DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 417, 422, 423, 455, and 460

[CMS–4190–P]

RIN 0938–AT97

Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicaid program, Medicare Cost Plan program, and Programs of All-Inclusive Care for the Elderly to implement certain sections of the Bipartisan Budget Act of 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, and the 21st Century Cures Act. This proposed rule would also enhance the Part C and D programs, codify several existing CMS policies, and implement other technical changes.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 6, 2020.

ADDRESSES: In commenting, please refer to file code CMS–4190–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

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

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4190–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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–4190–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Theresa Wachter, (410) 786–1157, or Cali Diehl, (410) 786–4053—General Questions.
Kimberlee Levin, (410) 786–2549—Part C Issues.
Lucia Patrone, (410) 786–8621—Part D Issues.
Kristy Nishimoto, (206) 615–2367—Beneficiary Enrollment and Appeals Issues.
Stacy Davis, (410) 786–7813—Part C and D Payment Issues.
Sabrina Sparkman, (410) 786–3209—PACE Issues.
Debra Drew, (410) 786–6827—Program Integrity Issues.
Melissa Seeley, (212) 616–2329—D–SNP Issues.

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://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Acronyms

AE Actuarial Equivalent
AEP Annual Coordinated Enrollment Period
AIC Amount in Controversy
ANOC Annual Notice of Change
ARB At-Risk Beneficiaries
BBA Bipartisan Budget Act
BBP Base Beneficiary Premium
BLS Bureau of Labor Statistics
CAHPS Consumer Assessment of Healthcare Providers and Systems
CARA Comprehensive Addiction and Recovery Act
CDC Centers for Disease Control and Prevention
CEAC Counties with Extreme Access Considerations
CMS Centers for Medicare & Medicaid Services
COI Collection of Information
CON Certificate of Need
COPD Chronic Obstructive Pulmonary Disease
C–SNP Chronic Condition Special Needs Plan
DME Durable Medical Equipment
DMP Drug Management Program
D–SNP Dual Eligible Special Needs Plan
ED Emergency Department
EGWP Employer Group Waiver Plan
EHR Electronic Health Record
EOC Evidence of Coverage
eRx E-Prescribing
ESRD End-Stage Renal Disease
FAD Frequently Abused Drug
FAQ Frequently Asked Question
FFS Fee-for-Service
FIDE SNP Fully Integrated Dual Eligible Special Needs Plan
FMV Fair Market Value
HEDIS Healthcare Effectiveness Data and Information Set
HHS Department of Health and Human Services
HIDE SNP Highly Integrated Dual Eligible Special Needs Plan
HIPAA Health Insurance Portability and Accountability Act of 1996
HOS Health Outcomes Survey
HPMS Health Plan Management System
HSD Health Service Delivery
ICD International Classification of Diseases
ICR Information Collection Requirement
IDR Integrated Data Repository
IDT Interdisciplinary Team
IMF Illicitly Manufactured Fentanyl
IRE Independent Review Entity
IRMAA Income-Related Monthly Adjustment Amount
I–SNP Institutional Special Needs Plan
IT Information Technology
LPPO Local Preferred Provider Organization
MA Medicare Advantage
MACPAC Medicaid and CHIP Payment and Access Commission
MAGI Modified Adjusted Gross Income
MA–PD Medicare Advantage Prescription Drug
MCO Managed Care Organization
MCMG Medicare Communications and Marketing Guidelines
MCS Improving or Maintaining Mental Health
MedPAC Medicare Payment Advisory Commission
MIPPA Medicare Improvements for Patients and Providers Act
MLR Medical Loss Ratio
MMA Medicare Prescription Drug, Improvement, and Modernization Act
MMCM Medicare Managed Care Manual
MME Morphine Milligram Equivalent

MMP Medicare-Medicaid Plan
MOC Model of Care
MOOP Maximum Out-of-Pocket
MPF Medicare Plan Finder
MSA Medical Savings Account
NAICS North American Industry Classification System
NBI MEDIC National Benefit Integrity Medicare Drug Integrity Contractor
NCQA National Committee for Quality Assurance
NMM Network Management Module
NPPES National Provider and Plan Enumeration System
NQF National Quality Forum
OACT Office of the Actuary
OEP Open Enrollment Period
OIG Office of Inspector General
OMB Office of Management and Budget
OMHA Office of Medicare Hearings and Appeals
OMS Overutilization Management System
OUD Opioid Use Disorder
PA Prior Authorization
PACE Programs of All-Inclusive Care for the Elderly
PAD Peripheral Artery Disease
PARB Potential At-Risk Beneficiary
PBP Plan Benefit Package
PCS Improving or Maintaining Physical Health
PDE Prescription Drug Event
PDP Prescription Drug Plan
PFFS Private Fee-for-Service
PIM Program Integrity Manual
PMPM Per Member Per Month
POS Point-of-Sale
PQA Pharmacy Quality Alliance
PRA Paperwork Reduction Act
QBP Quality Bonus Payment
QIA Quality Improvement Activity
RFA Regulatory Flexibility Act
RI Rewards and Incentives
RPPO Regional Preferred Provider Organization
RTBT Real Time Benefit Tool
SAE Service Area Expansion
SAR Service Area Reduction
SB Summary of Benefits
SBA Small Business Administration
SCD Sickle Cell Disease
SEP Special Election Period
SET Supervised Exercise Therapy
SIU Special Investigations Unit
SMID Standardized Material Identification
SNP Special Needs Plan
SOA Scope of Appointment
SPAP State Pharmaceutical Assistance Program
SSA Social Security Administration
SSBCI Special Supplemental Benefits for the Chronically Ill
SUPD Statin Use in Persons with Diabetes
SUPPORT Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment
TMP Timeliness Monitoring Project
UM Utilization Management
UMRA Unfunded Mandates Reform Act

I. Executive Summary

A. Executive Summary

1. Purpose

The primary purpose of this proposed rule is to implement certain sections of the following federal laws related to the Medicare Advantage (MA or Part C) and Prescription Drug Benefit (Part D) programs:

- The Bipartisan Budget Act of 2018 (hereinafter referred to as the BBA of 2018)
- The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (hereinafter referred to as the SUPPORT Act)
- The 21st Century Cures Act (hereinafter referred to as the Cures Act)

The rule would also include a number of changes to strengthen and improve the Part C and D programs, codify in regulation several CMS interpretive policies previously adopted through the annual Call Letter and other sub-regulatory guidance documents, and implement other technical changes for contract year 2021 and 2022. In the fall of 2017, CMS launched the Patients over Paperwork initiative. The key focus of this initiative is to reduce ''red tape'' that depletes resources from our healthcare system and wastes the time clinicians and other healthcare workers need to perform their primary mission—caring for patients.

In keeping with the success of this program, CMS continues to review its regulatory requirements and sub-regulatory policies to examine opportunities to prioritize the well-being of patients over the CMS requirements on the healthcare industry. In particular, the Patients over Paperwork initiative charges CMS to analyze the impact of existing requirements and remove unnecessary burdens. As part of this, CMS is streamlining and clarifying certain patient protections and codifying important sub-regulatory guidance in the Code of Federal Regulations. This provides an opportunity for the public to review and comment on proposed requirements and provides transparency into CMS's rules and guidance.

2. Summary of the Major Provisions

a. Mandatory Drug Management Programs (DMPs) (§ 423.153)

Section 704 of the Comprehensive Addiction and Recovery Act of 2016 (hereinafter referred to as CARA) included provisions permitting Part D sponsors to establish drug management programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs). Under the DMPs in place today, Part D sponsors engage in case management of potential at-risk beneficiaries (PARBs) through contact with their prescribers to determine whether the beneficiary is at-risk for prescription drug misuse or abuse. If a beneficiary is determined to be at-risk, after notifying the beneficiary in writing, the sponsor may limit their access to coverage of opioids and/or benzodiazepines to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale (POS) claim edit.

While the majority of Part D sponsors have already voluntarily implemented DMPs, CMS is proposing the requirement of mandatory implementation of DMPs by Part D sponsors, for plan years beginning on or after January 1, 2022, as required under section 2004 of the SUPPORT Act.

b. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

A past overdose is the risk factor most predictive for another overdose or suicide-related event.[1] In light of this fact, in section 2006 of the SUPPORT Act, Congress required CMS to include Part D beneficiaries with a history of opioid-related overdose (as defined by the Secretary) as PARBs under a Part D plan's DMP. CMS is also required under this section to notify the sponsor of such identifications. In line with this requirement, we are proposing to modify the definition of ''potential at-risk beneficiary'' at § 423.100 to include a Part D eligible individual who is identified as having a history of opioid-related overdose, as we propose to define it. Inclusion of beneficiaries with a history of opioid-related overdose as PARBs in DMPs will allow Part D plan sponsors and providers to work together to closely assess these beneficiaries' opioid use and determine whether any additional action is warranted.

c. Automatic Escalation to External Review Under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

CMS is proposing that, if on reconsideration a Part D sponsor affirms its denial of a DMP appeal, the case shall be automatically forwarded to the independent outside entity for review and resolution. We are proposing that a plan sponsor must forward the case to the independent outside entity by the expiration of the adjudication timeframe applicable to the plan level appeal. Finally, we are proposing conforming

[1] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul;112(7):1193–1201. doi: 10.1111/add.13774.

revisions to the notices that are sent to beneficiaries.

d. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

CMS proposes to undertake rulemaking to implement the provisions outlined in sections 2008 and 6063 of the SUPPORT Act, which are summarized in the following sections (1) and (2). Implementing these provisions will allow CMS, MA organizations and Medicare Part D plan sponsors (including MA organizations offering MA–PD plans) to share data and information regarding bad actors, take swift action based on such data and information, and achieve enhanced outcomes in our efforts to fight the opioid crisis. In addition, this regulation will provide the means for more effective referrals to law enforcement based on plan sponsor reporting, ultimately resulting in reduced beneficiary harm and greater savings for the Medicare program.

(1) Section 2008 of the SUPPORT Act

Title XVIII of the Social Security Act (the Act) provides authority for CMS to suspend payments to Medicare fee-for-service (FFS) providers and suppliers pending an investigation of a credible allegation of fraud, unless a good cause exception applies. While Part D plan sponsors currently have the discretion to suspend payments to pharmacies in the plans' networks, section 2008 requires that plan sponsors' payment suspensions based on credible allegations of fraud be implemented in the same manner as CMS implements such payment suspensions. Under this provision, plan sponsors are required to notify the Secretary of the imposition of a payment suspension that is based on a credible allegation of fraud and may do so using a secure website portal. The reporting requirement applicable to plan sponsors will only apply to suspended payments based on credible allegations of fraud as required by section 2008 and will not extend to other payment suspensions for which plan sponsors already have authority. Section 2008 also clarifies that a fraud hotline tip, without further evidence, is not considered a credible fraud allegation for payment suspension purposes.

(2) Section 6063 of the SUPPORT Act

Section 6063 requires the Secretary to establish a secure internet website portal to enable the sharing of data among MA plans, prescription drug plans, and the Secretary, and referrals of ''substantiated or suspicious activities'' of a provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse to initiate or assist with investigations conducted by eligible entities with a contract under section 1893 of the Act, such as a Medicare program integrity contractor. The Secretary is also required to use the portal to disseminate information to all MA plans and prescription drug plans on providers and suppliers that were referred to CMS for fraud, waste, and abuse in the last 12 months; were excluded or the subject of a payment suspension; are currently revoked from Medicare; or, for such plans that refer substantiated or suspicious activities to CMS, whether the related providers or suppliers were subject to administrative action for similar activities. The Secretary is required to define what constitutes substantiated or suspicious activities. Section 6063 specifies that a fraud hotline tip without further evidence shall not be treated as sufficient evidence for substantiated fraud, waste, or abuse.

Section 6063 also requires the Secretary to disseminate quarterly reports to MA plans and prescription drug plans on fraud, waste, and abuse schemes and suspicious activity trends reported through the portal. The Secretary's reports are to maintain the anonymity of information submitted by plans and to include administrative actions, opioid overprescribing information, and other data the Secretary, in consultation with stakeholders, determines important.

Beginning with plan year 2021, section 6063 also requires Part D plan sponsors to submit to the Secretary information on investigations, credible evidence of suspicious activities of providers or suppliers related to fraud, and other actions taken by the plans related to inappropriate opioid prescribing. The Secretary is required to issue regulations that define the term inappropriate prescribing with respect to opioids, identify a method to determine if providers are inappropriately prescribing, and identify the information plan sponsors are required to submit.

e. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

The Cures Act (Pub. L. 114–255) amended sections 1851, 1852, and 1853 of the Act to expand enrollment options for individuals with end stage renal disease (ESRD) and make associated payment and coverage changes to the MA and original Medicare programs. Specifically, since the beginning of the MA program, individuals with ESRD have not been able to enroll in MA plans subject to limited exceptions. Section 17006(a) of the Cures Act removed this prohibition effective for plan years beginning on or after January 1, 2021. We are proposing to codify this change with revisions to §§ 422.50(a)(2), 422.52, and 422.110.

f. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322)

With this new enrollment option, the Cures Act also made several payment changes in the MA and original Medicare FFS programs. Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude from the Medicare benefits an MA plan is required to cover for an MA enrollee coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs will be covered under the original Medicare FFS program. Section 17006(c)(2) of the Cures Act also amended section 1851(i) of the Act, providing that CMS may pay an entity other than the MA organization that offers the plan in which the individual is enrolled for expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act. We propose changes to our regulation at § 422.322 to align with these new statutory requirements.

g. Exclusion of Kidney Acquisition Costs From Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Since the original Medicare FFS program will cover costs of organ acquisitions for kidney transplants for individuals in an MA plan, section 17006(b) of the Cures Act also amended section 1853 of the Act to exclude these costs from the MA benchmarks used in determining payment to MA plans. Specifically, the Secretary, effective January 1, 2021, is required to exclude the estimate of standardized costs for payments for organ acquisitions for kidney transplants from MA benchmarks and capitation rates. We propose changes to our regulations at §§ 422.258(d) and 422.306 to align with these new statutory requirements.

h. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

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 (hereinafter referred to as the April 2018 final rule), we codified the methodology for the Star Ratings system for the MA and Part D programs, respectively, at §§ 422.160 through 422.166 and §§ 423.180 through 423.186. We will propose through rulemaking any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes.

At this time, in addition to routine measure updates and technical clarifications, we are proposing to further increase the weight of patient experience/complaints and access measures from a weight of 2 to 4. We are also proposing to directly remove outliers prior to calculating the cut points to further increase the predictability and stability of the Star Ratings system. We are also proposing to clarify some of the current rules around assigning Quality Bonus Payment (QBP) ratings and to codify existing policy for assigning QBP ratings for new contracts under existing parent organizations. Unless otherwise stated, data would be collected and performance measured using these proposed rules and regulations for the 2021 measurement period and the 2023 Star Ratings.

i. Permitting a Second, ''Preferred'', Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

We are proposing to allow Part D sponsors to establish up to two specialty tiers and design an exceptions process that exempts drugs on these tiers from tiering exceptions to non-specialty tiers. We propose that Part D sponsors would have the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the ingredient cost threshold established according to the methodology we are proposing and the requirements of the CMS formulary review and approval process under § 423.120(b)(2). To maintain Part D enrollee protections, we are proposing to codify a maximum allowable cost sharing that would apply to the higher cost-sharing specialty tier. Further, we propose to require that if there are two specialty tiers, one must be a ''preferred'' tier that offers lower cost sharing than the proposed maximum allowable specialty tier cost sharing.

We note that we are not proposing any revisions to § 423.578(c)(3)(ii), which requires Part D sponsors to provide coverage for a drug for which a tiering exception was approved at the cost sharing that applies to the preferred alternative. Because we propose that the exemption from tiering exceptions for specialty tier drugs would apply only to tiering exceptions to non-specialty tiers, our proposal would require Part D sponsors to permit tiering exception requests for drugs on the higher-cost specialty tier to the lower-cost specialty tier.

To improve transparency, we propose to codify current methodologies for cost sharing and calculations relative to the specialty tier, with some modifications. First, we propose to codify a maximum allowable cost sharing permitted for the specialty tiers of between 25 percent and 33 percent, depending on whether the plan includes a deductible, as described further in section V.F.4. of this proposed rule. We also propose to determine the specialty-tier cost threshold—meaning whether the drug has costs high enough to qualify for specialty tier placement—based on a 30-day equivalent supply. Additionally, we propose to base the determination of the specialty-tier cost threshold on the ingredient cost reported on the prescription drug event (PDE). We also propose to maintain a specialty-tier cost threshold for both specialty tiers that is set at level that, in general, reflects drugs with monthly ingredient costs that are in the top one percent, as described further in section V.F.6. of this proposed rule. Finally, we propose to adjust the threshold, in an increment of not less than ten percent, rounded to the nearest $10, when an annual analysis of PDE data shows that an adjustment is necessary to recalibrate the threshold so that it only reflects drugs with the top one percent of monthly ingredient costs. We propose to determine annually whether the adjustment would be triggered and announce the specialty-tier cost threshold annually.

j. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

This rule proposes to require that Part D plan sponsors implement, no later than January 1, 2022, a beneficiary real-time benefit tool (RTBT). This tool would allow enrollees to view a plan-defined subset of the information included in the prescriber RTBT system, which will include accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements). Plans would be permitted to use existing secure patient portals to fulfill this requirement, to develop a new portal, or use a computer application. Plans would be required to make this information available to enrollees who call the plans' customer service call center.

In order to encourage enrollees to use the beneficiary RTBT, we propose to allow plans to offer rewards and incentives (RI) to their enrollees who log onto the beneficiary RTBT or seek to access this information via the plan's customer service call center.

k. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

We are proposing to amend the MA medical loss ratio (MLR) regulation at § 422.2420 so that the incurred claims portion of the MLR numerator includes all amounts that an MA organization pays (including under capitation contracts) for covered services. Currently, incurred claims in the MLR numerator include direct claims paid to providers for covered services furnished to all enrollees under an MA contract. This proposal would include in the incurred claims portion of the MLR numerator amounts paid for covered services to individuals or entities that do not meet the definition of ''provider'' as defined at § 422.2.

We are also proposing to codify in the regulations at §§ 422.2440 and 423.2440 the definitions of partial, full, and non-credibility and the credibility factors that CMS published in the Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule (78 FR 31284) (hereinafter referred to as the May 2013 Medicare MLR final rule). We believe that it is more consistent with the policy and principles articulated in Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (October 9, 2019) that we define and publish the definitions of partial, full, and non-credibility and the credibility factors in the **Federal Register**, and that we codify these definitions and factors in the Code of Federal Regulations, as opposed to using the annual Advance Notice and Rate Announcement process, as specified in current §§ 422.2440 and 423.2440.

Additionally, we are proposing to amend § 422.2440 to provide for the application of a deductible factor to the

MLR calculation for MA medical savings account (MSA) contracts that receive a credibility adjustment. The proposed deductible factor would serve as a multiplier on the applicable credibility adjustment. This additional adjustment for MA MSAs is intended to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles, with high cost or outlier claims representing a larger portion of the overall claims experience of plans with high deductibles. The proposed deductible factor would reduce the risk that an MSA contract will fail to meet the MLR requirement as a result of random variations in claims experience. We are proposing to adopt the same deductible factors that apply under the commercial MLR regulations at 45 CFR part 158.

l. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

We are proposing to strengthen network adequacy rules for MA plans by codifying our existing network adequacy methodology and standards (with some modifications); we are also seeking comment on refining standards related to telehealth, maximum time and distance standards, and whether there are additional changes we should consider to improve MA plan access in all county types, such as to address the effect of Certificate of Need (CON) requirements, or whether there more specific changes we should consider to increase plan choice in more rural counties. The authorization of additional telehealth benefits pursuant to the BBA of 2018 incentivizes new ways for beneficiaries to access health care beginning in 2020. As a result, CMS has been examining its network adequacy standards overall to determine how contracted telehealth providers should be considered when evaluating the adequacy of an MA plan network. We propose to allow MA plans to receive a 10 percent credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with telehealth providers in the following provider specialty types: dermatology, psychiatry, cardiology, otolaryngology and neurology. We also are soliciting comment regarding whether we should expand this credit to other specialty provider types, such as nephrology for home dialysis and if this percentage ''credit'' should vary by county type.

