is furnishing MDPP services. This period begins when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary, and ends when one of the following occurs, whichever occurs first:

(i) The MDPP beneficiary's MDPP services period ends as described in § 410.79(c)(3) of this chapter.

(ii) The MDPP supplier knows that the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier.

(iii) The MDPP supplier has not had direct contact, either in person by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period, unless the lack of direct contact is due to the suspension or cancellation of MDPP services under

§ 410.79(e) of this chapter and the MDPP services are eventually resumed or restarted in accordance with § 410.79(e) of this chapter.

(b) * * *

(9) If the item or service is furnished during the COVID–19 Public Health Emergency or an 1135 waiver event that CMS has determined may disrupt in-person MDPP services, and the item or service is furnished to an MDPP beneficiary who is receiving MDPP services virtually, the MDPP beneficiary must be capable of using the item or service during the COVID–19 Public Health Emergency or the section 1135 waiver event, as applicable.

* * * * *

■ 36. Section 424.518 is amended by redesignating paragraphs (a)(1)(xii) through (xvi) as paragraphs (a)(1)(xiii) through (xvii) and adding a new paragraph (a)(1)(xii) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

* * * * *

(a) * * *

(1) * * *

(xii) Opioid treatment programs (if § 424.67(b)(3)(ii) applies).

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 37. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 38. Section 425.100 is amended by revising paragraph (b) to read as follows:

§ 425.100 General.

* * * * *

(b) An ACO is eligible to receive payments for shared savings under subpart G of this part if all of the following conditions are met:

(1) The ACO meets or exceeds the applicable minimum savings rate established under § 425.604, § 425.605, § 425.606, § 425.609 or § 425.610.

(2) The ACO meets the minimum quality performance standards established under § 425.500 (for performance years or a performance period beginning on or before January 1, 2020), or under the quality performance standard established under § 425.512 (for performance years beginning on or after January 1, 2021).

(3) The ACO otherwise maintains its eligibility to participate in the Shared Savings Program under this part.

* * * * *

§ 425.112 [Amended]

■ 39. Section 425.112 is amended in paragraph (b)(2)(i) by removing the reference ''§ 425.500'' and adding in its place the references ''§§ 425.500 or 425.510, as applicable''.

§ 425.200 [Amended]

■ 40. Section 425.200 is amended in paragraph (d) by removing the reference ''§ 425.500(c)'' and adding in its place the references ''§§ 425.500(c) or 425.510, as applicable''.

■ 41. Section 425.204 is amended by revising paragraphs (f)(3)(i) through (iv), (f)(4)(iv), and (f)(5) to read as follows:

§ 425.204 Content of the application.

* * * * *

(f) * * *

(3) * * *

(i) An ACO participating in Track 2 must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(ii) An ACO entering an agreement period in Levels C, D, or E of the BASIC track or the ENHANCED track must demonstrate the adequacy of its repayment mechanism prior to the start of its agreement period, prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(iii) An ACO entering an agreement period in Level A or Level B of the BASIC track must demonstrate the adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate in, or is automatically transitioned to a two-sided model, Level C, Level D, or Level E, of the BASIC track, prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(iv) An ACO that has submitted a request to renew its participation agreement must submit as part of the renewal request documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the ACO, provided that the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with paragraph (f)(6)(ii) of this section and the amount of the repayment mechanism complies with paragraph (f)(4) of this section.

(4) * * *

(iv)(A) In the case of an ACO that has submitted a request to renew its participation agreement for an agreement period starting on or after January 1, 2022 and that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the amount of the repayment mechanism must be equal to at least the amount calculated by CMS in accordance with paragraph (f)(4)(ii) of this section.

(B) Under the following circumstances, an ACO that renewed its participation agreement for an agreement period beginning on July 1, 2019, or January 1, 2020, may elect to decrease the amount of its repayment mechanism.

(*1*) The ACO elected to continue to use its existing repayment mechanism for the agreement period beginning on July 1, 2019, or January 1, 2020, and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated at the time of renewal application according to paragraph (f)(4)(ii) of this section.

(*2*) The repayment mechanism amount for performance year 2021, as recalculated pursuant to paragraph (f)(4)(iii) of this section, is less than the existing repayment mechanism amount.

(*3*) CMS will notify the ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism pursuant to this paragraph (f)(4)(iv)(B). The ACO must submit such election, together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of this paragraph (f).

(5) After the repayment mechanism has been used to repay any portion of shared losses owed to CMS, the ACO must replenish the amount of funds available through the repayment mechanism within 90 days. The resulting amount available through the repayment mechanism must be at least the amount specified by CMS in accordance with paragraph (f)(4) of this section.

* * * * *

■ 42. Section 425.224 is amended by revising paragraph (b)(1)(ii)(A) to read as follows:

§ 425.224 Application procedures for renewing ACOs and re-entering ACOs.

* * * * *

(b) * * *

(1) * * *
(ii) * * *
(A) Whether the ACO demonstrated a pattern of failure to meet the quality performance standards or met any of the criteria for termination under §§ 425.316(c)(1)(ii) or 425.316(c)(2)(ii).
* * * * *

§ 425.302 [Amended]

■ 43. Section 425.302 is amended in paragraph (a)(1) by removing the reference ''§ 425.500'' and adding in its place the references ''§§ 425.500 or 425.510, as applicable''.
■ 44. Section 425.316 is amended by revising paragraph (c) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(c) *Monitoring ACO compliance with quality performance standards.* To identify ACOs that are not meeting the quality performance standards, CMS will review an ACO's submission of quality measurement data under §§ 425.500 or 425.512. CMS may request additional documentation from an ACO, ACO participants, or ACO providers/suppliers, as appropriate. If an ACO does not meet quality performance standards or fails to report on one or more quality measures, CMS will take the following actions:

(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* (i) The ACO may be given a warning for the first time it fails to meet the minimum attainment level on at least 70 percent of the measures, as determined under § 425.502, in one or more domains and may be subject to a CAP. CMS may forgo the issuance of the warning letter depending on the nature and severity of the noncompliance and instead subject the ACO to actions set forth at § 425.216 or immediately terminate the ACO's participation agreement under § 425.218.

(ii) The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet quality performance standard in the following year, the agreement will be terminated.

(iii) An ACO will not qualify to share in savings in any year it fails to report accurately, completely, and timely on the quality performance measures.

(2) *For performance years beginning on or after January 1, 2021.* (i) If the ACO fails to meet the quality performance standard, CMS may take one or more of the actions prior to termination specified in § 425.216. Depending on the nature and severity of the noncompliance, CMS may forgo pre-termination actions and may immediately terminate the ACO's participation agreement under § 425.218.

(ii) CMS will terminate an ACO's participation agreement under any of the following circumstances:

(A) The ACO fails to meet the quality performance standard for 2 consecutive performance years within an agreement period.

(B) The ACO fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order.

(C) A renewing ACO or re-entering ACO fails to meet the quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period.

(D) A renewing ACO or re-entering ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period.

* * * * *

■ 45. Section 425.400 is amended by revising paragraph (c)(1)(iv) introductory text and adding paragraph (c)(1)(v) to read as follows:

§ 425.400 General.

* * * * *

(c) * * *
(1) * * *
(iv) For performance years (or a performance period) during 2019, and performance year 2020 as follows:
* * * * *

(v) For the performance year starting on January 1, 2021, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*3*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*4*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*5*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(*6*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(v)).

(*7*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*8*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*9*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*10*) 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*11*) 99495 and 99496 (codes for transitional care management services).

(*12*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0402 (code for the Welcome to Medicare visit).

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0442 (code for alcohol misuse screening service).

(*4*) G0443 (code for alcohol misuse counseling service).

(*5*) G0444 (code for annual depression screening service).

(*6*) G0463 (code for services furnished in ETA hospitals).

(*7*) G0506 (code for chronic care management).

(*8*) G2058 (code for non-complex chronic care management).

(*9*) G2064 and G2065 (codes for principal care management services).

(*10*) GCOL1 (code for psychiatric collaborative care model).

* * * * *

■ 46. Section 425.500 is amended by revising the section heading and paragraph (d) to read as follows:

§ 425.500 Measures to assess the quality of care furnished by an ACO for performance years (or a performance period) beginning on or before January 1, 2020.

* * * * *

(d) *Patient experience of care survey.* (1) For performance years (or a performance period) beginning in 2014 through 2019, ACOs must select a CMS-certified vendor to administer the survey and report the results accordingly.

(2) For performance year 2020, CMS waives the CAHPS for ACOs reporting

requirement and will assign all ACOs automatic credit for the CAHPS for ACOs survey measures.

* * * * *

■ 47. Section 425.502 is amended by revising the section heading to read as follows:

§ 425.502 Calculating the ACO quality performance score for performance years (or a performance period) beginning on or before January 1, 2020.

* * * * *

■ 48. Section 425.508 is amended by revising the paragraph (a) subject heading and adding paragraph (b) to read as follows:

§ 425.508 Incorporating quality reporting requirements related to the Quality Payment Program.

(a) *For performance years (or a performance period) beginning in 2017–2020.* * * *

(b) *For performance years beginning on or after January 1, 2021.* ACOs must submit the quality data via the Alternative Payment Model Performance Pathway (APP) established under § 414.1367 of this chapter, to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program.

■ 49. Section 425.510 is added to subpart F to read as follows:

§ 425.510 Application of the Alternative Payment Model Performance Pathway (APP) to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021.

(a) *General.* (1) CMS establishes quality performance measures to assess the quality of care furnished by the ACO. If the ACO demonstrates to CMS that it has satisfied the quality performance requirements in this subpart, and the ACO meets all other applicable requirements, the ACO is eligible to receive shared savings.

(2) CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both.

(b) *Quality reporting.* ACOs must report quality data via the APP established under § 414.1367 of this chapter, according to the method of submission established by CMS.

(c) *Audit and validation of data.* CMS retains the right to audit and validate quality data reported by an ACO under paragraph (b) of this section according to § 414.1390 of this chapter.

■ 50. Section 425.512 is added to subpart F to read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) *Establishing a quality performance standard.* (1) The quality performance standard is the overall standard the ACO must meet in order to be eligible to receive shared savings for a performance year. An ACO will not qualify to share in savings in any year it fails to meet the quality performance standard.

(2) For all ACOs, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this chapter, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores.

(3) If an ACO does not report any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP the ACO would not meet the quality performance standard.

(b) *Extreme and uncontrollable circumstances.* For performance year 2021 and subsequent performance years, including the applicable quality data reporting period for the performance year, CMS uses an alternative approach to calculating the quality score for ACOs affected by extreme and uncontrollable circumstances instead of the methodology specified in paragraph (a) of this section as follows:

(1) CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on either of the following:

(i) Twenty percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance.

(A) Assignment is determined under subpart E of this part.

(B) In making this determination, CMS uses the quarter four list of assigned beneficiaries.

(ii) The ACO's legal entity is located in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance. An ACO's legal entity location is based on the address on file for the ACO in CMS' ACO application and management system.

(2) If CMS determines the ACO meets the requirements of paragraph (b)(1) of this section, CMS calculates the ACO's quality score as follows:

(i) The ACO's minimum quality performance score is set to the equivalent of the 40th percentile MIPS Quality performance category score for the relevant performance year.

(ii) If the ACO reports quality data via the APP framework and meets data completeness and case minimum requirements, CMS will use the higher of the ACO's quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score.

(3) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(4) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity.

■ 51. Section 425.600 is amended by revising paragraph (f)(4)(i) to read as follows:

§ 425.600 Selection of risk model.

* * * * *

(f) * * *

(4) * * *

(i) The quality performance standard as described in § 425.502(a), for performance years (or a performance period) beginning on or before January 1, 2020.

* * * * *

■ 52. Section 425.601 is amended by revising paragraphs (a)(9) and (f)(5)(iv) to read as follows:

§ 425.601 Establishing, adjusting, and updating the benchmark for agreement periods beginning on July 1, 2019, and in subsequent years.

(a) * * *

(9) For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: for the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), and for a change to the beneficiary assignment methodology specified in subpart E of this part. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(ii) Redetermines the regional adjustment amount under paragraph

(a)(8) of this section, according to the ACO's assigned beneficiaries for BY3.

* * * * *

(f) * * *

(5) * * *

(iv) If during the term of the agreement period CMS adjusts the ACO's benchmark, as specified in paragraph (a)(9) of this section, CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage in paragraphs (f)(1) and (2) of this section used in calculating the adjustment under either paragraph (a)(8) or (e) of this section.

* * * * *

■ 53. Section 425.602 is amended by revising paragraph (a)(8) to read as follows:

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period beginning on or before January 1, 2018.

(a) * * *

(8) The ACO's benchmark is adjusted for the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b) and for a change to the beneficiary assignment methodology specified in subpart E of this part, as applicable, to take into account the expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

* * * * *

■ 54. Section 425.603 is amended by revising paragraphs (c)(8) and (c)(9)(ii)(B)(*4*)(*iv*) to read as follows:

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent agreement period beginning on or before January 1, 2019.

* * * * *

(c) * * *

(8) The ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), and for a change to the beneficiary assignment methodology specified in subpart E of this part. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(ii) Redetermines the regional adjustment amount under paragraph (c)(9) of this section, according to the ACO's assigned beneficiaries for BY3.

(9) * * *

(ii) * * *

(B) * * *

(*4*) * * *

(*iv*) If CMS adjusts the ACO's benchmark, as specified in paragraph (c)(8) of this section, CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage used in calculating the adjustment in paragraphs (c)(9)(ii)(B)(*1*) and (*2*) of this section.

* * * * *

■ 55. Section 425.604 is amended by revising paragraphs (c) and (d) to read as follows:

§ 425.604 Calculation of savings under the one-sided model.

* * * * *

(c) *Qualification for shared savings payment.* (1) For performance years (or a performance period) beginning on or before January 1, 2020. In order to qualify for shared savings, an ACO must meet or exceed its minimum savings rate determined under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) For the performance year beginning on January 1, 2021. To qualify for shared savings, an ACO must meet or exceed its minimum savings rate determined under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate.* (1) For performance years (or a performance period) beginning on or before January 1, 2020. An ACO that meets all the requirements for receiving shared savings payments under the one-sided model will receive a shared savings payment of up to 50 percent of all savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (e)(2) of this section).

(2) For the performance year beginning on January 1, 2021. An ACO that meets all the requirements for receiving shared savings payments under Track 1 will receive a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section).

* * * * *

■ 56. Section 425.605 is amended by revising paragraphs (c), (d)(1)(i)(A), (d)(1)(ii)(A), (d)(1)(iii)(A), (d)(1)(iv)(A), and (d)(1)(v)(A) to read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

* * * * *

(c) *Qualification for shared savings payment.* (1) For performance years beginning on or before January 1, 2020. To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) For performance years beginning on or after January 1, 2021. To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) * * *

(1) * * *

(i) * * *

(A) *Final sharing rate.* (*1*) For performance years beginning on or before January 1, 2020. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment of up to 40 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section).

(*2*) For performance years beginning on or after January 1, 2021. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment of 40 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section).

* * * * *

(ii) * * *

(A) *Final sharing rate.* (*1*) For performance years beginning on or before January 1, 2020. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment of up to 40 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance

payment limit described in paragraph (d)(1)(ii)(B) of this section).

(*2*) For performance years beginning on or after January 1, 2021. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment of 40 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section).

* * * * *

(iii) * * *

(A) *Final sharing rate.* (*1*) For performance years beginning on or before January 1, 2020. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section).

(*2*) For performance years beginning on or after January 1, 2021. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section).

* * * * *

(iv) * * *

(A) *Final sharing rate.* (*1*) For performance years beginning on or before January 1, 2020. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section).

(*2*) For performance years beginning on or after January 1, 2021. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section).

* * * * *

(v) * * *

(A) *Final sharing rate.* (*1*) For performance years beginning on or before January 1, 2020. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section).

(*2*) For performance years beginning on or after January 1, 2021. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section).

* * * * *

■ 57. Section 425.606 is amended by revising paragraphs (c), (d), and (f) to read as follows:

§ 425.606 Calculation of shared savings and losses under Track 2.

* * * * *

(c) *Qualification for shared savings payment.* (1) For performance years (or a performance period) beginning on or before January 1, 2020. To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) For the performance year beginning on January 1, 2021. To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate.* (1) For performance years (or a performance period) beginning on or before January 1, 2020. An ACO that meets all the requirements for receiving shared savings payments under Track 2 will receive a shared savings payment of up to 60 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (e)(2) of this section).

(2) For the performance year beginning on January 1, 2021. An ACO that meets all the requirements for receiving shared savings payments under Track 2 will receive a shared savings payment of 60 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section).

* * * * *

(f) *Shared loss rate.* (1) For performance years (or a performance period) beginning on or before January 1, 2020. For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on the inverse of its final sharing rate described in paragraph (d)(1) of this section (that is, 1 minus the final shared savings rate determined under paragraph (d)(1) of this section). The shared loss rate—

(i) May not exceed 60 percent; and

(ii) May not be less than 40 percent.

(2) For the performance year beginning on January 1, 2021. For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets the quality performance standard established in § 425.512, CMS determines the shared loss rate as follows:

(A) Calculate the quotient of the MIPS quality performance category points earned divided by the total MIPS quality performance category points available.

(B) Calculate the product of the quotient determined in paragraph (f)(2)(i)(A) of this section and 60 percent.

(C) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(2)(i)(B) of this section. The shared loss rate—

(*1*) May not exceed 60 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet the quality performance standard established in § 425.512, the shared loss rate is 60 percent.

* * * * *

■ 58. Section 425.610 is amended by revising paragraphs (c), (d), and (f) to read as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

* * * * *

(c) *Qualification for shared savings payment.* (1) For performance years (or a performance period) beginning on or before January 1, 2020. To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in

the Shared Savings Program under this part.

(2) For performance years beginning on or after January 1, 2021. To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate.* (1) For performance years (or a performance period) beginning on or before January 1, 2020. An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment of up to 75 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (e)(2) of this section).

(2) For performance years beginning on or after January 1, 2021. An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment of 75 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section).

* * * * *

(f) *Shared loss rate.* (1) For performance years (or a performance period) beginning on or before January 1, 2020. For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on the inverse of its final sharing rate described in paragraph (d)(1) of this section (that is, 1 minus the final shared savings rate determined under paragraph (d)(1) of this section). The shared loss rate—

(i) May not exceed 75 percent; and

(ii) May not be less than 40 percent.

(2) For performance years beginning on or after January 1, 2021. For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets the quality performance standard established in § 425.512, CMS determines the shared loss rate as follows:

(A) Calculate the quotient of the MIPS quality performance category points earned divided by the total MIPS quality performance category points available.

(B) Calculate the product of the quotient determined in paragraph (f)(2)(i)(A) of this section, and 75 percent.

(C) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(2)(i)(B) of this section. The shared loss rate—

(*1*) May not exceed 75 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet the quality performance standard established in § 425.512, the shared loss rate is 75 percent.

* * * * *

§ 425.800 [Amended]

■ 59. Section 425.800 is amended—

■ a. In paragraph (a)(1) by removing the references ''§ 425.500 and § 425.502'' and adding in its place the references ''§§ 425.500, 425.502, 425.510 and 425.512'';

■ b. In paragraph (a)(2) by removing the reference ''§ 425.502'' and adding in its place the references ''§§ 425.502 or 425.512, as applicable''; and

■ c. In paragraph (a)(6) by removing the reference ''§ 425.502'' and adding in its place the references ''§§ 425.502 or 425.512, as applicable''.

Dated: July 16, 2020.

Seema Verma

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 31, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix 1: MIPS Quality Measures

NOTE: Except as otherwise noted in this proposed rule, previously finalized measures and specialty measure sets will continue to apply for the 2023 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 #.

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TABLE Group A: New Quality Measures Proposed for the 2023 MIPS Payment Year and Future Years

A.1. Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System (MIPS) Groups

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	TBD
Description:	This measure is a re-specified version of the measure, "Risk-adjusted readmission rate (RARR) of unplanned readmission within 30 days of hospital discharge for any condition" (NQF 1789), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to MIPS participating clinician groups and assesses each group's readmission rate. The measure comprises a single summary score, derived from the results of five models, one for each of the following specialty cohorts (groups of discharge condition categories or procedure categories): medicine, surgery/gynecology, cardio-respiratory, cardiovascular, and neurology.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	The outcome for this measure is unplanned all-cause 30-day readmission. Readmission is defined as a subsequent inpatient admission to any acute care facility which occurs within 30 days of the discharge date of an eligible index admission. Any readmission is eligible to be counted as an outcome, except those that are considered planned. To align with data years used, the planned readmission algorithm version 4.0 was used to classify readmissions as planned or unplanned.
Denominator:	Patients eligible for inclusion in the measure have an index admission hospitalization to which the readmission outcome is attributed and includes admissions for patients: Enrolled in Medicare Fee-For-Service (FFS) Part A for the 12 months prior to the date of admission; Aged 65 or over; Discharged alive from a non-federal short-term acute care hospital; and, Not transferred to another acute care facility.
Exclusions:	1. Patients discharged against medical advice (AMA) are excluded. 2. Admissions for patients to a PPS-exempt cancer hospital are excluded. 3. Admissions primarily for medical treatment of cancer are excluded. 4. Admissions primarily for psychiatric disease are excluded. 5. Admissions for "rehabilitation care; fitting of prostheses and adjustment devices" (CCS 254) are excluded. 6. Admissions where patient cannot be attributed to a clinician group.
Measure Type:	Outcome
Measure Domain:	Communication and Care Coordination (section 1848(s)(1)(B)(iii) of the Act)
High Priority Measure:	Yes (Outcome)
Collection Type:	Administrative Claims
Measure Implementation:	MIPS eligible groups with at least 16 clinicians / 200 case minimum / 1 year performance period (January 1st – December 31st)
Rationale:	We are proposing this risk-adjusted administrative claims measure to address unplanned readmissions at the physician group level of Medicare aged > 65 patients. This measure is a re-specified version of the hospital-level measure, "Hospital-Wide All-Cause, Unplanned Readmission Measure" (NQF #1789), which has been in the MIPS program since 2017. In the event we do not finalize this measure, we would maintain the current measure Q458: All-Cause Hospital Readmission. The re-specification of this measure promotes a systems-level approach by clinicians and focus on high-risk conditions, such as COPD and heart failure. The measure was evaluated by the MAP and 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 in section 1848(q)(2)(D)(v) of the Act. A risk-adjusted readmission rate of 15.3 percent at the physician group level was provided by the measure developer. The readmission rate indicates a substantial need to reduce the expected rate and variation of rates across eligible physician groups. Physician groups have the capability to influence unplanned readmission outcomes by appropriate medication reconciliation at discharge, reduction of infection risk, and ensuring proper outpatient follow-up. As an administrative claims measure, there is no separate reporting burden. To maintain continuity with the existing measure Q458: All-Cause Hospital Readmission, the case minimum will remain at 200 cases for consistency in implementation. For 2023 payment determination, the performance period will include administrative claims from January 1, 2021 to December 31, 2021. For further information regarding the proposed implementation of this measure, please see IV.A.3.c.(1)(e)(i) of this proposed rule. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.

A.2. Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)

Category	Description
NQF #: / eCQM NQF #:	3493 / N/A
Quality #:	TBD
Description:	This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	The outcome for this measure is complication defined as acute myocardial infarction (AMI), pneumonia, and sepsis/septicemia/shock complications within seven days from the index admission date; death, surgical site bleeding, and pulmonary embolism within 30 days from the index admission; mechanical complications and periprosthetic joint infection/wound infection within 90 days of the index admission. The complication outcome is a dichotomous (yes/no) outcome. If a patient experiences one or more of these complications in the applicable time period, the complication outcome for that patient is counted in the measure as a "yes".
Denominator:	Patients eligible for inclusion in the measure are those age 65 years and older admitted to non-federal acute care hospitals. An index admission is the hospitalization during which an elective Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) procedure was performed and to which the complication outcome is attributed. Eligible index admissions are identified using International Classification of Diseases-Tenth Revision-Procedure Coding System (ICD-10-PCS) procedure codes in Medicare inpatient claims data. For risk adjustment and outcome assessment, patients must have continuous enrollment in Medicare fee-for-service (FFS) for 12 months prior to the procedure and 90 days after it. The measure cohort is fully harmonized with the existing hospital-level measure.
Exclusions:	This measure excludes from the denominator admissions for patients: 1. With a femur, hip or pelvic fracture coded in the principal discharge diagnosis field for the index admission. 2. Undergoing partial hip arthroplasty (PHA) procedures (with a concurrent Total Hip Arthroplasty or Total Knee Arthroplasty [THA/TKA]). 3. Undergoing revision procedures (with a concurrent THA/TKA). 4. Undergoing resurfacing procedures (with a concurrent THA/TKA). 5. With a mechanical complication coded in the principal discharge diagnosis field for the index admission. 6. With a malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field for the index admission. 7. With a procedure code for removal of implanted devices/prostheses. After excluding the above admissions to identify elective primary THA/TKA procedures, the measure also excludes admissions for patients: 8. Who were transferred to the index hospital. 9. Who leave the hospital against medical advice (AMA). 10. With more than two THA/TKA procedure codes during the index hospitalization. Note: The measure does not count complications that occur in the outpatient setting and do not require a readmission.
Measure Type:	Outcome
Measure Domain:	Patient Safety (section 1848(s)(1)(B)(ii) of the Act)
High Priority Measure:	Yes (Outcome)
Collection Type:	Administrative Claims
Measure Implementation:	MIPS eligible clinicians and groups / 25 case minimum / 3 year performance period (October 1st – September 30th)
Rationale:	We are proposing this risk-standardized complication rate administrative claims measure to incentivize improved coordination of care, thereby reducing the number of hospitalizations and days hospitalized for patients, reducing rates of complications, and promoting cost savings resulting from fewer hospitalizations. This measure can improve the quality of surgical care delivery and follow-up care for a common and costly surgical procedure performed for Medicare patients. This measure is a re-specified version of an existing, publicly reported hospital measure, NQF #1550, located at https://innovation.cms.gov/files/fact-sheet/bpciadvanced-fs-nqf1550.pdf. Additionally, as an administrative claims measure, there is no separate reporting burden. The measure was evaluated by the MAP and is supported for rulemaking and is NQF endorsed (NQF #3493). The measure steward indicated variability among providers and groups with the risk standardized complication rates (RSCR) ranging from 1.2 percent to 7.2 percent across the groups. In adapting the measure for MIPS eligible clinicians, it will assess the same cohort of patients as the hospital measure, but attribute complications to a larger number of entities with a typically lower volume. Thus, we anticipate that the MIPS THA/TKA complication measure will reflect meaningful variation across MIPS eligible clinicians. The median RSCR for MIPS eligible clinicians with more than 25 cases was 2.7 percent with a minimum interquartile range (IQR) of 2.4 percent - 3.2 percent. The median RSCR for MIPS eligible clinician groups with more than 25 cases was 2.8 percent, with a minimum IQR of 2.4 percent - 3.1 percent. This indicates that 50 percent of clinicians have a complication rate of 2.7 percent or more after adjusting for patient age and comorbidities. The best performing clinicians (1.2 percent) are performing 55.6 percent better than an average performer, while the worst performing clinicians (7.2 percent) are performing 166.7 percent worse than an average performer. The best performing clinician groups (1.4 percent) are performing 50 percent better than an average performer, while the worst performing clinicians (5.7 percent) are performing 103.6 percent worse than an average performer. The measure steward believes these results support meaningful variation in rates across clinician and clinician groups with room for improvement. This measure is a re-specification of the existing, publicly reported hospital-level total hip/knee arthroplasty (THA/TKA) 90-day complication measure and has been designed to align with the cohort and methods of that measure. This measure uses 36 months of administrative claims data to calculate risk-standardized complication rates (RSCRs) for MIPS eligible clinicians and MIPS eligible clinician groups with 25 or more cases within the 3-year performance period. This approach balances measure reliability with maximizing the number of clinicians or clinician groups measured. For 2023 payment determination, the performance period will include administrative claims from October 1, 2018 to September 30, 2021. The measure's numerator assesses the occurrence of complications in the 90 days following the index admission date; therefore, ending the 3-year performance period on September 30th of the calendar year will allow time for numerator assessment. Based on the information provided by the measures steward, we believe this measure is evidence-based and represents an important clinical outcome. For further information regarding the proposed implementation of this measure, please see IV.A.3.c.(1)(e)(i) of this proposed rule. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.