Additionally, in order to expand access to MA plans where network development can be challenging, we propose to modify the current network adequacy standards by codifying a reduced standard for the percentage of beneficiaries that must reside within the maximum time and distance standards in non-urban counties (Micro, Rural, and Counties with Extreme Access Considerations (CEAC) county type designations) for an MA plan to comply with the network adequacy standards. We also solicit comment about whether and how much of a percentage reduction would likely be required to incentivize MA penetration and whether the reduction should apply to all county types, or just non-urban counties.

m. Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

Sections 1851(e)(4) and 1860D–1(b)(3) of the Act establish special election periods (SEPs) during which, if certain circumstances exist, an individual may request enrollment in, or disenrollment from, MA and Part D plans. The Secretary also has the authority to create SEPs for individuals who meet other exceptional conditions. We are proposing to codify a number of SEPs that we have adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. Codifying our current policy for these SEPs will provide transparency and stability to the MA and Part D programs by ensuring that the SEPs are known and changed only through additional rulemaking. Among the proposed SEPs are the SEP for Individuals Affected by a FEMA-Declared Weather-Related Emergency or Major Disaster, the SEP for Employer/Union Group Health Plan (EGHP) elections, and the SEP for Individuals Who Disenroll in Connection with a CMS Sanction. We are also proposing to establish two additional SEPs for exceptional circumstances: the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.

n. Service Delivery Request Processes Under PACE (§§ 460.104 and 460.121)

Currently, PACE participants or their designated representatives may request to initiate, eliminate or continue a service, and in response, the PACE organization must process this request under the requirements at § 460.104(d)(2). These requests are commonly referred to by CMS and the industry as ''service delivery requests.'' In response to feedback from PACE organizations and advocacy groups, and based on our experience monitoring PACE organizations' compliance with our current requirements, we are proposing to move the requirements for processing service delivery requests from § 460.104(d)(2) and add them to a new § 460.121 in order to increase transparency for participants and reduce confusion for PACE organizations. We are also proposing to modify these provisions in order to reduce unnecessary burden on PACE organizations and eliminate unnecessary barriers for participants who have requested services that a PACE organization would be able to immediately approve. Specifically, we are proposing to more clearly define what constitutes a service delivery request, and provide transparent requirements for how those requests would be processed by the PACE organization, including who can make a request, how a request can be made, and the timeframe for processing a service delivery request. We are also proposing to allow the interdisciplinary team (IDT) to bypass the full processing of a service delivery request under the new proposed requirements under § 460.121 when the request can be approved in full by an IDT member at the time it is made. For all other service delivery requests that are brought to the IDT, we are proposing to maintain the requirement that an in-person reassessment must be conducted prior to a service delivery request being denied, but we are proposing to eliminate the requirement that a reassessment (either in-person or through remote technology) be conducted when a service delivery request can be approved. Lastly, we are proposing to add participant protections; specifically, we are proposing to increase notification requirements in order to ensure participants understand why their request was denied, and we are proposing to add reassessment criteria in order to ensure reassessments are meaningful to the service delivery request, and that the IDT takes them into consideration when rendering a decision.

o. Beneficiaries With Sickle Cell Disease (SCD) (§ 423.100)

Beneficiaries with active cancer-related pain, residing in a long-term care facility, or receiving hospice, palliative, or end-of-life care currently meet the definition of ''exempt individuals'' with respect to DMPs in § 423.100. Section 1860D–4(c)(5)(C)(ii)(III) of the Act provides the Secretary with the authority to elect to treat other beneficiaries as exempted from DMPs.

Due to concerns of misapplication of opioid restrictions in the sickle cell disease (SCD) patient population, CMS is proposing that, starting in plan year 2021, beneficiaries with SCD are classified as exempt individuals.

3. Summary of Costs and Benefits

BILLING CODE 4120–01–P

Provision	Description	Impact
a. Mandatory Drug Management Programs (DMPs) (§ 423.153)	This provision would codify the SUPPORT Act requirement making it mandatory that Part D sponsors implement DMPs, starting in plan year 2022.	There are costs of about $0.1 million a year with a 10-year total cost of $0.8 million.
b. Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)	This provision would require that CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose (as defined by the Secretary) and include such individuals as PARBs for prescription drug abuse under sponsors' DMPs.	Part D enrollees with a history of opioid-related overdose have higher than average drug costs. CMS estimates that Part D DMPs could save 5 percent in costs per year. After the first year, the reduction in drug utilization would result in an annual savings of $7.7 million to the Medicare Trust Fund resulting from reduced drug spending by beneficiaries. The costs for case management and related paperwork is estimated at $10.1 million annually after the first year.
c. Automatic Escalation to External Review under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)	CMS is proposing that if a Part D sponsor denies a DMP appeal, the case shall be automatically forwarded to the independent outside entity for review and resolution. We are proposing that a plan sponsor must forward the case to the independent outside entity by the expiration of the adjudication timeframe applicable to the plan level appeal. Finally, we are proposing conforming revisions to the notices that are sent to beneficiaries.	We estimate there will be about 28,600 appeals per year, of which 0.08 percent will be denied and automatically escalated to the independent review entity (IRE). Therefore, there are only about 23 cases (0.08 percent * 28,600) affected by this provision. Since most IRE cases are judged by a physician at a wage of $202.46, and typically an IRE will take at most 1 hour to review, the total burden is negligible (about $4,656.58 (23 cases * $202.46 * 1 hour)).

d. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)	CMS is proposing to implement two sections of the SUPPORT Act, which will-- (1) require Part D plan sponsors to notify the Secretary of the imposition of a payment suspension on pharmacies that is based on a credible allegation of fraud, impose such payment suspensions consistent with the manner in which CMS implements payment suspensions in fee-for service Medicare, and report such information using a secure website portal; (2) define inappropriate prescribing with respect to opioids; (3) require plan sponsors to submit to the Secretary information on investigations and other actions related to inappropriate opioid prescribing; (4) define "substantiated or suspicious activities" related to fraud, waste, or abuse; and (5) establish a secure portal which would enable the sharing of data and referrals of "substantiated or suspicious activities" related to fraud, waste, or abuse among plan sponsors, CMS, and CMS's program integrity contractors..	While we believe there may be savings generated through actions taken by plans that will conduct their own due diligence from the reporting and sharing of administrative actions between CMS and plans sponsors, as well as additional law enforcement actions, we cannot estimate the impact at this time. The reporting requirements will cost about $9.5 million a year after the first year.
e. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)	CMS is proposing to codify requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS proposes to remove the prohibition for beneficiaries with ESRD from enrolling in an MA plan.	Since there are no new provisions regarding enrollment of beneficiaries with ESRD, or kidney acquisition costs, in this regulation that are not in the Act; there are no impacts to report as resulting solely from this provision.
f. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322)	CMS is proposing to codify requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS proposes that MA organizations will no longer be responsible for costs for organ acquisitions for kidney transplants for their beneficiaries. Instead, CMS proposes to require that Medicare FFS cover the kidney acquisition costs for MA beneficiaries, effective 2021.	To estimate the impact, we used a pre-statute baseline. This analysis shows that FFS coverage of kidney acquisition costs for MA beneficiaries results in net costs to the Medicare Trust Funds ranging from $212 million in 2021 to $981 million in 2030.
g. Exclusion of Kidney Acquisition Costs from Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)	CMS is proposing to codify requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS proposes to remove costs for organ acquisitions for kidney transplants from the calculation of MA benchmarks and annual capitation rates.	To estimate the impact, we used a pre-statute baseline. This analysis shows that excluding kidney acquisition costs from MA benchmarks results in net savings estimated to range from $594 million in 2021 to $1,346 million in 2030.

h. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)	We are proposing routine measure updates and an increase in the weight of patient experience/complaints and access measures. We are also proposing some technical clarifications of the current rules for the QBP ratings methodology. We also propose the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers, to increase the stability and predictability of the star measure cut points.	Updating the patient experience/complaints and access measures weight would create a cost which is offset by using the Tukey outlier deletion. The net savings to the Medicare Trust Fund is $368.1 million in 2024; this will grow over time reaching $999.4 million by 2030. The net reduction in spending to the Medicare Trust Fund over 10 years is $4.9 billion.
i. Permitting a Second, "Preferred", Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)	CMS is proposing to (1) allow Part D sponsors to establish a second, "preferred," specialty tier at a lower cost-sharing threshold than the current specialty tier; (2) codify the existing maximum cost sharing for the highest specialty tier; (3) codify a methodology to determine annually the specialty tier cost threshold using ingredient cost and increase the threshold when certain conditions are met; (4) require sponsors to permit tiering exceptions between the two specialty tiers; and (5) permit sponsors to determine which drugs go on either tier.	Permitting Part D sponsors to establish a second, "preferred", specialty tier is unlikely to have a material impact on Part D costs.
j. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)	CMS is proposing to require that each Part D plan implement a beneficiary real time benefit tool. This tool should allow enrollees to view a plan-defined subset of the information included in the prescriber RTBT system which includes accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements) by January 1, 2022.	Adoption of a beneficiary RTBT will be an additional cost and burden on Part D sponsors. Based on our estimates, we believe this will cost Part D plans about $3.9 million for all plans in the first year based on the costs for them to reprogram their computer systems. Additionally, the voluntary provision of rewards by Part D sponsors to enrollees using RTBT will have an impact of $0.7 million in the first year, in order to implement the program, and $0.4 million in subsequent years in order to maintain the program.

k. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)	We are proposing to amend our MA MLR regulations. There are three proposals. (1) We are proposing to allow MA organizations to include in the MLR numerator as "incurred claims" all amounts paid for covered services, including amounts paid to individuals or entities that do not meet the definition of "provider" as defined at § 422.2. (2) We are also proposing to codify our definitions of partial, full, and non-credibility and credibility factors that CMS published in the May 2013 Medicare MLR final rule (78 FR 31296). (3) For MA MSA contracts receiving a credibility adjustment, we are proposing to apply a deductible factor to the MLR calculation in order to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles.	(1) Our proposed amendment to change the type of expenditures that can be included in "incurred claims" will have neutral dollar impact on the Medicare Trust Fund. These provisions will result in a transfer of funds from the Treasury, through the Medicare Trust Fund, to MA organizations. This transfer would take the form of a reduction in the remittance amounts withheld from MA capitated payments. The amount of this transfer is $35 to $55 million a year, resulting in plans obtaining $455 million over 10 years. (2) Codifying the definitions of partial, full, and non-credibility and the credibility factors, as proposed, is unlikely to have any impact on the Medicare Trust Fund. (3) Our proposal to add a deductible factor to the MLR calculation for MA MSA contracts is estimated to result in a gradually increasing cost to the Medicare Trust Fund of $1 to $6 million per year, and will result in a $43.2 million cost over 10 years.
l. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)	CMS is proposing to (1) strengthen network adequacy rules for MA and cost plans and make them more transparent to plans by codifying our existing network adequacy methodology and standards, with some modifications; (2) allow MA plans to receive a 10 percent credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with certain telehealth providers; and (3) reduce the required percentage of beneficiaries residing within maximum time and distance standards in certain county types (Micro, Rural, and CEAC).	Changes to network standards are unlikely to have any impact on the Medicare Trust Fund.

m. Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)	We are proposing to codify a number of SEPs that we have adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. We are also proposing to establish two new SEPs for exceptional circumstances: the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.	This provision codifies existing practice since MA organizations and Part D plan sponsors are currently assessing applicants' eligibility for election periods as part of existing enrollment processes. Consequently, the provision will not have added impact.
n. Service Delivery Request Processes under PACE (§§ 460.104 and 460.121)	CMS is proposing to revise the process by which PACE organizations address service delivery requests. Currently the IDT must determine the appropriate member(s) of the IDT to conduct a reassessment, perform a reassessment, and render a decision on each service delivery request. However, our experience shows that approximately 40 percent of all requests could be immediately approved in full by an IDT member. We are therefore removing the obligation for a request to be brought to the IDT or for a reassessment to be conducted when a member of the IDT receives and can approve a service delivery request in full at the time it is made. We are also proposing to remove the requirement to conduct a reassessment in response to a service delivery request except when a request would be partially or fully denied.	The proposed revisions create efficiencies which are estimated to create cost savings of $18.7 million in the first year and gradually increase to $23.9 million in 2030. The net savings over 10 years is $216.3 million dollars. The savings are true savings to PACE organizations as a result of reduced administrative burden.
o. Beneficiaries with Sickle Cell Disease (SCD) (§ 423.100)	CMS is proposing that beneficiaries with SCD are classified as exempted from DMPs starting in plan year 2021.	We estimate this provision will affect under 70 beneficiaries and therefore the impact is negligible.

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II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018

A. Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)

The BBA of 2018 (Pub. L. 115–123) was signed into law on February 9, 2018. The law included new authorities concerning supplemental benefits that may be offered to chronically ill enrollees in Medicare Advantage (MA) plans, specifically amending section 1852(a)(3) of the Act to add a new subparagraph (D) authorizing a new category of supplemental benefits that may be offered by MA plans. We discussed this new authority in the April 2018 final rule (83 FR 16481 through 16483).[2] We propose to codify the existing guidance (April 2019 Health Plan Management System (HPMS) Memo [3] and the 2020 Call Letter) [4] and parameters for these special supplemental benefits for chronically ill enrollees at § 422.102(f) to implement section 1852(a)(3)(D) of the Act.

Specifically, the BBA of 2018 amended section 1852(a)(3) of the Act to: (1) Authorize MA plans to provide additional supplemental benefits that have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee to chronically ill enrollees; (2) permit those additional supplemental benefits to be not primarily health related; (3) define ''chronically ill enrollee'' to limit eligibility for these additional supplemental benefits; and (4) authorize CMS to waive uniformity requirements in connection with this for eligible chronically ill enrollees. We refer to these benefits hereafter as Special Supplemental Benefits for the Chronically Ill (SSBCI). The heading for new subparagraph (D) of section 1852(a)(3) of the Act, as added by the BBA, states, ''Expanding supplemental benefits to meet the needs of chronically ill enrollees.'' Consistent with this text, this new category of supplemental benefits is intended to enable MA plans to better tailor benefit offerings, address gaps in care, and improve health outcomes for the chronically ill population. Section 1852(a)(3)(D)(ii) of the Act, as amended, defines a chronically ill enrollee as an individual who—

- Has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee;
- Has a high risk of hospitalization or other adverse health outcomes; and
- Requires intensive care coordination.

Thus, with respect to SSBCI benefits, we propose at § 422.102(f)(1)(i), to codify this definition of a chronically ill enrollee. Section 1859(f)(9) of the Act requires us to convene a panel of

[2] *https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf.*

[3] *https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/Supplemental_Benefits_Chronically_Ill_HPMS_042419.pdf.*

[4] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

clinical advisors to establish and update a list of conditions that meet the definition of a severe or disabling chronic condition under section 1859(b)(6)(B)(iii) of the Act, which provides how having such a condition is an eligibility criterion for a chronic care special needs plan. The standard for severe or disabling chronic condition under section 1859(b)(6)(B)(iii) of the Act is substantially similar to the criterion used in defining ''chronically ill enrollee'' for purposes of SSBCI eligibility. Under our proposal, MA plans may consider any enrollee with a condition identified on this list to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee. Further, an MA plan may consider any chronic condition not identified on this list if that condition is life threatening or significantly limits the overall health or function of the enrollee. CMS wishes to allow plans the flexibility to continue to innovate around providing care for their specific plan populations. This includes targeted chronic conditions. We recognize that there may be some conditions and/or a subset of conditions in a plan population that may meet the statutory definition of a chronic condition, but may not be present on the list. We encourage plans to identify needs within their unique plan population and do not wish to prevent a plan from addressing a condition or need in their population that may not be on the list. To reflect this policy, we are proposing at § 422.102(f)(1)(i)(B), regulation text indicating our intent to publish a non-exhaustive list of medically complex chronic conditions as determined by the panel as described in section 1859(b)(6)(B)(iii) to be life threatening or significantly limit the overall health or function of an individual.

MA plans are not required to submit to CMS the processes used to identify chronically ill enrollees that meet the three pronged definition of chronically ill enrollee. However, all three criteria must be met for an enrollee to be eligible for the SSBCI authorized under section 1852(a)(3)(D) of the Act. In subregulatory guidance (April 2019 HPMS Memo and the 2020 Call Letter), CMS noted that we expect MA plans to document their determinations about an enrollee's eligibility for SSBCI based on the statutory definition. We propose to codify this as a requirement at § 422.102(f)(3)(ii). In addition, we are also proposing at § 422.102(f)(3)(ii) to require plans to make information and documentation (for example, copies of the internal policies used to make the determinations, etc.) related to determining enrollee eligibility as a chronically ill enrollee available to CMS upon request.

We are proposing at paragraph (f)(1)(ii) the definition of SSBCI. In addition to limiting the class of enrollees who may be eligible to receive the new SSBCI benefits to the chronically ill, section 1852(a)(3)(D) of the Act requires that the specific supplemental benefit provided under this authority have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. We propose to codify this statutory requirement as part of the definition of SSBCI at § 422.102(f)(1)(ii). Because SSBCI are supplemental benefits, they must also comply with the criteria for supplemental benefits that we are proposing to codify at § 422.100(c)(2)(ii), which is discussed in detail in section VI.F. of this proposed rule. We considered whether the regulation for SSBCI should explicitly reference the requirements in § 422.100(c)(2)(ii) to make this clear and solicit comment on this point. Traditionally, CMS has defined supplemental benefits as benefits that: (1) Are primarily health related; (2) require the MA plan to incur a non-zero medical cost; and (3) are not covered under Medicare Parts A, B or D. In light of the authority in section 1852(a)(3)(D) of the Act for SSBCI, we are proposing to modify some aspects of this longstanding policy in this context. First, as the statute provides that SSBCI may be not primarily health related, we are proposing specific text on this point in both §§ 422.100(c)(2)(ii) and 422.102(f)(1)(ii). Second, we are proposing to clarify in § 422.100(c)(2)(ii)(B) that the MA organization incur a non-zero direct medical cost for all supplemental benefits applies in the context of SSBCI that are not primarily health related; in such cases, the MA organization must incur a non-zero direct non-administrative cost for the SSBCI. MA rules require plans to incur a non-zero direct medical cost for supplemental benefits. In the case of SSBCI, we are clarifying that such incurred cost should be a non-administrative cost for providing the benefit even if it is not necessarily a cost paid to a medical provider or facility because SSBCI benefits are not necessarily primarily health related. In all other respects not specifically addressed as part of our proposal, SSBCI would be treated like other supplemental benefits.

Under section 1852(a)(3)(D)(ii)(I) of the Act, SSBCI benefits may include items or services that are not primarily health related. As discussed in detail in section VI.F. of this proposed rule, a primarily health related benefit is an item or service that is used to diagnose, compensate for physical impairments, acts to ameliorate the functional/psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization. Therefore, at § 422.102(f)(1)(ii), we propose to codify as part of the definition of SSBCI that these benefits may be non-primarily health related SSBCI benefits, including a cross-reference to where we propose to codify the definition of primarily health related; however, in all cases, an SSBCI must have, with respect to a chronically ill enrollee, a reasonable expectation of improving or maintaining the health or overall function of the enrollee. By including it in the definition, we are implementing the statutory authority for MA plans to offer both primarily health and non-primarily health related SSBCI. In the 2019 HPMS memo, we provided examples of non-primarily health related SSBCI benefits. Those examples included: Meals (beyond a limited basis), food and produce, transportation for non-medical needs, pest control, indoor air quality and equipment and services, access to community or plan-sponsored programs and events to address enrollee social needs, (such as non-fitness club memberships, community or social clubs, park passes, etc.), complementary therapies (offered alongside traditional medical treatment), services supporting self-direction (for example. financial literacy classes, technology education, and language classes), structural home modifications, and general supports for living (for example. plan-sponsored housing consultations and/or subsidies for rent or assisted living communities or subsidies for utilities such as gas, electric, and water). We intend this guidance to be equally applicable to our proposed regulation.

Another provision of our proposed rule flows from the statutory authority for SSBCI to be not primarily health related. Unlike with traditional supplemental benefits, MA plans might not incur direct medical costs in furnishing or covering SSBCI. In the 2020 Call Letter, we issued guidance that so long as an MA plan incurs a non-zero non-administrative cost in connection with SSBCI, the benefits would be considered to meet this standard. As supplemental benefits, SSBCI may also take the same form as

traditional supplemental benefits. For example, reductions in cost sharing for benefits under the original Medicare fee-for-service program are an allowable supplemental benefit, as reflected in the definitions of mandatory supplemental benefit in § 422.2. Thus, SSBCI can be in the form of—

- Reduced cost sharing for Medicare covered benefits (such as to improve utilization of high-value services that meet the definition of SSBCI);
- Reduced cost sharing for primarily health related supplemental benefits;
- Additional primarily health related supplemental benefits; or
- Additional non-primarily health related supplemental benefits.

Eligibility for SSBCI must be determined based on identifying the enrollee as a chronically ill enrollee, using the statutory definition, and if the item or service has a reasonable expectation of improving or maintaining the health or overall function of the enrollee. In the April 2019 HPMS memo CMS clarified that MA plans can provide non-primarily health related supplemental benefits that address chronically ill enrollees' social determinants of health so long as the benefits maintain or improve the health or function of that chronically ill enrollee. MA plans may consider social determinants when determining eligibility for an SSBCI of health as a factor to help identify chronically ill enrollees whose health could be improved or maintained with SSBCI. However, MA plans may not use social determinants of health as the sole basis for determining eligibility for SSBCI. We propose to codify the ability of an MA plan to consider social determinants (for example, food and housing insecurity) when determining whether an SSBCI benefit is likely to improve or maintain the health of a chronically ill enrollee as described at § 422.102(f)(2)(iii).

Generally, § 422.100(d) and other regulations require all MA plan benefits to be offered uniformly to all enrollees residing in the service area of the plan. As explained in the April 2018 final rule (83 FR 16480 through 16485), MA plans may also provide access to services (or specific cost sharing or deductibles for specific benefits) that are tied to a disease state in a manner that ensures that similarly situated individuals are treated uniformly. Section 1852(a)(3)(D)(ii)(II) of the Act authorizes CMS to waive the uniformity requirements generally applicable to benefits covered by MA plans with respect to SSBCI, effective in CY 2020. As discussed in the April 2018 final rule (83 FR 16481 and 16482), this gives CMS the authority to allow MA plans to offer chronically ill enrollees supplemental benefits that are not uniform across the entire population of chronically ill enrollees in the MA plan and may vary SSBCI offered to the chronically ill as a specific SSBCI relates to the individual enrollee's specific medical condition and needs. We are proposing to codify the authority for this waiver at § 422.102(f)(2)(ii) such that upon approval by CMS, an MA plan may offer non-uniform SSBCI. In both the CY 2020 call letter and the April 2019 HPMS memo, we explained how we expect MA plans to have written policies based on objective criteria (for example, health risk assessments, review of claims data, etc.) for determining SSBCI eligibility to receive a particular SSBCI benefit, to document these criteria, and to make this information available to CMS upon request. We are also proposing to codify requirements at § 422.102(f)(3)(iii) and (iv) for MA plans that offer SSBCI to have written policies based on objective criteria, document those criteria, to document each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request. We believe that objective criteria are necessary to address potential beneficiary appeals, complaints, and/or general oversight activities performed by CMS. We are also proposing, at § 422.102(f)(3)(i), to require plans to have written policies for determining enrollee eligibility and must document its determination that an enrollee is a chronically ill enrollee based on the statutory definition codified in paragraph (f)(1)(i) of this section. And we are proposing to require plans to make information and documentation related to determining enrollee eligibility available to CMS upon request at § 422.102(f)(3)(ii). We also clarify here that the determination on the benefits an enrollee is entitled to receive under an MA plan's SSBCI is an organization determination that is subject to the requirements of part 422, subpart M, including the issuance of denial notices to enrollees.

This provision codifies already existing guidance and practices and therefore is not expected to have additional impact above current operating expenses. Additionally, this provision amends definitions and therefore does not impose any collection of information requirements.

B. Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)

Special needs plans (SNPs) are MA plans that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Section 50311 of the BBA of 2018 modified the requirements for C–SNPs in section 1859(f)(5) of the Act. Specifically, the amendments included the following:

- That the interdisciplinary team include a team of providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the C–SNP.
- That the C–SNP comply with requirements developed by CMS to provide face-to-face encounters with enrollees not less frequently than on an annual basis.
- That, as part of the mandatory model of care (MOC), the results of the initial assessment and annual reassessment required for each enrollee be addressed in the individual's individualized care plan.
- That, as part of the annual evaluation and approval of the MOC, CMS take into account whether the plan fulfilled the previous year's goals (as required under the model of care).
- That CMS establish a minimum benchmark for each element of the MOC and only approve a C–SNP's MOC if each element of the model of care meets such minimum benchmark applicable under the preceding sentence.

We are proposing to amend and add new regulations at § 422.101(f) to implement the BBA of 2018 amendments to section 1859(f) of the Act and extend them to all SNP types. Specifically, we propose to add new regulations, to be codified at § 422.101(f), to account for two new requirements governing SNP enrollee care management and three new requirements governing SNP model of care submissions.

The history of special needs plans in the MA program is nearly as long as the program itself. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (hereinafter referred to as the MMA) (Pub. L. 108–173) authorized CMS to contract with MA coordinated care plans that are specifically designed to provide targeted care to individuals with special needs. Originally SNPs were statutorily authorized for a limited period, but after several extensions of that authority, section 50311(a) of the BBA of 2018 permanently authorized SNPs. Under section 1859(f)(1) of the Act, SNPs are able to restrict enrollment to Medicare beneficiaries who are: (1) Institutionalized individuals, who are currently defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long-term care facility; (2) individuals entitled to

medical assistance under a state plan under Title XIX; or (3) other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP. As of July 2019, 321 SNP contracts with 734 SNP plans have at least 11 members.[5] These figures included 208 Dual Eligible SNP contracts (D–SNPs) with 480 D–SNP plans with at least 11 members, 57 Institutional SNP contracts (I–SNPs) with 125 I–SNP plans with at least 11 members, and 56 Chronic or Disabling Condition SNP contracts (C–SNPs) with 129 C–SNP plans with at least 11 members. For more discussion of the history of SNPs, please see Chapter 16b of the Medicare Managed Care Manual (MMCM).[6] This proposed rule would implement the provisions of the BBA of 2018 and establish new care management requirements at § 422.101(f) for all SNPs, including minimum benchmarks for SNP models of care.

Section 1859(f) of the Act and the current implementing regulations specify several requirements for SNPs. MA organizations that would like to offer a SNP are required to engage in an application process to demonstrate that they meet SNP specific requirements, including the requirement in § 422.101(f) that MA organizations offering a SNP implement an evidence based model of care (MOC) to be evaluated by the National Committee for Quality Assurance (NCQA); the requirement in § 422.107 that D–SNPs have a contract with the state Medicaid agencies in the states in which they operate; and the requirement in § 422.152(g) that SNPs conduct quality improvement programs. SNP applicants follow the same process in accordance with the same timeline as applicants seeking to contract to offer other MA plans.

Section 164 of the Medicare Improvements for Patients and Providers Act (hereinafter referred to as MIPPA) (Pub. L. 110–275) added care management requirements for all SNPs effective January 1, 2010, as set forth in section 1859(f)(5) of the Act (42 U.S.C. 1395w–28(f)). The new mandate required dual-eligible, institutional, and chronic condition SNPs to implement care management requirements which have two explicit components: An evidence-based model of care and a series of care management services. While the revisions made in the Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs interim final rule with comment (73 FR 54226), hereinafter referred to as the September 2008 final rule, simply reflected the substance of the new MIPPA provisions, the Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs proposed rule, hereinafter referred to as the May 2008 proposed rule (73 FR 28555), proposed other, related provisions which were finalized in the Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions final rule (hereinafter referred to as the January 2009 final rule) (74 FR 1493).

CMS had previously provided guidance and instructions in the 2008 and 2009 Call Letters,[7] [8] ''Special Needs Plan Solicitation,'' in order to more clearly establish and clarify delivery of care standards for SNPs and to codify standards. In the May 2008 proposed rule, CMS proposed that SNPs have networks with clinical expertise specific to the special needs population of the plan; use performance measures to evaluate models of care; and be able to coordinate and deliver care targeted to the frail/disabled, and those near the end of life based on appropriate protocols. Section 164 of the MIPPA subsequently added care management requirements for all SNPs as directed in section 1859(f)(5) of the Act (42 U.S.C. 1395w–28(f)), outlining new model of care requirements that include—(1) an appropriate network of providers and specialists to meet the specialized needs of the SNP target population; (2) a comprehensive initial health risk assessment and annual reassessments; (3) an individualized plan of care having goals and measurable outcomes; and (4) an interdisciplinary team to manage care. The MIPPA laid a statutory foundation for much of our regulatory standards for the model of care.

MOCs are a vital quality improvement tool and integral component for ensuring that the unique needs of each beneficiary enrolled in a SNP are identified and addressed. Section 3205 of the Patient Protection and Affordable Care Act of 2010 (hereinafter referred to as the Affordable Care Act) (Pub. L. 111–148) amended section 1859(f) of the Act to require that, starting in 2012, all SNPs be approved by NCQA based on standards developed by the Secretary. As provided under §§ 422.4(a)(iv), 422.101(f), and 422.152(g), the NCQA approval process is based on evaluation and approval of the SNP MOC, as per CMS guidance. Therefore, all SNPs must submit their MOCs to CMS for NCQA evaluation.

The MOC is organized to promote clarity and enhance the focus on care coordination, care transition, care needs and activities. The NCQA scoring approval process is based on scoring each of the clinical and non-clinical elements of the MOC as part of the SNP application.

The MOC narrative must include the following four elements:

- Description of the SNP Population.
- Care Coordination.
- SNP Provider Network.
- MOC Quality Measurement & Performance Improvement.

Each of the four elements is comprised of a set of required subcomponents, or factors, such as an identification and comprehensive description of the SNP-specific population. These subcomponents are reviewed and scored by NCQA and contribute to the overall score for that element. A full list of elements and factors, as well as CMS subregulatory guidance pertaining to MOC submission requirements and structure, can be found in Chapter 5 of the MMCM.

We propose to revise § 422.101(f) to implement certain new requirements added to section 1859(f)(5)(B) of the Act by the BBA of 2018 and to extend them to all SNP types. Specifically, we propose to revise § 422.101(f) to impose the new requirements governing SNP enrollee care management and SNP MOC submissions. Section 50311(c) of the BBA of 2018 amends section 1859(f)(5) of the Act to explicitly require improvements in care management and the establishment of a minimum benchmark for each element of the SNP model of care of a plan specific to C–SNP MOC submissions. We are proposing that these requirements be extended to all SNP plan types for several reasons. First, these additional requirements are consistent with current regulations and sub-regulatory guidance CMS provides to all SNPs regarding care management and MOC compliance. Second, we believe that these proposed

[5] See the following link for SNP plan and enrollment data: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data-Items/SNP-Comprehensive-Report-2019-07.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending.*

[6] Chapter 16b of the Medicare Managed Care Manual can be found at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c16b.pdf.*

[7] Announcement of Calendar Year (CY) 2008 Medicare Advantage Capitation Rates and Payment Policies can be found at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/announcement2008.pdf.*

[8] Announcement of Calendar Year (CY) 2009 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies can be found at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2009.pdf.*

regulations are important safeguards to preserve the quality of care for all special needs individuals, including those enrolled in D–SNPs and I–SNPs and not just those enrolled in C–SNPs. Given the prevalence of medically complex chronic conditions among I–SNP and D–SNP enrollees, we believe the proper application of these new care improvement requirements would improve care for enrollees with complex chronic conditions. Further, we believe that the application of multiple, different MOC standards would be operationally complex and burdensome for MA organizations that sponsor multiple SNP plan types, for instance, a D–SNP and a C–SNP. We welcome comment of the extension of the new care management and MOC requirements for C–SNPs to the care management and MOC requirements for all SNP types.

1. The Interdisciplinary Team in the Management of Care

First, we propose to implement the requirement in section 1859(f)(5)(B)(i) of the Act addressing the interdisciplinary team in an amendment to § 422.101(f)(1)(iii) that would, in addition to implementing the statutory requirement for C–SNPs, extend the requirement to all SNPs. Currently, § 422.101(f)(1)(iii) requires each SNP to use an interdisciplinary team in the management of care but does not include much detail about that requirement. We propose to amend paragraph (f)(1)(iii) to require that each MA organization offering a SNP plan must provide each enrollee with an interdisciplinary team in the management of care that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

As we noted in the January 2009 final rule, MIPPA required SNPs to conduct initial and annual comprehensive health risk assessments, develop and implement an individualized plan of care, and implement an interdisciplinary team for each beneficiary. We believe that combination of MIPPA's statutory elements and our regulatory prescription for the SNP model of care establishes the standardized architecture for effective care management while giving plans the flexibility to design the unique services and benefits that enable them to meet the identified needs of their target population. We believe this proposal, which amends paragraph (f)(1)(iii) and applies additional requirements pertaining to demonstrated expertise and training of interdisciplinary team providers to all SNPs, is consistent with the MIPPA requirements and the January 2009 final rule that provided the original authority regarding the use of interdisciplinary teams. All SNPs must have an interdisciplinary team to coordinate the delivery of services and benefits. However, one SNP may choose to contract with an interdisciplinary team to deliver care in community health clinics and another SNP may hire its team to deliver care in the home setting. Under the current rule, and our proposal, all SNPs must coordinate the delivery of services and benefits through integrated systems of communication among plan personnel, providers, and beneficiaries. However, one SNP may coordinate care through a telephonic connection among all stakeholders and a second SNP may coordinate care through an electronic system using Web-based records and electronic mail accessed exclusively by the plan, network providers, and beneficiaries. All SNPs must coordinate the delivery of specialized benefits and services that meet the needs of their most vulnerable beneficiaries. However, D–SNPs may need to coordinate Medicaid services while an institutional SNP may need to facilitate hospice care for its beneficiaries near the end of life. These examples demonstrate the variety of ways SNPs currently implement their systems of care, and we believe plans can and should provide enrollees with a team of providers with expertise and training that are appropriate for each individual enrollee.

Ultimately, we believe plans are in the best position to identify an interdisciplinary team with the appropriate expertise and training necessary to meet the clinical needs for each enrollee based on the medical and behavioral health conditions of their member population. We solicit comment on this proposed implementation of section 1859(f)(5)(B)(i) of the Act. We welcome feedback on how plans can meet the requirements for both demonstrated expertise and training in an applicable specialty.

2. Face-to-Face Annual Encounters

Second, we propose to implement the requirement in section 1859(f)(5)(B)(ii) of the Act requiring compliance with requirements (developed by CMS) to provide a face-to-face encounter with each enrollee. We are proposing that the face-to-face encounter be between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff on at least an annual basis, beginning within the first 12 months of enrollment, as feasible and with the individual's consent. A face-for-face encounter must be either in person or through a visual, real-time, interactive telehealth encounter. We propose to implement this requirement in a new paragraph (f)(1)(iv) of § 422.101 that would extend the requirement to all SNPs. We propose to require the MA organization to provide an annual face-to-face visit, that is in-person or by remote technology, to occur starting within the first 12 months of enrollment within the plan. For instance, a plan enrolling a beneficiary on October 1 would need to facilitate an in-person meeting by September 30th of the following year. Under our proposal, a visit to or by a member of an individual's interdisciplinary team or the plan's case management and coordination staff that perform clinical functions, such as direct beneficiary care, would meet this requirement. Examples of what these encounters may entail, though not limited to, include a member of an individual's interdisciplinary team or the plan's case management and coordination staff engaging with the enrollee to manage, treat and oversee (or coordinate) their health care, including preventive care included in the individualized care plan (ICP). Additional examples of such activities may include annual wellness visits and/or physicals, health risk assessment (HRA) completion, care plan review, health related education, and care coordination activities, but these are not the only activities that satisfy the proposed regulatory requirement. Encounters may also address any concerns related to physical, mental/behavioral health, and overall health status, including functional status. We anticipate that, consistent with good clinical practice, concerns are addressed and any appropriate referrals, follow-up, and care coordination activities provided or scheduled as necessary as a result of these face-to-face encounters. Plans should implement this requirement in a manner that honors any enrollee's decision not to participate in any qualifying encounter as noted previously.

Consistent with the authority for MA plans to offer additional telehealth benefits, under § 422.135 as finalized in the Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and

Medicaid Managed Care Programs for Years 2020 and 2021 Final Rule (hereinafter referred to as the April 2019 final rule), we are proposing that the face-to-face encounters required for all SNPs under this new rule may include visual, real-time, interactive telehealth encounters. As we noted in the April 2019 final rule, we believe MA additional telehealth benefits will increase access to patient-centered care by giving enrollees more control to determine when, where, and how they access benefits. We are seeking comment on proposed § 422.101(f)(1)(iv) and the suggested criteria for what constitutes a face-to-face encounter.

3. Health Risk Assessments and the SNP Enrollee's Individualized Care Plan

Third, we are proposing to codify the requirement in section 1859(f)(5)(B)(iii) of the Act that, as part of the C–SNP model of care, the results of the initial assessment and annual reassessment required for each enrollee be addressed in the individual's individualized care plan. As with the other provisions in section 1859(f)(5)(B) of the Act, we are proposing to extend this requirement to the model of care for all SNPs in revisions to § 422.101(f)(1)(i). Currently, MA organizations offering SNPs must conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual HRA, using a comprehensive risk assessment tool that CMS may review during oversight activities. We propose to revise § 422.101(f)(1)(i) by adding that the MA organization must ensure that results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan required under § 422.101(f)(1)(ii) are addressed in the individual's individualized care plan required under § 422.101(f)(1)(ii).

We believe that the HRA plays a critical role in coordinating the care of SNP enrollees. Section 1859(f)(5)(A) of the Act requires SNPs to conduct initial and annual comprehensive HRA, develop and implement an individualized plan of care, and implement an interdisciplinary team for each beneficiary. As noted in the January 2009 final rule, we believe that the combination of these statutory elements and our regulatory prescription for the SNP model of care establishes the standardized architecture for effective care management. We believe extending the requirement for the individualized care plan to address the results of the initial assessment and annual reassessment care to I–SNPs and D–SNPs, instead of limiting the requirement to C–SNPs, would further increase the effectiveness of the ICP and increase quality outcomes. We welcome comment concerning the amended regulation at § 422.101(f)(1)(i).

4. SNP Fulfillment of the Previous Year's MOC Goals

Fourth, we are proposing to codify the requirement in section 1859(f)(5)(B)(iv) of the Act that the evaluation and approval of the model of care take into account whether the plan fulfilled the previous MOC's goals and to extend this evaluation component to all SNP models of care, rather than limiting it to C–SNPs. We propose a new regulation at § 422.101(f)(3)(ii) that as part of the evaluation and approval of the SNP model of care, NCQA must evaluate whether goals were fulfilled from the previous model of care and plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment of the previous MOC's goals. If the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC. We are also proposing to move an existing regulation at § 422.101(f)(2)(vi) that requires all SNPs must submit their MOC to CMS for NCQA evaluation and approval in accordance with CMS guidance to a new paragraph at § 422.101(f)(3). The proposed paragraph at (f)(3)(i) would contain the same language as § 422.101(f)(2)(vi).