TABLE Group B: New Specialty Measures Sets and Modifications to Previously Finalized Specialty Measure Sets Finalized for the 2023 MIPS Payment Year and Future Years

We are proposing to modify the previously finalized specialty measures sets below based upon review of updates made to existing quality measure specifications, proposed the addition of new measures for inclusion in MIPS, and considered the feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remain static, but the individual measures have proposed substantive changes in Table Group D. In the first column, existing measures with substantive changes described in Table Group D are noted with an 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 represent fully 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 following specialty measure set was excluded from this group because we are not proposing any changes to this specialty measure set: Anesthesiology.

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. We 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**
*	0041 / 0041e	110	CMS147v10	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®)
	N/A / N/A	111	CMS127v9	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
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	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
* <SECTION ><SECTNO>§	0028 / 0028e	226	CMS138v9	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 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.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)	0022 / N/A	238	CMS156v9	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 / N/A	317	CMS22v9	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 / N/A	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 / N/A	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 / N/A	374	CMS50v9	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 / N/A	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**
* ! (Appropriate Use)	N/A / 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	This measure is being proposed for inclusion into the Allergy/Immunology specialty set based on previous stakeholder feedback during previous comment period. Allergists/immunologists treat and frequently manage sinusitis. As such, we agree with the stakeholder and propose to add to the Allergy/Immunology specialty set.
* ! (Appropriate Use)	N/A / 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	This measure is being proposed for inclusion into the Allergy/Immunology specialty set based on previous stakeholder feedback during previous comment period. Allergists/immunologists treat and frequently manage sinusitis. As such, we agree with the stakeholder and propose to add to the Allergy/Immunology specialty set.
! (Outcome)	N/A / 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	This measure is being proposed for inclusion into the Allergy/Immunology specialty set based on previous stakeholder feedback during previous comment period. Allergists/immunologists treat and frequently manage asthma. As such, we agree with the stakeholder and propose to add to the Allergy/Immunology specialty set.

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**
* <SECTION><SECTNO>§ ! (Efficiency)	N/A / 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	This measure is being proposed for inclusion into the Allergy/Immunology specialty set based on previous stakeholder feedback during previous comment period. Allergists/Immunologists treat and frequently manage asthma. As such, we agree with the stakeholder and propose to add to the Allergy/Immunology specialty set.

B.2. 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. We 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 Audiology specialty set.

B.2. Audiology

PREVIOUSLY FINALIZED MEASURES IN 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**
* ! (Patient Safety)	0419 / 0419 e	130	CMS68v10	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 / 0418 e	134	CMS2v10	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 or 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.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	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 / N/A	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 / 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
* ! (Care Coordination)	N/A / N/A	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.2. Audiology

PREVIOUSLY FINALIZED MEASURES IN 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**
* <SECTION><SECTNO>§	0028 / 0028e	226	CMS138v9	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 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 / 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
* ! (Patient Safety)	0101 / N/A	318	CMS139v9	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.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. We 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 Cardiology specialty set.

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**
* <SECTION> <SECTNO>§	0081 / 0081e	005	CMS135 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**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):** 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.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* <SECTION> <SECTNO>§	0067 / N/A	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
* <SECTION> <SECTNO>§	0070 / 0070e	007	CMS145 v9	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®)
* <SECTION> <SECTNO>§	0083 / 0083e	008	CMS144 v9	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 / N/A	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**
* <SECTION> <SECTNO>§	0066 / N/A	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
* <SECTION> <SECTNO>§	N/A / N/A	128	CMS69v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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	CMS68v10	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
* <SECTION> <SECTNO>§	0028 / 0028e	226	CMS138v9	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 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**
* <SECTION> <SECTNO>§ ! (Outcome)	N/A / N/A	236	CMS165 v9	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 overlapping the measurement period and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	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 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communi cation and Care Coordinati on	**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 / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Communit y/Populati on 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 / 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 Foundation

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 / 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 (ECIIO), 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 Foundation
! (Efficiency)	N/A / 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 Foundation
* <SECTION> <SECTNO>§	1525 / N/A	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 / 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 / N/A	374	CMS50v9	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 / N/A	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 / N/A	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 / N/A	438	CMS347 v4	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 / 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 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

MEASURES PROPOSED FOR **ADDITION** TO 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**	**Rationale for Inclusion**
*	0041 / 0041e	110	CMS147 v10	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 to include this measure in the Cardiology specialty set as it is clinically relevant to this clinician type.
	N/A / N/A	111	CMS127 v9	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 to include this measure in the Cardiology specialty set as it is clinically relevant to this clinician type.

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 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. We 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 specialty 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**
! (Outcome)	2474 / N/A	392	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**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
! (Outcome)	N/A / N/A	393	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**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.3b. Electrophysiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ELECTROPHYSIOLOGY SET Note: In this this proposed rule, we propose 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 / N/A	348	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.4. 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. We 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 Chiropractic Medicine specialty set.

B.4. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN 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**
* ! (Care Coordination)	N/A / N/A	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)	N/A / N/A	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.
* ! (Outcome)	N/A / N/A	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.

B.4. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN 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**
* ! (Outcome)	N/A / N/A	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) is 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)	N/A / N/A	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 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)	N/A / N/A	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.

B.4. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN 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**
* ! (Outcome)	N/A / N/A	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.
* ! (Outcome)	N/A / N/A	478	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.

B.5. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Clinical Social Work 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. We 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 Clinical Social Work specialty set.

B.5. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN 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**
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	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	CMS2v10	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 or 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.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / 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

B.5. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN 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**
* ! (Care Coordination)	N/A / 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 Psychiatric Association /American Academy of Neurology
* <SECTION><SECT NO>§ ! (Outcome)	0710 / 0710e	370	CMS159 v9	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
* ! (Patient Safety)	N/A / 1365e	382	CMS177 v9	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 / N/A	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
	2803 / N/A	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 / N/A	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.5. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN 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**
* ! (Care Coordination)	N/A / 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 Psychiatric Association /American Academy of Neurology
* <SECTION><SECT NO>§ ! (Outcome)	0710 / 0710e	370	CMS159 v9	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
* ! (Patient Safety)	N/A / 1365e	382	CMS177 v9	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 / N/A	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
	2803 / N/A	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 / N/A	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.5. 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**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims, 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 are proposing in Table D.9 to expand the measure's applicability to include coding that would include clinical social worker clinician type. With the expanded patient population and the clinically relevance to this clinician type, we are proposing to add to the Clinical Social Work specialty set.

B.6. 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. We 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.6. 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 / N/A	378	CMS75v10	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 / N/A	379	CMS74v10	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.7. 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. We 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.7. 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 v10	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 / 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 / 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 1 month of diagnosis.	American Academy of Dermatology
* <SECTION>< SECTNO>§	0028 / 0028e	226	CMS138v9	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 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®)
* ! (Care Coordination)	N/A / 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

B.7. 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**
*	N/A / N/A	317	CMS22 v9	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 / N/A	374	CMS50 v9	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 / N/A	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 / 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 / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (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.7. Dermatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE DERMATOLOGY SET Note: In this this proposed rule, we propose 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 / 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/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.	American Academy of Dermatology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.8. 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. We 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.8. 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 / 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 / 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 / N/A	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
! (Care Coordination)	0509 / N/A	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
! (Appropriate Use)	N/A / 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.8. 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 / 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 / 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 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 less than or equal to 1.0 cm. • Adrenal lesion greater than 1.0 cm but less than or equal to 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.	American College of Radiology
! (Appropriate Use)	N/A / 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 / 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 computed tomography (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.8. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE DIAGNOSTIC RADIOLOGY SET Note: In this this proposed rule, we propose 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 / N/A	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 2023 MIPS payment year. See Table C for rationale.

B.9. 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. We 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.9. 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 / N/A	066	CMS146 v9	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 / N/A	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
*	N/A / 0104e	107	CMS161 v9	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®)
* <SECTION> <SECTNO> § ! (Appropriate Use)	0058 / N/A	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 / 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 / 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 / N/A	317	CMS22v 9	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.9. 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 / 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
* ! (Appropriate Use)	N/A / 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
* ! (Efficiency)	N/A / N/A	415	N/A	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 provider who have an indication for a head CT.	American College of Emergency Physicians
* ! (Efficiency)	N/A / 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.9. Emergency Medicine

MEASURES PROPOSED FOR **ADDITION** TO 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**	**Rationale for Inclusion**
*	0053 / N/A	418	N/A	Medicare Part B Claims Specifications, MIPS CQM 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 6 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 6 months after the fracture.	National Committee for Quality Assurance	We are proposing in Table D.89 to expand the clinical setting to include Emergency Medicine. With the expanded patient population and the clinically relevance to this clinician type, we are proposing to add to the Emergency Medicine specialty set.

B.9. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE EMERGENCY MEDICINE SET Note: In this this proposed rule, we propose 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 / N/A	333	N/A	MIPS CQM 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.10. 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. We 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 Endocrinology specialty set.

B.10. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN 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**
* <SECTION><SECTNO>§ ! (Outcome)	0059 / N/A	001	CMS122 v9	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
	0046 / N/A	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
* <SECTION><SECTNO>§	0055 / N/A	117	CMS131 v9	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 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.	National Committee for Quality Assurance
* <SECTION><SECTNO>§	0066 / N/A	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
* <SECTION><SECTNO>§	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 / N/A	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

B.10. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN 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**
* <SECTION><SECTNO>§	N/A / N/A	128	CMS69v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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	CMS68v10	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	CMS2v10	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 or 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.	Centers for Medicare & Medicaid Services
* <SECTION><SECTNO>§	0028 / 0028e	226	CMS138v9	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 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. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN 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**
* <SECTION><SECTNO>§ ! (Outcome)	N/A / N/A	236	CMS165 v9	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 overlapping the measurement period and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	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
*	0053 / N/A	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 6 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 6 months after the fracture.	National Committee for Quality Assurance
*	N/A / N/A	438	CMS347 v4	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 / N/A	462	CMS645 v4	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 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.10. 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**
*	0041 / 0041e	110	CMS147 v10	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 to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type.
	N/A / N/A	111	CMS127 v9	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 to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type.

B.11. 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. We 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.11. 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**
* <SECTION>< SECTNO>§ ! (Outcome)	0059 / N/A	001	CMS122 v9	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
* <SECTION>< SECTNO>§	0081 / 0081e	005	CMS135 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**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):** 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.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* <SECTION>< SECTNO>§	0067 / N/A	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
* <SECTION>< SECTNO>§	0070 / 0070e	007	CMS145 v9	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®)
* <SECTION>< SECTNO>§	0083 / 0083e	008	CMS144 v9	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.11. 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**
	N/A / N/A	009	CMS128 v9	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
	0046 / N/A	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 / N/A	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 / 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
* <SECTION><SECTNO>§ ! (Appropriate Use)	0069 / N/A	065	CMS154v9	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
* <SECTION><SECTNO>§ ! (Appropriate Use)	N/A / N/A	066	CMS146v9	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 / N/A	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
*	N/A / 0104e	107	CMS161 v9	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®)

B.11. 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**
*	0041 / 0041e	110	CMS147 v10	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®)
	N/A / N/A	111	CMS127 v9	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
* <SECTION><SECTNO>§	2372 / N/A	112	CMS125 v9	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 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.	National Committee for Quality Assurance
* <SECTION><SECTNO>§	0034 / N/A	113	CMS130 v9	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
* <SECTION><SECTNO>§ ! (Appropriate Use)	0058 / N/A	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
* <SECTION><SECTNO>§	0055 / N/A	117	CMS131 v9	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 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.	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**
* <SECTION><SECTNO>§	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 / N/A	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
* <SECTION><SECTNO>§	N/A / N/A	128	CMS69v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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	CMS68v10	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	CMS2v10	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 or 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.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	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 / N/A	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 / 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

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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)	N/A / N/A	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
* <SECTION>< SECTNO>§	0028 / 0028e	226	CMS138v9	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 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®)
* <SECTION>< SECTNO>§ ! (Outcome)	N/A / N/A	236	CMS165v9	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 overlapping the measurement period and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v9	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 / N/A	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

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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 / N/A	305	CMS137 v9	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 including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. • 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.	National Committee for Quality Assurance
* <SECTION>< SECTNO>§	N/A / N/A	309	CMS124 v9	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 / N/A	317	CMS22v 9	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 v9	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**
<SECTION><SECTNO>§ ! (Patient Experience)	0005 / N/A	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)
* <SECTION><SECTNO>§	1525 / N/A	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 / 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
* ! (Appropriate Use)	N/A / 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
§ ! (Outcome)	2082 / N/A	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 / N/A	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

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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**
* <SECTION>< SECTNO>§ ! (Outcome)	0710 / 0710e	370	CMS159 v9	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 / N/A	374	CMS50v 9	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 / N/A	377	CMS90v 10	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 / N/A	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
*	N/A / 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®)
* <SECTION>< SECTNO>§	1407 / N/A	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 / 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
* <SECTION>< SECTNO>§	N/A / 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®)

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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 / 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 / N/A	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 / N/A	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 6 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 6 months after the fracture.	National Committee for Quality Assurance
*	2152 / N/A	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 / N/A	438	CMS347 v4	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 / 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 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 / 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
* <SECTION>< SECTNO>§ ! (Efficiency)	N/A / 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 / N/A	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 / 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 / 3475e	472	CMS249 v3	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 / N/A	475	CMS349 v3	eCQM Specifications	Process	Community /Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

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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)	0576 / N/A	391	N/A	MIPS CQM Specifications	Process	Communication and 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 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.	National Committee for Quality Assurance	We are proposing to add this measure to the Family Medicine specialty set. Stakeholders commented, as we agree, that the Family Medicine set include several quality measures that address mental health and substance use disorders. Given the high rates that patients are assessed or treated for these conditions within this specialty, they recommended the inclusion of this measure within the Family Medicine specialty set.

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PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SET Note: In this this proposed rule, we propose 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 / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE FAMILY MEDICINE SET Note: In this this proposed rule, we propose 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 / 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/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.	American Academy of Dermatology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.12. 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. We 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.12. 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 / N/A	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
* <SECTION> <SECTNO>§	N/A / N/A	128	CMS69v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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	CMS68v10	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 / N/A	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

B.12. 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**
* <SECTION> <SECTNO>§	0028 / 0028e	226	CMS138 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: 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 / 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 / N/A	317	CMS22v9	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 / N/A	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 / N/A	374	CMS50v9	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.12. 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**
§	N/A / 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 / N/A	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 / 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 / N/A	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®)
* <SECTION> <SECTNO>§ ! (Efficiency)	N/A / N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**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.12. Gastroenterology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GASTROENTEROLOGY SET Note: In this this proposed rule, we propose 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 / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.13 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. We 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.13. 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 / N/A	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 / 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 / N/A	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
* <SECTION><SECTNO>§	N/A / N/A	128	CMS69 v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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 v10	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.13. 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**
* <SECTION><SECTNO>§	0028 / 0028e	226	CMS138v9	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 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 / 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
*	N/A / N/A	317	CMS22v9	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 / 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
! (Outcome)	N/A / 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 / 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 / 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 / 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 / N/A	374	CMS50v9	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.13. 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 / N/A	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.14. 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. We 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.14. 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 / N/A	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 / N/A	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 / 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
*	0041 / 0041e	110	CMS147v10	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®)
	N/A / N/A	111	CMS127v9	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
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	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.14. 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**
! (Patient Safety)	0101 / N/A	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 / N/A	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 / 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	CMS156v9	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 / 2872e	281	CMS149v9	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 / 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 Psychiatric Association/ American Academy of Neurology
*	N/A / 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 Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	N/A / 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 Psychiatric Association/ American Academy of Neurology

B.14. 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**
* ! (Care Coordination)	N/A / 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 Psychiatric Association/ American Academy of Neurology
* <SECTION><SECTNO>§ ! (Outcome)	0710 / 0710e	370	CMS159v9	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
* <SECTION><SECTNO>§ ! (Outcome)	0213 / N/A	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)	N/A / N/A	476	CMS159v9	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 (AUA) Symptom Index (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

B.14. Geriatrics

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE GERIATRICS SET Note: In this this proposed rule, we propose 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 / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.15. 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. We 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.15. 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**
* <SECTION><SECTNO>§	0081 / 0081e	005	CMS135 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**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):** 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.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* <SECTION><SECTNO>§	0083 / 0083e	008	CMS144 v9	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 / N/A	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 / N/A	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.15. 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	CMS68v10	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.16. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final 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. We 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 were proposed to be added, and measures that were proposed for removal, as applicable. We request comment on the measures available in the proposed Infectious Disease specialty set.

B.16. 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**
*	0041 / 0041e	110	CMS147 v10	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®)
	N/A / N/A	111	CMS127 v9	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
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	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 / N/A	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 / N/A	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 / N/A	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	CMS349	eCQM	Process	Community/	**HIV Screening:**	Centers for

B.16. 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**
	N/A		v3	Specifications		Population Health	Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Disease Control and Prevention

B.17. 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. We 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.17. 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**
* <SECTION> <SECTNO> § ! (Outcome)	0059 / N/A	001	CMS122v9	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
* <SECTION> <SECTNO> §	0081 / 0081e	005	CMS135v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**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):** 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.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* <SECTION> <SECTNO> §	0067 / N/A	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
* <SECTION> <SECTNO> §	0070 / 0070e	007	CMS145v9	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®)
* <SECTION><SECTNO>§	0083 / 0083e	008	CMS144v9	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.17. 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 / N/A	009	CMS128v9	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
	0046 / N/A	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 / N/A	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 / 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)	0654 / N/A	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
*	0041 / 0041e	110	CMS147v10	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®)
	N/A / N/A	111	CMS127v9	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

B.17. 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)	0058 / N/A	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	CMS131v9	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 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.	National Committee for Quality Assurance
* §	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
*	0417 / N/A	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
* §	N/A / N/A	128	CMS69v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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	CMS68v10	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.17. 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	CMS2v10	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 or 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.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	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 / N/A	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 / 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	CMS138v9	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 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 / N/A	236	CMS165v9	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 overlapping the measurement period and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance

B.17. 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 Safety)	0022 / N/A	238	CMS156v9	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 / N/A	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 / 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 / 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
* ! (Opioid)	N/A / N/A	305	CMS137v9	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 including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. • 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.	National Committee for Quality Assurance

B.17. 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 / N/A	309	CMS124v9	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 / N/A	317	CMS22 v9	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	CMS139v9	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
§ ! (Patient Experience)	0005 / N/A	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 / N/A	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 / 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

B.17. 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 / 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
§ ! (Outcome)	2082 / N/A	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 / N/A	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	CMS159v9	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 / N/A	374	CMS50 v9	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 / N/A	377	CMS90 v10	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 / N/A	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
*	N/A / 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 / 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.17. 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 / 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 / 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 / N/A	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 / N/A	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 6 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 6 months after the fracture.	National Committee for Quality Assurance
*	2152 / N/A	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 / N/A	438	CMS347v4	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

B.17. 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)	N/A / 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 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
§ ! (Appropriate Use)	N/A / 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 / 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 / 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 / 3475e	472	CMS249v3	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 / N/A	475	CMS349v3	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.17. 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 / 0104e	107	CMS161 v9	eCQM Measure 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®)	We are proposing to add this measure to the Internal Medicine specialty set. Stakeholders commented, and we agree, that the Internal Medicine set include several quality measures that address mental health and substance use disorders. Given the high rates that patients are assessed or treated for these conditions within this specialty, they recommended the inclusion of this measure within the Internal Medicine specialty set.
* ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQM Specifications	Process	Communication and 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 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.	National Committee for Quality Assurance	We are proposing to add this measure to the Internal Medicine specialty set. Stakeholders commented, and we agree, that the Family Medicine set include several quality measures that address mental health and substance use disorders. Given the high rates that patients are assessed or treated for these conditions within this specialty, they recommended the inclusion of this measure within the Internal Medicine specialty set.

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SET Note: In this this proposed rule, we propose 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 / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERNAL MEDICINE SET Note: In this this proposed rule, we propose 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 / 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/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.	American Academy of Dermatology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.18. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this proposed rule, the Interventional 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. We 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 Interventional Radiology specialty set.

B.18. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL 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)	2726 / N/A	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
* ! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims 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 / N/A	374	CMS50v9	MIPS CQMs Specifications, eCQM 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 / 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 / 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 / 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
	N/A / N/A	421	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology

B.18. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE INTERVENTIONAL RADIOLOGY SET Note: In this this proposed rule, we propose 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 / N/A	437	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure:** Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.	Society of Interventional Radiology	This measure is being proposed for removal beginning with the 2023 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. We 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 / N/A	009	CMS128 v9	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
*	N/A/ / 0104e	107	CMS161 v9	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®)
* §	N/A / N/A	128	CMS69v 9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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 10	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	CMS2v10	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 or 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.	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**
* ! (Patient Safety)	N/A / 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 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: 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 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 / 2872e	281	CMS149 v9	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 / 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 Psychiatric Association/ American Academy of Neurology
*	N/A / 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 Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	N/A / 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 Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / 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 Psychiatric Association/ 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 / N/A	317	CMS22v9	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 / N/A	366	CMS136 v10	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	CMS159 v9	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 / N/A	374	CMS50v9	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 / 1365e	382	CMS177 v9	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 / N/A	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
* ! (Care Coordination)	0576 / N/A	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 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.	National Committee for Quality Assurance

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**
	2803 / N/A	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 / N/A	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 / 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.20. 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. We 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.20. 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 v9	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 / N/A	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
*	0041 / 0041e	110	CMS147 v10	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®)
	N/A / N/A	111	CMS127 v9	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
* §	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

B.20. 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**
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	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 / N/A	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
*	N/A / N/A	317	CMS22v9	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	CMS139v9	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 / 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. 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. We 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.21. 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 / N/A	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	CMS68v10	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	CMS2v10	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 or 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.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	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 / N/A	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 / 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

B.21. 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 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: 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 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 / 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:** 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.	American Academy of Neurology
*	N/A / 2872e	281	CMS149 v9	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 / 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 Psychiatric Association/ American Academy of Neurology
*	N/A / 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 Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	N/A / 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 Psychiatric Association/ American Academy of Neurology

B.21. 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)	N/A / 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 Psychiatric Association/ American Academy of Neurology
*	N/A / 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 / 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 / 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 / N/A	317	CMS22v 9	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 / N/A	374	CMS50v 9	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 / 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 / N/A	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
* ! (Efficiency)	N/A / 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

B.21. 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**
*	2152 / N/A	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.21. 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**
*	N/A / 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 Neurology specialty set based upon stakeholder feedback, as it is clinically relevant to this clinician type.
*	N/A / 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 Neurology specialty set based upon stakeholder feedback, as it is clinically relevant to this clinician type.