We intend that NCQA would determine whether each SNP, as part of the evaluation and MOC approval process, provided adequate information to evaluate the regulation under § 422.101(f)(3)(ii) as well as whether the SNP met goals from the previous MOC submission. It is implicit in the evaluation of the MOC and the requirement for the SNP to submit relevant information that the information submitted by the SNP must be adequate for NCQA to use to evaluate whether the goals from the prior MOC have been fulfilled. We solicit comment whether more explicit requirements on this point should be part of the regulation text.

The proposed regulation at § 422.101(f)(3)(ii) aligns with our current guidance on the MOC submission and review process regarding SNP fulfillment of goals. Currently, all SNPs are required to identify and clearly define measureable goals and health outcomes as part of their model of care under MOC 4, Element B: Measureable Goals and Health Outcomes for the MOC as defined in Chapter 5 of the MMCM. CMS believes that it is critical for all SNPs to use the results of the quality performance indicators and measures to support ongoing improvement of the MOC, and that all SNPs should continuously assess and evaluate plan quality outcomes. MOC 4, Element B currently contains the following parameters:

- Identify and define the measurable goals and health outcomes used to improve the health care needs of SNP beneficiaries.
- Identify specific beneficiary health outcome measures used to measure overall SNP population health outcomes at the plan level.
- Describe how the SNP establishes methods to assess and track the MOC's impact on SNP beneficiaries' health outcomes.
- Describe the processes and procedures the SNP will use to determine if health outcome goals are met.
- Describe the steps the SNP will take if goals are not met in the expected timeframe.

For SNPs submitting their initial MOC, NCQA will evaluate the information under MOC 4 Element B as the setting of clearly definable and measurable goals and health outcomes in their MOC for the upcoming MOC period of performance. For the following submission year, the plan will be evaluated on whether the measurable goals and health outcomes set in the initial MOC were achieved.

Plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval under this paragraph. We propose specific regulation text on this point at § 422.101(f)(3)(ii)(B). We seek comment on the new regulation at § 422.101(f)(3)(ii).

5. Establishing a Minimum Benchmark for Each Element of the SNP Model of Care

Finally, we propose new regulation text at § 422.101(f)(3)(iii) to impose the requirement for benchmarks to be met for a MOC to be approved. Section 1859(f)(5)(B)(v) of the Act requires that the Secretary establish a minimum benchmark for each element of the C–SNP model of care, and that the MOC can only be approved if each element meets a minimum benchmark. We propose in § 422.101(f)(3)(iii) to implement these benchmarks for all SNP models of care. Given that medically complex conditions are found in enrollees across all SNP types and

that implementation to C–SNPs alone would be operationally challenging for plans offering multiple SNP types, we believe it is appropriate to extend this requirement to all SNPs. Each SNP model of care would be evaluated based on a minimum benchmark for each of the four elements. Currently, each subfactor of a MOC element is valued at 0–4 points with the score of each element based on the number of factors met for that specific element; the aggregate total of all possible points across all elements equals 60, which is then converted to percentage scores based on the number of total points received. We propose that each element of the MOC must meet a minimum benchmark of 50 percent of total points as allotted, and a plan's MOC would only be approved if each element of the model of care meets the applicable minimum benchmark.

We welcome comment on the proposed § 422.101(f)(3)(iii). Specifically, we are seeking comment to our proposed benchmark and scoring criteria as they impact the evaluation of SNP models of care.

C. Coverage Gap Discount Program Updates (§§ 423.100 and 423.2305)

We propose to amend our regulations at §§ 423.100 (definition of applicable drug) and 423.2305 (determination of coverage gap discount) to reflect recent changes to the relevant statutory provisions. Sections 53113 and 53116 of the BBA of 2018 amended section 1860D–14A of the Act to (a) increase the coverage gap discount for applicable drugs from 50 to 70 percent of the negotiated price beginning in plan year 2019, and (b) revise the definition of an applicable drug to include biosimilar biological products, also beginning in plan year 2019.

Specifically, section 53116 of the BBA of 2018 revised the definition of ''discounted price,'' meaning the price provided to the beneficiary, in section 1860D–14A(g)(4)(A) of the Act to mean, for a plan year after 2018, 30 percent of the negotiated price. This means that the coverage gap discount is 70 percent, rather than 50 percent. To make our regulations consistent with this change, we propose to amend the definition of ''applicable discount'' in § 423.2305 to provide that, with respect to a plan year after plan year 2018, the applicable discount is 70 percent of the portion of the negotiated price (as defined in § 423.2305) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

Section 53113 of the BBA of 2018 amended section 1860D–14A(g)(2)(A) of the Act to specify that biologic products licensed under subsection (k) (that is, biosimilar and interchangeable biological products) are excluded from the coverage gap discount program only with respect to plan years before 2019. Therefore, we are proposing to revise the definition of applicable drug at § 423.100 to specify that such biological products are excluded only for plan years before 2019. Accordingly, biosimilar products are included in the Discount Program beginning for plan year 2019.

D. Part D Income Related Monthly Adjustment Amount (IRMAA) Calculation Update for Part D Premium Amounts (§ 423.286)

Section 3308 of the Affordable Care Act amended section 1860D–13(a) of the Act and imposed an income-related monthly adjustment amount for Medicare Part D (hereinafter referred to as Part D–IRMAA) for beneficiaries whose modified adjusted gross income (MAGI) exceeds the same income threshold amount tiers established under section 1839(i) of the Act with respect to the Medicare Part B income-related monthly adjustment amount (Part B–IRMAA). The Part D–IRMAA is an amount that a beneficiary pays in addition to the monthly plan premium for Medicare prescription drug coverage under the Part D plan in which the beneficiary is enrolled when the beneficiary's MAGI is above the specified threshold.

The Part D–IRMAA income tiers mirror those established for the Part B–IRMAA. As specified in section 1839(i) of the Act, when the Part B–IRMAA went into effect in 2007, individuals and joint tax filers enrolled in Medicare Part B whose modified adjusted gross income exceeded $80,000 and $160,000, respectively, were assessed the Part B–IRMAA on a sliding scale. As specified in section 1839(i)(5) of the Act, each dollar amount within the income threshold tiers shall be adjusted annually based on the Consumer Price Index (CPI). As a result of the annual adjustment, for calendar year 2010, the income threshold amounts had increased to reflect the four income threshold amount tiers for individuals and joint tax filers whose modified adjusted gross income exceeded $85,000 and $170,000, respectively. (We note that section 3402 of the Affordable Care Act froze the income thresholds for 2011 through 2019 at the level established for 2010.)

Consistent with section 3308 of the Affordable Care Act, the Part D–IRMAA is calculated using the Part D national base beneficiary premium (BBP) and the applicable premium percentage (P) as follows: BBP × [(P − 25.5 percent)/25.5 percent]. The premium percentage used in the calculation will depend on the level of the Part D enrollee's modified adjusted gross income.

Section 3308 of the Affordable Care Act requires CMS to provide the Social Security Administration (SSA) with the national base beneficiary premium amount used to calculate the Part D–IRMAA no later than September 15 of each year, starting in 2010. Also effective in 2010, CMS must provide SSA no later than October 15 of each year, with: (1) The modified adjusted gross income threshold ranges; (2) the applicable percentages established for Part D–IRMAA in accordance with section 1839 of the Act; (3) the corresponding monthly adjustment amounts; and (4) any other information SSA deems necessary to carry out Part D–IRMAA.

To determine a beneficiary's IRMAA, SSA considers the beneficiary's MAGI, together with their tax filing status, to determine the percentage of the: (1) Unsubsidized Medicare Part B premium the beneficiary must pay; and (2) cost of basic Medicare prescription drug coverage that the beneficiary must pay.

Since the implementation of the Part D–IRMAA in 2011, subsequent revisions to the statute have modified the associated income tiers used in IRMAA calculations:

- Section 402 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, revised the income thresholds for the Part B- and Part D–IRMAA income groups such that beneficiaries with incomes greater than $85,000 but not more than $107,000 were required to pay 35 percent of Part B and Part D program costs; beneficiaries with incomes greater than $107,000 but not more than $133,500 would pay 50 percent of Part B and Part D program costs; beneficiaries with incomes greater than $133,500 but not more than $160,000 would pay 65 percent of Part B and Part D program costs; while beneficiaries with incomes greater than $160,000 were required to pay 80 percent of Part B and Part D program costs.
- Section 53114 of the BBA of 2018 revised the MAGI ranges again such that, beginning in 2019, beneficiaries with incomes greater than $500,000 ($750,000 for joint tax filers) are required to pay 85 percent of program costs (an increase from 80 percent).

We are proposing to revise § 423.286(d)(4)(ii) for consistency with the changes made by section 53114 of

the BBA of 2018 and to make other technical changes to ensure that the calculations used in the methodology for updating Part D–IRMAA are described correctly. We propose to remove the language ''the product of the quotient obtained by dividing the applicable premium percentage specified in § 418.2120 (35, 50, 65, or 80 percent) that is based on the level of the Part D enrollee's modified adjusted gross income for the calendar year reduced by 25.5 percent and the base beneficiary premium as determined under paragraph (c) of this section'' and replace it with the product of the standard base beneficiary premium, as determined under paragraph (c) of this section, and the ratio of the applicable premium percentage specified in 20 CFR 418.2120, reduced by 25.5 percent; divided by 25.5 percent (that is, premium percentage − 25.5)/25.5).

We are not scoring this provision in the Regulatory Impact Analysis section since it codifies existing guidance. We believe all stakeholders are already following the current guidance. We are also not scoring this provision in the Collection of Information section since we believe all information impacts of this provision have already been accounted for under OMB control number 0938–0964 (CMS–10141), but seek comment on this assumption.

E. Contracting Standards for Dual Eligible Special Needs Plan (D–SNP) Look-Alikes (§ 422.514)

Special needs plans (SNPs) are MA plans created by the MMA that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under section 1859 of the Act, SNPs are able to restrict enrollment to: (1) Institutionalized individuals, who are currently defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long term care facility; (2) individuals entitled to medical assistance under a State Plan under Title XIX; or (3) other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP. As of July 2019, there are 321 SNP contracts with 734 SNP plans that have at least 11 members, including all of the following:

- 480 dual eligible SNPs (D–SNPs).
- 125 institutional SNPs (I–SNPs).
- 129 chronic or disabling condition SNPs (C–SNPs).[9]

Beneficiaries who are dually eligible for both Medicare and Medicaid can face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in—(1) missed opportunities to provide appropriate, high-quality care and improve health outcomes; and (2) undesirable outcomes, such as avoidable hospitalizations and poor beneficiary experiences. Advancing policies and programs that integrate care for dually eligible individuals is one way in which we seek to address such fragmentation. Under plans that offer integrated care, dually eligible individuals receive the full array of Medicaid and Medicare benefits through a single delivery system, thereby improving care coordination, quality of care, and beneficiary satisfaction, and reducing administrative burden. Some studies have shown that highly integrated managed care programs perform well on quality of care indicators and enrollee satisfaction.[10]

D–SNPs are intended to integrate or coordinate care for this population more effectively than standard MA plans or the original Medicare fee-for-service program by focusing enrollment and care management on dually eligible individuals. As of July 2019, approximately 2.6 million dually eligible individuals (1 of every 5 dually eligible individuals) were enrolled in 480 D–SNPs.

Federal statute and implementing regulations have established several requirements for D–SNPs in addition to those that apply to all MA plans, including all of the following:

- *Health risk assessment.* Section 164 of MIPPA amended section 1859(f) of the Act to require all SNPs to conduct an initial assessment and an annual reassessment of an enrollee's physical, psychosocial, and functional needs. Implementing regulations are codified at § 422.101(f)(1)(i).
- *Model of care.* Section 164 of MIPPA amended section 1859(f) of the Act to require all SNPs to have in place an evidence-based model of care with appropriate networks of providers and specialists. Implementing regulations are codified at § 422.101(f).
- *Comprehensive written statement.* Section 164 of MIPPA amended section 1859(f) of the Act to require D–SNPs to provide each prospective enrollee, prior to enrollment, with a comprehensive written statement that describes the benefits and cost-sharing protections to which the beneficiary is entitled under Medicaid and which of those Medicaid benefits are covered by the D–SNP. Implementing regulations are codified at § 422.111(b)(2)(iii).
- *State Medicaid agency contract.* Section 164 of MIPPA also amended section 1859(f) of the Act to require that D–SNPs contract with the state Medicaid agency to provide benefits, or arrange for the provision of Medicaid benefits, which may include long-term care services consistent with state policy, to which an individual is entitled. Notwithstanding this requirement for D–SNPs, section 164(c)(4) of MIPPA stipulated that a state is in no way obligated to contract with a D–SNP, which therefore provides states with significant control over the availability of D–SNPs. Implementing regulations are codified at § 422.107.

These requirements promote coordination of care. Additionally, the state Medicaid agency contracting requirement allows states the flexibility to require greater integration of Medicare and Medicaid benefits from the D–SNPs in their markets. For example, to develop products that integrate Medicare and Medicaid coverage, several states—including Arizona, Hawaii, Idaho, Massachusetts, Minnesota, New Jersey, and Tennessee—operate Medicaid managed care programs for dually eligible individuals in which the state requires that the Medicaid managed care organizations (MCOs) serving dually eligible individuals offer a companion D–SNP product. These states also require specific care coordination or data sharing activities in their contracts with D–SNPs.[11]

[9] Centers for Medicare & Medicaid Services. *SNP Comprehensive Report.* (July 2019) Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[10] See Kim, H., Charlesworth, C.J., McConnell, K.J., Valentine, J.B., and Grabowski, D.C. ''Comparing Care for Dual-Eligibles Across Coverage Models: Empirical Evidence From Oregon'', *Medical Care Research and Review,* (November 15, 2017) 1–17. Retrieved from *http://journals.sagepub.com/doi/abs/10.1177/1077558717740206;* Anderson, W.L., Feng, Z., & Long, S.K. *Minnesota Managed Care Longitudinal Data Analysis,* prepared for the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE) (March 31, 2016). Retrieved from *https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis;* Health Management Associates. *Value Assessment of the Senior Care Options (SCO) Program* (July 21, 2015). Retrieved from *http://www.mahp.com/wp-content/uploads/2017/04/SCO-White-Paper-HMA-2015_07_20-Final.pdf;* and Medicare Payment Advisory Committee. ''Chapter 2, Care coordination programs for dual-eligible beneficiaries.'' In *June 2012 Report to Congress: Medicare and Health Care Delivery System* (June 16, 2012). Retrieved from *http://www.medpac.gov/docs/default-source/reports/jun12_entirereport.pdf?sfvrsn=0.*

[11] See Verdier, J., Kruse, A., Sweetland Lester, R., Philip, A.M., and Chelminsky, D. *State Contracting*

More recently, section 50311(b) of the BBA of 2018 amended section 1859 of the Act to add new requirements for D–SNPs, beginning in 2021. These requirements, along with clarifications to existing regulations, were codified in the April 2019 final rule (84 FR 15680 through 15844).

• *Minimum integration standards.* As required under section 1859(f)(8)(D)(i) of the Act, as added by the BBA of 2018, all D–SNPs must meet certain new minimum criteria for integration of Medicare and Medicaid benefits for 2021 and subsequent years. To achieve the minimum integration standards, we codified in the April 2019 final rule that a D–SNP must: (1) Be a fully integrated dual eligible (FIDE) SNP; (2) be a highly integrated dual eligible (HIDE) SNP; or (3) have a contract with the state to notify the state, or the state's designee, of high-risk individuals' hospital and skilled nursing facility admissions. Section 1859(f)(8)(D)(ii) of the Act provides that for the years 2021 through 2025, if the Secretary determines that a D–SNP fails to meet one of these integration standards, the Secretary may prevent the D–SNP from enrolling new members. These provisions are codified in amendments to §§ 422.2, 422.107(d), and 422.752(d) that are effective January 1, 2021.

• *Medicaid coordination:* We interpreted the meaning of the requirement in section 1859(f)(3)(D) of the Act, originally codified at § 422.107(b), that the MA organization has responsibility under the contract for providing benefits or arranging for benefits to be provided for individuals entitled to Medicaid as requiring a D–SNP, at a minimum, to coordinate the delivery of Medicare and Medicaid benefits. This requirement is reflected in an amendment to the D–SNP definition at § 422.2, effective January 1, 2020. In addition, an amendment to § 422.562(a)(5), also effective January 1, 2020, requires all D–SNPs to make assistance available to individuals filing a grievance or appeal for Medicaid services.

• *Unified appeals and grievances.* Sections 1859(f)(8)(B) and (C) of the Act require development of unified grievance and appeals processes for D–SNPs, to the extent feasible, to be applicable beginning 2021. We finalized definitions at § 422.561 and implementing regulations, effective January 1, 2021, at §§ 422.560, 422.562, 422.566, 422.629 through 422.634, 438.210, 438.400, and 438.402 in the April 2019 final rule. For 2021 and subsequent years, integrated D–SNPs with exclusively aligned enrollment, termed ''applicable integrated plans,'' must establish integrated grievance and appeals systems using integrated timeframes, notices, and processes. New rules under § 422.632, also effective January 1, 2021, require continuation of benefits pending appeal for enrollees in applicable integrated plans.

The pattern of federal legislation, CMS rulemaking, and state use of D–SNP contracting requirements has incrementally created new requirements for D–SNPs that have generally promoted additional beneficiary protections, coordination of care, and integration of Medicare and Medicaid coverage for dually eligible individuals. While many of these requirements impose additional burdens for D–SNPs, they have not impeded enrollment growth in these plans. Total D–SNP enrollment has more than doubled from one million in 2010 to 2.6 million in 2019.[12] Participation of MA organizations is robust, and most markets are stable and competitive.

In its June 2018 and 2019 reports to Congress, the Medicare Payment Advisory Commission (MedPAC) describes the emergence of ''D–SNP look-alike'' plans that have similar levels of dual eligible enrollment as D–SNPs. For example, MedPAC analysis of 2016 data in select California counties found that, as a percentage of total enrollment, dually eligible individuals accounted for 97 percent of enrollment in D–SNPs and 95 percent in D–SNP look-alikes—compared to 10 percent in other MA plans. Analysis of 2017 enrollment nationally showed multiple D–SNP look-alikes in which dually eligible individuals account for more than 95 percent of total enrollment.[13] Although section 1859(b)(6) of the Act establishes D–SNPs as the only type of MA plan that can exclusively enroll dually eligible individuals, the data show that D–SNP look-alikes have levels of dual eligible enrollment that are virtually indistinguishable from those of D–SNPs and far above those of the typical MA plan.

We believe the low enrollment of non-dually eligible individuals in D–SNP look-alikes results from benefits and cost-sharing that, like the benefits and cost-sharing offered by D–SNPs, are designed to attract only dually eligible individuals. In contrast to non-SNP MA plans, both D–SNPs and D–SNP look-alikes allocate a lower percentage of MA rebate dollars received under the bidding process at § 422.266 to reducing Medicare cost-sharing and a higher percentage of rebate dollars to supplemental medical benefits such as dental, hearing, and vision services. With such a benefit design, many D–SNP look-alikes technically require members to pay higher cost sharing on Parts A and B services than most MA plans require, which we believe dissuades most non-dually eligible Medicare beneficiaries from enrolling. However, because most dually eligible individuals are Qualified Medicare Beneficiaries (QMBs) who are not required to pay Medicare cost sharing, we believe they are not dissuaded from enrolling in these non-D–SNPs by the relatively higher cost sharing. A similar dynamic exists for Part D premiums and high deductibles, both of which are covered by the Part D low-income subsidy that dually eligible individuals receive. We believe that such benefit designs are unattractive for Medicare beneficiaries who are not dually eligible individuals because they would need to cover these costs out-of-pocket. Despite the similarities with D–SNPs in terms of levels of dual eligible enrollment and benefits and cost-sharing design, D–SNP look-alikes are regulated as non-SNP MA plans and are not subject to the federal regulatory and state contracting requirements applicable to D–SNPs.