B.21. Neurology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE NEUROLOGY SET Note: In this this proposed rule, we propose 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 / 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 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 (IIRQoL) 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.22. 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. We 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.22. 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 / N/A	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 / 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 (LDUII), 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	CMS68v10	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 / 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.22. 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 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: 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 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 / 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 / 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 / N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** 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 3 months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** 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	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** 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 3 months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** 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.	Minnesota Community Measurement

B.22. 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 / N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** 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 3 months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** 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. * hereafter referred to as VAS Pain	Minnesota Community Measurement

B.22. Neurosurgical

MEASURES PROPOSED FOR **ADDITION** TO 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**	**Rationale for Inclusion**
! (Outcome)	N/A / 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 Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons	We propose to include this measure in the Neurosurgical specialty set as we received previous stakeholder feedback to include this measure within the specialty set. We agree with that stakeholder that it is clinically relevant to this clinician type.
! (Outcome)	N/A / 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	We propose to include this measure in the Neurosurgical specialty set as we received previous stakeholder feedback to include this measure within the specialty set. We agree with that stakeholder that it is clinically relevant to this clinician type.

B.23. 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. We 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 Nutrition/Dietician specialty set.

B.23. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN 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**
* § ! (Outcome)	0059 / N/A	001	CMS122v9	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
* §	N/A / N/A	128	CMS69v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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	CMS68v10	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)	N/A / 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

B.23. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN 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**
§	N/A / N/A	239	CMS155v9	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
*	2152 / N/A	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.24. 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. We 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.24. 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 / N/A	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 / 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
*	0041 / 0041e	110	CMS147 v10	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®)
	N/A / N/A	111	CMS127 v9	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
* §	2372 / N/A	112	CMS125 v9	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 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.	National Committee for Quality Assurance

B.24. 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 / N/A	128	CMS69v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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	CMS68v10	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	CMS138v9	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 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 / N/A	236	CMS165v9	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 overlapping the measurement period and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / 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

B.24. 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 / N/A	309	CMS124 v9	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 / N/A	310	CMS153 v9	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 / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population IIealth	**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 / N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse):** 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.	Centers for Medicare & Medicaid Services
* ! (Care Coordinatio n)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	Communicat ion 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 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.	Centers for Medicare & Medicaid Services
* ! (Care Coordinatio n)	N/A / N/A	374	CMS50v 9	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 / N/A	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.24. 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**
*	0053 / N/A	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 6 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 6 months after the fracture.	National Committee for Quality Assurance
! (Patient Safety)	2063 / N/A	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 Urogynecologic Society
! (Patient Safety)	N/A / 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 / N/A	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 / 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 repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A / 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 / 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 / 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 / N/A	448	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Workup Prior to Endometrial Ablation:** 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.	Centers for Medicare & Medicaid Services

B.24. 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**
! (Appropriate Use)	N/A / 3475e	472	CMS249 v3	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 / N/A	475	CMS349 v3	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.24. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OBSTETRICS/GYNECOLOGY SET Note: In this this proposed rule, we propose 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 / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.25a. 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. We 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 Oncology/Hematology specialty set.

B.25a. 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 / N/A	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 / 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
	N/A / 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®)
§ ! (Appropriate Use)	0389 / 0389e	102	CMS129v10	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 who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
*	0041 / 0041e	110	CMS147v10	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®)

B.25a. 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 / N/A	111	CMS127v9	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
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	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	CMS157v9	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 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Pain:** 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.	American Society of Clinical Oncology
* §	0028 / 0028e	226	CMS138v9	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 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®)
§	1853 / N/A	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

B.25a. 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 / N/A	317	CMS22v9	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 / N/A	374	CMS50v9	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 / N/A	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 / N/A	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)	1858 / N/A	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 / N/A	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 / N/A	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

B.25a. 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)	0210 / N/A	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 / N/A	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 / N/A	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
*	N/A / N/A	462	CMS645v4	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 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.25a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE ONCOLOGY/HEMATOLOGY SET Note: In this this proposed rule, we propose 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 / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.25b. 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. We 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.25b. 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 v10	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 who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157 v9	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 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Pain:** 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.	American Society of Clinical Oncology

B.26. 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. We 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.26. 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	CMS143v9	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 / N/A	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)	N/A / N/A	019	CMS142v9	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	CMS131v9	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 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.	National Committee for Quality Assurance

B.26. 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	CMS68v10	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 / N/A	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	CMS133v9	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years 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.	Physician Consortium for Performance Improvement Foundation (PCPI®)
* §	0028 / 0028e	226	CMS138v9	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 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.26. 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)	N/A / N/A	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
! (Patient Experience)	N/A / 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
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	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 / 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 / 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 / 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.26. Ophthalmology

MEASURES PROPOSED FOR **ADDITION** TO 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**	**Rationale for Inclusion**
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	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 are proposing in Table D.48 to expand the measure's applicability to include the ophthalmology patient population. With the expanded patient population and the clinical relevance to this clinician type, we are proposing to add to the Ophthalmology specialty set.

B.27. 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. We 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.27. 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 / N/A	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 / 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 / N/A	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
* §	N/A / N/A	128	CMS69 v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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.27. 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 Safety)	0419 / 0419e	130	CMS68 v10	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 10	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 or 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.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	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 / N/A	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 / 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
	N/A / 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 > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* ! (Care Coordination)	N/A / N/A	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.27. 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**
* ! (Outcome)	N/A / N/A	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.
* ! (Outcome)	N/A / N/A	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)	N/A / N/A	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) is 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.

B.27. 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**
* ! (Outcome)	N/A / N/A	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 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)	N/A / N/A	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)	N/A / N/A	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.27. 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	CMS13 8v9	Medicare Part B Claims 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 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 / N/A	317	CMS22 v9	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	CMS13 9v9	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 / N/A	350	N/A	MIPS CQMs Specifications	Process	Communicatio n 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 / 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.27. 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 / 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 / N/A	374	CMS50 v9	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 / N/A	375	CMS66 v9	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 / N/A	376	CMS56 v9	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 / N/A	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 / N/A	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 6 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 6 months after the fracture.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** 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 3 months (6 to 20 weeks) postoperatively.	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 / N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** 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	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** 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 3 months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** 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.	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	470	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Primary Total Knee Replacement:** 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.	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** 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 3 months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* ! (Outcome)	N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** 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. * hereafter referred to as VAS Pain	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 / N/A	478	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.

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE ORTHOPEDIC SURGERY SET

Note: In this this proposed rule, we propose 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 / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 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.		This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.28. 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. We 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.28. 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 / N/A	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 / 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 / N/A	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	CMS154v9	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 / N/A	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
*	0041 / 0041e	110	CMS147v10	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®)

B.28. 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
	N/A / N/A	111	CMS127v9	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
* §	N/A / N/A	128	CMS69 v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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 v10	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 / N/A	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 / N/A	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	CMS138v9	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 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 / 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

B.28. 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**
*	N/A / 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 / 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
*	N/A / N/A	317	CMS22 v9	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	CMS139v9	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 / 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
* ! (Appropriate Use)	N/A / 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
! (Outcome)	N/A / 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 / 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 / N/A	374	CMS50 v9	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.28. 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**
! (Outcome)	N/A / 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
	2803 / N/A	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 / N/A	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 / N/A	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

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PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE OTOLARYNGOLOGY SET Note: In this this proposed rule, we propose 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 / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.29. 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. We 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.29. 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**
	1854 / N/A	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
§	1853 / N/A	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
* ! (Care Coordination)	N/A / 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
! (Care Coordination)	N/A / 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
! (Care Coordination)	N/A / 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
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (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.30. 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. We 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.30. 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	CMS154v9	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 / N/A	066	CMS146v9	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 / N/A	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
*	0041 / 0041e	110	CMS147v10	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®)
*	0418 / 0418e	134	CMS2v10	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 or 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.	Centers for Medicare & Medicaid Services
§	0409 / N/A	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.30. 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 / N/A	239	CMS155v9	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 / N/A	240	CMS117v9	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 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.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	305	CMS137v9	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 including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. • 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.	National Committee for Quality Assurance
§	N/A / N/A	310	CMS153v9	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.30. 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 / N/A	366	CMS13 6v10	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	CMS15 9v9	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
*	N/A / N/A	379	CMS74 v10	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)	N/A / 1365e	382	CMS17 7v9	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 / N/A	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 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.	National Committee for Quality Assurance
* §	1407 / N/A	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 / 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.30. 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 / N/A	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 / 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 / N/A	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.30. 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**
* § ! (Appropriate Use)	0058 / N/A	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	We are proposing in Table D.18 to expand the measure's applicability to include the pediatric patient population. With the expanded patient population and the clinical relevance to this clinician type, we are proposing to add to the Pediatric specialty set.

B.31. 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. We 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 Medicine specialty set.

B.31. 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 / N/A	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 / N/A	128	CMS69 v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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 / 0419 e	130	CMS68 v10	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 / N/A	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 / N/A	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
* ! (Care Coordination)	N/A / N/A	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.31. 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**
* §	0028 / 0028 e	226	CMS138v9	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 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 / N/A	317	CMS22v9	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 / N/A	374	CMS50v9	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 / N/A	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 / N/A	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 / 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.31. Physical Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PHYSICAL MEDICINE SET Note: In this this proposed rule, we propose 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 / 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 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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 6 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.		This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.32. 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. We 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.32. 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 Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0417 / N/A	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 / N/A	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
* §	N/A / N/A	128	CMS69v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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	CMS68v10	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	CMS2v10	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 or 14 days prior to 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.	Centers for Medicare & Medicaid Services

B.32. 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 Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0101 / N/A	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 / N/A	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 / 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
* ! (Care Coordination)	N/A / N/A	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)	N/A / N/A	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.
* ! (Outcome)	N/A / N/A	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.

B.32. 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 Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	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) is 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)	N/A / N/A	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 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)	N/A / N/A	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.

B.32. 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 Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	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.
* §	0028 / 0028e	226	CMS138 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: 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 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 / 2872e	281	CMS149 v9	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®)
* ! (Care Coordination)	N/A / 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 Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	0101 / N/A	318	CMS139 v9	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.32. 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 Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	478	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.

B.32. 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**
*	N/A / 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 proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.
* ! (Patient Safety)	N/A / 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 proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.

B.32. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR REMOVAL FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET Note: In this this proposed rule, we propose 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 / 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 Psychiatric Association/ American Academy of Neurology	We propose to remove this measure from the Physical Therapy/Occupational Therapy set as it is duplicative of measure Q182: Functional Outcome Assessment. Measure Q182 includes much of the patient population in measure Q282, but is more robust in that is requires more frequent assessments and a plan of care.

B.33. 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. We 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 Plastic Surgery specialty set.

B.33. 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 / N/A	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 / 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	CMS68v10	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.33. 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 v9	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 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 / N/A	317	CMS22v9	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 / 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 / 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 / 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 / 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.34. 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. We 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.34. 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 / N/A	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 / N/A	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
* §	N/A / N/A	128	CMS69v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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 / N/A	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 / N/A	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	CMS138v9	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 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.34. 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**
* ! (Patient Safety)	0101 / N/A	318	CMS139 v9	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.35. 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. We 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.35. 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 v9	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
	0046 / N/A	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 / N/A	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
*	0041 / 0041e	110	CMS147 v10	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®)
	N/A / N/A	111	CMS127 v9	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

B.35. 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 v9	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 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.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130 v9	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 / N/A	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 / N/A	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
* §	N/A / N/A	128	CMS69v 9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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.35. 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	CMS68v10	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	CMS2v10	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 or 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.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	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 / N/A	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
* ! (Care Coordination)	N/A / N/A	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.35. 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**
* §	0028 / 0028e	226	CMS138 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: 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 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 / N/A	317	CMS22v 9	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 / N/A	374	CMS50v 9	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 / N/A	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 / N/A	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®)

B.35. 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 / N/A	438	CMS347 v4	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 / N/A	475	CMS349 v3	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.35. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE PREVENTIVE MEDICINE SET Note: In this this proposed rule, we propose 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 / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.36. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final 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. We 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 were proposed to be added, and measures that were proposed for removal, as applicable. We request comment on the measures available in the proposed Pulmonology specialty set.

B.36. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN 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**
* ! (Care Coordination)	0326 / N/A	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
*	0102 / N/A	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
* §	N/A / N/A	128	CMS69v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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	CMS68v10	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	CMS138v9	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 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.36. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN 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**
* § ! (Outcome)	N/A / N/A	236	CMS165 v9	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 overlapping the measurement period and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	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 / 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 / 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
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	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 / 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
*	2152 / N/A	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 / 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

B.36. 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**
*	0041 / 0041e	110	CMS147 v10	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 to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	N/A / N/A	111	CMS127 v9	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 to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.

B.37. 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. We 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.37. Rheumatology

PREVIOUSLY FINALIZED 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**
	0046 / N/A	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 / N/A	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
*	0041 / 0041e	110	CMS147 v10	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®)
	N/A / N/A	111	CMS127 v9	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
* §	N/A / N/A	128	CMS69v 9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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 10	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.37. Rheumatology

PREVIOUSLY FINALIZED 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 / 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
	2523 / 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 using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.	American College of Rheumatology
*	N/A / 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
*	N/A / 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 > 5 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 v9	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 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 / N/A	236	CMS165 v9	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 overlapping the measurement period and whose most recent blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance

B.37. Rheumatology

PREVIOUSLY FINALIZED 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**
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	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 / N/A	317	CMS22v 9	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 / N/A	374	CMS50v 9	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 / N/A	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.37. Rheumatology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE RHEUMATOLOGY SET Note: In this this proposed rule, we propose 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 / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.38. 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. We 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.38. 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 / N/A	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 v9	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 v9	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 / N/A	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
*	0041 / 0041e	110	CMS147 v10	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®)
* §	0066 / N/A	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

B.38. 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**
! (Patient Safety)	0101 / N/A	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 / N/A	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 / 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 / N/A	317	CMS22v9	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 / N/A	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.38. 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 / N/A	111	CMS127 v9	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 to include this measure in the Skilled Nursing Facility specialty set as it is clinically relevant to this clinician type.
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	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 are proposing in Table D.48 to expand the measure's applicability to include the skilled nursing facility patient population. With the expanded patient population and the clinical relevance to this clinician type, we are proposing to add to the Skilled Nursing Facility specialty set.

B.39. 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. We 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 Speech Language Pathology specialty set.

B.39. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN 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**
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	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)	N/A / 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
* ! (Care Coordination)	N/A / N/A	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 / 0028e	226	CMS138v9	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 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.39. 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**
*	0418 / 0418e	134	CMS2v10	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 or 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.	Centers for Medicare & Medicaid Services	We are proposing to add this measure to the Speech Language Pathology specialty set as the specific codes were finalized for inclusion in 2020 performance period. We propose to include this measure in the Speech Language Pathology specialty set as it is clinically relevant to this clinician type.

B.40. 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. We 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.40. 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 / N/A	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 / 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 / N/A	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	CMS68v10	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 / N/A	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
! (Outcome)	0114 / N/A	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

B.40. 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)	0115 / N/A	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 / 0028e	226	CMS138v9	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 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 / N/A	317	CMS22v9	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 / 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 / N/A	374	CMS50v9	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 / N/A	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.40. 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)	0119 / N/A	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.40. Thoracic Surgery

MEASURES PROPOSED FOR **ADDITION** TO 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**	**Rationale for Inclusion**
	0236 / N/A	044	N/A	MIPS CQM 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	This measure is being proposed to be added to the Thoracic Surgery set as it is clinically relevant to this clinician type. This set includes additional CABG quality measures and inclusion of this measure would allow for a complete assessment of quality for this surgical procedure.

B.41. 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. We 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.41. 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 v9	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 / N/A	066	CMS146 v9	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 / N/A	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 / N/A	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 10	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	CMS138 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: 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 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.41. 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**
*	N/A / N/A	317	CMS22v9	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
* ! (Appropriate Use)	N/A / 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
! (Appropriate Use)	N/A / 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
	2803 / N/A	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 / N/A	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 / N/A	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.41. Urgent Care

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE URGENT CARE SET Note: In this this proposed rule, we propose 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 / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.42. 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. We 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.42. 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 / 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 / N/A	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 / 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 v10	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 who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
	0390 / N/A	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prostate Cancer: Combination Androgen Deprivation Therapy for IIigh 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

B.42. 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**
* §	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
* §	N/A / N/A	128	CMS69v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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	CMS68v10	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	CMS138 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: 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 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 / 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

B.42. 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**
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for Hlgh 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 / 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 / N/A	374	CMS50v9	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 / 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 / N/A	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 / 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 repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A / 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 / 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

B.42. 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**
*	N/A / N/A	462	CMS645 v4	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 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
* ! (Outcome)	N/A / N/A	476	CMS771 v2	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 (AUS) Symptom Index (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

B.42. Urology

PREVIOUSLY FINALIZED MEASURES PROPOSED FOR **REMOVAL** FROM THE UROLOGY SET Note: In this this proposed rule, we propose 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 / 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	This measure is being proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.43. 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. We 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.43. 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 / N/A	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 / 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 / N/A	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 / N/A	128	CMS69v9	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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 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	CMS68v10	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.43. 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**
* §	0028 / 0028e	226	CMS138 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: 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 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 / N/A	236	CMS165 v9	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 overlapping the measurement period and whose blood pressure was adequately controlled (< 140/90 mmHg) during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / 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 (AAA) who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons
! (Outcome)	N/A / 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 / 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 Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons

B.43. 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**
*	N/A / N/A	317	CMS22v9	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 / 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 / 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 / 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 / N/A	374	CMS50v9	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 / N/A	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 / 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

B.43. 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 / 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 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)

TABLE Group C: Previously Finalized Quality Measures Proposed for Removal in the 2023 MIPS Payment Year and Future Years

In this proposed rule, we propose to remove 14 previously finalized quality measures from the MIPS Program for the 2021 MIPS performance period/2023 MIPS payment year and future years. These measures are discussed in detail below. Our measure removal criteria was discussed in the CY 2019 PFS 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. Beginning with the 2020 MIPS performance period/2022 MIPS payment year, we also refer readers to the CY 2020 PFS final rule (84 FR 62957 through 62959) for additional quality measure removal criteria.

TABLE Group C: Previously Finalized Quality Measures Proposed for Removal in the 2023 MIPS Payment Year and Future Years

C.1. Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	024
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	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.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the measure supports communication between the physician treating the fracture and the clinician managing the patient's on-going care, but does not ensure that the patient receives the appropriate treatment or testing for osteoporosis. We believe measure Q418: Osteoporosis Management in Women Who Had a Fracture represents a more robust quality outcome in the management of patients with osteoporosis who experience a fracture since the clinical focus of this measure is the care of the patient rather than just the communication of the care plan for on-going post fracture care.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.2. Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	048
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	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 measures initiative. This is a process measure that only requires an assessment for the presence or absence of urinary incontinence, which by itself may not have a meaningful direct impact on patient care as the screening itself does not indicate a plan of care was implemented. Additionally, the Medicare Part B Claims Measure Specifications collection type has reached the end of the topped out lifecycle (82 53640).
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.3. Hematology: Multiple Myeloma: Treatment with Bisphosphonates

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	069
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	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.
Measure Steward:	American Society of Hematology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a

	quality measure from the MIPS program because the measure does not align with current treatment guidelines and could inadvertently penalize eligible clinicians who are treating patients appropriately (i.e., Prolia), by excluding those patients instead of being numerator compliant. As currently constructed, the measure may produce misleading results.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.4. Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms

Category	**Description**
NQF # / eCQM NQF #:	0508 / N/A
Quality #:	146
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of final reports for screening mammograms that are classified as "probably benign".
Measure Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	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 0.428 percent for the MIPS CQMs Specifications collection type and 0.253 percent for the Medicare Part B Claims Measure 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 and the Medicare Part B Claims Measure Specifications collection type 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/824/2020%20MIPS%20Quality%20Benchmarks.zip
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.5. Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse)

Category	**Description**
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	333
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Collection Type:	MIPS CQMs Specifications
Measure Description:	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.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal	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 has reached the end of the topped out lifecycle and has a high performance rate of 2.834 percent for the MIPS CQMs Specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. Given this measure's continued topped out status, we believe it has a limited opportunity to improve clinical outcomes. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/824/2020%20MIPS%20Quality%20Benchmarks.zip
In the Circumstance the Measure is Retained	We would update the denominator eligible encounters to include telehealth encounters as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

C.6. 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 / N/A
Quality #:	337
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	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.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	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 to measure Q176: Rheumatoid Arthritis (RA): Tuberculosis Screening because we are proposing in Table D.33 substantive changes to measure Q176 that would broaden the denominator by removing the disease specificity criteria. Therefore, the patient population will overlap between these measures; however, measure Q176 has a broader eligible patient population. In the event the proposed substantive change to measure Q176 is not finalized, we would consider maintaining this measure to ensure this patient population is being assessed for appropriate tuberculosis screening.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.7. Implantable Cardioverter-Defibrillator (ICD) Complications Rate

Category	**Description**
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	348
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	MIPS CQMs Specifications
Measure Description:	Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	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 measures 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 performance periods suggests this is not an important clinical topic for MIPS eligible clinicians.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.8. Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options

Category	**Description**
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	390
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	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.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the request of the measure steward because this measure does not align with the advancements in hepatitis C treatments. There are now curative treatments over an 8-12-week period with few side effects. Additionally, the measure is at risk of capturing "chronic HCV" patients who are no longer viremic, which would not necessitate HCV shared decision making.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.9.Opioid Therapy Follow-up Evaluation

Category	**Description**
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	408
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications

Measure Description:	All patients 18 and older prescribed opiates for longer than 6 weeks duration who had a follow-up evaluation conducted at least every 3 months during Opioid Therapy documented in the medical record.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the request of the measure steward because this measure does not align with the most recent guidelines. The measure steward will not be further reviewing or updating the measure specifications, citing the measure is topped out and there are newer opioid measures to report that are not topped out.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.10.Documentation of Signed Opioid Treatment Agreement

Category	**Description**
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	412
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the request of the measure steward because this measure does not align with the most recent guidelines. The measure steward will not be further reviewing or updating the measure specifications, citing the measure is topped out and there are newer opioid measures to report that are not topped out.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.11.Evaluation or Interview for Risk of Opioid Misuse

Category	**Description**
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	414
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	All patients 18 and older prescribed opiates for longer than 6 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.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the request of the measure steward because this measure does not align with the most recent guidelines. The measure steward will not be further reviewing or updating the measure specifications, citing the measure is topped out and there are newer opioid measures to report that are not topped out.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.12. Quality of Life Assessment for Patients With Primary Headache Disorders

Category	**Description**
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	435
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	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.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale for Removal	We propose the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the measure steward's request as it is no longer being maintained for inclusion. As there are various tools that providers may

	choose to use, it difficult to compare measure performance across MIPS eligible clinicians. Additionally, the scores are difficult to capture within the EHR leading to difficulties in determining whether the QoL is being maintained or improving over time.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.13. Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure

Category	**Description**
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	437
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	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 1.854 percent for the MIPS CQMs Specifications collection type and 1.031 percent for the Medicare Part B Claims Measure 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 and the Medicare Part B Claims Measure Specifications collection type 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/824/2020%20MIPS%20Quality%20Benchmarks.zip
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

C.14. All-Cause Hospital Readmission

Category	**Description**
NQF # / eCQM NQF #:	1789 / N/A
Quality #:	458
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	Administrative Claims
Measure Description:	The 30-day All-Cause Hospital Readmission measure is a risk-standardized readmission rate for beneficiaries age 65 or older who were hospitalized at a short-stay acute care hospital and experienced an unplanned readmission for any cause to an acute care hospital within 30 days of discharge.
Measure Steward:	Yale University
High Priority Measure:	No
Measure Type:	Outcome
Rationale for Removal	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 to the new measure being proposed in Table A.1. for the 2021 performance period: Table A.1: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups. This proposed new measure is a re-specification of the hospital-level measure and promotes a systems level approach by clinicians, making it a more applicable measure to MIPS eligible clinicians. In the event we do not finalize the proposed new measure: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups, we would maintain this current measure Q458: All-Cause Hospital Readmission.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement proposed for this measure.

TABLE Group D: Previously Finalized Quality Measures with Substantive Changes Proposed for the 2023 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 #.

The D Tables within the NPRM provide the substantive changes proposed for the quality measures in CY 2021. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2021 may not be identified within the NPRM due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2021 CPT and ICD-10 updates and assessment of these codes inclusion by the Measure Steward, these changes may be postponed until CY 2022. The 2021 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program Resource Library at https://qpp.cms.gov/about/resource-library.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature but we believe are important to communicate to stakeholders. These changes align with the scope of the current coding, however, this will expand or contract the current eligible population, therefore, review the current year measure specification and the 2021 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes. Language has also been added, to all applicable 2021 quality measure specifications, in the form of an 'Instructions Note', to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only in the instance telehealth encounters have not been previously allowed as denominator eligible, will the D table corresponding to that measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
NQF # / eCQM NQF #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v9
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% during the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications. **Updated denominator exclusion: For the eCQM Specification collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types:** Revised: Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. **Updated denominator exclusion: For the MIPS CQMs Specifications and Medicare Part B Claims Measure Specification collection type:** Added coding to identify patients with advanced illness and frailty **Updated numerator options: For the MIPS CQM Specifications and Medicare Part B Claims Measure Specifications collection type:** Stratified the Performance Not Met numerator option into three: **Performance Not Met:** Most recent hemoglobin A1c (HbA1c) level < 7.0% **Performance Not Met:** Most recent hemoglobin A1c (HbA1c) level greater than or equal to 7.0% and less than 8.0% **Performance Not Met:** Most recent hemoglobin A1c (HbA1c) level greater than or equal to 8.0% and less than or equal to 9.0% **Updated numerator instructions: For the MIPS CQM Specifications and Medicare Part B Claims Measure Specifications collection type:** Added: Do not include HbA1c levels reported by the patient. Added: Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period.

Category	Description
	Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we propose adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. The numerator options for Performance Not Met are being stratified to have the ability to better assess hemoglobin A1c levels within the patient population that showed better control. Instructions have been added to ensure the correct patient population as the measure intent is to assess hemoglobin A1c control in Type 1 or Type 2 diabetics and not those patients who have diabetes due to another condition. We propose to remove the CMS Web Interface Measure Specifications collection type. This collection type is proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this proposed rule.