D–SNP look-alikes first emerged in certain California markets in 2013, after the state placed enrollment restrictions on D–SNPs in areas served by Medicare-Medicaid Plans (MMPs) participating in the Financial Alignment Initiative. Enrollment in D–SNP look-alikes has increased substantially since that time. In these California markets, MedPAC found that D–SNP look-alike enrollment grew from around 5,000 in 2013 to over 95,000 in 2017.[14] MedPAC also explored enrollment trends more broadly, identifying 31 non-SNP

with Medicare Advantage Dual Eligible Special Needs Plans: Issues and Options (November 2016). Retrieved from *https://www.integratedcareresourcecenter.com/sites/default/files/ICRC_DSNP_Issues_Options.pdf.*

[12] Centers for Medicare & Medicaid Services. *SNP Comprehensive Report* (July 2010 & July 2019). Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[13] See *June 2018 MedPAC Report to Congress, Chapter 9* at *http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0* and *June 2019 MedPAC Report to Congress, Chapter 12* at *http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.*

[14] See *June 2018 MedPAC Report to Congress, Chapter 9* at *http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.*

plans[15] operating in 2017 in which dually eligible individuals comprised 80 percent or more of total plan enrollment. These 31 plans, which operated in 10 states (mostly in California and Florida), included approximately 151,000 enrollees. MedPAC estimated that in 2019 enrollment would increase to 193,000 beneficiaries in 54 D–SNP look-alikes across 13 states.[16]

It is not clear that D–SNP look-alikes are essential to the implementation of the Medicare Advantage program or to access to coverage or care for Medicare beneficiaries. Unlike the non-SNP MA plans in which many dually eligible individuals enroll, D–SNP look-alikes do, however, have the near-exclusive levels of dual eligible enrollment that the statute envisions only for D–SNPs that must meet additional Medicare and Medicaid coordination and integration requirements. Most D–SNP look-like enrollment is in markets that feature numerous other plan choices for beneficiaries. Only about 1.2 percent of dually eligible enrollees in traditional MA plans (that is, non-SNP MA plans) are in plans with 80 percent or higher dually eligible enrollment. The data also show that traditional MA plans that are not D–SNP look-alikes can attract dually eligible enrollment; 97 percent of dually eligible individuals enrolled in non-SNP MA plans are in a plan with dual eligible enrollment of 30 percent or less.[17]

The proliferation and growth of D–SNP look-alikes raises multiple areas of concern as follows:

• *Effective implementation of BBA of 2018 requirements.* As discussed earlier in this proposed rule, beginning in contract year 2021, all D–SNPs must meet new minimum criteria for Medicare and Medicaid integration. D–SNP look-alikes hinder meaningful implementation of these statutory requirements. By creating and offering these D–SNP look-alikes that target the same dually eligible individuals who are intended to benefit from integrated D–SNPs, MA organizations are circumventing the new integration requirements.

• *Meaningful integration.* Several states use the state Medicaid agency contracting requirements for D–SNPs at § 422.107 to promote greater Medicare-Medicaid integration. In such states, the state and D–SNP establish specific care coordination protocols, data sharing processes, and other activities to promote better beneficiary experiences. Proliferation of D–SNP look-alikes, for which the same state contracting requirement does not apply, impedes states from using their contracting authority under section 1859 of the Act to ensure that plans predominantly serving dually eligible individuals are working toward those goals. In its comments to CMS for the April 2019 final rule, the Medicaid and CHIP Payment and Access Commission (MACPAC) expressed concern that the growth of D–SNP look-alikes may undermine efforts to promote increased integration through D–SNPs and urged CMS to continue to monitor the growth of look-alikes and determine if further action is needed.[18] As we noted earlier, studies have shown that highly integrated managed care programs perform well on quality of care indicators and enrollee satisfaction.

• *Care coordination requirements.* To better serve the dually eligible population, MIPPA and implementing regulations require D–SNPs to provide periodic health risk assessments, develop individualized care plans for their members, and develop and seek CMS approval for their models of care. These requirements do not apply to D–SNP look-alikes. As a result, nothing requires the D–SNP look-alikes to deliver the types of care coordination that Congress established as statutory requirements for plans that are designed for dually eligible individuals.

• *Beneficiary confusion.* The prevalence of the D–SNP look-alikes has led to instances of misleading marketing by brokers and agents that misrepresent to dually eligible individuals the characteristics of such look-alike plans, especially where the plans have marketed themselves as being special Medicaid-focused plans. We continue to learn of these marketing practices from our own review of broker materials, investigating complaints we have received, and reports from advocacy organizations.[19] Confusing and misleading marketing efforts may violate § 422.2268(a)(1) and (2) which this proposed rule proposes to redesignate as § 422.2262(a)(1)(i) and (iii) which prohibits MA organizations from providing information that is inaccurate or misleading and from engaging in activities that could mislead or confuse Medicare beneficiaries or misrepresent the MA organization. For that reason, and as discussed elsewhere in this proposed rule, we propose at § 422.2262(a)(1)(xvi) to codify previous subregulatory guidance from the Medicare Communications and Marketing Guidelines prohibiting MA organizations, with respect to their non-D–SNP plans, from marketing their plan as if it were a D–SNP, implying that their plan is designed for dually eligible individuals, targeting their marketing efforts exclusively to dually eligible individuals, or claiming a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for that plan is in place.

We sought comments on the impact of D–SNP look-alikes in Medicare and Medicaid in the 2020 Draft Call Letter.[20] Specifically, we sought comment on topics related to the extent to which D–SNP look-alikes impact informed consumer choice; competition and innovation; the provision of high-quality coordinated care that addresses the full spectrum of dually eligible individuals' care and service needs; state Medicaid policy and operations; financial incentives; provider burden; and development and sustainability of products for dually eligible individuals through which an enrollee can receive all Medicare and Medicaid services from one organization.

As discussed in the 2020 Final Call Letter, we received comments from a range of stakeholders, including states, beneficiary advocates, and MA organizations and Medicaid MCOs.[21] Overall, the comments reinforced our concern that the proliferation of D–SNP look-alikes impedes progress toward developing products that meaningfully integrate Medicare and Medicaid benefits for dually eligible individuals. Commenters believed that D–SNP look-alikes allow MA organizations to circumvent enrollment restrictions and federal regulatory and state contracting requirements for D–SNPs and MMPs, undercutting efforts to lower costs and improve the quality of care.

As we noted in the 2020 Final Call Letter, commenters highlighted three areas that warranted further investigation and analysis and potential rulemaking: Benefit design and

[15] MedPAC also excluded employer group waiver plans (EGWPs) and a select group of medical savings account (MSA) plans.

[16] See *June 2018 MedPAC Report to Congress, Chapter 9* at *http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0* and *June 2019 MedPAC Report to Congress, Chapter 12* at *http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.*

[17] Ibid.

[18] Available at *https://www.macpac.gov/wp-content/uploads/2018/12/Comments-on-Changes-to-MA-the-Medicare-prescription-drug-benefit-PACE-Medicaid-fee-for-service-and-managed-care.pdf.*

[19] Justice in Aging, *Dual Eligible Special Needs Plan (D–SNP) Look-Alikes: A Primer* (July 2019) at *https://www.justiceinaging.org/wp-content/uploads/2019/07/D-SNP-Look-Alikes-A-Primer.pdf.*

[20] Available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

[21] Ibid.

nondiscrimination; beneficiary education, marketing, and broker compensation; and enhanced requirements for MA plans with high proportions of dually eligible enrollees. Some stakeholders suggested that benefit design used by D–SNP look-alikes appears to violate the prohibition at § 422.100(f)(2) against benefit designs that are discriminatory and against steering subsets of beneficiaries to specific plans, since their design targets dually eligible individuals.

We also received broad support for efforts to ensure that MA organizations do not market D–SNP look-alikes as plans that coordinate Medicaid benefits, as particularly suited to dually eligible individuals, or as uniquely subject to rules that protect dually eligible individuals from cost sharing or for which Medicaid pays the full amount of plan cost sharing. Lastly, several commenters recommended that CMS require MA plans with high proportions of dually eligible individuals to meet D–SNP regulatory requirements, including the requirement to contract with the state Medicaid agency.

To address these concerns, we are proposing at § 422.514(d) that CMS not enter into or renew a contract for a D–SNP look-alike in any state where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals. We also propose to establish procedures for transitioning enrollees from D–SNP look-likes to other MA plans in new regulation text at § 422.514(e). The proposed new contracting standards would effectively ensure all MA plans that predominantly serve dually eligible individuals integrate delivery of Medicare and Medicaid services and coordinate care consistent with the statutory and regulatory requirements for D–SNPs wherever it is feasible to do so.

Under our authority to adopt standards implementing the Part C statute and to add contract terms in sections 1856(b) and 1857(e)(1) of the Act, we are proposing to establish contracting standards for MA organizations based on their projected dually eligible enrollment in plan bids or on the proportion of dually eligible enrollees actually enrolled in the plan. A high rate of enrollment by dually eligible individuals in a non-D–SNP would allow us to identify non-SNP MA plans that are intended to predominantly enroll dually eligible individuals (that is, D–SNP look-alikes). We propose exceptions to these contracting standards for all SNPs. We believe that our proposal is an effective way to ensure that MA organizations do not undermine the statutory requirements established for D–SNPs by designing non-SNP MA plans to predominantly enroll dually eligible individuals. We believe that failure to adopt these exceptions could compromise the statutory and regulatory framework for D–SNPs. Any MA organization, by designing its benefits and outreach strategy to target dually eligible enrollment, practices that the enrollment patterns of D–SNP look-alikes show MA organizations are readily adopting, can offer an MA plan with high rates—in some cases almost 100 percent—of dually eligible enrollment without implementing any of the care management or Medicaid coordination activities that federal law requires of D–SNPs. States' ability to set contract terms for D–SNPs, including terms that limit contracted D–SNPs to entities that deliver integrated Medicare and Medicaid benefits, as provided under section 1859 of the Act, is likewise subverted by D–SNP look-alikes. Our proposal is especially critical as we approach implementation of new D–SNP requirements included in the BBA of 2018.

To prevent the undermining of the statutory and regulatory framework for D–SNPs, we therefore propose to establish a new regulation precluding CMS from entering into or renewing a contract for an MA plan that an MA organization offers, or proposes to offer, with enrollment of dually eligible individuals that exceeds specific enrollment thresholds. This proposed regulation would apply in any state where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals. Section 1856(b)(1) of the Act provides the Secretary with the authority to establish in regulation other standards not otherwise specified in statute that are both consistent with Part C statutory requirements and necessary to carry out the MA program. Our proposed regulations would ensure applicability and compliance with the statutory framework for D–SNPs. Additionally, section 1857(e)(1) of the Act authorizes the Secretary to establish MA organization contract terms and conditions that are necessary and appropriate and not inconsistent with other Part C statutory requirements. We believe that our proposed contract terms prohibiting the offering of D–SNP look-alikes is not inconsistent with the Part C statute and is necessary and appropriate to retain the integrity of the D–SNP statutory framework. Under the statute, only D–SNPs can primarily enroll dually eligible individuals, and D–SNPs must meet certain requirements. Our proposal would ensure that a non-SNP MA plan that, in practice, enrolls primarily dually eligible individuals under the conditions outlined in our proposal does not skirt the specific statutory and regulatory requirements designed to meet the specific needs of dually eligible individuals.

We propose not to enter into or renew MA contracts for an MA plan for an upcoming plan year when that MA plan is identified as exceeding specific enrollment thresholds for dually eligible individuals. However, MA organizations with plans identified as exceeding the enrollment threshold that also have approved D–SNPs for the following plan year would be permitted to transition dually eligible enrollees from D–SNP look-alikes to D–SNPs for which the individuals are eligible. We would permit this transition process to minimize disruptions to beneficiary coverage and allow enrollees in these D–SNP look-alikes to benefit from the statutory and regulatory care coordination and Medicaid integration requirements. We describe the specific changes we are proposing to § 422.514 as follows.

We propose changing the title of § 422.514 by removing the word ''minimum'' because the changes we propose to § 422.514 reflect an additional type of enrollment requirement beyond the minimum enrollment requirements currently articulated in § 422.514. We also propose to change the title of paragraph (a) from ''Basic rule'' to ''Minimum enrollment rules'' for clarity due to the proposed change to the scope of § 422.514.

We propose a new paragraph (d) to establish new contract requirements related to dual eligible enrollment. The proposed requirement at paragraph (d) would apply for an MA plan that is not a special needs plan for special needs individuals as defined in § 422.2. We propose applying this requirement only to non-SNP plans to allow for the predominant dually eligible enrollment that characterizes D–SNPs, I–SNPs, and some C–SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. For D–SNPs, the rationale for the exception is obvious—these MA plans enroll dually eligible individuals by statute. I–SNPs, by virtue of enrolling institutionalized individuals, or community-residing individuals who, but for the long-term services and supports they receive, otherwise reside in a long-term care institution, typically have high proportions of dually eligible individuals who qualify to receive

Medicaid long-term care benefits. In July 2017, 92 percent of I–SNP enrollees were dually eligible individuals.[22] Certain C–SNPs also have a relatively high proportion of dually eligible individuals because the chronic conditions these plans target are more prevalent among dually eligible individuals. For example, in July 2017, dually eligible individual enrollment in one end-stage renal disease (ESRD) C–SNP was 49 percent of total enrollment, in one HIV/AIDS C–SNP was 68 percent of total enrollment, and in one chronic and disabling mental health conditions C–SNP was 83 percent of total enrollment.[23] We would not want our proposed requirements to limit C–SNP enrollment by dually eligible individuals who could benefit from a plan that employs a specialized model of care, periodic health risk assessments, and other techniques that result in specialized, comprehensive care for individuals with certain chronic conditions.

The proposed requirement at paragraph (d) would be limited to states where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals, such as MMPs. We propose this limitation because it is only in such states that the implementation of D–SNP requirements necessitates our proposed new contracting requirements. That is, in a state with no D–SNPs or comparable managed care plans like MMPs, the D–SNP requirements have not had any relevance historically. There are no plans contracted with the state to implement the D–SNP requirements or otherwise integrate Medicare and Medicaid services, and therefore the operation of a D–SNP look-alike would not have any material impact on the full implementation of federal D–SNP requirements. In such states, the existence of D–SNP look-alikes is not impeding state or federal implementation of any requirements for enhanced care coordination and Medicaid integration by providing a vehicle for MA organizations to avoid compliance with those requirements that are imposed on D–SNPs or comparable managed care plans like MMPs. Therefore, we do not believe it is critical for our proposed requirements in paragraph (d) to apply in such states.

As of July 2019, eight states do not have any D–SNPs. We believe there are two main reasons for the absence of D–SNPs in these states. First, the rural nature of some states makes it challenging for any MA plan, including a D–SNP, to operate because of the sparse Medicare population and the difficulty in establishing networks. Second, some state Medicaid agencies have decided not to contract with any D–SNPs, either because the agency is not pursuing integration of Medicare and Medicaid through managed care, or is pursuing integrated care through MMPs.

We believe the proposed limitation on the states where the proposed dual eligible enrollment requirement would apply would continue to protect states' ability to contract with plans—including for Medicaid behavioral health services and long-term supports and services—in a manner that promotes integration and coordination of benefits and a more seamless experience for dually eligible individuals in such plans. Based on the type of plan, states use different contracting mechanisms to establish such requirements. In particular, states establish three-way contracts with MMPs, state Medicaid agency contracts with D–SNPs, and other contracts with Medicaid MCOs affiliated with D–SNPs for the delivery of Medicaid benefits. Each type of contract between the state and plan can effectively establish integration and coordination of benefits requirements.

However, we recognize that the limitation would allow, in certain states, D–SNP look-alikes that do not meet the minimum D–SNP requirements for data sharing or care coordination. We seek comment on whether the absence of these data sharing and care coordination requirements for D–SNP look-alikes in states where they could continue to operate under our proposed rule disadvantages the dually eligible individuals in D–SNP look-alikes and whether we should extend the proposed requirement at paragraph (d) to all states.

We propose to add new paragraphs (d)(1) and (2) that would require that CMS not enter into or renew a contract, for plan year 2022 or subsequent years, for an MA plan that is a non-SNP plan that either:

- Projects in its bid submitted under § 422.254 that 80 percent or more of the plan's total enrollment are enrollees entitled to medical assistance under a state plan under Title XIX, or
- Has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under Title XIX, unless the MA plan has been active for less than one year and has enrollment of 200 or fewer individuals at the time of such determination.

We believe that using either enrollment scenario is necessary to ensure that both new D–SNP look-alikes are not offered and that current, or existing, D–SNP look-alikes are not continued.

Proposed paragraph (d)(2), which would allow us to identify D–SNP look-alikes based on actual enrollment, would limit the prohibition to MA plans that have been active for one or more years and with enrollment equal to or greater than 200 individuals at the time of CMS' determination under proposed paragraph (d)(2). This limitation on our proposed contract requirement during a plan's first year is important because an early enrollment pattern may not be representative of the enrollment profile the plan will experience at a point of greater maturity.

To provide an example of how CMS would implement proposed paragraph (d)(2) in the first year, CMS would review MA plan enrollment data for January 2021 to determine if actual enrollment consists of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under Title XIX. CMS would not enter into or renew the contract for contract year 2022 for an MA plan that exceeds the 80 percent threshold unless the MA plan has been active for less than one year and has January 2021 enrollment of 200 or fewer individuals.

We believe focusing on the proportion of dually eligible enrollment, both in bids and actual enrollment, is the best way to identify D–SNP look-alikes because it is the net result of benefit design and marketing strategies and less subject to gaming by plans than other alternatives, as discussed later in this preamble. We propose a threshold for dually eligible enrollment at 80 percent of a non-SNP MA plan's enrollment because it far exceeds the share of dually eligible individuals in any given market and, therefore, would not be the result for any plan that had not intended to achieve high dually eligible enrollment. MedPAC analysis shows that in most MA markets, the proportion of dually eligible individuals as a percentage of total enrollment is clustered in the 10 to 25 percent range and in no county exceeds 50 percent.[24] We believe the proportion of dually eligible enrollment as a percentage of

[22] CMS, Chronic Conditions Data Warehouse, Part D Plan Characteristics File and Master Beneficiary Summary File, Final 2017 MBSF created in January 2019.

[23] Ibid.

[24] *June 2019 MedPAC Report to Congress, Chapter 12* at *http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.*

total plan enrollment is therefore a reliable indicator or proxy for identifying a non-SNP MA plan that the MA organization intends to have exclusive or predominantly dually eligible enrollment in without being subject to the D–SNP integration and care coordination requirements. MedPAC data show that our proposed threshold would have minimal impact on total dually eligible enrollment in non-SNP MA plans. Among dually eligible enrollees in traditional MA plans, only about 1.2 percent are in plans in which dually eligible individuals make up 80 percent or more of total plan enrollment. Also, 97 percent of dually eligible individuals enrolled in traditional MA plans are enrolled in a plan with 30 percent or less dually eligible enrollment, which indicates that traditional MA plans do not have to create D–SNP look-alikes to attract dually eligible individuals.[25]

We considered an alternative discussed by MedPAC in its June 2019 report to Congress for identifying traditional MA plans with predominantly dually eligible enrollment: Setting the bar at the higher of 50 percent dually eligible enrollment or the proportion of dually eligible MA-eligible individuals in the plan service area plus 15 percentage points. We also considered setting a lower threshold for dually eligible enrollment at a point between 50 percent and our proposed 80 percent threshold. However, we opted to propose an enrollment threshold of 80 percent or higher as an indicator that the plan is designed to attract disproportionate dually eligible enrollment because it aligns with MedPAC's 2019 research findings, provides a threshold that would be easier for MA organizations to determine prospectively, and would be easier for CMS to implement. We seek comment on whether these alternative enrollment thresholds are preferable.