D.2 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)

Category	Description
NQF # / eCQM NQF #:	0081 / 0081e
Quality#:	005
CMS eCQM ID:	CMS135v9
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 or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated the denominator exception logic**: **For the eCQM Specifications collection type:** Added sacubitril in the Allergy/Intolerance logic. **Updated denominator: For all collection types:** Submission Criteria 1: Added telehealth as eligible for all encounters.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to include sacubitril in the Allergy/Intolerance logic as this is one of the components of ARNI and an allergy to this ingredient would be a clinically appropriate reason for allowing a denominator exception for this patient population. We propose to add telehealth encounters as denominator eligible for submission criteria 1 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.3 Coronary Artery Disease (CAD): Antiplatelet Therapy

Category	Description
NQF # / eCQM NQF #:	0067 / N/A
Quality#:	006
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 coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.4 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:	CMS145v9
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 a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.
Substantive Change:	**Updated logic: For the eCQM Specifications collection type:** Added constraint to measure logic in instances when the patient has both prior (within the past 3 years) MI and LVEF < 40%. **The guidance is revised to read: For the eCQM Specifications collection type:** Beta-blocker therapy: - For patients with prior MI, beta-blocker therapy includes any agent within the beta-blocker drug class. As of 2015, no recommendations or evidence are cited in current stable ischemic heart disease guidelines for preferential use of specific agents - For patients with prior LVEF <40%, beta-blocker therapy includes the following: bisoprolol, carvedilol, or sustained release metoprolol succinate. The requirement of two or more visits is to establish that the eligible professional or eligible clinician has an existing relationship with the patient. A range value should satisfy the logic requirement for 'Ejection Fraction' as long as the ranged observation value clearly meets the less than 40% threshold noted in the denominator logic. A range that is inclusive of or greater than 40% would not meet the measure requirement. If a patient has had a myocardial infarction (MI) within the past 3 years and a current or prior LVEF < 40% (or moderate or severe LVSD), the patient should only be counted in Population Criteria 1. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. Beta-blocker therapy: **The instructions are revised to read: For the MIPS CQMs Specifications collection type**: This measure is to be submitted a minimum of once per performance period for all patients with a diagnosis of CAD seen during the performance period. Only patients who had at least two denominator-eligible visits during the performance period will be counted for Submission Criteria 1 and Submission Criteria 2 of this measure. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure for the primary management of patients with CAD based on the services provided and the measure-specific denominator coding. The MIPS eligible clinician should submit data on one of the submission criteria, depending on the clinical findings. If the patient has CAD or history of cardiac surgery and a current or prior LVEF < 40% (or moderate or severe LVSD), use Submission Criteria 1. If the patient has CAD or history of cardiac surgery and has a prior (within the past 3 years) MI, use Submission Criteria 2. The 3-year lookback period for the prior MI should be from the time of the encounter that is used to qualify for the denominator and evaluate the numerator. If the patient has had an MI within the past 3 years and has a current or prior LVEF < 40% (or moderate or severe LVSD), the MIPS eligible clinician should submit quality-data codes for Submission Criteria 1 and this will count as appropriate submission for this patient. **Updated denominator criteria: For all collection type:** Added telehealth as eligible for all encounters. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Denominator Criteria One: Revised: Left ventricular ejection fraction (LVEF) < 40% or documentation of moderate or severe LVSD. **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the eCQM Specifications collection type logic to improvement alignment with measure intent as it will add constraints to help prevent double counting of patients who had both a myocardial infarction and LVEF < 40% within the past 3 years. Additionally, the guidance is being revised to help clarify which population eligible patients should be included for the purposes of this measure. We also propose to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. For both the eCQM Specifications and MIPS CQMs Specifications collection types, the guidance and instructions have been updated, respectively, to add moderate or severe LVSD as a proxy for LVEF < 40%. The measure steward's Technical Expert Panel (TEP) determined that moderate or severe LVSD is an appropriate proxy and aligns with the intent of the measure. We agree with this addition as LVSD can be "defined as a left ventricular ejection fraction less than 40 percent or a narrative description consistent with moderate or severe systolic dysfunction." (Per the Joint Commission Specifications Manual (v2018A)). Additionally, we propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.5 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LSVD)

Category	Description
NQF # / eCQM NQF #:	0083 / 0083e
Quality#:	008
CMS eCQM ID:	CMS144v9
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:	**Updated denominator: For all collection types:** Submission Criteria 1: Added telehealth as eligible for all encounters. **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication.
Steward:	Physician Consortium For Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is 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 revise the 'Medical Reason' value set for the eCQM Specifications collection type based upon expert and stakeholder feedback to remove codes based upon intent of concepts which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception.

D.6 Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation

Category	Description
NQF # / eCQM NQF #:	0086 / 0086e
Quality#:	012
CMS eCQM ID:	CMS143v9
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 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.
Substantive Change:	**Modified collection type:** eCQM Specifications **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types as they have reached the end of the topped out lifecycle as finalized in 82 FR 53640. However, the benchmarking data continues to show a gap for the eCQM Specifications collection type, as such, the measure will be retained for this collection type. We also propose to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. We propose to remove telehealth encounters from the denominator of the eCQM Specifications collection type as telehealth is not an appropriate setting for this measure, as well as to align with the other collection types. This guidance can be found in a separate document that will be published on the eCQI Resource Center.

D.7 Age-Related Macular Degeneration (AMD): Dilated Macular Examination

Category	Description
NQF # / eCQM NQF #:	0087 / N/A
Quality#:	014
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 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.
Substantive Change:	**Updated numerator definition: For all collection types:** Revised: Severity of Macular Degeneration – Early, intermediate and advanced; or active choroidal neovascularization, inactive choroidal neovascularization, or with inactive scar.
Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the definition referencing the clinical stages for the 'Severity of Macular Degeneration' to clarify and align the concept with ICD-10 terminology. Adding clarity that these codes are clinically relevant and applicable.

D.8 Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	019
CMS eCQM ID:	CMS142v9
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	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:	**Update numerator logic: For the eCQM Specifications collection type**: Removed "sender" and "recipient" attributes. **Updated value set/coding: For the eCQM Specifications collection type**: Removed "sender" and "recipient" attributes. **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove the "sender" and "recipient" attributes from the numerator logic and the value set/coding of the eCQM Specifications collection type and revert to the numerator logic from performance year 2019. These attributes increased burden and were difficult to implement. We also propose to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts, which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. We propose to remove telehealth encounters from the denominator of the eCQM Specifications collection type as telehealth is not an appropriate setting for this measure, as well as to align with the other collection types. This guidance can be found in a separate document that will be published on the eCQI Resource Center.

D.9 Advance Care Plan

Category	Description
NQF # / eCQM NQF #:	0326 / N/A
Quality#:	047
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 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.
Substantive Change:	**Updated denominator: For all collection types:** Added clinical social worker clinician type.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add the clinical social worker clinician type to the denominator eligible encounters as this clinical concept is applicable to their scope of practice since these clinicians are integral to ensuring patients have up to date advance care plans and/or surrogate decision makers documented within the medical record.

D.10 Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy

Category	Description
NQF # / eCQM NQF #:	0102 / N/A
Quality#:	052
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 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.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications
Steward:	American Thoracic Society
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640. As captured in the 2020 Benchmark File, this collection type also has high performance rate. 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.

D.11 Appropriate Treatment for Children with Upper Respiratory Infection (URI)

Category	Description
NQF # / eCQM NQF #:	0069 / N/A
Quality#:	065
CMS eCQM ID:	CMS154v9
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	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 3 days after the episode.
Substantive Change:	**The title is revised from 'Appropriate Treatment for Children with Upper Respiratory Infection (URI)' to:** Appropriate Treatment for Upper Respiratory Infection (URI) **The description is revised to read:** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event. **The initial patient population is revised to read: For the eCQM Specifications collection type:** Outpatient visits, telephone visits, online assessments, observation stays or emergency department visits with a diagnosis of URI during the measurement period among patients 3 months of age and older. **Updated stratification: For the eCQM Specifications collection type:** 3 months-17 years, 18-64 years, 65 years and older. **The guidance is revised to read: For the eCQM Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period This eCQM is an episode-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The denominator is revised to read: For the MIPS CQMs Specifications collection type:** Outpatient visits, telephone visits, online assessments, observation stays or emergency department visits with a diagnosis of upper respiratory infection (URI) during the measurement period among patients 3 months of age and older. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Revised: Patients aged 3 months of age and older on date of encounter. Revised denominator eligible coding to include telehealth with qualified nonphysician health care professional. **The denominator instruction is revised to read: For the MIPS CQMs Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. If the patient has more than one episode in a 31-day period, include only the first episode. **Updated denominator exclusion:** **For the eCQMs Specifications collection type:** Added: 1. Exclude URI episodes when the patient had a competing comorbid condition during the 12 months prior to or on the episode date. Revised: 1. Exclude URI episodes when the patient had a new or refill prescription of antibiotics in the 30 days prior to or on the episode date. 2. Exclude URI episodes when the patient had competing diagnosis on or 3 days after the episode date. 3. Exclude URI episodes when the patient had hospice care overlapping with the measurement period. **For MIPS CQMs Specifications collection type:** Added: 1. URI episodes where the patient had a competing comorbid condition during the 12 months prior to or on the episode date (e.g., tuberculosis, neutropenia, cystic fibrosis, chronic bronchitis, pulmonary edema, respiratory failure, rheumatoid lung disease). 2. URI episodes when the patient had a new or refill prescription of antibiotics (Table 1) in the 30 days prior to or on the episode date. Revised: 1. URI episodes when the patient had competing diagnoses on or 3 days after the episode date (e.g., intestinal infection, pertussis, bacterial infection, Lyme disease, otitis media, acute sinusitis, acute pharyngitis, acute tonsillitis, chronic sinusitis, infection of the pharynx/larynx/tonsils/adenoids, prostatitis, cellulitis, mastoiditis, or bone infections, acute lymphadenitis, impetigo, skin staph infections, pneumonia/gonococcal infections, venereal disease (syphilis, chlamydia, inflammatory diseases [female reproductive organs]), infections of the kidney, cystitis or UTI, and acne). Removed: 1. Children who are taking antibiotics in the 30 days prior to the date of the encounter during which the diagnosis was established. **The numerator is revised to read:** **For the eCQMs Specifications collection type:** URI episodes without a prescription for antibiotic medication on or 3 days after the outpatient visit, telephone visit, online assessment, observation stay or emergency department visit for an upper respiratory infection. **For the MIPS CQMs Specifications collection type:** URI episodes without a prescription for antibiotic medication (from Table 1) on or 3 days after the outpatient visit, telephone visit, online assessment, observation stay or emergency department visit for an upper respiratory infection.

Category	Description
	The numerator instruction is revised to read: For the MIPS CQMs Specifications collection type: For performance, the measure will be calculated as the number of patient's encounter(s) where antibiotics from Table 1 were neither prescribed nor dispensed on or within 3 days of the episode for URI over the total number of encounters in the denominator. A higher score indicates appropriate treatment of patients with URI (e.g., the proportion for whom antibiotics were not prescribed or dispensed following the episode). Delayed prescriptions (where an antibiotic was prescribed and patient was instructed to delay taking the antibiotic) are considered "Performance Not Met". Table 1 - Antibiotic Medications Note: This list should be used when assessing antibiotic prescriptions for the denominator exclusion and numerator components. Revised: Table 1 Antibiotic Medication: Added Penicillin G benzathine and removed 'Miscellaneous Antibiotics Category' (Erythromycin-sulfisoxazole) **Updated value set: For the eCQM Specifications collection type:** Added 'Aggressive periodontitis' to the value set for competing diagnosis. Added telehealth services value set to eligible encounters.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose the measure language be updated to reflect a broader denominator eligible population by revising the age to include all patients over 3 months of age as concerns regarding overuse of antibiotics are not limited to the pediatric population. This will allow for clinicians to report on both pediatric and adult patients. The denominator instructions and guidance are revised to clarify that only the first episode should be included if a patient has multiple episodes in a 31-day period. The denominator exclusions have been updated to reflect the change in age range and to align language with the measure submission frequency. Additionally, a denominator exclusion has been added to remove patients with competing comorbid conditions from the denominator population as it may be clinically appropriate and warranted to treat them with antibiotics in accordance with appropriate care. The numerator note for the MIPS CQMs Specifications collection type was updated to clarify use of delayed prescriptions and the antibiotic medication table. Given the intent of the measure is to assess appropriate antibiotic use, delayed prescriptions will be considered numerator non-compliant as this would still constitute prescribing an antibiotic. The antibiotic medication table was also updated to be clinically relevant. The eCQM Specifications collection type value set for competing diagnosis was updated to include aggressive periodontitis as it is clinically relevant to the denominator exclusion intent. Additionally, a telehealth services value set was added to the eligible encounters for a more complete patient population.

D.12 Appropriate Testing for Children with Pharyngitis

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	066
CMS eCQM ID:	CMS146v9
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:	**The title is revised from 'Appropriate Testing for Children with Pharyngitis' to:** Appropriate Testing for Pharyngitis **The description is revised to read:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test. **The guidance is revised to read: For the eCQM Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. This eCQM is an episode-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The initial patient population is revised to read: For the eCQM Specifications collection type:** Outpatient, telephone, online assessment, observation, or emergency department (ED) visits with a diagnosis of pharyngitis and an antibiotic dispensing event among patients 3 years or older. **The denominator is revised to read: For the MIPS CQMs Specifications collection type**: Outpatient, telephone, online assessment, observation, or emergency department (ED) visits with a diagnosis of pharyngitis and an antibiotic dispending event among patients 3 years or older. **Updated denominator criteria: For the MIPS CQMs Specifications collection type**: Revised denominator eligible coding to include telehealth with qualified nonphysician health care professional. **The denominator instructions are revised to read: For the MIPS CQMs Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. If a patient has more than one eligible episode in a 31-day period, include only the first eligible episode. **Updated denominator exclusion:** **For the eCQMs Specifications collection type:** Added: 1. Exclude episodes where the patient had a competing comorbid condition during the 12 months prior to or on the episode date. Revised: 1. Exclude episodes where the patient is taking antibiotics in the 30 days prior to the episode date. 2. Exclude episodes when the patient had hospice care overlapping with the measurement period. 3. Exclude episodes where the patient had a competing diagnosis within 3 days after the episode date. **For MIPS CQMs Specifications collection type:** Added: 1. Episodes where the patient had a competing comorbid condition during the 12 months prior to or on the episode date (e.g., tuberculosis, neutropenia, cystic fibrosis, chronic bronchitis, pulmonary edema, respiratory failure, rheumatoid lung disease). Revised: 1. Episodes where the patient is taking antibiotics (Table 1) in the 30 days prior to the episode date. 2. Episodes where the patient had a competing diagnosis within 3 days after the episode date (e.g., intestinal infection, pertussis, bacterial infection, Lyme disease, otitis media, acute sinusitis, chronic sinusitis, infection of the pharynx/larynx/tonsils/ adenoids, prostatitis, cellulitis, mastoiditis, or bone infections, acute lymphadenitis, impetigo, skin staph infections, pneumonia/gonococcal infections, venereal disease (syphilis, chlamydia, inflammatory diseases [female reproductive organs]), infections of the kidney, cystitis or UTI). **Updated Table 1: For the MIPS CQMs Specifications collection type:** Added: Note: This list should be used when assessing antibiotic prescriptions for the denominator and denominator exclusion components. Revised: Table 1 – Antibiotic Medication: Added Penicillin G benzathine and removed 'Miscellaneous Antibiotics Category' (Erythromycin-sulfisoxazole) **The numerator is revised to read: For all collection types**: A group A streptococcus test in the 7-day period from 3 days prior to the episode date through 3 days after the episode date. **Updated stratification**: **For the eCQM Specifications collection type:** 3-17 years, 18-64 years, 65 years and older. **Updated value set: For the eCQM Specifications collection type:** Added telehealth services value set to eligible encounters.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose the measure language be updated to reflect a broader denominator eligible population by revising the age to include all patients over 3 months of age as concerns regarding appropriate testing are not limited to the pediatric population. This will allow for clinicians to report on both pediatric and adult patients. The denominator instructions and guidance are revised to clarify

Category	Description
	that only the first episode should be included if a patient has multiple episodes in a 31-day period. The denominator exclusions have been updated to reflect the change in age range and to align language with the measure submission frequency. Additionally, a denominator exclusion has been added to remove patients with competing comorbid conditions from the denominator population as it may be clinically appropriate and warranted to treat them with antibiotics in accordance with appropriate care. For the MIPS CQMs Specifications collection type, Table 1 was updated to remain clinically relevant and a note was added to clarify usage of Table 1 for the purposes of this measure. The eCQM Specifications collection type value set for competing diagnosis was updated to include aggressive periodontitis as it is clinically relevant to the denominator exclusion intent. Additionally, a telehealth services value set was added to the eligible encounters for a more complete patient population.

D.13 Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use

Category	Description
NQF # / eCQM NQF #:	654/N/A
Quality#:	093
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 patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.
Substantive Change:	**Updated denominator: For all collection types**: Added telehealth as eligible encounter.
Steward:	American Academy of Otolaryngology – Head and Neck Surgery
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.14 Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 0104e
Quality#:	107
CMS eCQM ID:	CMS161v9
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:	**The description is revised to read:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit. **Updated guidance:** Added: In recognition of the growing use of integrated and team-based care, the diagnosis of dementia and the assessment of cognitive function need not be performed by the same provider or clinician. **The initial patient population is revised to read:** Patient visits during which a new diagnosis of MDD, single or recurrent episode, was identified. **The numerator is revised to read:** Patient visits during which a new diagnosis of MDD, single or recurrent episode, was identified and a suicide risk assessment was completed during the visit.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the description, initial patient population, and numerator language to better align with the measure intent and clarify that the measure is episodic in nature. The measure steward updated the guidance statement based upon technical expert feedback to reflect that team-based care would be appropriate for this measure. We agree that this guidance update is clinically appropriate and aligns better with clinical care workflows.

D.15 Preventive Care and Screening: Influenza Immunization

Category	Description
NQF # / eCQM NQF #:	0041 / 0041e
Quality#:	110
CMS eCQM ID:	CMS147v10
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 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.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications **Updated guidance: For the eCQM Specifications collection type:** Revised: Due to the changing stance 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 to review the guidelines for each flu season to determine appropriateness of the LAIV and other formulations of the flu vaccine. Should the LAIV be recommended for administration for a particular flu season, eligible professional or clinician may consider one of the following options: 1) satisfy the numerator by reporting either previous receipt or using the CVX 88 for unspecified formulation, 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 is a patient-based measure. **Updated denominator note: For the Medicare Part B Claims Measure Specifications collection type:** Added: For the purposes of the program, to submit on the flu season 2020-2021, the patient must have a qualifying encounter between January 1 and March 31, 2021. to submit on the flu season 2021-2022, the patient must have a qualifying encounter between October 1 and December 31, 2021. A qualifying encounter needs to occur within the flu season that is being submitted; any additional encounter(s) may occur at any time within the measurement period. **Updated denominator exception: For the eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication. **Updated denominator: For all collection types:** Added telehealth as eligible encounter.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the denominator note for the Medicare Part B Claims Measure Specifications collection type to add clarity and align the language with the MIPS CQMs Specifications collection type. We propose to update the guidance for the eCQM Specifications collection type to better align with the updated CDC/ACIP clinical guidelines and to clarify the intent of the measure. We also propose to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. We propose to add telehealth encounters as denominator eligible as the telehealth setting is 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 remove the CMS Web Interface Measure Specifications collection type. This collection type is proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this proposed rule.

D.16 Breast Cancer Screening

Category	Description
NQF # / eCQM NQF #:	2372 / N/A
Quality#:	112
CMS eCQM ID:	CMS125v9
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 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.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications **Updated denominator exclusion: For the eCQM Specifications collection type:** Removed logic and value set related to unilateral mastectomy. **Updated denominator exclusion: For the eCQM Specifications collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications collection type and the MIPS CQMs Specifications collection type:** Added coding to identify patients with advanced illness and frailty
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. For the eCQM Specifications collection, we propose removing the logic and value set related to unilateral mastectomy to ensure that all patients with existing breast tissue are included in the initial patient population as it is important they receive screening for breast cancer on remaining breast tissue. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we propose adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure We propose to remove the CMS Web Interface Measure Specifications collection type. This collection type is proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this proposed rule.

D.17 Colorectal Cancer Screening

Category	Description
NQF # / eCQM NQF #:	0034 / N/A
Quality#:	113
CMS eCQM ID:	CMS130v9
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:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications. **Updated denominator exclusion: For the eCQM Specifications collection type:** Revised: 1. Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. 2. Exclude patients with a diagnosis or past history of total colectomy or colorectal cancer. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator criteria: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types**: Removed coding not applicable to preventive value sets. **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period. **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added coding to identify patients with advanced illness and frailty.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. For the eCQM Specifications collection type we also propose to revise the language for the exclusion for diagnosis or past history of total colectomy or colorectal cancer for clarity and to align with the other denominator exclusions. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we propose adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. We propose to remove denominator eligible coding that is not applicable to a preventive value set and may not be appropriate for inclusion in the measure's denominator eligible patient population. We propose to remove the CMS Web Interface Measure Specifications collection type. This collection type is proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this proposed rule.

D.18 Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis

Category	Description
NQF # / eCQM NQF #:	0058 / N/A
Quality#:	116
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 adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.
Substantive Change:	**The title is revised from 'Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis' to:** Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis. **The description is revised to read:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event. **The instructions are revised to read:** This measure is to be submitted at each occurrence of acute bronchitis/bronchiolitis during the performance period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. **The denominator is revised to read:** All patients aged 3 months or older with an outpatient, telephone visit, online assessment, observation visit or emergency department (ED) visit with a diagnosis of acute bronchitis/bronchiolitis during the measurement period. **Updated denominator criteria:** Revised: Patients 3 months of age and older on date of encounter. Added: Diagnosis for bronchiolitis. **Updated denominator exclusion:** Revised: 1. Outpatient, ED or Observation visits that result in an inpatient admission. Added: 2. Acute bronchitis/bronchiolitis episodes when the patient had a new or refill prescription of antibiotics (Table 1) in the 30 days prior to or on the episode date. **The denominator note is revised to read:** Do not include outpatient, ED or observation visits that result in an inpatient admission. When an outpatient, ED or observation visit and an inpatient stay are billed on separate claims, the visit results in an inpatient stay when the outpatient/ED/observation date of service occurs on the day prior to the admission date or any time during the admission (admission date through discharge date). An outpatient, ED or observation visit billed on the same claim as an inpatient stay is considered a visit that resulted in an inpatient stay. **The numerator instructions are revised to read:** For performance, the measure will be calculated as the number of patient encounters where antibiotics were neither prescribed nor dispensed on or within 3 days of the episode for acute bronchitis/bronchiolitis over the total number of encounters in the denominator (patients aged 3 months and older with an outpatient, telephone, online assessment, observation or ED visit for acute bronchitis/bronchiolitis). A higher score indicates appropriate treatment of patients with acute bronchitis/bronchiolitis (e.g., the proportion for whom antibiotics were not prescribed or dispensed on or 3 days after the encounter). Delayed prescriptions (where an antibiotic was prescribed and patient was instructed to delay taking the antibiotic) are considered "Performance Not Met". **Updated numerator instructions:** Added: Note: This list should be used when assessing antibiotic prescriptions for the denominator exclusion and numerator components. Removed "Norfloxacin" from Table 1 – Antibiotic Medications.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose the measure language be updated to reflect a broader denominator eligible population by revising the age to include all patients over 3 months of age as concerns regarding appropriate use of antibiotics are not limited to the adult population. This will allow for clinicians to report on both pediatric and adult patients. The title, description, instructions, and denominator are also being revised to include the diagnosis of bronchiolitis as denominator eligible to better align with the broadened age range as bronchiolitis is more commonly seen in babies and children. The diagnosis is clinically relevant to the intent of this measure. The denominator exclusion and denominator note are revised to better clarify that all visits resulting in an inpatient admission should be excluded as it may be clinically appropriate and warranted to treat them with antibiotics in accordance with appropriate care. The numerator instructions have been updated to align language with the denominator patient population updates, as well as to clarify that delayed prescriptions are still considered to be a "Performance Not Met" as the clinician is still prescribing or dispensing a prescription, which does not align with the measure's intent.

D.19 Diabetes: Eye Exam

Category	Description
NQF # / eCQM NQF #:	0055 / N/A
Quality#:	117
CMS eCQM ID:	CMS131v9
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 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.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications:** Revised: Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added coding to identify patients with advanced illness and frailty. **The numerator options are revised to read: For the MIPS CQM Specifications and Medicare Part B Claims Measure Specifications collection type:** **Performance Met:** • Dilated retinal eye exam with interpretation by an ophthalmologist or optometrist documented and reviewed. • Dilated retinal eye exam with interpretation by an ophthalmologist or optometrist documented and reviewed; without evidence of retinopathy. • 7 standard field stereoscopic photos with interpretation by an ophthalmologist or optometrist documented and reviewed. • 7 standard field stereoscopic photos with interpretation by an ophthalmologist or optometrist documented and reviewed; without evidence of retinopathy. • Eye imaging validated to match diagnosis from 7 standard field stereoscopic photos results documented and reviewed. • Eye imaging validated to match diagnosis from 7 standard field stereoscopic photos results documented and reviewed, without evidence of retinopathy. • Low risk for retinopathy (no evidence of retinopathy in the prior year)*. **Performance Not Met:** • Dilated eye exam was not performed, reason not otherwise specified. **Updated numerator options note: For the MIPS CQM Specifications and Medicare Part B Claims Measure Specifications collection type:** Removed: ****Note:** For Performance Year 2020 reporting, the Centers for Medicare & Medicaid Services and the American Medical Association have approved the use of the 8P modifier with HCPCS codes to report the Performance Not Met numerator option for Quality ID #117.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we propose adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. The numerator options are being updated to stratify numerator compliant patients into those who are complaint and those who are compliant with evidence of retinopathy. This granularity will give a better picture of the patient population and the percentage of those patients who did not have evidence of retinopathy, and may fall into low risk for retinopathy, for the purposes of this measure. The numerator option note associated with the "Performance Not Met" option is being removed as it will not be applicable as the numerator options are being updated.

D.20 Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Category	Description
NQF # / eCQM NQF #:	0066 / N/A
Quality#:	118
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 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.
Substantive Change:	**Updated denominator criteria**: Added: Eligible coding for the additional patient encounter is identical to 'Patient encounter during the performance period' criteria. **Updated denominator:** Added telehealth as eligible for all encounters.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. Additionally, we propose to clarify the denominator eligible coding for the two visits necessary for denominator eligibility.

D.21 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: For the eCQM Specifications collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic**: **For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For the MIPS CQMs Specifications collection type:** Revised: Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period **Updated denominator exclusion: For the MIPS CQMs Specifications collection type**: Added coding to identify patients with advanced illness and frailty.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we propose adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure.

D.22 Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation

Category	Description
NQF # / eCQM NQF #:	0417 / N/A
Quality#:	126
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 diabetes mellitus who had a neurological examination of their lower extremities within 12 months.
Substantive Change:	**Updated denominator exception:** Added: Clinician documented that patient had medical reason for not performing lower extremity neurological exam.
Steward:	American Podiatric Medical Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add a denominator exception for patients with medical reasons for not performing a lower extremity neurological exam. As there may be instances where a patient is denominator eligible, however, a lower extremity neurological exam would not be reasonably performed due the presence of a burn, ulceration, or infection, for example. Adding this denominator exception allows the MIPS eligible clinician to exercise their clinical judgement as to when it is not feasible to perform a lower extremity neurological exam.

D.23 Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear

Category	Description
NQF # / eCQM NQF #:	0416 / N/A
Quality#:	127
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 diabetes mellitus who were evaluated for proper footwear and sizing.
Substantive Change:	**Updated denominator exclusion:** Added: Clinician documented that patient was not an eligible candidate for evaluation of footwear as patient is bilateral lower extremity amputee.
Steward:	American Podiatric Medical Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add a denominator exclusion for bilateral lower extremity amputee as this patient population is not applicable to this measure and should not be included in the denominator eligible patient population.

D.24 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	128
CMS eCQM ID:	CMS69v9
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 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m2.
Substantive Change:	**The description is revised to read:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous 12 months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters. **Updated guidance: For the eCQM Specifications collection type:** Removed: Review the following to apply the Medical Reason exception criteria: The Medical Reason exception could include, but is not limited to, the following patients as deemed appropriate by the health care provider: * Elderly patients (65 or older) for whom weight reduction/weight gain would complicate other underlying health conditions such as the following examples: * Illness or physical disability * Mental illness, dementia, confusion * Nutritional deficiency such as Vitamin/mineral deficiency * Patients in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status Revised: See denominator exception section for examples. **Updated definition: For all collection types:** Added: Normal BMI Parameters – Age 18 years and older BMI >= 18.5 and < 25 kg/m2 **For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: Not Eligible for BMI Calculation or Follow-Up Plan (Denominator Exclusion) – A patient is not eligible if one or more of the following reasons are documented: • Patients receiving palliative or hospice care on the date of the current encounter or any time prior to the current encounter • Patients who are pregnant on the date of the current encounter or any time during the measurement period prior to the current encounter Patients with no documented BMI or a documented BMI outside normal parameters and a documented reason for not completing BMI follow-up plan during the current encounter or within the previous 12 months of the current encounter (Denominator Exception) • Patients with a documented medical reason for not documenting BMI or for not documenting a follow-up plan for a BMI outside normal parameters (e.g., elderly patients (65 or older) for whom weight reduction/weight gain would complicate other underlying health conditions such as illness or physical disability, mental illness, dementia, confusion, or nutritional deficiency such as vitamin/mineral deficiency; patients in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status) • Patients who refuse measurement of height and/or weight on the date of the current encounter or any time during the measurement period prior to the current encounter **Updated denominator exclusion: For the eCQM Specifications collection type:** Removed: Patients who refuse measurement of height and/or weight. Added: Hospice care value sets **Updated denominator exception:** **For the eCQM Specifications collection type:** Added: Patients who refuse measurement of height and/or weight. Revised: Patients with a documented medical reason for not documenting BMI or for not documenting a follow-up plan for a BMI outside normal parameters (e.g., elderly patients (65 or older) for whom weight reduction/weight gain would complicate other underlying health conditions such as illness or physical disability, mental illness, dementia, confusion, or nutritional deficiency such as vitamin/mineral deficiency; patients in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). **For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection type:** Added: BMI not documented due to medical reason OR patient refusal of height or weight measurement. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	Centers for Medicare & Medicaid Services

Category	Description
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure description language to reduce redundancy throughout the specification and clarify the intent. The guidance for the eCQM Specifications collection type was updated to move the medical reason exception language to the denominator exceptions header as this language is more suitable for this field. The definition for "Normal BMI Parameters" was moved to the definition section as it is more applicable here and helps readability. During the change review process, the patient refusal denominator exclusion was moved to the denominator exception. We agree that patient refusal is more appropriately classified as a denominator exception as the patient would still be denominator eligible. For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection type, the definitions for the denominator exclusion and denominator exception were updated to reflect the changes and to align language across collection types. Additionally, a denominator exception was added to reflect the definition revisions and capture patients for whom BMI was not documented due to medical reasons or patient refusal. We propose to remove telehealth encounters from the denominator of the eCQM Specifications collection type as telehealth is not an appropriate setting for this measure, as well as to align with the other collection types. This guidance can be found in a separate document that will be published on the eCQI Resource Center.

D.25 Documentation of Current Medications in the Medical Record

Category	Description
NQF # / eCQM NQF #:	0419 / 0419e
Quality#:	130
CMS eCQM ID:	CMS68v10
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**The description is revised to read: For all collection types:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. **The guidance is revised to read: For the eCQM Specifications collection type**: This eCQM is an episode-based measure. This measure is to be reported for every encounter during the measurement period. Eligible professionals or eligible clinicians reporting this measure may document medication information received from the patient, authorized representative(s), caregiver(s) or other available healthcare resources. This list must include all known prescriptions, over-the-counter (OTC) products, herbals, vitamins, minerals, dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration. This measure should also be reported if the eligible professional or eligible clinician documented the patient is not currently taking any medications. By reporting the action described in this measure, the provider attests to having documented a list of current medications utilizing all immediate resources available at the time of the encounter. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The denominator exception is revised to read: For the eCQM Specifications collection type:** Documentation of a medical reason(s) for not documenting, updating, or reviewing the patient's current medications list (e.g., patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). **The numerator is revised to read: For all collection types:** Eligible professional or eligible clinician attests to documenting, updating or reviewing the patient's current medications using all immediate resources available on the date of the encounter. **Updated numerator note: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added: This list must include ALL known prescriptions, over-the-counter (OTC) products, herbals, vitamins, minerals, dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration. **Updated denominator exception: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection type:** Revised: Documentation of a medical reason(s) for not documenting, updating, or reviewing the patient's current medications list (e.g., patient is in an urgent or emergent medical situation).
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the measure description to remove language that is more appropriate for the guidance/notes sections of the measure specification. This will help with measure intent, clarity, and readability. The guidance for the eCQM Specifications collection type has been updated to clarify the intent of the measure. The intent is to document all known prescriptions, since the measure steward believes that MIPS eligible clinician should not be held accountable for information that is not available utilizing all immediate resources. The denominator exception was updated in all collection types to add clarity regarding use of the denominator exception and to align the language throughout the specification. The numerator notes for the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types was updated with information removed from the description. This information outlines what is necessary for numerator compliance and is better suited for the numerator notes section for ease of use.

D.26 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	0418 / 0418e
Quality#:	134
CMS eCQM ID:	CMS2v10
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 or 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.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, and MIPS CQMs Specifications. **The description is revised to read: For all collection types:** 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. **The definition is revised to read: For all collection types:** Screening: Completion of a clinical or diagnostic tool used to identify people at risk of developing or having a certain disease or condition, even in the absence of symptoms. Standardized Depression Screening Tool: A normalized and validated depression screening tool developed for the patient population in which it is being utilized Examples of standardized depression screening tools include but are not limited to: * Adolescent Screening Tools (12-17 years) * Patient Health Questionnaire for Adolescents (PHQ-A) * Beck Depression Inventory-Primary Care Version (BDI-PC) * Mood Feeling Questionnaire (MFQ) * Center for Epidemiologic Studies Depression Scale (CES-D) * Patient Health Questionnaire (PHQ-9) * Pediatric Symptom Checklist (PSC-17) * PRIME MD-PHQ2 * Adult Screening Tools (18 years and older) * Patient Health Questionnaire (PHQ9) * Beck Depression Inventory (BDI or BDI-II) * Center for Epidemiologic Studies Depression Scale (CES-D) * Depression Scale (DEPS) * Duke Anxiety-Depression Scale (DADS) * Geriatric Depression Scale (GDS) * Cornell Scale for Depression in Dementia (CSDD) * PRIME MD-PHQ2 * Hamilton Rating Scale for Depression (HAM-D) * Quick Inventory of Depressive Symptomatology Self-Report (QID-SR) * Computerized Adaptive Testing Depression Inventory (CAT-DI) * Computerized Adaptive Diagnostic Screener (CAD-MDD) * Perinatal Screening Tools * Edinburgh Postnatal Depression Scale * Postpartum Depression Screening Scale * Patient Health Questionnaire 9 (PHQ-9) * Beck Depression Inventory * Beck Depression Inventory-II * Center for Epidemiologic Studies Depression Scale * Zung Self-rating Depression Scale Follow-Up Plan: Documented follow-up for a positive depression screening must include one or more of the following: * Referral to a practitioner who is qualified to diagnose and treat depression * Pharmacological interventions * Other interventions or follow-up for the diagnosis or treatment of depression **The numerator definition is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection type:** Examples of a follow-up plan include but are not limited to: • Referral to a practitioner or program for further evaluation for depression, for example, referral to a psychiatrist, psychologist, social worker, mental health counselor, or other mental health service such as family or group therapy, support group, depression management program, or other service for treatment of depression • Other interventions designed to treat depression such as behavioral health evaluation, psychotherapy, pharmacological interventions, or additional treatment options Patients with a Documented Reason for not Screening for Depression (Denominator Exception) Patient Reason(s) Patient refuses to participate OR

Category	Description
	Medical Reason(s) Documentation of medical reason for not screening patient for depression (e.g., cognitive, functional, or motivational limitations that may impact accuracy of results; patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status) **Updated denominator exclusion definition: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection type:** Revised: Not Eligible for Depression Screening or Follow-Up Plan (Denominator Exclusion) Patients who have been diagnosed with bipolar disorder- F31.10, F31.11, F31.12, F31.13, F31.2, F31.30, F31.31, F31.32, F31.4, F31.5, F31.60, F31.61, F31.62, F31.63, F31.64, F31.70, F31.71, F31.72, F31.73, F31.74, F31.75, F31.76, F31.77, F31.78, F31.81, F31.89, F31.9 Patients who have been diagnosed with depression-- F01.51, F32.0, F32.1, F32.2, F32.3, F32.4, F32.5, F32.89, F32.9, F33.0, F33.1, F33.2, F33.3, F33.40, F33.41, F33.42, F33.8, F33.9, F34.1, F34.81, F34.89, F43.21, F43.23, F53.0, F53.1, O90.6, O99.340, O99.341, O99.342, O99.343, O99.345 **The guidance is revised to read: For the eCQM Specifications collection type:** A depression screen is completed 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 must be documented on the date of the encounter, such as referral to a practitioner who is qualified to treat depression, pharmacological interventions or other interventions for the treatment of depression. This eCQM is a patient-based measure. Depression screening is required once per measurement period, not at all encounters. The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have ever been diagnosed with depression or bipolar disorder will be excluded from the measure. Screening Tools: * An age-appropriate, standardized, and validated depression screening tool must be used for numerator compliance. * The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record * The depression screening must be reviewed and addressed in the office of the provider, filing the code, on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention as determined by the provider practice * The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter * The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool Follow-Up Plan: The follow-up plan must be related to a positive depression screening, for example: "Patient referred for psychiatric evaluation due to positive depression screening." Examples of a follow-up plan include but are not limited to: * Referral to a practitioner or program for further evaluation for depression, for example, referral to a psychiatrist, psychologist, social worker, mental health counselor, or other mental health service such as family or group therapy, support group, depression management program, or other service for treatment of depression * Other interventions designed to treat depression such as behavioral health evaluation, psychotherapy, pharmacological interventions, or additional treatment options Should a patient screen positive for depression, a clinician should opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool will not qualify as a follow-up plan. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated denominator criteria: For the Medicare Part B Claims Measures Specifications and the MIPS CQMs Specifications collection types:** Revised: Patients aged ≥ 12 years. **For the eCQM Specifications collection type:** Added physical therapy MIPS eligible clinician. **Updated denominator note: For the Medicare Part B Claims Measures Specifications and the MIPS CQMs Specifications collection types:** Added: The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have ever been diagnosed with depression or bipolar disorder will be excluded from the measure. **Updated denominator exclusion:** **For the eCQM Specifications collection type:** Revised: Patients who have been diagnosed with depression or with bipolar disorder. **For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection type:** Revised: Documentation stating the patient has had a diagnosis of depression or has had a diagnosis of bipolar disorder. **Updated numerator: For the eCQM Specifications collection type:** Removed additional evaluation or assessment for depression and suicide risk assessment as follow-up from the measure in header and from technical specifications and add guidance statement regarding suicide risk assessment. **The numerator instruction is revised to read: For the Medicare Part B Claims Measures Specifications collection type and the MIPS CQM Specifications collection type:** A depression screen is completed 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

Category	Description
	plan must be documented on the date of the encounter, such as referral to a practitioner who is qualified to treat depression, pharmacological interventions or other interventions for the treatment of depression. Depression screening is required once per measurement period, not at all encounters. An age-appropriate, standardized, and validated depression screening tool must be used for numerator compliance. The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record. The depression screening must be reviewed and addressed in the office of the provider on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention as determined by the provider practice. The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter. The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Should a patient screen positive for depression, a clinician should opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool, will not qualify as a follow-up plan.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the description to provide clarity and better align with the measure intent. We propose to update the measure language in the definitions, guidance, and numerator note sections to provide clarity as to what constitutes a follow-up plan. The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, since that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Additionally, suicide risk assessments have been removed as a numerator compliant follow-up plan option as this should be completed when appropriate and based on the assessment by the clinician regarding the severity of the patient's symptoms of depression at the time of depression screening. We also propose to update the measure language and denominator exclusions to reflect that this measure is screening of depression for patients who have not been previously diagnosed or have an active diagnosis of depression or bipolar disorder. This preventive measure assesses screening and follow up plan for patients that are screened positive for depression. We also propose to update the denominator criteria for the Medicare Part B Claims Measure Specifications and the MIPS CQM Specifications collection types to align with the measure denominator language which states patients age 12 or older at the beginning of the measurement period. Additionally, we propose to add the physical therapy MIPS eligible clinician type based on stakeholder feedback regarding the applicability of this measure to this clinician type. We propose to remove the CMS Web Interface Measure Specifications collection type. This collection type is proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this proposed rule.

D.27 Melanoma: Continuity of Care – Recall System

Category	Description
NQF # / eCQM NQF #:	N/A/N/A
Quality#:	137
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, 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.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Structure
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.28 Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care

Category	Description
NQF # / eCQM NQF #:	0563 / N/A
Quality#:	141
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 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.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications
Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications as it shows very high performance year after year leaving little opportunity to drive improvement in quality outcomes. 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.

D.29 Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
NQF # / eCQM NQF #:	0384 / 0384e
Quality#:	143
CMS eCQM ID:	CMS157v9
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 logic**: **For the eCQM Specifications collection type:** Revised logic to limit the date range for chemotherapy administered within 31 days before and after the measurement period. Added definition: Chemotherapy within 30 days Prior and After the Measurement Period. **The guidance is revised to read: For the eCQM Specifications collection type:** This eCQM 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 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. A lookback (retrospective) period of 7 days, including the billing date, may be used to identify the actual face-to-face encounter, which is required to assess the numerator. Therefore, pain intensity should be quantified during the face-to-face encounter occurring on the actual billing date or within the 6 days prior to the billing date. 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. Pain intensity should be quantified using a standard instrument, such as a 0-10 numerical rating scale, visual analog scale, a categorical scale, or pictorial scale. Examples include the Faces Pain Rating Scale and the Brief Pain Inventory (BPI). This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated Instructions: For the MIPS CQM Specifications collection type:** Revised note to reflect both face-to-face and telehealth encounters are allowed. **The denominator note is revised to read: For the MIPS CQMs Specifications collection type:** For the reporting purposes for this measure, in instances where CPT code 77427 is reported, the billing date, which may or may not be the same date as the face-to-face or telehealth encounter with the physician, should be used to pull the appropriate patient population into the denominator. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face or telehealth encounter during the series of treatments. A lookback (retrospective) period of 7 days, including the billing date, may be used to identify the actual face-to-face or telehealth encounter, which is required to assess the numerator. Therefore, pain intensity should be quantified during the face-to-face or telehealth encounter occurring on the actual billing date or within the 6 days prior to the billing date. **Updated denominator: For all collection types:** Added telehealth as eligible encounter.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the logic within the eCQM Specifications collection type to limit the range of time for chemotherapy procedures to only capture the chemotherapy procedures that satisfy the measure requirements. This will decrease implementation burden for some MIPS eligible clinicians while improving reporting capabilities for some practices. Additionally, the eCQM Specifications and MIPS CQMs Specifications collection types the guidance/denominator note is proposed to be revised to allow for a lookback period when utilizing CPT codes that may not have the same billing and encounter date. This will align more closely with actual clinical workflow and encounter billing practices. We propose to add telehealth encounters as denominator eligible for submission criteria 1 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.30 Oncology: Medical and Radiation - Plan of Care for Pain

Category	Description
NQF # / eCQM NQF #:	0383 / N/A
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 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.
Substantive Change:	**Updated instructions:** Added: THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE: 1) All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who report having pain OR 2) All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain **The denominator is revised to read:** Submission Criteria 1: All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who reporting having pain Denominator (Submission Criteria 1): All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who report having pain Submission Criteria 2: All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain Denominator (Submission Criteria 2): All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain **Updated denominator: For all collection types:** Added telehealth as eligible encounter. **Updated denominator criteria:** Revised: Submission Criteria One • Removed coding for radiation therapy Submission Criteria Two • Added coding for cancer diagnosis • Added coding for patient procedure **Updated denominator note: For Submission Criteria Two:** Added: For the reporting purposes of this measure, in instances where CPT code77427 is reported, the billing date, which may or may not be the same date as the face-to-face or telehealth encounter with the physician, should be used to pull the appropriate patient population into the denominator. 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. **The numerator is revised to read:** NUMERATOR (SUBMISSION CRITERIA 1): Patient visits that included a documented plan of care to address pain. NUMERATOR (SUBMISSION CRITERIA 2): Patient visits that included a documented plan of care to address pain. **Updated numerator instructions: For Submission Criteria Two:** Added: A documented plan of care may include: use of opioids, nonopioid analgesics, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval. **Updated numerator options: For Submission Criteria Two:** Added: **Performance Met:** Plan of care to address pain documented **Performance Not Met:** Plan of care for pain not documented, reason not otherwise specified
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to separate the measure into two submission criteria based upon treatment to add clarity based on stakeholder feedback. This also aligns the measure with the format of measure Q143: Oncology: Medical and Radiation – Pain Intensity Quantified. The patient procedure coding was updated to ensure only coding applicable to the updated submission criteria is included within the denominator criteria. We propose to add telehealth encounters as denominator eligible for submission criteria 1 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.31 Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	145
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:	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).
Substantive Change:	**Updated numerator instructions: For all collection types:** Added: Documentation: Information populating the final report may reside in a dedicated field in the electronic health record (EHR) or picture archiving and communication system (PACS), however fluoroscopy exposure dose or time should be included in the final report to be readily accessible in all circumstances.
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the denominator criteria encounter coding to ensure that all of the codes are associated with fluoroscopy and to create a more complete patient population. Additionally, we propose to add numerator instructions to further clarify how the fluoroscopy information should be recorded in the final report to be numerator compliant and meet the intent of the measure.

D.32 Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	147
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 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.
Substantive Change:	**The denominator is revised to read: For all collection types:** All final reports for patients, regardless of age, undergoing bone planar and whole body scintigraphy.
Steward:	Society of Nuclear Medicine and Molecular Imaging
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the denominator to account for encounter codes that can be utilized for imaging other than bone scintigraphy. This will narrow the eligible patient population to those using bone imaging agents and only assess MIPS eligible clinicians that are relevant to this measure's intent.

D.33 Rheumatoid Arthritis (RA): Tuberculosis Screening

Category	Description
NQF # / eCQM NQF #:	N/A / 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:	**The title is revised from 'Rheumatoid Arthritis (RA): Tuberculosis Screening' to:** Tuberculosis Screening Prior to First Course Biologic Therapy **The description is revised to read:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period. **The instructions are revised to read:** This measure is to be submitted a minimum of once per performance period for patients who are being considered or prescribed a first course of biologic disease-modifying anti-rheumatic drug therapy seen during the performance period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. **The denominator is revised to read:** All patients aged 18 years and older who are receiving a first course of therapy using a biologic DMARD. **The denominator instructions are updated to read:** Patients are considered to be receiving a first course of therapy using a biologic DMARD only if they have been prescribed DMARD biologic therapy during the measurement period and were not prescribed DMARD biologic therapy in the 12 months preceding the encounter where DMARD biologic therapy was newly started. Biologic DMARD therapy includes:-Abatacept (Orencia) -Adalimumab (HUMIRA) -Anakinra (Kineret) -Baricitinib (Olumiant) -Canakinumab (ILARIS) -Certolizumab pegol and lyophilized certolizumab pegol (CIMZIA) -Denosumab (Prolia) -Etanercept (Enbrel) -Golimumab (Simponi) -Infliximab (REMICADE) -Infliximab-dyyb (Inflectra) -Infliximab-abda (Renflexis) -Sarilumab (KEVZARA) -Secukinumab (Cosentyx) -Tocilizumab (ACTEMRA) -Tofacitinib (XELJANZ) -Ustekinumab (STELARA) The list of biologic DMARD therapies is subject to change as new therapies are approved by the FDA. **Updated denominator criteria:** Removed: 'Diagnosis for RA' criteria Revised**:** Patient receiving first-time biologic disease modifying anti-rheumatic drug therapy **Updated denominator:** Added telehealth as eligible encounter. **The numerator is revised to read:** Patients for whom any record of TB testing is documented or performed (PPD, IFN-gamma release assays, or other appropriate method) in the medical record in the 12 months preceding the biologic prescription. **Updated numerator definition:** Removed 'Biologic DMARD Therapy' definition. **Updated numerator options:** Revised: **Performance Met:** TB screening performed and results interpreted within 12 months prior to initiation of first-time biologic disease modifying anti-rheumatic drug therapy.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to expand the measure to remove disease specificity from the measure to assess all patients prescribed a first course biologic DMARD therapy. This will expand monitoring of patient safety guidance compliance to all patients initiating DMARD therapy. The language throughout the measure has been updated to align with the change in patient population. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.34 Rheumatoid Arthritis (RA): Functional Status Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	178
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) for whom a functional status assessment was performed at least once within 12 months.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.35 Rheumatoid Arthritis (RA): Glucocorticoid Management

Category	Description
NQF # / eCQM NQF #:	N/A / 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 > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.36 Elder Maltreatment Screen and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / 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: For all collection types:** Added care management services.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add coding applicable to chronic care management services as these capture encounters where screening may occur and is an appropriate patient population for this measure.

D.37 Functional Outcome Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
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: For all collection types:** Added home health and domiciliary/rest home settings. **The numerator note is revised to read: For all collection types**: The intent of this measure is for a functional outcome assessment tool to be utilized at a minimum of every 30 days but submission is only required at each qualifying encounter due to coding limitations. Therefore, for visits occurring within 30 days of a previously documented functional outcome assessment, the numerator quality-data code G8942 should be used for submission purposes. **Updated numerator definition: For all collection types**: Revised: Current (Functional Outcome Assessment) – A patient having a documented functional outcome assessment utilizing a standardized tool and a care plan if indicated at a qualifying encounter within the previous 30 days.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add the home health and domiciliary/rest home settings as denominator eligible settings as functional assessments may occur at these visits and would lead to a more complete denominator eligible patient population. Additionally, we propose to update the definition for 'Current (Functional Outcome Assessment)' and the numerator note to clarify the measure intent, which is to only report for qualifying encounters and not each visit.

D.38 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:	CMS133v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years 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.
Substantive Change:	**Updated numerator: For the eCQM Specifications collection type:** Added data element: "Best Corrected Visual Acuity Exam Using Snellen Chart" (2.16.840.1.113883.3.526.3.1560)
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	For the eCQM Specifications collection type, we propose to add a data element for "Best Corrected Visual Acuity Exam Using Snellin Chart" allowing an alternative method to capture an exam commonly used in clinical practice that may not have been accurately captured prior. This added numerator compliant option is clinically in line with the measure intent and appropriate for inclusion.