Under our proposal for paragraph (d)(2), we would annually make the determination whether an MA organization has a non-SNP MA plan with actual enrollment exceeding the established threshold using the plan's enrollment in January of the current year. We intend to make such evaluations and issue the necessary information to affected MA organizations early in the coverage year. Even without a notice from CMS, we expect that each MA organization would be able to independently determine the level of dually eligible enrollment in its MA plan. Upon receiving the notice from CMS that this proposed prohibition on contracting with D–SNP look-alikes is triggered, the MA organization would then have the opportunity to make an informed business decision to: (1) As necessary, apply and contract for a new D–SNP for the forthcoming contract year; (2) create a new MA plan or plans through the annual bid submission process; or (3) terminate the D–SNP look-alike plan and not submit a bid for the following contract year.

In proposed paragraph (e), we propose a process and procedures for transitioning individuals who are enrolled in a D–SNP look-alike to another MA–PD plan (or plans) offered by the MA organization to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. Enrollees in MA plans that an MA organization cannot continue to operate as a result of our proposal may choose new forms of coverage for the following plan year, including a new MA or MA–PD plan or through the original Medicare fee-for-service program. Under our proposal, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in proposed paragraph (d)(2) could transition enrollees into another MA–PD plan (or plans) offered by the same MA organization, as long as any such MA–PD plan meets certain proposed criteria described in this section. As stated in paragraph (e)(2), this proposed transition process would allow MA enrollees to be transitioned from one MA plan offered by an MA organization to another MA–PD plan (or plans) without having to fill out an election form or otherwise indicate their enrollment choice as typically required, but it would also permit the enrollee to make an affirmative choice for another MA plan of his or her choosing. Enrollees would still have the opportunity to choose their own plan during this transition process because of how the proposed transition process would overlap with the annual coordinated election period.

Proposed paragraph (e)(1) specifies that, for coverage effective January 1 of the next year, the MA organization could only transition individuals from the D–SNP look-alike that is not being renewed into one or more MA plans (including a D–SNP) if such individuals are eligible to enroll in the receiving plan(s) in accordance with §§ 422.50 through 422.53. Thus, the individual would have to reside in the service area of the new plan and otherwise meet eligibility requirements for it. The proposed process would allow, but not require, the MA organization to transition dually eligible enrollees from a D–SNP look-alike into one or more D–SNPs offered under the MA organization, or another MA organization that shares the same parent organization as the MA organization, and therefore allow enrollees to benefit not only from continued coverage under the same parent organization but also from the care coordination and Medicaid benefit integration offered by a D–SNP.

We also propose at paragraphs (e)(1)(i) through (iii) specific criteria for any MA plan to receive enrollment through this transition process. Our policy goal for this process is to ensure that enrollees receive coverage under their new MA plan that is similarly affordable as the plan that would not be permitted for the next year. Under paragraph (e)(1)(i), we propose to allow a terminating D–SNP look-alike to transition enrollment to another non-SNP plan (or plans) only if the resulting total enrollment in each of the MA plans receiving enrollment consists of less than 80 percent dually eligible individuals. SNPs receiving transitioned enrollment would not be subject to the proposed dual eligible enrollment requirement. The percent of dually eligible individuals in the resulting total enrollment would have to be determined prospectively in order for us to make a timely decision on whether to allow for an MA organization to transition enrollment into a non-SNP MA plan or plans. As described at proposed paragraph (e)(3), we would make such determination by adding the cohort of enrollees that the MA organization proposes to enroll into a different non-SNP plan to the April enrollment of the receiving plan and calculating the resulting percent of dually eligible enrollment. We would make this calculation for each non-SNP plan into which the MA organization proposes to transition enrollment. This proposed criterion would ensure that the enrollment transitions under this regulation do not result in another non-SNP MA plan being treated as a D–SNP look-alike under proposed paragraph (d). Proposed paragraph (e)(1)(ii) would require that any plan receiving transitioned enrollment be an MA–PD plan as defined in § 422.2. Proposed paragraph (e)(1)(iii) would require that any MA plan receiving transitioned enrollment from a D–SNP look-alike have a combined Part C and D beneficiary premium of $0 after application of the premium subsidy for

[25] See *June 2018 MedPAC Report to Congress, Chapter 9* at *http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0* and *June 2019 MedPAC Report to Congress, Chapter 12* at *http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.*

full subsidy eligible individuals described at § 423.780(a).

As proposed in paragraph (e)(2)(ii), the MA organization would be required to describe changes to MA–PD benefits and provide information about the MA–PD plan into which the individual is enrolled in the Annual Notice of Change that the MA organization must send, consistent with § 422.111(a), (d), and (e) and proposed § 422.2267(e)(3). Consistent with § 422.111(d)(2), enrollees would receive this Annual Notice of Change (ANOC) describing the change in plan enrollment and any differences in plan enrollment at least 15 days prior to the first day of the annual election period. By proposing that this information is provided before the annual election period through this reference to the ANOC, we believe that we are ensuring that each enrollee affected by a transition under this proposal would have the information necessary to decide if they wish to change plans rather than be transitioned to the MA organization's other plan. By timing the notice with the annual open enrollment period, our proposal ensures that affected enrollees retain the opportunity to choose another MA plan or the original Medicare fee-for-service program and a Prescription Drug Plan.

As proposed in paragraph (e)(4), in cases where an MA organization does not transition some or all current enrollees from a D–SNP look-alike plan to one or more of the MA organization's other plans as provided in proposed paragraph (e)(1), it would be required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2). This proposal ensures that affected enrollees who would otherwise be disenrolled to the original Medicare fee-for-service program have an opportunity during the annual open enrollment period to make a different enrollment election.

This proposed transition process is conceptually similar to ''crosswalk exception'' procedures historically allowed by CMS and proposed at § 422.530, as described in section VI.C. of this proposed rule. However, in contrast to the proposed crosswalk exceptions, our proposal would allow the transition process to apply across legal entities offered by MA organizations under the same parent organization, as well as different plan types (for example, non-SNP to SNP). Allowing this type of enrollment transition process would minimize disruptions in coverage for dually eligible individuals enrolled in a D–SNP look-alike (who could be transitioned to a D–SNP or a non-D–SNP) and the small number of Medicare-only individuals enrolled in a D–SNP look-alike plan (who could be transitioned into a non-SNP MA plan operated by the same MA organization). Because this transition process is not the same as the crosswalk process, our proposal codifies it as part of § 422.514.

We considered an alternative that would require transitioning any dually eligible individuals into a D–SNP for which they were eligible if such a plan is offered by the MA organization. We opted for proposing a less prescriptive set of transition rules, recognizing a potentially wide array of transition scenarios, but seek comment on this alternative. In addition, we seek comment on whether additional criteria for the receiving plan are necessary to protect beneficiaries who are affected by this proposed prohibition on renewing MA plans that meet the criteria in proposed § 422.514(d).

We intend for the transition process to take effect in time for D–SNP look-alikes operating in 2020 to utilize the transition process for enrollments to be effective January 1, 2021. This will allow current MA–PD plans that expect to meet the enrollment threshold in proposed paragraph (d)(2) to retain some or all of their current enrollment by transitioning these individuals to other MA–PD plans offered by the same MA organization a year before CMS implements any plan terminations under this proposal. Contract terminations for plans that are specified in proposed paragraph (d)(2) would take effect no earlier than December 31, 2021, because, as specified in the proposed regulation text, such terminations would apply only beginning for plan year 2022. However, the proposed provision at paragraph (e)(1) allowing an MA organization to transition enrollees from a D–SNP look-alike plan into one or more MA–PD plans offered by that MA organization would be effective after the publication of a final rule in 2020. That is, if our proposal is finalized, we would work with plans that expect to have enrollment of dually eligible individuals that exceeds the enrollment threshold in proposed paragraph (d)(2) for Contract Year 2021 to confirm eligibility for the transition process and take necessary operational steps in 2020 to allow transition of enrollees from those plans into new MA–PD plans offered by the same MA organization on January 1, 2021, because CMS would not renew those contracts for 2022.

Overall, our proposal focuses on dually eligible beneficiaries as a percentage of a plan's total enrollment. We considered using alternative criteria instead of, or in addition to, the percentage of projected or actual dually eligible enrollment, to identify non-SNP MA plans designed to exclusively or predominantly enroll dually eligible individuals. In particular, we considered identifying D–SNP look-alikes by the benefit design these plans typically offer—relatively high Parts A and B cost sharing and a high Part D deductible that make the plans unattractive to Medicare-only beneficiaries, supplemental benefits like dental and hearing services and over-the-counter drugs that mimic typical D–SNP offerings, and a premium for Part D coverage that is fully covered by the Part D low-income subsidy. We also considered using the percentage of MA rebate dollars allocated to buy down Parts A and B cost sharing compared to other supplemental benefits—D–SNP look-alikes typically allocate a greater percentage to the latter—as a way to identify D–SNP look-alikes. However, we chose our proposal over these alternatives for multiple reasons. First, we are concerned that further regulating benefit design in this way could inadvertently diminish benefit flexibility that genuinely improves competition and choice, without necessarily being designed to undermine rules applicable to D–SNPs. For example, it is conceivable that future benefit designs would be precluded by any benefit and cost sharing criteria we established to eliminate D–SNP look-alikes, even if those benefit designs would not have drawn a high percentage of dually eligible individuals based on factors that we cannot currently foresee. Second, we determined that MA organizations could likely avoid any new limitations on benefit design through small tweaks to their benefit design or allocation of MA rebate dollars. Most importantly, we determined that the best indicator that a MA organization intends a plan to have exclusive or predominantly dually eligible enrollment is in the enrollment it projects in the bid and in the enrollment it actually achieves. Finally, we believe the criteria to identify D–SNP look-alikes should mirror the principal criterion that distinguishes D–SNPs from other MA plans in statute the ability to have enrollment that exclusively, or predominantly, consists of dual eligible individuals—which enables a D–SNP to integrate and coordinate the delivery of Medicaid services and necessitates the additional care coordination to meet the needs of this vulnerable population. We seek comment on whether these alternative criteria should be used instead of, or in addition to, the criteria we are

proposing for identifying D–SNP look-alikes and applying contracting prohibition.

III. Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

A. Mandatory Drug Management Programs (DMPs) (§ 423.153)

1. Summary and Background of DMPs

The SUPPORT Act made changes to the requirements for Part D DMPs to enhance Part D sponsors' ability to reduce the abuse or misuse of opioid medications in their prescription drug benefit plans. CMS is proposing two corresponding changes to the Part D DMP provisions codified in § 423.153(f): (1) Requiring Part D sponsors to adopt DMPs with respect to a plan year on or after January 1, 2022, as required under section 2004 of the SUPPORT Act; and (2) requiring inclusion of Part D beneficiaries with a history of opioid-related overdose in sponsors' DMPs beginning January 1, 2021, as required under section 2006 of the SUPPORT Act. In addition, CMS is proposing an additional category of exempt beneficiaries, for example, those with sickle cell disease, from DMPs and proposing several technical clarifications to the DMP regulations, which are described in subsequent paragraphs.

CARA amended the Act and included new authority for the establishment of DMPs in Medicare Part D, effective on or after January 1, 2019. CMS established through notice and comment rulemaking a framework at § 423.153(f) under which Part D plan sponsors may establish a DMP for beneficiaries at-risk for prescription drug abuse, or ''at-risk beneficiaries'' (ARBs) (defined in § 423.100).

Under the DMPs in place today, CMS identifies ''potential at-risk beneficiaries'' (PARBs) (defined in § 423.100) who meet the clinical guidelines described in § 423.153(f)(16), which we refer to as the minimum Overutilization Management System (OMS) criteria. The OMS reports such beneficiaries to their Part D plans for case management under their DMP. There are also supplemental clinical guidelines, or supplemental OMS criteria, which Part D sponsors can apply themselves to identify additional potential at-risk beneficiaries.

The OMS criteria used to identify PARBs are based on a history of filling opioids from multiple doctors and/or multiple pharmacies. Once PARBs are identified, plan sponsors engage in case management of these beneficiaries through contact with their prescribers to determine whether the beneficiary is at-risk for prescription drug misuse or abuse. If a sponsor determines through case management that a PARB is at-risk, after notifying the beneficiary in writing, the sponsor may limit their access to coverage of opioids and/or benzodiazepines to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale (POS) claim edit. This process does not apply to ''exempted beneficiaries'' (defined at § 423.100). Exempted beneficiaries currently include those being treated for active cancer-related pain, residing in a long-term care facility, receiving hospice care or receiving palliative or end-of-life care, but we are proposing, in section VIII.N. of this proposed rule, to exempt beneficiaries with sickle cell disease beginning with plan year 2021.

CMS data has shown value from plan sponsors engaging in case management. From 2011 [26] through 2017, there was a 76 percent decrease in the number of Part D potential at-risk beneficiaries (almost 22,500 beneficiaries) who met the applicable OMS criteria under the prior opioid overutilization policy. Part D sponsors also implemented 4,375 beneficiary-specific POS opioid claim edits through 2017. Early analysis of the coverage limitations (for example, pharmacy and prescriber limitations and beneficiary-specific POS claim edits) implemented under DMPs through the second quarter of 2019 continues to show a relatively low application of coverage limitations by Part D sponsors. However, this is not unexpected,[27] as the design of the DMP process is for Part D sponsors to engage in beneficiary-specific casework with the PARB's prescribing physicians to address the unique needs of the beneficiary and coordinate care. Nevertheless, the availability and use of coverage limitations by sponsors remains important, necessary, and appropriate in certain clinical situations.

2. Mandatory Drug Management Programs (DMPs)

Section 2004 of the SUPPORT Act requires that, no later than January 1, 2022, Part D sponsors must have established DMPs. We are proposing to amend regulatory language at § 423.153(f) to reflect this requirement. We note that while implementation of DMPs has been optional since 2019, when Part D sponsors could first adopt them, 85.9 percent of Part D contracts in calendar year 2019 and 87.2 percent for calendar year 2020 adopted DMPs to address opioid overutilization among their enrollees. Thus, of about 49 million beneficiaries who were enrolled in the Medicare Part D program in 2019, about 48.5 million enrollees (99 percent) were covered under Part D contracts that offered a DMP already. Our internal analysis estimates that only 158 additional PARBs will be identified due to making DMPs mandatory by meeting the current minimum OMS criteria.

B. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

Under section 2006 of the SUPPORT Act, CMS is required to identify Part D beneficiaries with a history of opioid-related overdose (as defined by the Secretary), and such individuals must be included as PARBs for prescription drug abuse under a Part D plan's DMP. CMS is also required under this section to notify the sponsor of such identifications. In line with this requirement, we are proposing to modify the definition of ''potential at-risk beneficiary'' at § 423.100 to include a Part D eligible individual who is identified as having a history of opioid-related overdose, as we propose to define it.

We propose to define ''history of opioid-related overdose'' to mean that for the Part D beneficiary, a recent claim has been submitted [28] that contains a principal diagnosis code reflecting an opioid overdose, regardless of the type of opioid and at least one recent PDE for an opioid dispensed to such beneficiary has been submitted.

We propose to operationalize this proposed definition by: (1) Using diagnoses that include both prescription and illicit opioid overdoses; (2) using a 12-month lookback period from the end of each OMS reporting quarter, for record of opioid-related overdose within Medicare fee-for-service (FFS) claims

[26] In developing the Medicare Part D opioid overutilization policy and OMS which began in 2013, we conducted pilots and testing in 2012. Therefore, we use 2011 as the pre-pilot/pre-policy measurement period. DMPs incorporated the OMS criteria and case management approach established in the opioid overutilization policy.

[27] See discussion p. 16690: ICRs Regarding the Implementation of the Comprehensive Addictions and Recovery Act of 2018 (CARA) Provisions (§ 423.153) in the April 2018 final rule (83 FR 16440).

[28] Claim date for meeting lookback period criteria based on the claim dates of service, admission date or date the claim was loaded into CMS's data warehouse.

and Medicare Advantage Encounter data (excluding those not enrolled in a Part D plan, whether an MA–PD or standalone PDP plan); and (3) using a 6-month lookback period from the end of each OMS reporting quarter, for record of a recent Part D opioid PDE. The number of unique beneficiaries identified under this proposal is approximately 18,268.

Our rationale for this proposal is that a past overdose is the risk factor most predictive for another overdose or suicide-related event.[29] We propose using diagnoses that include both prescription and illicit opioid overdoses because an opioid overdose may result from prescription or illicit opioids alone or in combination, and the statute does not distinguish based on type of opioid. Further, in the case of prescription opioids, the diagnosis code does not indicate if the prescription was legally obtained and used by the intended patient. Lastly, we propose to define history of opioid-related overdose to include only those instances where the enrollee also recently filled an opioid prescription under their Part D benefit, because the existence of an opioid PDE means sponsors would have an opioid prescriber with whom to conduct case management, which is an integral part of the DMP process.

Other factors we took into consideration for our proposal: First, as to including both prescription and illicit opioid overdose diagnoses, we considered that the Part D program is a prescription drug benefit program and, therefore, considered defining a history of opioid-related overdose as only including those overdoses involving validly prescribed and taken prescription opioids. However, given the risks associated with opioid-related overdose, we believe the best policy is to include both types of overdoses. Also, we cannot accurately identify whether an illicit or prescription opioid drug or drugs contributed to an overdose, and even if we could, we cannot determine whether a prescription opioid that contributed to the overdose was legally obtained and taken. Thus, our approach also overcomes limitations in the diagnosis data available (described further in this section of this proposed rule). The Alternatives Considered section of the Regulatory Impact Analysis (section X.D.1. of this proposed rule) provides a more in-depth review of the various other approaches considered and the projected numbers of affected enrollees.

Second, we note that the proposed 12-month lookback period of Medicare FFS claims and Medicare Advantage Encounter data to identify enrollees with a history of opioid-related overdose, which aligns with the measurement period used for active cancer diagnosis data in the current OMS criteria, takes into account program size and factors in patterns of beneficiaries who overdose more than once. We think 12 months is the appropriate lookback period to identify the beneficiaries who are at the most risk. When using Medicare fee-for-service inpatient data, we noted that a two-year lookback period (between July 2016 and June 2018) for Medicare beneficiaries who overdosed more than once almost proportionately doubles the number of overdoses compared to a one-year lookback (July 2017 to June 2018); however, 90 percent of the beneficiaries who had more than one opioid-related overdose episode, had a subsequent overdose episode on average within 12 months. In our methodology, we used the calendar month and year of opioid-related overdose events to identify each episode and also found that 95 percent of the beneficiaries had a subsequent overdose episode on average within 14 months and 99 percent of the beneficiaries had a subsequent overdose episode on average within 19 months. Thus, a 12-month lookback period strikes a better balance in identifying beneficiaries who would be at risk of having another opioid-related overdose taking into consideration the drug management program size.

Third, while we considered reporting any enrollees who have a history of opioid-related overdose during the 12-month lookback period, regardless of whether there is an opioid PDE, we believe our proposal to report only those enrollees who also recently filled a Part D opioid prescription should increase the likelihood for the sponsor to conduct successful provider outreach for case management. This aligns with the 6-month measurement period used for opioid PDE records in the current OMS criteria. We solicit feedback on the proposed 12-month lookback period for identifying claims for opioid-related overdose and the proposal to report only those enrollees with at least one Part D opioid PDE within the prior 6 months.

To derive an estimated population of PARBs identified under this proposal, we identified beneficiaries with inpatient, outpatient or professional FFS or encounter data opioid overdose claims based on the principal International Classification of Disease (ICD)-10 diagnosis codes (see Table 1) during the 12-month measurement period from 07/01/2017 to 06/30/2018 and at least one recent Part D opioid PDE from 01/01/2018 to 06/30/2018. We excluded beneficiaries if they were identified as having elected hospice, in a resident facility, had palliative care diagnosis, and/or had a death date during the last 6 months (01/01/2018–06/30/2018). We also excluded beneficiaries if they had active cancer during the 12-month lookback period (07/01/2017–06/30/2018). This is consistent with the measurement period used to identify these attributes in the current OMS criteria. Finally, we excluded beneficiaries who were not Part D enrolled during the last month of the OMS measurement period. Again, the number of unique beneficiaries identified under this proposal is 18,268. To align with our current OMS quarterly reporting frequency, we ran additional simulations using 2018 data and estimated that about 4,500 new beneficiaries with an opioid related overdose would be identified every quarter.

TABLE 1—LIST OF OPIOID-RELATED OVERDOSE CODES INCLUDED IN ANALYSIS

Overdose type	ICD–10 diagnosis codes [30]
Any Opioid	T40.0 (opium), T40.1 (heroin), T40.2 (natural/semisynthetic opioids including hydrocodone and oxycodone), T40.3 (methadone), T40.4 (synthetic opioids other methadone including fentanyl and tramadol) and T40.6 (other and unspecified narcotics).
Prescription Opioid	T40.2 (natural/semisynthetic opioids including hydrocodone and oxycodone), T40.3 (methadone), and T40.6 (other and unspecified narcotics).
Illicit Opioid	T40.1 (heroin) and T40.4 (synthetic opioids other methadone likely illicitly manufactured fentanyl).

[29] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul;112(7):1193–1201. doi: 10.1111/add.13774.

[30] ICD–10 diagnosis codes related to underdosing, adverse effects and assault are excluded.

Table 1 categorizes the diagnoses codes we used to derive our estimate, as well as the other options in section X.D.1. of this proposed rule. As previously noted, there are limitations when using diagnosis data to identify opioid-related overdoses. An additional limitation is that there is an unspecified opioid overdose code, which requires that assumptions be made in order to classify an overdose code as prescription or illicit. We classified code 40.2 (other opioids), as a prescription opioid overdose, but in some cases oxycodone may have been obtained illegally. We classified code 40.4 (other synthetic opioids) as illicit opioid overdose but in some cases fentanyl may have been obtained by prescription. We made these designations in order for our proposal to align with Centers for Disease Control and Prevention's (CDC) practice of defining all fentanyl overdoses (synthetic opioids other than methadone) as likely illicit.[31]

As noted earlier in this proposed rule, Part D sponsors with DMPs must conduct case management for each PARB identified by CMS through OMS which includes sending written information to the beneficiary's prescribers that the beneficiary met the clinical guidelines/OMS criteria and is a PARB. Currently, case management under DMPs generally addresses safety concerns related to opioid prescriptions for Part D beneficiaries involving multiple prescribers/pharmacies. We continue to encourage providers to consult state-based prescription drug monitoring programs before prescribing opioids to reduce the number of beneficiaries meeting the current OMS criteria. However, under this proposal, the nature of the safety concern for the Part D beneficiaries who must be identified and reported to sponsors by OMS is different. Sponsors will communicate with providers about potential safety concerns due to the beneficiary's history of opioid-related overdose, and the provider may or may not already be aware of this history and the beneficiary may or may not be using multiple opioid prescribers/pharmacies. Thus, our proposal is similar to PARBs who are reported by OMS with a benzodiazepine flag, as a particular provider may or may not be aware that a beneficiary is taking benzodiazepines in addition to opioids.

Such communication is an opportunity for sponsors, through their DMPs, to offer information to, and/or discuss with, providers the risk factors relevant to opioid use and a prior overdose history, and to make prescribers aware of the tools available under a DMP to assist them in managing their patient's care, as they consider prescription opioid use of their patient. The provider should also consider prescribing the beneficiary an opioid-reversal agent if they are newly aware of the beneficiary's history of opioid-related overdose and DMPs should notify providers and patients of the coverage of naloxone and its availability through their plan. As with any beneficiary in a DMP, the goal is the best-possible, coordinated, and safe care for each unique patient as determined by their provider(s), and not to stigmatize the patient; nor abruptly taper or discontinue their medications, nor unnecessarily or abruptly remove the patient from a provider's practice.

We solicit comments on whether our proposal needs any additional features to facilitate the case management process for PARBs with a history of opioid related overdose, such as written sponsor-provider communication and/or to address the anticipated effects of this type of sponsor-provider collaboration. We recognize that the model beneficiary notices[32] provided by CMS may need to be revised to incorporate a PARB having a history of opioid-related overdose (noted in section IX.B.3. of this proposed rule).

C. Information on the Safe Disposal of Prescription Drugs (§ 422.111)

Section 6103 of the SUPPORT Act amends section 1852 of the Act by adding a new subsection (n). Section 1852(n)(1) requires MA plans to provide information on the safe disposal of prescription drugs when furnishing an in-home health risk assessment. Section 1852(n)(2) requires us to establish, through rulemaking, criteria that we determine appropriate with respect to information provided to an individual during an in-home health risk assessment to ensure that he or she is sufficiently educated on the safe disposal of prescription drugs that are controlled substances.

In order to implement the requirements of section 1852(n)(1) for MA plans, CMS proposes to revise the § 422.111, Disclosure Requirements, to add a paragraph (j), which would require MA plans that furnish an in-home health risk assessment on or after January 1, 2021, to include both verbal (when possible) and written information on the safe disposal of prescription drugs that are controlled substances in such assessment. Consistent with section 1852(n)(1), we propose that information must include details on drug takeback programs and safe in-home disposal methods.

In educating beneficiaries about the safe disposal of medications that are controlled substances, we propose MA plans would communicate to beneficiaries in writing and, when feasible, verbally. We propose that MA plans must do the following to ensure that the individual is sufficiently educated on the safe disposal of controlled substances: (1) Advise the enrollee that unused medications should be disposed of as soon as possible; (2) advise the enrollee that the US Drug Enforcement Administration allows unused prescription medications to be mailed back to pharmacies or other authorized sites using packages made available at such pharmacies or other authorized sites; (3) advise the enrollee that the preferred method of disposing of controlled substances is to bring them to a drug take back site; (4) identify drug take back sites that are within the enrollee's MA plan service area or that are nearest to the enrollee's residence; and (5) instruct the enrollee on the safe disposal of medications that can be discarded in the household trash or safely flushed. Although we are not proposing to require MA plans to provide more specific instructions with respect to drug disposal, we are proposing that the communication to enrollees provide the following additional guidance: If a drug can be safely disposed of in the enrollee's home, the enrollee should conceal or remove any personal information, including Rx number, on any empty medication containers. If a drug can be discarded in the trash, the enrollee should mix the drugs with an undesirable substance such as dirt or used coffee grounds, place the mixture in a sealed container such as an empty margarine tub, and discard in the trash.

We also propose that the written communication include a web link to the information available on the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following address: *https://www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html.* We note that the safe disposal of drugs guidance at this website can be used for all medications not just medications that

[31] Current information reported about overdose deaths in NVSS does not distinguish pharmaceutical fentanyl from illicitly manufactured fentanyl (IMF). Opioid Data Analysis and Resources. Available from: *https://www.cdc.gov/drugoverdose/data/analysis.html.*

[32] Notice documents available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Drug-Management-Program-Notices-.zip.*

are controlled substances. We believe that plan communications consistent with the standard on this website provides enrollees with sufficient information for proper disposal of controlled substances in their community.

D. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

Sponsors of Part D prescription drug plans, including MA–PDs and standalone PDPs, must disclose certain information about their Part D plans to each enrollee in a clear, accurate, and standardized form at the time of enrollment and at least annually thereafter under section 1860D–4(a)(1)(a) of the Act. Among the drug specific information that sponsors must provide pursuant to section 1860D–4(a)(1)(B) of the Act is information about the plan formulary, pharmacy networks, beneficiary cost-sharing requirements, and the availability of medication therapy management (MTM) and DMPs.

Section 6102 of the SUPPORT Act amended section 1860D–4(a)(1)(B) of the Act to require that, for plan year 2021 and each subsequent plan year, Part D sponsors also must disclose to each enrollee, with respect to the treatment of pain, information about the risks of prolonged opioid use. In addition to this information, with respect to the treatment of pain, MA–PD sponsors must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans. Sponsors of standalone PDPs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B.

Section 6102 of the SUPPORT Act also amended section 1860D–4(a)(1)(C) of the Act to permit Part D sponsors to disclose this opioid risk and alternative treatment coverage information to only a subset of plan enrollees, such as enrollees who have been prescribed an opioid in the previous 2-year period, rather than disclosing the information to each plan enrollee. To implement section 6102, we propose to amend our regulations at § 423.128 to reflect that Part D sponsors may provide such information to a subset of such enrollees, in accordance with section 1860D–4(a)(1)(C), in lieu of providing it to all enrollees.

If a sponsor does not send the information to all enrollees, we have a few suggested subsets of enrollees for sponsors to consider and the estimated number of enrollees in each subset, as shown in Table 2. The estimates are based on 2018 Part D PDE data and do not include the populations that are exempted from Part D opioid policies in 2021, for example, enrollees with active cancer-related pain, in hospice, in a resident facility, or in palliative care. Sponsors may or may not choose to adopt one of the suggestions, and sponsors may or may not exempt the same beneficiaries that are exempted from other Part D opioid policies.

However, we thought that providing some options, along with Part D program-wide data, would be useful to sponsors, as they decide to which enrollees they will disclose the required opioid risk and alternate pain treatment coverage information. We are also interested in comments identifying other possible appropriate subsets of enrollees.

TABLE 2—SUGGESTED SUBSET OPTIONS TO RECEIVE EDUCATION ON OPIOID RISKS AND ALTERNATE TREATMENTS *

Subset	Suggested subset	Number of enrollees in this subset	Percent of total opioid users
1	All Part D Enrollees	46,759,911	N/A
2	Any opioid use in last 2 years	16,134,063	100
3	Any opioid use in past year	11,027,271	100
4	7 days continuous opioid use	7,163,615	65
5	Greater than 30 days continuous opioid use, 7 day or less gap	3,816,731	35
6	Greater than 90 days continuous opioid use, 7 day or less gap	2,698,064	24

* All figures based on 2018 PDE data as of 7/6/2019, except subset 2 which is based on 2017 and 2018 PDE data. Beneficiaries were excluded from the opioid use subsets if they were in hospice, in a resident facility, or had a palliative care diagnosis (07/01/2018–12/31/2018). Beneficiaries were also excluded if they had a cancer diagnosis (01/01/2018–12/31/2018). No exclusions were applied to the all Part D enrollees figure (subset 1).

The first suggested option is for sponsors to disclose the opioid risk and alternate coverage information to all Part D enrollees. This option has the advantage of disseminating the information most widely—to approximately 46,759,911 enrollees—and not trying to determine which enrollees may need the information more than other enrollees. Beneficiaries may receive information about risks and treatment alternatives before they use opioids under this option. However, this option has the disadvantage of being largely over-inclusive, in the sense that a significant number of enrollees will receive information that is not, and may never be, pertinent to them.

The second suggested option is to disclose the opioid information to the subset suggested by the SUPPORT Act, which is enrollees who have been prescribed an opioid in the previous 2-year period, approximately 16,134,063 enrollees. This option has the advantage of targeting enrollees who have actually used opioids, but has the disadvantage of not being as proactive as the first option, while also still including enrollees who may not have used opioids in quite some time; may only have used them for short-term acute use; and may not take them again soon or ever.

The third suggestion option is to disclose the opioid information to the subset of all opioid users in the Part D program who had at least one opioid prescription in a year, which would be 11,027,271 enrollees based on 2018 estimates. This option still has the advantage of a fairly wide dissemination of information about the risk of opioid use and coverage of alternate pain treatment; however, it would also mean that the information would be sent to enrollees who only took opioids for short-term acute use; are no longer taking opioids; or may never take them again.

The fourth suggested option is to disclose the opioid information to the subset of enrollees who have a greater than 7 days of continued opioid use. This option would disseminate the information to 7,163,615 enrollees, who represent well over the majority (65%) of opioid users in the Part D program. While this subset is much more targeted than the other suggested subsets, it would involve sending the information to enrollees who may still be in the acute phase of opioid use and may not

transition to chronic use, as three-quarters of opioids users in 2018 had less than 90 days of opioid use. Moreover, our internal analysis shows that opioid prescriptions are filled with a median day supply of 30 days. Thus, the greater than 7 day use criteria would include enrollees who have not yet received a subsequent opioid fill after an initial opioid prescription or received fills with a smaller days' supply.

A fifth suggested option is to disclose this information to the subset of enrollees with greater than 30 days of continuous opioid use without more than a 7 day gap. This subset would be approximately 3,816,731 enrollees, which is 35% of opioid users. This suggested option attempts to strike a balance of not sending the information to enrollees who are less at risk for prolonged opioid use and to proactively educate enrollees who could be at risk before progression to chronic opioid use. However, no option can precisely distinguish between enrollees who will only use opioids for an acute period and those who will progress to chronic use, putting them at greater risk of complications. Of note, this option does not account for providing the information before the enrollee begins opioid use.

A sixth and final suggested option is to disclose this information to the subset of enrollees with greater than greater than 90 days continuous opioid use, without more than a 7 day gap. This option involves approximately 2,698,064 enrollees which represent 24% of opioid users in the Part D program. While this option involves the smallest number of Part D enrollees, it has the disadvantage that the information will be disclosed to enrollees who are more likely already chronic users of opioids. While the information may still be useful to them if they are concerned about the risks of opioids and interested in alternate treatments, this option would not have a proactive aspect for enrollees who are not yet chronic opioid users.

For these suggested options, we note that we considered opioid use to be ''continuous'' even if there is a short break, such as 7 days or fewer, in opioid utilization. To illustrate our suggested approach, if a beneficiary filled an opioid prescription on 01/01/2018 for a 5 day supply and another on 01/10/2018 for a 10 days, this beneficiary would have a continuous opioid use days of 20 days ==that is a 5 days + 10 days + 5 ''gap days.'' This approach would not take into account early refills, but rather allow up to a 7 days gap period to accommodate for varying prescription refills and beneficiary opioid utilization patterns.

Section 1860D–4(a)(1)(C) also permits Part D sponsors to disclose the required information to enrollees through mail or electronic means. Given the importance of the information, we suggest that sponsors only send it electronically if the enrollee has consented to receiving plan information in electronic form.

The existing regulatory framework for the information that must be disclosed pursuant to section 1860D–4(a)(1) of the Act is § 423.128. CMS proposes to use this existing regulatory framework to codify the opioid risk and alternative pain treatment coverage information that Part D sponsors must disseminate pursuant to section 6102 of the SUPPORT Act. Specifically, CMS proposes to revise § 423.128(a) to provide that, except as provided in new paragraph (b)(11), information specified in paragraph (b) must be provided to each enrollee annually in a clear, accurate, and standardized form. We propose in new paragraph (b)(11) that the plan would be required to disclose to each enrollee, with respect to the treatment of pain, the risks associated with prolonged opioid use and coverage of alternative therapies, unless the plan elects to provide such information to a subset of enrollees, as discussed previously.

To assist Part D sponsors in providing clear and accurate information to enrollees, we refer MA–PDs and standalone PDPs to CMS' pain management website (*https://www.medicare.gov/coverage/pain-management*), which contains coverage information on non-pharmacological therapies, devices, and non-opioid medications for the treatment of pain under the Medicare fee-for-service program. Part D sponsors would be able to be use this information to convey the required alternative treatment coverage information MA–PD sponsors can consult this website as well, however, they would also be required to add any additional coverage that they provide under their plans to their standardized forms. We believe that both MA–PDs and standalone PDPs should be able to describe the risks of prolonged opioid use, as they both provide drug coverage and thus have expertise in the use of drugs. However, we refer Part D sponsors to the U.S. Department of Health and Human Services website as an additional resource that contains information about the risks of opioids, as well as a searchable index for local treatment centers addressing substance abuse and mental health consultations. (See *https://www.hhs.gov/opioids/*)

E. Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153)

We propose to amend Part D Medication Therapy Management (MTM) program requirements in § 423.153 to conform with the relevant SUPPORT Act provisions. The SUPPORT Act modified MTM program requirements for Medicare Part D plans beginning January 1, 2021, by expanding the population of beneficiaries who are targeted for MTM program enrollment (''targeted beneficiaries'') to include at-risk beneficiaries (ARBs), and by adding a new service component requirement for all targeted beneficiaries. More specifically, first, section 6064 of the SUPPORT Act amended section 1860D–4(c)(2)(A)(ii) of the Act by adding a new provision requiring that ARBs be targeted for enrollment in the Part D plan's MTM program. Our proposal to implement this provision would be codified at § 423.153(d)(2). Second, section 6103 of the SUPPORT Act amended the MTM program requirements in section 1860D–4(c)(2)(B) of the Act by requiring Part D plans to provide enrollees with information about the safe disposal of prescription drugs that are controlled substances, including information on drug takeback programs, in-home disposal, and cost-effective means for safe disposal of such drugs. Our proposal to implement this provision would be codified at § 423.153(d)(1)(vii)(E).

We wish to provide some background on Part D MTM programs before further delineating our proposal to revise the definition of ''targeted beneficiaries'' for purposes of MTM to include beneficiaries who are determined to be at-risk beneficiaries (ARBs) under Part D sponsors' drug management programs (DMPs), meaning beneficiaries who are at-risk for prescription drug abuse. Please refer to sections III.A. and III.B. of this proposed rule for more information about DMPs.

MTM programs serve as integral components of the Medicare Part D benefit. All Part D sponsors are required to have an MTM program that is designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions (see section 1860D–4(c)(2)). The Act also establishes general patient eligibility and service intervention requirements that CMS has implemented through regulation in

§ 423.153(d). Each Part D sponsor has the latitude to develop specific eligibility criteria for its own MTM program, as long as the criteria target beneficiaries who: (1) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment; (2) are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and (3) are likely to incur costs for covered Part D drugs in an amount greater than or equal to the specified cost threshold ($4,255 for plan year 2020). The MTM cost threshold is increased each year by the annual percentage specified in § 423.104(d)(5)(iv). CMS reviews Part D sponsor submissions to ensure compliance with MTM requirements. Section 423.153(d)(6) requires each Part D sponsor to provide information regarding the procedures and performance of its MTM program to CMS for review.

1. ARBs and MTM

As part of codifying the framework for DMPs in 2018, CMS codified a definition of an ARB in § 423.100. An ARB is defined as a Part D eligible individual—(1) who is—(i) Identified using clinical guidelines (as defined in § 423.100); (ii) Not an exempted beneficiary; and (iii) Determined to be at-risk for misuse or abuse of such frequently abused drugs (FADs) under a Part D sponsor's drug management program in accordance with the requirements of § 423.153(f); or (2) With respect to whom a Part D sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an at-risk beneficiary (as defined in the paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment. Please refer to sections III.A. and III.B. of this proposed rule for more information about DMPs.

Under our proposed revisions to § 423.153(d) to implement sections 6064 and 6103 of the SUPPORT Act, at-risk beneficiaries, as defined in § 423.100 would be targeted for enrollment in a sponsor's MTM program. The existing criteria that Part D sponsors currently use to target beneficiaries for MTM program enrollment would remain unchanged, so that two groups of enrollees would now be targeted for enrollment: the first group would include enrollees who meet the existing criteria (multiple chronic diseases, multiple Part D drugs and Part D drug costs); and the second group would include enrollees who are determined to be at-risk beneficiaries under § 423.100. The MTM program requirements would be the same for all targeted beneficiaries enrolled in a Part D sponsor's MTM program, regardless of whether they were targeted for enrollment based upon the existing criteria or because they are at-risk beneficiaries.

Under this proposal, Part D sponsors would be required to automatically enroll all at-risk beneficiaries in their MTM programs on an opt-out only basis as required in § 423.153(d)(1)(v). In addition, Part D sponsors would be required to offer each at-risk beneficiary enrolled in the MTM program the same minimum level of MTM services as specified in § 423.153(d)(1)(vii) that sponsors currently are required to offer to beneficiaries enrolled in their MTM program.