D.39 Radiology: Stenosis Measurement in Carotid Imaging Reports

Category	Description
NQF # / eCQM NQF #:	0507 / N/A
Quality#:	195
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 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.
Substantive Change:	**The instructions are revised to read: For all collection types:** This measure is to be submitted each time a carotid imaging study is performed during the performance period for patients aged 18 years and older during the submission period. There is no diagnosis associated with this measure. Merit-based Incentive Payment System (MIPS) eligible clinicians who provide the professional component of diagnostic imaging studies of the carotids will submit this measure. **The denominator is revised to read: For all collection types**: All final reports for carotid imaging studies (neck MR angiography [MRA], neck CT angiography [CTA], neck duplex ultrasound, carotid angiogram) performed on patients aged 18 years and older during the submission period. **Updated denominator criteria: For all collection types:** Added: Patients aged ≥ 18 years on date of encounter.
Steward:	American College of Radiology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure's eligible patient population to include only patients aged 18 years and older. This will allow for closer monitoring regarding who is eligible and more appropriate for inclusion in the eligible patient population, which will decrease overall burden for the clinicians reporting this measure.

D.40 Functional Status Change for Patients with Knee Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
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:	**The description is revised to read:** 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 FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). 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 level, 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). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exclusion:** Revised: Patient unable to complete the LEPF PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility and an adequate proxy is not available. **The numerator is revised to read:** Patients who were presented with the LEPF 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. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown). **Updated numerator options:** Revised: **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the knee impairment not measured because the patient did not complete the LEPF PROM at Initial Evaluation and/or near Discharge, reason not given.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to update the description, denominator exclusion, numerator statement, and numerator options to reflect the change in functional assessment tool, Knee FS PROM to the LEPF PROM. The assessment is being revised to address scientific updates and maintenance necessary for item-response theory based outcome measures. We propose to update the denominator exception language to add clarity and better align with measure's intent.

D.41 Functional Status Change for Patients with Hip Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
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:	**The description is revised to read:** 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 FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). 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 level, 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). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exclusion:** Revised: Patient unable to complete the LEPF PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility and an adequate proxy is not available. **The numerator is revised to read:** Patients who were presented with the LEPF 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. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown). **Updated numerator options:** Revised: **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the hip impairment not measured because the patient did not complete the LEPF PROM at Initial Evaluation and/or near discharge, reason not given.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to update the description, denominator exclusion, numerator statement, and numerator options to reflect the change in functional assessment tool, Hip FS PROM to the LEPF PROM. The assessment is being revised to address scientific updates and maintenance necessary for item-response theory based outcome measures. We propose to update the denominator exception language to add clarity and better align with measure's intent.

D.42 Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
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) is 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:	**The description is revised to read:** 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) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). 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 level, 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). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator criteria:** Revised ICD-10 coding for 'With a lower leg, foot, or ankle impairment and/or diagnosis pertaining to a functional deficit affecting lower leg, foot, or ankle'. **Updated denominator exclusion:** Revised: Patient unable to complete the LEPF PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility and an adequate proxy is not available. **The numerator is revised to read:** Patients who were presented with the LEPF 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. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown). **Updated numerator options:** Revised: **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the lower leg, foot or ankle impairment not measured because the patient did not complete the LEPF PROM at Initial Evaluation and/or near discharge, reason not given.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to update the description, denominator exclusion, numerator statement, and numerator options to reflect the change in functional assessment tool, Hip FS PROM to the LEPF PROM. The assessment is being revised to address scientific updates and maintenance necessary for item-response theory based outcome measures. We propose to update the denominator exception language to add clarity and better align with measure's intent. Additionally, we propose to update the ICD-10 coding related to the denominator criteria statement, 'With a lower leg, foot, or ankle impairment and/or diagnosis pertaining to a functional deficit affecting lower leg, foot, or ankle,' to align with current coding.

D.43 Functional Status Change for Patients with Low Back Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
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 to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** 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 FOTO Low Back FS patient-reported outcome measure (PROM). 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 level, 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). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to refine the description for easier readability. We propose to update the denominator exception language to add clarity and better align and communicate the measure's intent.

D.44 Functional Status Change for Patients with Shoulder Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
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:	**The description is revised to read:** 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 FOTO Shoulder FS patient-reported outcome measure (PROM). 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 level, 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). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to refine the description for easier readability. We propose to update the denominator exception language to add clarity and better align and communicate the measure's intent.

D.45 Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
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:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years− with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). 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 level, 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). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to refine the description for easier readability. We propose to update the denominator exception language to add clarity and better align and communicate the measure's intent.

D.46 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / eCQM NQF #:	0028 / 0028e
Quality#:	226
CMS eCQM ID:	CMS138v9
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 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:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, and MIPS CQMs Specifications. **The description is revised to read: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. **The description is revised to read: For the eCQM Specifications collection type**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 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 12 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 12 months AND who received tobacco cessation intervention if identified as a tobacco user **Updated instructions: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised the language to reflect a 12-month timeframe for the look back period and assessment of clinical quality action. **Updated guidance: For the eCQM Specifications collection type:** Revised: To satisfy the intent of this measure, a patient must have at least one tobacco use screening during the 12-month period. If a patient has multiple tobacco use screenings during the 12-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. Added: To promote a team-based approach to patient care, the 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. **Updated denominator: For all collection types:** Added Physical Therapy MIPS eligible clinician and telehealth as eligible encounters for all submission criteria. **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication. **Updated logic: For the eCQM Specifications collection type:** Revised to reflect a 12-month timeframe for the look back period and assessment of clinical quality action. **Updated numerator: For the eCQM Specifications collection type:** Revised to reflect a 12-month timeframe for the look back period and assessment of clinical quality action. Additionally, revised the logic to unlink the intervention from having to occur after the tobacco user status. **Updated numerator: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised to reflect a 12-month timeframe for the look back period and assessment of clinical quality action. **Updated numerator note: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised to reflect a 12-month timeframe for the look back period and assessment of clinical quality action.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the measure to shorten the look back period to 12 months and require that tobacco screening and cessation, if patient screened positive, occur every 12 months. The revision is based upon stakeholder feedback, input from the eCQM clinical review process, and the measure steward's technical expert panel (TEP). We agree that it is important to do this annually

Category	Description
	as tobacco use is an important population health concern and smoking is the leading cause of preventable death (https://www.cdc.gov/tobacco/data_statistics/fact_sheets/index.htm). The language throughout the measure specification is being revised to reflect this update. Additionally, we propose to add physical therapy MIPS eligible clinicians to the denominator eligible encounters as this is applicable to their scope of practice. For the eCQM Specifications collection type we propose to unlink the intervention from having to occur after the tobacco status within the measure logic. This revision is better aligned with the clinical reality that for patients actively trying to quit a plan will be in place and further tobacco cessation intervention is redundant, as well as lessening the burden of clinicians, especially for those patients who are not planning on quitting. The measure steward updated the guidance statement based upon technical expert feedback to reflect that team-based care would be appropriate for this measure. We agree that this guidance update is clinically appropriate and aligns better with clinical care workflows. Additionally, we propose to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. We propose to add telehealth encounters as denominator eligible as the telehealth setting is 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 remove the CMS Web Interface Measure Specifications collection type. This collection type is proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this proposed rule. 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.47 Controlling High Blood Pressure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	236
CMS eCQM ID:	CMS165v9
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 overlapping the measurement period and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specification and MIPS CQMs Specifications **Updated denominator note: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added: The diagnosis of essential hypertension must be present sometime between 1 year prior to the measurement period and before the end of the measurement period (January 1, 2020 through December 31, 2021). **Updated denominator exclusion: For the eCQM Specification collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For the MIPS CQMs Specifications and Medicare Part B Claims Measure Specification collection type:** Added coding to identify patients with advanced illness and frailty **Updated logic: For the eCQM Specifications collection type:** Change to the Essential Hypertension Diagnosis definition logic used to define the initial patient population requires hypertension overlap the measurement period indicating hypertension must be present prior to and during the measurement period. **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: 1. Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period. 2. Patients 66-80 years of age 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 66-80 years of age 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 Added: 1. Patients 81 years of age and older with at least one claim/encounter for frailty during the measurement period. **Updated instructions note/numerator note: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added: • Reported by or taken by the patient (with the exception of BP values taken by a remote monitoring device, which are then reported to the provider).
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose that the denominator exclusion language and logic be updated in all collection types to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. For the eCQM Specifications collection type we propose to update the logic to allow for new hypertension diagnoses within the first 6 months of the performance period to better align with the intent of the measure. We propose to add a denominator note to clarify the patient population eligible for the measure and to reflect the revision in timing for the essential hypertension diagnosis; ensuring patients that should be assessed are included within the denominator eligible patient population. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we propose adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. We also propose to update the instructions note and the numerator note to add clarity regarding the use of remote monitoring devices for the purposes of this measure in response to stakeholder feedback. We propose to remove the CMS Web Interface Measure Specifications collection type. This collection type is proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this proposed rule.

D.48 Use of High-Risk Medications in the Elderly

Category	Description
NQF # / eCQM NQF #:	0022 / N/A
Quality#:	238
CMS eCQM ID:	CMS156v9
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:	**The title is revised from 'Use of High-Risk Medications in the Elderly' to:** Use of High-Risk Medications in Older Adults. **The description is revised to read:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications. **Updated measure analytics: For all collection types**: One performance rate. **The guidance is revised to read: For the eCQM Specifications collection type**: The intent of the measure is to assess if the patient has been prescribed at least two of the same high-risk medications on different days. The intent of the measure is to assess if the reporting provider ordered the high-risk medication(s). If the patient had a high-risk medication previously prescribed by another provider, they would not be counted towards the numerator unless the reporting provider also ordered a high-risk medication for them. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated instructions: For the MIPS CQMs Specifications collection type:** Removed language related to the submission of two performance rates and two submission criteria. **Updated denominator: For all collection types:** Removed submission criteria one. **For MIPS CQMs Specifications collection type:** Added ophthalmology, skilled nursing facility, and domiciliary/rest home settings and preventive care services. **The numerator is revised to read: For all collection type**: Patients with at least two orders for the same high-risk medication on different days during the measurement period. **Updated numerator: For the MIPS CQMs Specifications collection type:** Removed submission criteria one numerator. Revised High-Risk Medications at any dose or duration Table 1: Added: Pyrilamine, Orphenadrine, Chlordiazepoxide-clidinium, Methscopolamine, Glimepiride Removed: Clidinium Chloradiazepoxide, Ticlopidine, Pentazocine **For the eCQM Specifications collection type:** Added medication value sets: Scopolamine, Secobarbital, Propantheline, Doxylamine, Ergoloid Mesylates, Butalbital, Amobarbital, Pentobarbital
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove submission criteria one from this measure and continue to assess the percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications. This change will lessen clinician burden while still assessing an important aspect of patient safety. This patient population is a better assessment of the riskier, longer-term use and allows MIPS eligible clinicians/groups to address potentially inappropriate medication dispensing to improve quality outcomes. The eCQM Specifications collection type added medication value sets to the numerator to align with the Beers Criteria for Potentially Inappropriate Medication list, as well as to reflect expert review and stakeholder feedback. These updates ensure all high-risk medications are being assessed for numerator compliance. The MIPS CQMs Specifications collection type was revised to align medications across collection types. 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.49 Cardiac Rehabilitation Patient Referral from an Outpatient Setting

Category	Description
NQF # / eCQM NQF #:	0643 / N/A
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:** Added Skilled Nursing Facility, Domiciliary/Rest Home, Home Visit, and Outpatient Consultation settings. Added telehealth as eligible encounter.
Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add settings, Skilled Nursing Facility, Domiciliary/Rest Home, Home Visit, and Outpatient Consultation, as denominator eligible as they are clinically relevant settings that can ensure that patients receive or continue outpatient cardiac rehabilitation to support positive outcomes in their clinical care. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.50 Biopsy Follow-Up

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	265
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.51 Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy

Category	Description
NQF # / eCQM NQF #:	N/A / 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:	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.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications **The denominator is revised to read:** All females, including all individuals of childbearing potential (12 years and older) with a diagnosis of epilepsy. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type. The limited patient population and adoption of the quality measure for this collection type does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. We propose the denominator statement be revised to be more inclusive of the eligible patient population. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.52 Sleep Apnea: Severity Assessment at Initial Diagnosis

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	277
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 obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.53 Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	279
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.54 Dementia: Cognitive Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 2872e
Quality#:	281
CMS eCQM ID:	CMS149v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	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.
Substantive Change:	**The guidance is revised to read:** Use of a standardized tool or instrument to assess cognition other than those listed will meet numerator performance. Standardized tools can be mapped to the concept "Intervention, Performed": "Cognitive Assessment" included in the numerator logic below. The requirement of two or more visits is to establish that the eligible professional or eligible clinician has an existing relationship with the patient. In recognition of the growing use of integrated and team-based care, the diagnosis of dementia and the assessment of cognitive function need not be performed by the same provider or clinician. The DSM-5 has replaced the term dementia with major neurocognitive disorder and mild neurocognitive disorder. For the purposes of this measure, the terms are equivalent. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward's technical expert panel suggested adding language within the guidance statement to reflect that team-based care is appropriate for this measure. We agree that this is an important concept and applicable to this measure, adding the language helps to clarify the measure intent.

D.55 Dementia: Functional Status Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	282
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 an assessment of functional status was performed at least once in the last 12 months.
Substantive Change:	**The definition is revised to read:** Assessment of functional status - Functional status is assessed by use of a validated tool, direct assessment of the patient, or by querying a knowledgeable informant. A direct assessment of functional status includes an evaluation of the patient's ability to perform instrumental activities of daily living (IADL) and basic activities of daily living (ADL). **Updated denominator:** Added telehealth as eligible encounter. **The numerator instructions are revised to read:** To meet this measure, providers must assess BOTH IADL and ADL performance. 1. IADL Assessment (users must meet one of the two below bullets to meet IADL assessment component) • To meet the measure's IADL component using a validated tool, providers must use one of the following tools: ○ Lawton Instrumental Activities of Daily Living Scale ○ Bristol Activities of Daily Living Scale ○ Katz Index of Independence in Activities of Daily Living ○ Functional Activities Questionnaire ○ Functional Independence Measure Instrument • To meet the measure's IADL component using a direct assessment, providers must document 3 out of the following 5 domains. ○ Cleaning or hobbies ○ Money management, ○ Medication management, ○ Transportation, and ○ Cooking or communication 2. ADL Assessment (users must meet one of the two below bullets to meet ADL assessment component) • To meet the measure's ADL component using a validated tool, providers must use either: ○ Barthel ADL Index ○ Bristol Activities of Daily Living Scale • To meet the measure's ADL component using a direct assessment, providers must document 3 out of the following 7 domains. ○ Grooming, ○ Bathing, ○ Dressing, ○ Eating, ○ Toileting, ○ Gait, and ○ Transferring **The numerator notes is revised to read:** The 12-month look back period is defined as 12 months from the date of the denominator eligible encounter. Denominator Exception(s) are determined on the date of the denominator eligible encounter. Documentation of advanced stage dementia and caregiver knowledge is limited would meet the measure exception criteria. **The denominator exception is revised to read**: Documentation of advanced stage dementia and caregiver knowledge is limited.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose the measure definition and numerator instructions to provide clarity regarding expectations for numerator compliance. This updated language should address any stakeholder confusion for implementing the measure. The numerator note was updated to align with revised denominator exception. We propose to update the denominator exception to reduce ambiguity regarding patient scenarios where an exception is clinically appropriate. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.56 Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management

Category	Description
NQF # / eCQM NQF #:	N/A / 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:	**Updated denominator:** Added telehealth as eligible encounter. **The definition is revised to read:** Behavioral and Psychiatric Symptoms Screening - Screening is defined as using a validated instrument or directly examining the patient or knowledgeable informant to determine the presence or absence of symptoms from three domains: Activity disturbances, mood disturbances (including depression), and thought and perceptional disturbances. The following validated instruments can be used to meet the measure: • Dementia Signs and Symptoms (DSS) Scale • Neuropsychiatric Inventory (NPI) • Minimum Data Set (MDS) (suggested for nursing home only). **Updated numerator instructions:** Added: Thought and perceptual disturbances under 'Thought and perceptual disturbances'. Revised: Examples of reliable and valid instruments that can be used to assess behavioral and psychiatric symptoms are: Dementia Signs and Symptoms (DSS) Scale or Neuropsychiatric Inventory (NPI). For patients residing in nursing homes, it may be the Minimum Data Set (MDS). Other reliable and valid instruments may be used to assess individual measure components for activity disturbances, mood disturbances including depression, and thought and perceptual disturbances.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the definition to remove 'positive', as this was not appropriate or aligned with the definition for the purposes of this measure. Additionally, information regarding approved screening instruments was moved to this section as it is more appropriately in this section of the measure specification. We propose to update the numerator instructions to add 'thought and perceptual disturbance' and provide greater clarity regarding the requirements of numerator compliance for this measure. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.57 Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia

Category	Description
NQF # / eCQM NQF #:	N/A / 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:	**The denominator exception is revised to read**: Documentation patient unable to communicate and informant not available. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the denominator exception to better align with real-world clinical scenarios where safety screening could not be completed and therefore no mitigation recommendations could be provided. This change aids clinicians reporting the measure with an exception to excuse them from performance in a clinical situation they are unable to control. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.58 Dementia: Education and Support of Caregivers for Patients with Dementia

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	288
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 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.
Substantive Change:	**Updated denominator:** Added telehealth as eligible encounter. **Updated denominator exceptions:** Revised: Patient does not have a caregiver. Added: 1. Documentation caregiver is trained and certified in dementia care. 2. Patient/caregiver dyad has been referred to appropriate resources and connection to those resources is confirmed.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to revise the denominator exception to reduce ambiguity regarding patient scenarios where an exception is clinically appropriate. Additionally, we propose to add two denominator exceptions to further clarity clinical scenarios where it may not be appropriate to attribute the quality action to that MIPS eligible clinician. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.59 Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A / 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:	**The description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms once in the past 12 months. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure description to include the word 'once' to provide added clarity regarding measure intent. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.60 Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	291
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 cognitive impairment or dysfunction in the past 12 months.
Substantive Change:	**The description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once in the past 12 months. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure description to include the word 'once' to provide added clarity regarding measure intent. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.61 Parkinson's Disease: Rehabilitative Therapy Options

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	293
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**The description is revised to read:** 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 once in the past 12 months. **Updated denominator exception**: Removed: Documentation of medical reason(s) for not discussing rehabilitative therapy options with patient (or caregiver). **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the measure description to include the word 'once' to provide added clarity regarding measure intent. Additionally, we propose to remove the denominator exception which allowed for medical reason(s) for not discussing rehabilitative therapy options. We agree that MIPS eligible clinicians should discuss rehabilitative therapy options with all patients/caregivers as these therapies play an important role in not only improving function in the patient, but also their quality of life. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.62 Initiation and Engagement of Alcohol and Other Drug Dependence Treatment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	305
CMS eCQM ID:	CMS137v9
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. 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.
Substantive Change:	**The definition is revised to read:** The initiation visit is the first visit for alcohol or other drug dependence treatment within 14 days after a diagnosis of alcohol or other drug dependence. Treatment includes inpatient AOD admissions, outpatient visits, intensive outpatient encounters or partial hospitalization. The Intake Period: January 1-November 13 of the measurement year. The Intake Period is used to capture new episodes of Alcohol or Drug Dependence. The November 13 cut-off date ensures that all services can occur before the measurement period ends. **Updated numerator logic**: Updated 47 days to 48 days for the period within which Initial Dependence Diagnosis must occur. **Updated stratification logic:** Refinement of CQL logic to include patients at age 17 at end of measurement period.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the definition to revise the intake period to ensure all services can occur before the performance period ends. The numerator logic timing is also updated to reflect this change.

D.63 Cervical Cancer Screening

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	309
CMS eCQM ID:	CMS124v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	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.
Substantive Change:	**The description is revised to read:** 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 within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years **The guidance is revised to read:** To ensure the measure is only looking for a cervical cytology test only after a woman turns 21 years of age, the youngest age in the initial population is 23. Patient self-report for procedures, as well as diagnostic studies should be recorded in 'Procedure, Performed' template or 'Diagnostic Study, Performed' template in QRDA-1. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. This eCQM is a patient-based measure. **The numerator is revised to read:** Women with one or more screenings for cervical cancer. Appropriate screenings are defined by any one of the following criteria: * Cervical cytology performed during the measurement period or the two years prior to the measurement period for women who are at least 21 years old at the time of the test * Cervical human papillomavirus (HPV) testing performed during the measurement period or the four years prior to the measurement period for women who are 30 years or older at the time of the test. **Updated logic**: Updated logic definition to use HPV only every 5 years and remove Pap test.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure to align with current clinical guidelines, which removes the Pap test requirement and allow IIPV only testing every 5 years. This update is reflected in revisions to the description, guidance, numerator, and logic.

D.64 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	317
CMS eCQM ID:	CMS22v9
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims 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:	**The description is revised to read: For all collection types:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive. **The guidance is revised to read: For the eCQM Specifications collection type**: This eCQM is an episode-based measure and should be reported at every visit for patients aged 18 years and older. This measure will be calculated based upon the clinical actions performed at every visit during the measurement period for each patient. The measure requires that blood pressure measurements (i.e., diastolic and systolic) be obtained during each visit to determine the blood pressure reading used to evaluate if an intervention is needed. Both the systolic and diastolic blood pressure measurements are required for inclusion. If there are multiple blood pressures obtained during a patient visit, only the last, or most recent, pressure measurement will be used to evaluate the measure requirements. The intent of this measure is to screen patients for high blood pressure and provide recommended follow-up as indicated. The documented follow-up plan must be related to the current blood pressure reading as indicated, example: "Patient referred to primary care provider for BP management." This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The instructions are revised to read: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs collections type:** This measure is to be submitted at each visit for patients seen during the measurement period. Merit-based Incentive Payment System (MIPS) eligible clinicians who submit the measure must perform the blood pressure screening at each patient visit by a MIPS eligible clinician and may not obtain measurements from external sources. **The initial patient population is revised to read: For the eCQM Specifications collection type:** All patient visits for patients aged 18 years and older at the beginning of the measurement period. **The denominator is revised to read: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs collections type:** All patient visits for patients aged 18 years and older at the beginning of the measurement period. **The denominator exception is revised to read: For the eCQM Specifications collection type**: 1. Documentation of medical reason(s) for not screening for high blood pressure (e.g., patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). 2. Documentation of patient reason(s) for not screening for blood pressure measurements or for not ordering an appropriate follow-up intervention if patient is pre-hypertensive or hypertensive (e.g., patient refuses). **Updated denominator exception logic: For the eCQM Specifications collection type:** Added: 1. Follow-up within 1 year 2. Follow-up within 4 weeks **The numerator is revised to read: For all collection types:** Patient visits where patients were screened for high blood pressure AND have a recommended follow-up plan documented, as indicated, if the blood pressure is pre-hypertensive or hypertensive. **Updated numerator definition: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: Patients with a Documented Reason for not Screening or no Follow-Up Plan for HIgh Blood Pressure (Denominator Exception) – • Documentation of medical reason(s) for not screening for high blood pressure (e.g., patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). • Documentation of patient reason(s) for not screening for blood pressure measurements or for not ordering an appropriate follow-up intervention if patient is pre-hypertensive or hypertensive (e.g., patient refuses). **The numerator notes is revised to read: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Although the recommended screening interval for a normal BP reading is every 2 years, to meet the intent of this measure, BP screening and follow-up must be performed at every patient visit. For patients with Normal blood pressure, a follow-up plan is not required (G8783). Denominator Exception(s) are determined on the date of the denominator eligible encounter. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure frequency so that the clinical quality action is occurring at all denominator eligible visits. Hypertension is a prevalent condition, and the United States Preventive Services Task Force (USPSTF) found good evidence that

Category	Description
	screening for and treatment of high blood pressure in adults substantially reduces the incidence of cardiovascular events. In alignment with this update, the measure language has been revised to reflect the change in frequency to all visits. Additionally, the eCQM Specifications collection type revised the logic to align with the measure's reporting frequency update, as well as updating the denominator exception logic to add two elements that were missing from the existing logic to ensure that all valid denominator exception options are accounted for within the logic. The denominator exception language was revised in the eCQM Specifications collection type to follow best practices and add clarity to implementing the measure. To align with this update, the definition for denominator exception was revised in the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types. We propose to remove telehealth encounters from the denominator of the eCQM Specifications collection type as telehealth is not an appropriate setting for this measure, as well as to align with the other collection types. This guidance can be found in a separate document that will be published on the eCQI Resource Center. 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.65 Falls: Screening for Future Fall Risk

Category	Description
NQF # / eCQM NQF #:	0101 / N/A
Quality#:	318
CMS eCQM ID:	CMS139v9
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.
Substantive Change:	**Modified collection type:** eCQM Specifications **Updated denominator exclusion: For the eCQM Specifications collection type:** Removed: Exclude patients who were non-ambulatory at some point in the measurement period.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove the denominator exclusion for non-ambulatory patients to address implementation challenges as there is a lack of available documentation for a non-ambulatory status. We propose to remove the CMS Web Interface Measure Specifications collection type. This collection type is proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this proposed rule.

D.66 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
NQF # / eCQM NQF #:	1525 / N/A
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:	**The denominator is revised to read: For all collection types:** All patients aged 18 years and older with a diagnosis of nonvalvular AF or atrial flutter who do not have a documented CHA_2DS_2-VASc risk score of 0 or 1 for men or 0, 1, or 2 for women. **The denominator/numerator note is revised to read: For all collection types:** The intent of the denominator exclusion G9931 is to allow patients with a low risk for a thromboembolic event (i.e. a CHA_2DS_2-VASc score of 0 or 1 for men or 0, 1, or 2 for women) to be excluded from the sample. This denominator exclusion serves as documentation that a patient's risk for a thromboembolic event was appropriately assessed using the CHA_2DS_2-VASc scoring tool and that the risk was low enough to not warrant anticoagulation treatment. To exclude low risk patients, eligible clinicians must use the CHA_2DS_2-VASc assessment tool to determine a patient's risk score and must document either the numeric score (i.e. 0 or 1 for men or 0, 1, or 2 for women) or all the individual risk factors assessed to support an assessment of the CHA_2DS_2-VASc score. **Updated denominator exclusion: For all collection types:** Revised: Documentation of CHA_2DS_2-VASc risk score of 0 or 1 for men; 0, 1, or 2 for women. **Updated denominator: For all collection types:** Added telehealth as eligible encounter.
Steward:	American College of Cardiology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the measure to reflect the updated guidelines regarding when it is clinically appropriate to prescribe an oral anticoagulant for patients that are diagnosed with atrial fibrillation or atrial flutter. This update is reflected in the denominator statement, denominator note, and denominator exclusion. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.67 Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	331
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 viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.68 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 / 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**: Added telehealth as eligible encounter.
Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.69 Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A / 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 < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication.
Substantive Change:	**The 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 by cesarean section (C-section), or early inductions of labor, without medical indication. **Updated instructions:** Revised: This measure is to be submitted each time a procedure is performed for patients undergoing delivery by C-section, or induction of labor, at less than 39 weeks gestation during the performance period. **The denominator is revised to read:** All patients, regardless of age, who gave birth during a 12-month period delivering a live singleton at < 39 weeks of gestation completed. **The numerator is revised to read:** Patients who had elective deliveries by C-section, or early inductions of labor, without medical indication. **Updated numerator options:** Revised: **Performance Met:** Early elective delivery by C-section, or early elective induction, not performed (< 39 weeks gestation). **Performance Not Met:** Early elective delivery by C-section, or early elective induction, performed (< 39 weeks gestation).
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update the description and instructions to provide further clarity regarding what suffices for elective deliveries. Additionally, we propose to move the "without medical indication" from the denominator to the numerator as the denominator should capture all patients with a single live birth at less than 39 weeks gestation. The numerator assesses whether or not there was medical indication for an early elective delivery by C-section, or early elective induction. This update will better align the language with the measure intent.

D.70 Maternity Care: Postpartum Follow-up and Care Coordination

Category	Description
NQF # / eCQM NQF #:	N/A / 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 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.
Substantive Change:	**The description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 8 weeks of giving birth and received the following at the postpartum visit: 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.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the measure description for clarity and readability so that it is easy to understand the measure intent.

D.71 Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	364
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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).
Substantive Change:	**Updated denominator note:** Added: Granulomas, hamartomas or lesions with internal fat, or other characteristically benign findings are not considered incidental findings in the context or intent of this measure. Therefore, they are not included in the measure denominator. However, generally accepted radiology practices should be followed for communication and management of these characteristically benign findings.
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add language to the denominator note to add clarity as to which incidental findings are not appropriate for the purposes of this measure. Some incidental findings are widely known to be benign and would therefore not necessitate a specific documentation of a recommendation of no follow-up. This will reduce clinician burden and ensure only the appropriate patients are included in the denominator eligible population.

D.72 Depression Remission at Twelve Months

Category	Description
NQF # / eCQM NQF #:	0710 / 0710e
Quality#:	370
CMS eCQM ID:	CMS159v9
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:	**Modified collection type:** eCQM Specifications and MIPS CQMs Specifications **Updated guidance: For the eCQM Specifications collection type:** Added: When a baseline assessment is conducted with PHQ 9M, the follow-up assessment can use either a PHQ 9M or PHQ 9. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated denominator: For the MIPS CQMs Specifications collection type:** Added telehealth with qualified non-physician healthcare professional. **Updated denominator exclusion: For the eCQM Specifications collection type:** Revised: Patients with a diagnosis of personality disorder emotionally labile.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to update the guidance for eCQM Specifications collection type to add clarity regarding the assessment that may be used for the follow-up assessment for the purposes of meeting performance for this measure. Additionally, we propose to revise the denominator exclusion language for a diagnosis of personality disorder to further clarify ensuring the correct patient population is being excluded from quality action assessment. We propose to update the denominator of the MIPS CQMs Specifications collection type to include telehealth encounters with qualified non-physician healthcare professionals as it would be appropriate to assess this patient population for numerator compliance. We propose to remove the CMS Web Interface Measure Specifications collection type. This collection type is proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this proposed rule.

D.73 Closing the Referral Loop: Receipt of Specialist Report

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	374
CMS eCQM ID:	CMS50v9
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**Updated logic: For the eCQM Specifications collection type:** Updated logic for 'First Referral During Measurement Period' to allow an additional, optional way to capture the first referral. **Updated denominator: For all collection types:** Added telehealth as eligible encounter. **Updated numerator: For the eCQM Specifications collection type:** Removed pathology consult note from 'Consultant Report' value set.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the logic for 'First Referral During Measurement Period' to allow for a referral order, in addition to a referral being performed. This revision is consistent with the measure intent and provides options to capture the first referral within the electronic medical record. Additionally, we propose to remove the pathology consult note from the 'Consultant Report' value set based upon terminology updates as the availability of the general consult note is available as an option. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.74 Functional Status Assessments for Congestive Heart Failure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	377
CMS eCQM ID:	CMS90v10
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 logic**: **Initial Patient Population**: Revised timing of congestive heart failure (CHF) diagnosis in the initial population logic so it overlaps before the measurement period. **Qualifying Encounter:** Revised timing of the encounter from the start of the measurement period to the end of the measure period. **Numerator:** • Revised to ensure assessments completed during the encounter count toward the numerator. • Revised KCCQ logic to address the 6 domain subcategories used to account for the KCCQ assessment total score. • Added the KCCQ Total Assessment Score logic to include the summary score as an option to meet the KCCQ assessment requirement. • Revised timing and logic of the follow-up functional status assessment (FSA) to relate to the initial FSA performed and not the encounter. • Revised measurement period for the Veterans RAND 12 Item Health Survey (VR-12) to allow for the initial FSA to occur prior to the measurement period if the encounter occurs within the first few days of the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the initial patient population logic to ensure the CHF diagnosis occurs before the denominator eligible encounter, which aligns more closely with the measure intent. We propose to update the qualifying encounter logic to account for leap year. This refinement will eliminate the need to adjust the number of days for leap years. Additionally, we propose to update the numerator logic for the Kansas City Cardiomyopathy Questionnaire (KCCQ) FSA so that it can be reported by either utilizing the six domain subcategories or the total score. This added flexibility better aligns with different clinical workflows, and is consistent with measure intent. The logic and timing were revised to relate to the initial functional status (FSA) and not the encounter to better align with the measure intent. We propose, to all the VR-12, to allow for the initial FSA to occur prior to the measurement in the instance the encounter occurs within the first few days of the measurement period to improve harmonization with the measure intent.

D.75 Children Who Have Dental Decay or Cavities

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	378
CMS eCQM ID:	CMS75v10
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 description is revised to read**: Percentage of children, 6 months - 20 years of age, who have had tooth decay or cavities during the measurement period. **The stratification is revised to read:** None **The initial patient population is revised to read:** Children, 6 months - 20 years of age, with a visit during the measurement period. **Updated denominator:** Removed: "Office Visit" (2.16.840.1.113883.3.464.1003.101.12.1001) "Preventive Care - Established Office Visit, 0 to 17" (2.16.840.1.113883.3.464.1003.101.12.1024) "Preventive Care Services - Established Office Visit, 18 and Up" (2.16.840.1.113883.3.464.1003.101.12.1025) "Preventive Care Services-Initial Office Visit, 18 and Up" (2.16.840.1.113883.3.464.1003.101.12.1023) "Preventive Care- Initial Office Visit, 0 to 17" (2.16.840.1.113883.3.464.1003.101.12.1022)
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to raise the minimum age for this measure to 6 months to better align with average tooth eruption. Children under 6 months of age are less likely to have teeth and would therefore not meet numerator criteria, which is why they are being removed from the initial patient population. Additionally, we propose to update the denominator to limit the denominator eligible encounters to the "Clinical Oral Evaluation" value set as the clinical quality action is more appropriate for the dentistry MIPS eligible clinician.

D.76 Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	379
CMS eCQM ID:	CMS74v10
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 description is revised to read**: Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period. **The stratification is revised to read:** Population 1: age 6 months-5 years Population 2: age 6-12 Population 3: age 13-20 **The initial patient population is revised to read:** Children, 6 months - 20 years of age, with a visit during the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to raise the minimum age for this measure to 6 months to better align with average tooth eruption. Children under 6 months of age are less likely to have teeth and would therefore not meet numerator criteria, which is why they are being removed from the initial patient population.

D.77 Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 1365e
Quality#:	382
CMS eCQM ID:	CMS177v9
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 guidance:** Added: In recognition of the growing use of integrated and team-based care, the diagnosis of depression and the assessment for suicide risk need not be performed by the same provider or clinician.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	The measure steward updated the guidance statement based upon technical expert feedback to reflect that team-based care would be appropriate for this measure. We agree that this guidance update is clinically appropriate and aligns better with clinical care workflows.

D.78 Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Category	Description
NQF # / eCQM NQF #:	1879 / N/A
Quality#:	383
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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).
Substantive Change:	**The description is revised to read:** Percentage of individuals at least 18 years of age with schizophrenia or schizoaffective disorder as of the beginning of the performance period 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 performance period. **Updated instructions:** Revised: This measure is to be submitted a minimum of once per performance period for all patients with a preexisting (before the performance period) diagnosis of schizophrenia or schizoaffective disorder who are seen during the performance period. **The denominator statement is revised to read:** Individuals at least 18 years of age with schizophrenia or schizoaffective disorder as of the beginning of the performance period and at least two prescriptions filled for antipsychotic medications during the performance period. **Updated denominator criteria:** Revised the timing for the diagnosis for schizophrenia or schizoaffective disorder to be prior to the performance period. **Updated denominator exclusion:** Added opioid abuse with intoxication with perceptual disturbance to diagnosis for dementia. **Updated numerator note:** Revised: PDC NUMERATOR: The PDC numerator is the sum of the days covered by the days' supply of all antipsychotic prescriptions. The period covered by the PDC starts on the day within the performance period when the first prescription is filled (i.e., the index date) and lasts through the end of the performance period, or death, whichever comes first. For prescriptions with a days' supply that extends beyond the end of the performance period, count only the days for which the drug was available to the individual during the performance period. If there are prescriptions for the same drug (generic name) on the same date of service, keep the prescription with the largest days' supply. If prescriptions for the same drug (generic name) overlap, then adjust the prescription start date to be the day after the previous fill has ended.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We propose to update the measure language to reflect that the diagnosis of schizophrenia or schizoaffective disorder should be prior to the performance period as this aligns more closely to the intent of the measure and allows for assessment of medication adherence over a longer timeframe. We propose to remove the "12 consecutive months" from the description as this was causing confusion amongst MIPS eligible clinicians. The denominator exclusion coding was expanded to include opioid abuse with intoxication with perceptual disturbance as this is appropriate for identifying patients with a dementia diagnosis and therefore, applicable to the denominator exclusion. Additionally, we propose to update the numerator note to clarify that the index date is the date the prescription was first filled during the performance period.

D.79 Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	386
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 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.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.80 Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	387
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, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.81 Follow-Up After Hospitalization for Mental Illness (FUH)

Category	Description
NQF # / eCQM NQF #:	0576 / N/A
Quality#:	391
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and 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 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.
Substantive Change:	**Updated numerator options:** Revised: Submission Criteria 1: **Performance Met:** Patient received follow-up within 30 days after discharge.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the performance met numerator option to align with the numerator statement, which prohibits the use of visits that occur on the date of discharge, as this would not meet the intent of the measure.

D.82 Immunizations for Adolescents

Category	Description
NQF # / eCQM NQF #:	1407 / N/A
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:	**The description is revised to read**: The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to revise the description to detail the components within the measure. This allows for a more clear understanding of the intent of the measure.

D.83 Lung Cancer Reporting (Biopsy/Cytology Specimens)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	395
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:	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.
Substantive Change:	**The numerator is revised to read: For all collection types**: Biopsy and cytology specimen reports with a diagnosis of primary non-small cell lung cancer classified into specific histologic type (including but not limited to squamous cell carcinoma, adenocarcinoma, large cell carcinoma) OR classified as NSCLC-NOS with an explanation included in the pathology report.
Steward:	College of American Pathologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the numerator statement to more clearly detail the acceptable histologic types. This revision, provided based on stakeholder feedback, includes keywords that are can be used in clinical practice.

D.84 One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	400
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 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.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.85 Appropriate Follow-up Imaging for Incidental Abdominal Lesions

Category	Description
NQF # / eCQM NQF #:	N/A / 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 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 less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 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
Substantive Change:	**The description is revised to read:** Percentage of final reports for 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 less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic 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: For all collection types**: 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) or • Adrenal lesion less than or equal to 1.0 cm or • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **Updated denominator criteria: For all collection types:** Removed diagnostic ultrasound procedures. **The denominator note is revised to read: For all collection types:** The intent of this measure is to ensure patients with incidental findings that are highly likely to be benign do not receive follow up imaging routinely. * "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 IIU. (ACR, 2017) When reporting this measure, masses and lesions that do not meet all the criteria for "no further work-up" as provided in Management of the Incidental Renal Mass on CT: A White Paper of the ACR Incidental Findings Committee or the Management of the Incidental Adrenal Mass on CT: A White Paper of the ACR Incidental Findings Committee should not be considered in the context or intent of this measure. However, generally accepted radiology practices should be followed for communication and management of any characteristically benign findings. A measure performance goal of 100% should not substitute for clinical judgment in individual cases. **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type:** Removed numerator note. **Updated numerator options: For all collection types:** Revised: **Performance Not Met:** Final reports for imaging studies with follow-up imaging recommended, or final reports that do not include a specific recommendation of no follow-up.
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the numerator options to add clarifying language that accounts for those instances where no follow-up recommendation is given within the final reports for imaging studies. The intent of the measure includes the documentation of follow-up recommendations within the final report. Additionally, we propose to remove diagnostic ultrasound procedures from the denominator eligible criteria as it does not align with the intent of the measure.

D.86 Psoriasis: Clinical Response to Systemic Medications

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	410
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 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.
Substantive Change:	**The instructions are revised to read:** This measure is to be submitted a minimum of once per performance period for all patients during the performance period. The most recent denominator eligible encounter in which the numerator action was performed, should be used. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to revise the instructions language to clarify what denominator eligible encounter should be used when assessing the quality action. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

D.87 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 / N/A
Quality#:	415
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	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 provider who have an indication for a head CT.
Substantive Change:	**Updated denominator criteria:** Diagnosis for minor blunt head trauma - removed coding for fracture of skull and facial bones and superficial injury of neck. **The definition is revised to read:** Indications for a head CT in patients presenting to the emergency department for minor blunt head trauma: Patients with no loss of consciousness (LOC) AND no post-traumatic amnesia AND any one of the following: • GCS score less than 15 • Severe headache • Vomiting • Age 65 years and older • Physical signs of a basilar skull fracture (signs include haemotympanum, "raccoon" eyes, cerebrospinal fluid leakage from the ear or nose, Battle's sign) • Focal neurological deficit • Coagulopathy • Thrombocytopenia • Currently taking any of the following anticoagulant medications**: apixaban, argatroban, betrixaban, bivalirudin, dabigatran, dalteparin, desirudin, edoxaban, enoxaparin, fondaparinux, heparin, rivaroxaban, warfarin • Dangerous mechanism of injury (i.e., ejection from a motor vehicle, a pedestrian struck, and a fall from a height of more than 3 feet or 5 stairs) OR Patients with either LOC OR Posttraumatic amnesia AND any one of the following: • GCS score less than 15 • Headache • Age 60 years and older, and less than 65 years • Drug/alcohol intoxication • Short-term memory deficits • Evidence of trauma above the clavicles (physical location, any trauma to the head or neck [i.e., laceration, abrasion, bruising, ecchymosis, hematoma, swelling, fracture]) • Posttraumatic seizure.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We propose to update the coding for 'Diagnosis of minor blunt head trauma' base on the measure steward's clinical expert input as closed fractures of the skull and facial bones, as well as concepts that relate to neck of below the head anatomical locations. The measures intent is to capture those patients with minor blunt head trauma and the fractures captured above are not clinically appropriate for the denominator criteria and should not be assessed for the purposes of this measure. We propose revisions to the definition language to improve clarity regarding indications for a head CT for the purposes of this measure. We agree that these revisions better define how to determine appropriate indication(s) for a head CT.

D.88 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 / N/A
Quality#:	416
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 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 criteria:** Diagnosis for minor blunt head trauma - removed coding for fracture of skull and facial bones and superficial injury of neck. **The numerator definition is revised to read: For all collection types:** Low Risk for Traumatic Brain Injury according to PECARN prediction rules – Patients can be classified as low risk if ALL of the following are met: • No signs of altered mental status (e.g., agitation, somnolence, repetitive questioning, slow response to verbal communication) OR no GCS < 15 • No signs of basilar skull fracture (signs include haemotympanum, "raccoon" eyes, cerebrospinal fluid leakage from the ear or nose, Battle's sign) • No loss of consciousness • No vomiting • No severe mechanism of injury (i.e., motor vehicle crash with patient ejection, death of another passenger, or rollover; pedestrian or bicyclist without helmet struck by a motorized vehicle; falls of more than 5 feet; or head struck by a high-impact object) • No severe headache.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We propose to update the coding for 'Diagnosis of minor blunt head trauma' base on the measure steward's clinical expert input as closed fractures of the skull and facial bones, as well as concepts that relate to neck of below the head anatomical locations. The measures intent is to capture those patients with minor blunt head trauma and the fractures captured above are not clinically appropriate for the denominator criteria and should not be assessed for the purposes of this measure. We propose revisions to the definition language to improve clarity regarding low risk for traumatic brain injury (TBI) for the purposes of this measure. We agree that these revisions better define how to appropriately determine whether the patient is low risk for traumatic brain injury or not.

D.89 Osteoporosis Management in Women Who Had a Fracture

Category	Description
NQF # / eCQM NQF #:	0053 / N/A
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 6 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 6 months after the fracture.
Substantive Change:	**Updated denominator criteria: For all collection types**: Option 1: Added denominator eligible patient encounters including discharge, outpatient observation, outpatient consultation, emergency department, home services, preventive medicine and counseling, work related/medical disability, care planning, and annual well check. **Updated denominator exclusions: For all collection type**: Option 1 and Option 2: Revised: 1. Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during 6 months prior to the measurement period through December 31 of the measurement period. 2. Patient 66 - 80 years of age and had 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. Patients 66 - 80 years of age and had 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. Added: 1. Patients 81 years of age and older with at least one claim/encounter for frailty during 6 months prior to the measurement period through December 31 of the measurement period. **Updated denominator exclusion: For all collection types:** For Option 1 and Option 2: Added coding to identify patients with advanced illness and frailty **Updated definition: For all collection types:** Revised: Pharmacologic Therapy – U.S. Food and Drug Administration approved pharmacologic options for osteoporosis prevention and/or treatment of postmenopausal osteoporosis include: bisphosphonates, alendronate, alendronate-cholecalciferol, ibandronate, risedronate, zoledronic acid, teriparatide, denosumab, abaloparatide, romosozumab, and raloxifine.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to expand the eligible encounter coding for Option 1 to include all relevant encounters and create a more complete eligible patient population. We propose that the denominator exclusion language and logic be updated in all collection types to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. A denominator exclusion was added to remove patient 81 years of age and older with a frailty encounter during the measurement period as patients within this age stratification are more appropriately assessed less stringently when determine if they should be excluded from the eligible patient population. Additionally, we propose adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. We propose to update the definition for pharmacologic therapy to align with the current U.S. Food and Drug Administration approved pharmacologic options for osteoporosis prevention and/or treatment of postmenopausal osteoporosis.

D.90 Overuse of Imaging for the Evaluation of Primary Headache

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	419
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 patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications **Updated denominator criteria:** Removed inpatient setting. Removed "Patients with no clinical indications for imaging of the head". Added telehealth as eligible encounter. **Updated denominator instructions:** Removed denominator instructions. **Updated denominator exclusion:** Added: Patients with clinical indications for imaging of the head • Head trauma • New or change in headache above 50 years of age • Abnormal neurologic exam • Headache radiating to the neck • Positional headaches • Temporal headaches in patients over 55 years of age • New onset headache in pre-school children or younger (<6 years of age) • New onset headache in pediatric patients with disabilities for which headache is a concern as inferred from behavior • Occipital headache in children • Thunderclap headache • Trigeminal pain • Persistent headaches **Updated denominator exception:** Revised: Imaging needed as part of a clinical trial; or other clinician ordered the study.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to remove the Medicare Part B Claims Measure Specifications collection type. The limited adoption of the quality measure for this collection type does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. We propose to update the denominator criteria to remove the inpatient setting as this measure is appropriate for the outpatient setting only. We propose to remove the denominator criteria for patients with no clinical indications for head imaging and replace it with a denominator exclusion that clarifies patients with clinical indications for whom imaging of the head would be clinically relevant and warranted. The denominator instructions were removed as they were duplicative of the added denominator exclusion. Additionally, we propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. The denominator exception is being updated to delete outdated language and no longer allows for system reason(s).

D.91 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Category	Description
NQF # / eCQM NQF #:	2152 / N/A
Quality#:	431
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**The description is revised to read:** 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 12 months AND who received brief counseling if identified as an unhealthy alcohol user. **Updated instructions:** Revised: For the purposes of the measure, the most recent denominator eligible encounter should be used to determine if the numerator action for the submission criteria was performed within the 12-month look back period. Added: This measure will be calculated with 3 performance rates: 1) 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 12 months 2) Percentage of patients aged 18 years and older who were identified as unhealthy alcohol users who received brief counseling 3) 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 12 months AND who received brief counseling if identified as unhealthy alcohol users The denominator of submission criteria 2 is a subset of the resulting numerator for submission criteria 1, as submission criteria 2 is limited to assessing if patients identified as unhealthy alcohol users received brief counseling. For all patients, submission criteria 1 and 3 are applicable, but submission criteria 2 will only be applicable for those patients who are identified as unhealthy alcohol users. Therefore, data for every patient that meets the age and encounter requirements will only be submitted for submission criteria 1 and 3, whereas data submitted for submission criteria 2 will be for a subset of patients who meet the age and encounter requirements, as the denominator has been further limited to those who were identified as unhealthy alcohol users. THERE ARE THREE SUBMISSION CRITERIA FOR THIS MEASURE: 1) All patients who were screened for unhealthy alcohol use using a systematic screening method AND 2) All patients who were identified as unhealthy alcohol users who received brief counseling AND 3) All patients who were screened for unhealthy alcohol use using a systematic screening method and, if identified as unhealthy alcohol users received brief counseling, or were not identified as unhealthy alcohol users This measure contains three submission criteria which aim to identify patients who were screened for unhealthy alcohol use using a systematic screening method (submission criteria 1), patients who were identified as unhealthy alcohol users and who received brief counseling (submission criteria 2), and a comprehensive look at the overall performance on unhealthy alcohol use screening and brief counseling (submission criteria 3). By separating this measure into various submission criteria, the MIPS eligible professional or MIPS eligible clinician will be able to better ascertain where gaps in performance exist, and identify opportunities for improvement. The overall rate (submission criteria 3) should be utilized to compare performance to published versions of this measure prior to the 2021 performance year, when the measure had a single performance rate. For accountability reporting in the CMS MIPS program, the rate for submission criteria 2 is used for performance. **The denominator is revised to read:** Submission Criteria 1: All patients aged 18 years and older seen for at least two visits or at least one preventive visit during the measurement period. Submission Criteria 2: All patients aged 18 years and older seen for at least two visits or at least one preventive visit during the measurement period who were screened for unhealthy alcohol use and identified as an unhealthy alcohol user. Submission Criteria 3: All patients aged 18 years and older seen for at least two visits or at least one preventive visit during the measurement period. **Updated denominator:** Added telehealth as eligible encounter. **The numerator is revised to read:** Submission Criteria 1: Patients who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months. Submission Criteria 2: Patients who received brief counseling. Submission Criteria 3: Patients who were screened for unhealthy alcohol use using a systematic screening method at least once within 12 months AND who received brief counseling if identified as an unhealthy alcohol user. **The numerator definition is revised to read**: Submission Criteria 1: Systematic screening method – For purposes of this measure, one of the following systematic methods to assess unhealthy alcohol use must be utilized. Systematic screening methods and thresholds for defining unhealthy alcohol use include: • AUDIT Screening Instrument (score ≥ 4) • AUDIT-C Screening Instrument (score ≥ 4 for men; score ≥ 3 for women) • Single Question Screening - How many times in the past year have you had 5 (for men) or 4 (for women and all adults older than 65 years) or more drinks in a day? (response ≥ 1). Submission Criteria 2 and 3:

Category	Description
	Brief counseling – Brief counseling for unhealthy alcohol use refers to one or more counseling sessions, a minimum of 5-15 minutes, which may include: feedback on alcohol use and harms; identification of high risk situations for drinking and coping strategies; increased motivation and the development of a personal plan to reduce drinking. **Updated numerator note**: Submission Criteria 1: Added: To satisfy the intent of this measure, a patient must have at least one screening for unhealthy alcohol use during the 12-month period. If a patient has multiple screenings for unhealthy alcohol use during the 12-month period, only the most recent screening, which has a documented status of unhealthy alcohol user or unhealthy alcohol non-user, will be used to satisfy the measure requirements. Submission Criteria 2: Added: In the event that a patient is screened for unhealthy alcohol use and identified as an unhealthy user but did not receive brief alcohol cessation counseling submit GXXXX. Denominator Exception(s) are determined on the date of the most recent denominator eligible encounter for all submission criteria. Submission Criteria 3: Added: To satisfy the intent of this measure, a patient must have at least one unhealthy alcohol use screening during the 12-month period. If a patient has multiple unhealthy alcohol use screenings during the 12-month period, only the most recent screening, which has a documented status of unhealthy alcohol user or unhealthy alcohol non-user, will be used to satisfy the measure requirements. In the event that a patient is screened for unhealthy alcohol use and identified as an unhealthy user but did not receive brief alcohol cessation counseling submit G9624. Denominator Exception(s) are determined on the date of the most recent denominator eligible encounter for all submission criteria. **Updated numerator options:** **Submission Criteria 1:** Revised: **Performance Met:** Patient identified as an unhealthy alcohol user when screened for unhealthy alcohol use using a systematic screening method. **Performance Not Met:** Patient not screened for unhealthy alcohol use using a systematic screening method, reason not given. **Submission Criteria 2:** Added: **Performance Met:** Patient identified as an unhealthy alcohol user received brief counseling. **Denominator Exception:** Documentation of medical reason(s) for not providing brief counseling (e.g., limited life expectancy, other medical reasons). **Performance Not Met:** Patient did not receive brief counseling if identified as an unhealthy alcohol user, reason not given. **Submission Criteria 3:** **Performance Met:** Patient identified as an unhealthy alcohol user when screened for unhealthy alcohol use using a systematic screening method and received brief counseling. **Performance Met:** Patient not identified as an unhealthy alcohol user when screened for unhealthy alcohol use using a systematic screening method. **Denominator Exception:** Documentation of medical reason(s) for not screening for unhealthy alcohol use (e.g., limited life expectancy, other medical reasons). **Denominator Exception:** Documentation of medical reason(s) for not providing brief counseling if identified as an unhealthy alcohol user (e.g., limited life expectancy, other medical reasons). **Performance Not Met:** Patient not screened for unhealthy alcohol use using a systematic screening method OR patient did not receive brief counseling if identified as an unhealthy alcohol user, reason not given. **Updated performance rate calculation:** Revised into three submission criteria. Submission Criteria 2 will be used for benchmarking purposes.
Steward:	Physician Consortium for Performance Improvement Foundation (PCPI®)
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to update the measure overall by splitting the measure into separate populations for three submission criteria. This will allow MIPS eligible clinicians to more readily find where the gaps in performance lie, allowing them to be better informed and able to adjust to improve quality care and patient outcomes. We propose to revise the measure to shorten the look back period to 12 months and require that unhealthy alcohol screening who received brief counseling, if patient screened positive, occur every 12 months. The revision is based upon stakeholder feedback and input from the eCQM Clinical Review Process (CRP) and the measure steward's technical expert panel (TEP) and we agree that it is important to do this annually excessive alcohol use is one of the most common causes of premature mortality in the United States (https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/unhealthy-alcohol-use-in-adolescents-and-adults-screening-and-behavioral-counseling-interventions). The numerator definition for Systematic screening method has been revised to align with current recommendations for the AUDIT C and the Single Questions Screening threshold. We propose to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. 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.92 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	438
CMS eCQM ID:	CMS347v4
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:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications **Updated denominator logic: For the eCQM Specifications collection type:** Added "CABG, PCI Procedure" 2.16.840.1.113762.1.4.1138.566 value set. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Added Hospice Care value sets. **The numerator definition is revised to read: For the MIPS CQMs Specifications collection type**: Statin therapy - Administration of one or more of a group of medications that are used to lower plasma lipoprotein levels in the treatment of hyperlipoproteinemia. Table 1 - Statin Medication Therapy List (NOTE: List does NOT include dosage): Atorvastatin, Fluvastatin, Lovastatin (Mevinolin), Pitavastatin, Pravastatin Sodium, Rosuvastatin Calcium, Simvastatin, Amlodipine Besylate/Atorvastatin, Ezetimibe/Simvastatin **Updated denominator note: For the MIPS CQMs Specifications collection type**: Revised: Denominator Exclusions should be active at any time during the measurement period. **Updated denominator: For the MIPS CQMs Specifications collection type:** Added telehealth as eligible encounters for all submission criteria.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add a value set to the eCQM Specifications collection type denominator to allow for the use of CPT and HCPCS codes for reporting patients who have had a CABG or PCI for inclusion within the denominator. This will improve data capture to ensure a more complete patient population. Additionally, a Hospice Care value set was added to align with the measure intent to exclude both palliative care and hospice patients. We propose to add telehealth encounters as denominator eligible for the MIPS CQMs Specifications collection type as the telehealth setting is 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 update the numerator definition for the MIPS CQMs Specifications collection type to include a table of medications within this section and not in the clinical recommendations statement to ensure MIPS eligible clinicians are following these recommendations based on the clinical guidelines. Additionally, we propose to update the denominator note to add clarity regarding when the denominator exclusion would be assessed within the medical record for the purposes of reporting this measure. We propose to remove the CMS Web Interface Measure Specifications collection type. This collection type is proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this proposed rule.

D.93 Age Appropriate Screening Colonoscopy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	439
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
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:	**The description is revised to read:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31. **The denominator is revised to read:** All screening colonoscopy examinations performed on patients greater than or equal to 50 years of age during the encounter period. **Updated denominator criteria:** Revised: All patients greater than or equal to 50 years of age on date of encounter receiving a colonoscopy for screening purposes only. **The numerator is revised to read:** Screening colonoscopies performed in patients greater than or equal to 86 years of age. **The numerator options are revised to read:** **Performance Met:** Patients greater than or equal to 86 years of age who underwent a screening colonoscopy and did not have a history of colorectal cancer or other valid medical reason for the colonoscopy, including: iron deficiency anemia, lower gastrointestinal bleeding, Crohn's Disease (i.e., regional enteritis), familial adenomatous polyposis, Lynch Syndrome (i.e., hereditary non-polyposis colorectal cancer), inflammatory bowel disease, ulcerative colitis, abnormal finding of gastrointestinal tract, or changes in bowel habits. **Denominator Exception:** Documentation of medical reason(s) for a colonoscopy performed on a patient greater than or equal to 86 years of age (e.g., iron deficiency anemia, lower gastrointestinal bleeding, Crohn's Disease (i.e., regional enteritis), familial history of adenomatous polyposis, Lynch Syndrome (i.e., hereditary non-polyposis colorectal cancer), inflammatory bowel disease, ulcerative colitis, abnormal finding of gastrointestinal tract, or changes in bowel habits). **Performance Not Met:** Patients greater than or equal to 86 years of age who received a colonoscopy for an assessment of signs/symptoms of GI tract illness, and/or because the patient meets high risk criteria, and/or to follow-up on previously diagnosed advanced lesions. **Performance Not Met:** Patients between 50 and 85 years of age who received a screening colonoscopy during the performance period.
Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We propose to update the denominator population to include all patients aged 50 and older to ensure a more complete patient population as the intent of the measure is to assess age appropriate screening colonoscopies, which include patients under the age of 86 years. The description, denominator, and denominator criteria have been updated to reflect these revisions. The numerator and numerator options have been revised to more clearly reflect the patient population and a performance not met numerator option was added to reflect the expanded denominator eligible patient population. 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.94 Medication Management for People with Asthma

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	444
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 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.
Substantive Change:	**Updated numerator:** Updated medication table to split medications by controller versus reliever and adding 'Medication List' and 'Route' column. Asthma Controller Medications: Dyphylline-guaifenesin, Omalizumab, Benralizumab, Mepolizumab, Reslizumab, Budesonide-formoterol, Fluticasone-salmeterol, Fluticasone-vilanterol, Formoterol-mometasone, Beclomethasone, Budesonide, Ciclesonide, Flunisolide, Fluticasone, Mometasone, Montelukast, Zafirlukast, Zileuton, Theophylline. Asthma Reliever Medications: Albuterol, Levalbuterol.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the medications table to ensure the list includes current and appropriate medications for the purposes of meeting performance of this measure. The measure specification medication tables were reformatted for clarity and readability.

D.95 Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy

Category	Description
NQF # / eCQM NQF #:	1858 / N/A
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:	**The title is revised from 'Trastuzumab received by patients with AJCC stage I (T1c) - III and HER2 positive breast cancer receiving adjuvant chemotherapy' to:** Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer. **The description is revised to read**: Percentage of female patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer for whom appropriate treatment is initiated. **The denominator is revised to read**: All female breast cancer patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer. **Updated denominator criteria**: Revised: Female patients age 18-70 years on date of encounter. Removed: Breast Adjuvant Chemotherapy administered. **Updated denominator exclusions:** Removed: • Patient transferred to practice after initiation of chemotherapy. • Patient has metastatic disease at diagnosis. Added: • Patients with pregnancy during adjuvant treatment course. **The numerator is revised to read:** Patients whose adjuvant treatment course includes both chemotherapy and HER2-targeted therapy. **The numerator note is revised to read**: The quality action of this measure is the appropriateness of treatment rather than timeliness of treatment. The timing of administration of HER2-targeted therapies is expected to vary depending on the cytotoxic agents used. The numerator statement is intended to capture an adjuvant treatment course that includes both chemotherapy and HER2-targeted therapy, independent of possible administration sequences. Adjuvant chemotherapy is defined as a chemotherapy regimen initiated within 6 months of cancer diagnosis. An FDA-approved trastuzumad biosimilar is an appropriate substitute for trastuzumab. **The numerator options are revised to read:** **Performance Met:** Patient received adjuvant treatment course including both chemotherapy and HER2-targeted therapy. **Denominator Exception:** Reason for not administering adjuvant treatment course including both chemotherapy and IIER2-targeted therapy (e.g. poor performance status (ECOG 3-4; Karnofsky ≤50), cardiac contraindications, insufficient renal function, insufficient hepatic function, other active or secondary cancer diagnoses, other medical contraindications, patients who died during initial treatment course or transferred during or after initial treatment course). **Performance Not Met:** Patient did not receive adjuvant treatment course including both chemotherapy and HER2-targeted therapy.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to expand the scope and clinical focus of the measure to include all female patients age 18 – 70 years with stage I (T1c) - III HEr2 positive breast cancer, allowing for assessment of chemotherapy within the numerator, necessitating the removal of the denominator criteria for chemotherapy. NCCN recommendations support the administration of chemotherapy and trastuzumab for this patient population. We propose to remove the current denominator exclusions and add new denominator exclusions based upon feasibility testing which determined these histologies are rare enough and are unlikely to have HER2 positivity such that it is not necessary to specifically target for removal from the denominator population. We agree that these exclusions are not appropriate for inclusion. The added denominator exclusions reflect the measure's change in clinical scope and allows for removal of patients for whom treatment with chemotherapy and HER2-targeted therapy would not be appropriate. The measure steward's technical expert panel acknowledged that patients who fail to receive timely treatment may also fail to receive appropriate treatment. Because the quality action of this measure is appropriateness rather than timeliness of treatment, a broader timeframe is utilized to capture patients who may be less likely to receive appropriate treatment, therefore, 6 months was chosen to define adjuvant chemotherapy. The inclusion of an FDA-approved trastuzumab biosimilar as substitute for trastuzumab is in accordance with updated NCCN breast cancer guidelines. We agree with this revision to the numerator note as it clarifies the updated measure scope and aligns with current clinical guidelines. Additionally, we propose to update the numerator options to reflect the updated scope and clinical focus of the 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.96 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

Category	Description
NQF # / eCQM NQF #:	1859 / N/A
Quality#:	451
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.

D.97 Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies

Category	Description
NQF # / eCQM NQF #:	1860 / N/A
Quality#:	452
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	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.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.

D.98 Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0210 / N/A
Quality#:	453
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.

D.99 Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0213 / N/A
Quality#:	455
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.

D.100 Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0216 / N/A
Quality#:	457
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who died from cancer and admitted to hospice and spent less than 3 days there.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We propose to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.

D.101 Back Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / 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:	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 3 months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agree that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.

D.102 Back Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / 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:	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
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agree that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.

D.103 Leg Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / 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:	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 3 months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agree that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.

D.104 Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	462
CMS eCQM ID:	CMS645v4
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 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:	**Updated definition:** Added: First Androgen Deprivation Therapy - The First Androgen Deprivation Therapy (ADT) is measured as the first order or administration of ADT for an anticipated period of 12 months or greater to a patient with prostate cancer.
Steward:	Oregon Urology Institute
High Priority Measure:	No
Measure Type:	Process
Rationale:	We propose to add a definition for 'First Androgen Deprivation Therapy' to clarify the timing of the bone density evaluation necessary for numerator compliance.

D.105 Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use

Category	Description
NQF # / eCQM NQF #:	0657 / N/A
Quality#:	464
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 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.

D.106 Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	468
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.
Substantive Change:	**Updated instructions:** Revised: This measure is to be submitted a minimum of once per performance period for all adults aged 18 years and older with pharmacotherapy for OUD seen during the measurement period that meet additional denominator criteria described below. **The denominator is revised to read:** Adults aged 18 years and older who had a qualifying encounter during the performance year, and a diagnosis of OUD and pharmacotherapy for OUD during the denominator identification period. Eligibility to submit results for a patient requires a qualifying encounter in the performance year, i.e., between January 1, 2021, and December 31, 2021. Solely administering or prescribing OUD medication does not convey eligibility to submit. If a patient has a qualifying encounter within the performance year, the patient is included in the denominator, if the following criteria are met in the denominator identification period between July 1, 2020, and June 30, 2021: • Have a diagnosis of OUD • Receive pharmacotherapy for OUD **Updated denominator definition:** Added: Qualifying Encounter – Encounter during the performance year. Revised: Denominator Identification Period – The period in which eligible adults receive pharmacotherapy for OUD. The denominator identification period is defined as the 12-month period from 07/1/2020 to 6/30/2021. The denominator identification period includes the first 6 months of the reporting year and the last 6 months of the previous year to ensure that all included patients can be observed for at least 180 days of treatment in the reporting year. Patients started on treatment in the second half of the reporting year will be included in the denominator of the subsequent year. The patient must have at least one OUD medication and one visit with a OUD diagnosis during the denominator identification period to be eligible for the measure. **Updated denominator criteria:** Revised: Adults aged ≥ 18 years on date of qualifying encounter. Encounter during the measurement period. **Updated denominator exclusion:** Removed: Pharmacotherapy for OUD initiated after June 30th of 2020. **The numerator note is revised to read:** Numerator compliance is expected to be determined within an 18-month period that includes the measurement period and the 6 months prior to the measurement period (July 1, 2020– December 31, 2021).
Steward:	University of Southern California
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We propose to update the measure to ensure the denominator eligible encounter occurs within the current performance period and the initiation of pharmacotherapy for opioid use disorder (OUD) occurs within the denominator identification period to allow for assessment of at least 180 days for continuous pharmacotherapy for OUD. Additionally, we propose to update the definitions by adding an additional definition of qualifying encounter to clarify which encounters are denominator eligible and revising the denominator identification period definition to align with and clarify the changes to the denominator in regards to timing and eligibility. The numerator note is being revised to align with these changes outlined above and reiterates the guidance pertaining to the timeframes allowed for clinicians to determine if the patient was on at least 180 days for continuous. pharmacotherapy for OUD

D.107 Functional Status After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / 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:	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.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agree that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.

D.108 Functional Status After Primary Total Knee Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / 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:	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.
Substantive Change:	**The description is revised to read:** 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) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively. **Updated instructions:** Revised: NOTE: This measure is a target-based measure, where the numerator is met by having a one-year postoperative Oxford Knee Score (OKS) greater than or equal to 37 or a KOOS, JR score greater than or equal to 71. It is expressed as a proportion or rate. Patients having received a primary total knee replacement procedure who are not assessed for functional status postoperatively remain in the denominator and are considered as not meeting the target. The measure intent is that MIPS eligible clinicians will submit all denominator eligible procedures for performance calculation. **The numerator is revised to read**: All eligible patients whose functional status is greater than or equal to 37 on the Oxford Knee Score (OKS) or greater than or equal to 71 on the KOOS, JR patient reported outcome tool at one year (9 to 15 months) postoperatively. **Updated numerator definition:** Added: KOOS, JR - The KOOS, JR was developed from the original long version of the Knee injury and Osteoarthritis Outcome Score (KOOS) survey using Rasch analysis. The KOOS, JR contains 7 items from the original KOOS survey. Items are coded from 0 to 4, none to extreme respectively. KOOS, JR is scored by summing the raw response (range 0-28) and then converting it to an interval score using the table provided below. The interval score ranges from 0 to 100 where 0 represents total knee disability and 100 represents perfect knee health. This short form tool was developed by Stephen Lyman, PhD at the Hospital for Specialty Surgery in 2017. https://www.hss.edu/hoos-jr-koos-jr-outcomes-surveys.asp KOOS, JR 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 71. **The numerator note is revised to read:** The following situations are those in which the numerator targets cannot be reached and Performance Not Met (M1046) is submitted: • Oxford Knee Score (OKS) or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) 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 or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) • Postoperative Oxford Knee Score (OKS) or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) is administered less than 9 Months or greater than 15 Months • Postoperative Oxford Knee Score (OKS) is less than 37 or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) is less than 71. **The numerator options are revised to read:** **Performance Met:** Functional status measured by the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively was greater than or equal to 37 or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) was greater than or equal to 71. **Performance Not Met:** Functional status measured by the Oxford Knee Score (OKS) or the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) at one year (9 to 15 months) postoperatively was less than 37. **Performance Not Met:** Functional status measured by the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively was less than 37 or the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) was less than 71.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to update the measure to allow for the inclusion of the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) tool as numerator compliance. The KOOS, JR is recommended by the American Academy of Orthopaedic Surgeons (AAOS) and is part of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation and is an appropriate tool for the purposes of this measure. The language was updated throughout the measure to reflect this update and to define numerator compliance when utilizing the KOOS, JR tool.

D.109 Functional Status After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / 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:	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 3 months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agree that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.

D.110 Leg Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / 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:	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. * hereafter referred to as VAS Pain.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agree that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.

D.111 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 / N/A
Quality#:	476
CMS eCQM ID:	CMS771v2
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure 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.
Substantive Change:	**The title is revised from 'International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia' to:** Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	Large Urology Group Practice Association and Oregon Urology Institute
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to shorten the title to replace the very specific score wording with more general wording to be more consistent with definitions and language used within the measure. We propose to remove telehealth encounters from the denominator and denominator exclusions as telehealth is not an appropriate setting for this measure. This guidance can be found in a separate document that will be published on the eCQI Resource Center.

D.112 Functional Status Change for Patients with Neck Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	478
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:	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).
Substantive Change:	**The description is revised to read:** This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). 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 level, 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/paper-pencil). **The definition is revised to read**: **Functional Deficit** – Limitation or impairment of physical abilities/function resulting in evaluation and inclusion in a treatment plan of care. **Treatment Episode** –A Treatment Episode is defined as beginning with an Initial Evaluation for a functional neck 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 neck deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Initial Evaluation** – An Initial Evaluation is the first encounter for a functional deficit involving the neck 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 (M1143). A patient presenting with a neck impairment, who has had an interruption of a Treatment Episode for the same functional neck deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. **Discharge** Discharge is accompanied by a treatment finalization and evaluation completion M-Code (Mxxx) identifying the close of a Treatment Episode for the same neck 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. **Encounter** – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. Patient Reported – The patient directly provides answers to the FS measure items using a standardized, reliable and valid, computerized adaptive testing or short form (static/paper and pencil-type) method. If the patient cannot reliably respond independently (for example, in the presence of cognitive deficits), a suitable proxy may provide answers. **The denominator is revised to read**: All patients aged 14 years and older with neck impairments who initiated a Treatment Episode. **Updated denominator criteria**: Revised: All patients aged ≥14 years on date of Initial Evaluation. Added: With a neck impairment and/or diagnosis pertaining to a functional deficit affecting the neck. **Updated denominator** exclusions: Removed: Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Added: Patient unable to complete the Neck FS PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility, and an adequate proxy is not available. **The numerator is revised to read:** Patients who were presented with the Neck 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. **The numerator definition is revised to read:** **Patient's Functional Status Score** – A functional status score is produced when the patient completes the functional status patient-reported outcome measure (either by short form or computerized adaptive testing administration). The functional status score is continuous and linear. Scores range from 0 to 100 with higher scores meaning higher functional abilities. The measure is standardized, and the scores are validated for the measurement of function for this population. **Patient's Functional Status Change Score** – A functional status change score is calculated by subtracting the Patient's Functional Status Score at Initial Evaluation from the Patient's Functional Status Score at Discharge. **Predicted Functional Status Change Score** – Functional Status Change Scores for patients are risk adjusted using multiple linear regression methods that include the following independent variables: Patient's Functional Status Score at Initial Evaluation, patient age, symptom acuity, surgical history, gender, specific co- morbidities, use of medication for the condition at Initial Evaluation, exercise history, history of previous treatment for the condition and type of post-surgical status. The Patient's Functional Status Change Score is the dependent variable. For each patient completing a functional status assessment at Initial Evaluation (Intake), the regression model provides a risk-adjusted prediction of functional status change at Discharge. **Risk-Adjusted Functional Status Change Residual Score** – The difference between the raw non-risk- adjusted Patient's Functional Status Change Score and the Risk-Adjusted Predicted Functional Status Change Score (raw minus predicted) is the

Category	Description
	Risk-Adjusted Functional Status Change Residual Score, which is in the same units as the Patient's Functional Status Scores, and should be interpreted as the unit of functional status change different than predicted given the risk-adjustment variables of the patient being treated. As such, the Risk-Adjusted Residual Change Score represents Risk-Adjusted Change corrected for the level of severity of the patient. Risk-Adjusted Residual Change Scores of zero (0) or greater (> 0) should be interpreted as functional status change scores that were predicted or better than predicted given the risk- adjustment variables of the patient, and risk-adjusted residual change scores less than zero (< 0) should be interpreted as functional status change scores that were less than predicted given the risk-adjustment variables of the patient. Aggregated Risk-Adjusted Residual Scores allow meaningful comparisons amongst clinicians or clinics. **Updated numerator note:** Removed all. **The numerator options are revised to read:** **Performance Met:** Risk-Adjusted Functional Status Change Residual Score for the neck impairment successfully calculated and the score was equal to zero (0) or greater than zero (> 0) **Denominator Exceptions:** 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown. 4. Patient refused to participate. **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the neck impairment not measured because the patient did not complete the Neck FS PROM at Initial Evaluation and/or near Discharge, reason not given. **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the neck impairment successfully calculated and the score was less than zero (< 0).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We propose to update the measure to align with the other Focus on Therapeutic Outcomes, Inc. (FOTO) measures within MIPS. This will lessen MIPS eligible clinician burden when reporting this measure in conjunction with FOTO's other measures as the structure and content will now align. Definitions were inlcuded to add clarity and provide guidance when reporting this measure. Additonal denominator criteria for patients with a neck impairment and/or diagnosis pertaining to a functional deficit affect the neck was included to further define the appropriate patient population for this measure. Additionally, the denominator exclusions and exceptions were updated, along with the other numerator options, to align across all FOTO measures for consistency. 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.

APPENDIX 2: IMPROVEMENT ACTIVITIES

NOTE: In this proposed rule, for the CY 2021 performance period and future years, we are proposing to modify two previously adopted improvement activities in the Inventory. These modifications are discussed in detail below.

Table A: Proposed Changes to Previously Adopted Improvement Activities for the MIPS CY 2021 Performance Period and Future Years

Current Improvement Activity	
Current Activity ID:	**IA_BE_4**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Engagement of patient through implementation of improvements in patient portal
Current Activity Description:	Access to an enhanced patient portal that provides up to date information related to relevant chronic disease health, blood pressure control, and includes interactive features allowing patients to enter health information and/or enables bidirectional communication about medication changes and adherence.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 QPP final rule (81 FR 77825). This proposed modification would add language to include caregivers as additional potential users of the patient portal, instead of just patients and clinicians, given the important role caregivers can play in bidirectional information exchange regarding the clinical care of the patient. This proposed modification also would add language to clarify that the portal's use should be for "bidirectional information exchange between the patient and their provider" and "the primary use…should be clinical, and not administrative." In addition, the proposed modifications would replace existing description with a nonexhaustive list of examples of bidirectional portal functions that are clinical rather than administrative. The list of examples would include: "brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; and any relevant acute or chronic disease management."
Proposed Revised Activity Description:	To receive credit for this activity, MIPS eligible clinicians must provide access to an enhanced patient/caregiver portal that allows users (patients or caregivers and their clinicians) to engage in bidirectional information exchange. The primary use of this portal should be clinical and not administrative. Examples of the use of such a portal include, but are not limited to: brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; or any relevant acute or chronic disease management.
Current Improvement Activity	
Current Activity ID:	**IA_AHE_7**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Comprehensive Eye Exams
Current Activity Description:	To receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by providing literature and/or facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign and/or referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America and the American Optometric Association's VISION USA. This activity is intended for: • Non-ophthalmologists / optometrists who refer patients to an ophthalmologist/optometrist; • Ophthalmologists/optometrists caring for underserved patients at no cost; or

	• Any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high-risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2019 PFS final rule (83 FR 59452). This proposed modification would add language that expands the types of services that eligible clinicians can promote to underserved and/or high-risk populations to receive credit for this activity. Specifically, we are proposing to add the following sentence: "promoting access to vision rehabilitation services as appropriate for individuals with chronic vision impairment." Also, "or vision rehabilitation services" would be added to the end of the activity description. These modifications would broaden this improvement activity to eligible clinicians who promote vision rehabilitation services, if they are serving patients with vision impairments detected during comprehensive eye exams.
Proposed Revised Activity Description:	To receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by any one or more of the following: • providing literature, • facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign, • referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America and the American Optometric Association's VISION USA, or • promoting access to vision rehabilitation services as appropriate for individuals with chronic vision impairment. This activity is intended for: • Non-ophthalmologists / optometrists who refer patients to an ophthalmologist/optometrist; • Ophthalmologists/optometrists caring for underserved patients at no cost; or • Any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high-risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams or vision rehabilitation services.

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