This means, in addition to interventions for both beneficiaries and prescribers, sponsors must offer ARBs an annual comprehensive medication review (CMR) under § 423.153(d)(1)(vii)(B). By way of background, CMS has developed a Standardized Format that an MTM provider must use to summarize the results of the CMR and recommended action plan for the beneficiary (reference CMS–10396, OMB Control Number 0938–1154). The CMR must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider. Section 423.153(d)(1)(vii)(B)(*2*) provides that in the event the beneficiary is offered the annual CMR and is unable to accept the offer to participate, the MTM provider may reach out to the beneficiary's prescriber, caregiver, or other authorized individual. The CMS Standardized Format provides instructions for those circumstances. In the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes; Final Rule (77 FR 22140), we explained that when the beneficiary is cognitively impaired and cannot make decisions regarding his or her medical needs (that is, is unable to accept the offer to participate), we recommend that the pharmacist or qualified provider reach out to the beneficiary's prescriber, caregiver, or other authorized individual, such as the resident's health care proxy or legal guardian, to take part in the beneficiary's CMR. However, this recommendation applies only to those situations where fulfilment of that statutory obligation is not reasonably possible because the beneficiary is cognitively impaired; it does not apply to situations where the sponsor is unable to reach the beneficiary (such as no response by mail, no response after one or more phone attempts, or lack of phone number or address), if there is no evidence of cognitive impairment, or the beneficiary declines the CMR offer. When the CMR is performed with an authorized individual participating on the beneficiary's behalf, the MTM provider should discuss the delivery of the CMS Standardized Format and any accompanying summary materials with the beneficiary's representative to determine to whom and where they should be sent. The CMR summary should be delivered to the beneficiary's authorized representative, such as the health care power of attorney or the enrollee's representative.[33] Currently, the CMS Standardized Format is not in a machine-readable format because it is designed for sharing with the beneficiary, although the MTM provider may elect to share the information with the beneficiary's provider as well.

In addition to the CMR, the minimum level of MTM services also includes a requirement at § 423.153(d)(1)(vii)(C) for the plan to provide targeted medication reviews (TMRs) to all MTM program enrollees no less often than quarterly following MTM enrollment with follow-up interventions when necessary. Thus, under our proposal, Part D sponsors would have to provide TMRs to ARBs enrolled in their MTM program. As additional background, CMS has not provided a standardized format for the TMR service, and the MTM provider should determine the patient's unmet medication-related needs and use the TMR to follow up with the patient (or prescriber) as appropriate. The follow-up interventions with MTM-enrolled beneficiaries should be person-to-person, if possible, but may be delivered via the mail or other means. Sponsors may determine how to tailor the follow-up interventions based on the specific needs or medication use issues of the beneficiary. The MTM provider should seek to resolve any recurring issues that exist with the patient, as well as to identify any new opportunities that are identified. Therefore, while the follow-up intervention that results from a TMR may be person-to-person, the TMR is distinct from a CMR because the TMR is focused on specific actual or potential medication-related problems (see

[33] See Standardized Format FAQ: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MTM-Program-Standardized-Format-Revisions-v082917.zip.*

annual MTM Program guidance memo).[34]

Like all other targeted beneficiaries, ARBs would be required to be enrolled in the Part D sponsor's MTM program using an opt-out method of enrollment.[35] As explained in the MTM Program guidance memo, following enrollment in the MTM program, a beneficiary may refuse or decline individual services without having to disenroll from the program. For example, if an enrolled ARB declines the annual CMR, § 423.153(d)(1)(vii)(C) still requires the sponsor to offer interventions to the prescriber and perform TMRs at least quarterly to assess medication use on an on-going basis. In addition, sponsors should not wait for the beneficiary to accept the offer for the CMR and should perform TMRs and provide interventions to the beneficiary's prescriber once the beneficiary is enrolled in the MTM program. Part D sponsors are encouraged to use more than one approach when possible to reach all eligible targeted beneficiaries to offer MTM services versus only reaching out via passive offers. Sponsors may increase beneficiary engagement by following up with beneficiaries who do not respond to initial offers (for example, by providing telephonic outreach after mailed outreach). Also, sponsors are expected to put in place safeguards against discrimination based on the nature of their MTM interventions (for example, using TTY if phone based, Braille if mail based, etc.).

Including ARBs in Part D MTM programs as proposed would provide Part D sponsors with another tool to address opioid misuse among the Part D beneficiaries they serve. DMPs primarily involve a prescriber-centric approach through case management to promote safer use of opioids and benzodiazepines and care coordination. In contrast, MTM leverages a beneficiary-centric approach to improve the beneficiary's medication use and reduce the risk of adverse events involving all of the medications the beneficiary is taking (including opioids and other FADs). We encourage sponsors to design MTM interventions for this new population of targeted beneficiaries to reflect their simultaneous inclusion in the sponsors' DMPs. For example, MTM services for these beneficiaries may include beneficiary and/or prescriber interventions or discussions to assess the risks and benefits of ongoing opioid use, discuss beneficiary goals and alternative treatment options, talk about how to prevent prescription drug misuse and overdose, review access to naloxone, assess concurrent use of benzodiazepines or other potentiator drugs that may increase the risk for adverse events or overdose, review common side effects, and discuss safe storage and safe disposal of medications. (As noted later in this section, beginning in 2021, MTM services furnished to all targeted beneficiaries must include the provision of certain information on the safe disposal of prescription drugs that are controlled substances.) We recommend that plans consult existing clinical guidelines, such as those issued by the Centers for Disease Control and Prevention for Prescribing Opioids for Chronic Pain,[36] when developing MTM strategies and materials. These materials may help plans design MTM interventions such that treatment decisions to start, stop or reduce prescription opioids are individualized and carefully considered between the prescriber and at-risk beneficiary. Interventions should not promote abrupt tapering or discontinuation of opioids.

Because we propose that beneficiaries would be targeted for MTM services on the basis of being an ARB, this means that the beneficiary will have received a second written notice in accordance with DMP regulations at § 423.153(f)(6). CMS solicits input into how sponsors can best coordinate DMPs and MTM programs and effectively perform outreach to offer MTM services. We also seek feedback on how to leverage MTM services to improve medication use and reduce the risk of adverse events in this population, how to measure the quality of MTM services delivered, and how to increase meaningful engagement of the new target population in MTM. Lastly, we seek comments on the type of information that CMS should use to monitor the impact of MTM services on at-risk beneficiaries, who will now be targeted for MTM services.

As the annual CMR is a key element of the MTM services, we have evaluated the CMS Standardized Format to determine how it might be modified in order to accommodate the new population of at-risk beneficiaries that will be enrolled in Part D sponsors' MTM programs. The Standardized Format for the CMR must be approved by the Office of Management and Budget (OMB) through the Paperwork Reduction Act (PRA) process. OMB has approved the current version of the standardized format (CMS–10396; OMB control number: 0938–1154) until August 31, 2020. Based on the results of feedback from limited cognitive interviews with consumers and other stakeholders conducted in 2018, we had intended to propose revisions to the Standardized Format to optimize the utility of the CMR summary for beneficiaries while reducing burden on Part D sponsors through a standalone PRA package approval process as we did when the Standardized Format was originally developed. However, the changes proposed in this proposed rule will also require changes to the Standardized Format for the CMR summary to account for information provided to MTM enrollees about the safe disposal of prescription medications that are controlled substances, as discussed later in this section. In order to allow Part D plans to review all proposed changes to the document together, in section IX.B.5. of this proposed rule we are proposing a new format for the Standardized Format and seeking public comment.

Also, we encourage sponsors to share the CMR summary with the beneficiaries' prescribers, including those the sponsor engaged in case management under DMPs, to help them coordinate care for these beneficiaries. In order to facilitate the transfer of information from the CMR to the Electronic Health Record (EHR), we are considering modifying the CMS Standardized Format to allow the form to be completed in a machine readable format. In the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers Proposed Rule (84 FR 7610), CMS proposed a framework for the sharing of data across the industry, which we believe may be suitable to use when conveying data from the MTM provider to the prescriber. The policies in that proposed rule would encourage use of Health Level Seven (HL7®) Fast

[34] See Annual MTM Program Guidance Memo, April 5, 2019, CY 2020 Medication Therapy Management Program Guidance and Submission Instructions: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Memo-Contract-Year-2020-Medication-Therapy-Management-MTM-Program-Submission-v-041019-.pdf.*

[35] See § 423.153(d)(1)(v).

[36] Accessible at *https://www.cdc.gov/mmwr/ volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.*

Healthcare Interoperability Resources (FHIR®)-based APIs to make other health information more widely accessible. We are seeking feedback on whether using HL7®-enabled CMRs could positively impact the sharing of CMR data with the prescriber for an MTM enrollee. We also seek input on the value of encouraging Part D MTM providers to use FHIR-enabled platforms when providing MTM to Part D enrollees to facilitate integration of the MTM service elements into prescribers' EHRs.

2. Information on Safe Disposal of Prescription Drugs That Are Controlled Substances for MTM Enrollees

The information we previously provided about CMRs and TMRs is also relevant to our proposal to implement Section 6103 of the SUPPORT Act, which, as we described at the beginning of this section, amended the MTM requirements in section 1860D–4(c)(2)(B) of the Act. Section 6103 added a new requirement that Part D plans provide beneficiaries enrolled in their MTM program with information about the safe disposal of prescription drugs that are controlled substances, including information on drug takeback programs, in-home disposal, and cost-effective means for safe disposal of such drugs. To implement this new requirement, we propose that Part D sponsors would be required to provide this information to all beneficiaries enrolled in their MTM programs at least annually, as part of the CMR or through the quarterly TMRs or follow up. Furthermore, while not required, we encourage sponsors to provide information on safe disposal of all medications, not just controlled substances, to MTM enrollees.

Section 6103 of the SUPPORT Act states that the information provided to beneficiaries regarding safe disposal of prescription drugs that are controlled substances must meet the criteria established in section 1852(n)(2) of the Act, including information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal. Section 1852(n)(2) states that the Secretary shall, through rulemaking, establish criteria the Secretary determines appropriate to ensure that the information provided to an individual sufficiently educates the individual on the safe disposal of prescription drugs that are controlled substances. We describe our proposed criteria and requirements for MA plans to furnish information on safe disposal of controlled substances when providing an in-home health risk assessment in section III.C. of this proposed rule and propose to codify these requirements in a new provision of the regulations at § 422.111(j); in this section we are proposing that Part D plans would be required to furnish materials in their MTM programs regarding safe disposal of prescription drugs that are controlled substances that meet the criteria specified in § 422.111(j). Like MA plans, Part D plans would retain the flexibility to refine their educational materials based on updated information and/or on beneficiary feedback, so long as the materials meet the proposed criteria. Section 1860D–4(c)(2)(B)(ii) expressly directs that the information on safe disposal furnished as part of an MTM program meet the criteria established under section 1852(n)(2) for MA plans. Accordingly, to ensure consistency and to avoid burdening MA–PD plans with creating separate documents addressing safe disposal for purposes of conducting in-home health risk assessments and their MTM programs, CMS believes it is appropriate to apply the same criteria specified in the proposed provision at § 422.111(j) to MTM programs by including a reference to the requirements of § 422.111(j) in the regulation at § 423.153(d) governing MTM programs.

When developing the proposal to codify section 6103 of the SUPPORT Act, we considered proposing to require that safe disposal be addressed during the CMR session. Because the required information would appear to be a natural topic of interest when reviewing a beneficiary's medication history; the MTM provider could provide information in the medication action plan section of the CMR summary on drug takeback programs and safe in-home disposal methods, as required by the SUPPORT Act. This would allow the beneficiary to have all pertinent reference materials within the Standardized Format and also avoid the MTM provider having to mail a separate document to the beneficiary.

However, granting MTM providers the flexibility to furnish safe disposal information to MTM recipients during the CMR session, as part of a quarterly TMR, or through another follow-up service could have significant advantages over requiring that the information be provided during the CMR session. For example, beneficiaries may decline the CMR, which would result in their not receiving safe disposal information as required. On the other hand, quarterly TMRs are performed for all eligible enrollees, meaning that safe disposal information could be circulated to all eligible beneficiaries, not just those who accept the CMR service. In the event that a beneficiary does not receive a CMR that includes safe disposal information, the plan would need to ensure that a TMR that includes safe disposal information is provided to the beneficiary either in person (such as at the pharmacy) or by mail. Additionally, as plan sponsors begin quarterly TMRs immediately upon enrolling a beneficiary in the MTM program, beneficiaries could receive this important information soon after qualifying for MTM rather than waiting for a CMR to be scheduled. Based on these considerations, we propose to give Part D plans the discretion to furnish safe disposal information to the beneficiary during the CMR, a TMR, or another follow up service, depending upon the circumstances, as long as the required information is shared with each MTM program enrollee at least once per year. Specifically, we are proposing to revise § 423.153(d)(1)(vii) to include a requirement that all MTM enrollees receive at least annually, as part of the CMR, a TMR, or another follow up service, information about safe disposal of prescription drugs that are controlled substances, take back programs, in-home disposal, and cost-effective means of safe disposal that meets the criteria in § 422.111(j).

F. Automatic Escalation to External Review Under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

CARA amended the Act to include new authority for Medicare Part D drug management programs effective on or after January 1, 2019. Final regulations were published in the April 2018 final rule (83 FR 16440) and provided at § 423.153(f), that a plan sponsor may establish a drug management program (DMP) for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs. If an enrollee is identified as at-risk under a DMP, the individual has the right to appeal an at-risk determination under the rules in part 423, subparts M and U. In addition to the right to appeal an at-risk determination, an enrollee has the right to appeal the implementation of point-of-sale claim edits for frequently abused drugs that are specific to an at-risk beneficiary or a limitation of access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers or dispensed to the beneficiary by one or more network pharmacies (lock-in).

In the April 2018 final rule, we explained that the Secretary had discretion under the statute to provide

for automatic escalation of drug management program appeals to external review. We declined to exercise that discretion based on comments we received that cited to administrative efficiencies in using the existing Part D appeal process that is familiar to enrollees and plans. Accordingly, we implemented a final rule that follows the existing Part D benefit appeals process. Under existing Part D benefit appeals procedures, there is no automatic escalation to external review for adverse appeal decisions; instead, the enrollee (or prescriber, on behalf of the enrollee) must request review by the Part D IRE. Under the existing process, cases are auto-forwarded to the IRE only when the plan fails to issue a coverage determination within the applicable timeframe.

Subsequently, section 2007 of the SUPPORT Act amended section 1860D–4(c)(5) of the Act to require that, if on reconsideration a Part D sponsor affirms its denial of a DMP appeal, in whole or in part, the case shall be automatically forwarded to the independent outside entity contracted with the Secretary for review and resolution. We are proposing rules to codify that provision. For consistency with existing appeals regulations at part 422, subparts M and U, and for purposes of this proposal, the independent outside entity contracted with the Secretary is referred to as the Part D independent review entity (IRE) that is contracted with CMS to perform reconsiderations under the Part D program.

To implement the changes required by the SUPPORT Act, we are proposing revisions to the requirements for the content of the initial notice at § 423.153(f)(5)(ii)(C)(*3*) and the requirements for the second notice at § 423.153(f)(6)(ii)(C)(*4*)(*iii*). Specifically, we are proposing that these notices explain that if on redetermination a plan sponsor affirms its at-risk decision, in whole or in part, the enrollee's case shall be automatically forwarded to the IRE for review and resolution. While section 2007 of the SUPPORT Act refers to a plan sponsor affirming its denial, in whole or in part, on ''reconsideration,'' we are proposing revisions that reference a plan sponsor's ''redetermination,'' which is the term used throughout part 423, subparts M and U to describe the plan level appeal. We believe that use of the term ''redetermination'' is consistent with the intent of the SUPPORT Act that adverse plan level appeals be automatically forwarded to the IRE so that the IRE can review and resolve outstanding issues related to the individual's at-risk status under the plan sponsor's DMP.

We are also proposing to revise the requirements related to adjudication timeframes and responsibilities for making redeterminations at § 423.590 by adding paragraph (i) to state that if on redetermination the plan sponsor affirms, in whole or in part, its decision related to an at-risk determination under a DMP in accordance with § 423.153(f), the plan sponsor must forward the case to the IRE by the expiration of the applicable adjudication timeframe under paragraph (a)(2), (b)(2), or (d)(1) of § 423.590. We believe that requiring plan sponsors to automatically forward these cases within existing adjudication timeframes will promote timely review and resolution of issues remaining in dispute in accordance with the SUPPORT Act.

We are also proposing to revise § 423.600(b) to clarify that the requirement that the IRE solicit the views of the prescribing physician or other prescriber applies to determinations that are auto-forwarded to the IRE. Under this proposal, the Part D IRE would be required to accept and process cases where the plan sponsor has affirmed its denial on redetermination of an issue related to at-risk determinations made under § 423.153(f). In addition to the proposed change at § 423.600(b) as previously described, necessary modifications would be made to the Part D IRE's contract upon finalization of rules to implement section 2007 of the SUPPORT Act.

We believe these proposed changes related to auto-forwarding of adverse plan level appeals involving at-risk determinations made under plan sponsor DMPs afford the intended protections to individuals identified as at-risk and are consistent with the provisions of the SUPPORT Act. We welcome feedback on these proposals.

G. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

1. Medicare Parts C and D Fraud Efforts

CMS's role in overseeing the Medicare program is to ensure that payments are made correctly and that fraud, waste, and abuse are prevented and detected. Failure to do so endangers the Trust Funds and can even result in harm to beneficiaries. CMS has established various regulations over the years to address potentially fraudulent and abusive behavior in Medicare Parts C and D. For instance, 42 CFR 424.535(a)(14)(i) addresses improper prescribing practices and permits CMS to revoke a physician's or other eligible professional's enrollment if he or she has a pattern or practice of prescribing Part D drugs that is abusive or represents a threat to the health and safety of Medicare beneficiaries or both.

2. SUPPORT Act—Sections 2008 and 6063

a. Background

Opioid use disorder (OUD) and deaths from prescription and illegal opioid overdoses have reached alarming levels. The CDC estimated 47,000 overdose deaths were from opioids in 2017, and 36 percent of those deaths involved prescription opioids.[37] On October 26, 2017, Acting Health and Human Services Secretary, Eric D. Hargan, declared a nationwide public health emergency on the opioid crisis as requested by President Donald Trump.[38] This public health emergency has since been renewed several times by Secretary Alex M. Azar II.[39]

Section 2008 of the SUPPORT Act amends and adds several sections of the Act to address the concept of a ''credible allegation of fraud.'' Specifically:

- Sections 2008(a) and (b) of the SUPPORT Act amended sections 1860D–12(b) and 1857(f)(3) of the Act, respectively, by adding new requirements for Medicare Part D plan sponsors and MA organizations offering MA–PD plans. Specifically, the provisions—

++ Apply certain parts of section 1862(o) of the Act, regarding payment suspensions based on credible allegations of fraud, to Medicare Part D plan sponsors and MA organizations offering MA–PD plans, allowing them to impose payment suspensions on pharmacies in the same manner as these provisions apply to CMS;

++ Require these Part D plan sponsors and MA organizations offering MA–PD plans to notify the Secretary regarding the imposition of a payment suspension on a pharmacy pending an investigation of a credible allegation of fraud and does not extend the requirement to report to the Secretary other payment suspensions for which plan sponsors already have authority.

++ Require this notification to be made such as via a secure internet website portal (or other successor technology) established under section 1859(i).

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

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

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

• Section 2008(d) of the SUPPORT Act, which amended section 1862(o) of the Act, states that a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud.

The effective date for these provisions of section 2008 of the SUPPORT Act is for plan years beginning on or after January 1, 2020.

Section 6063(a) of the SUPPORT Act, which added a new paragraph (i)(1) to section 1859 of the Act, requires the following:

• The Secretary, after consultation with stakeholders, shall establish a secure web-based program integrity portal (or other successor technology) that would allow secure communication among the Secretary, MA plans, and prescription drug plans, as well as eligible entities with a contract under section 1893, such as Medicare program integrity contractors. The purpose is to enable, through the portal:

++ The referral by such plans of substantiated or suspicious activities (as defined by the Secretary) of a provider of services (including a prescriber) or supplier related to fraud, waste, or abuse for the purpose of initiating or assisting investigations conducted by the eligible entity; and

++ Data sharing among such MA plans, prescription drug plans, and the Secretary.

• The Secretary shall disseminate the following information to MA plans and prescription drug plans via the portal: (1) Providers and suppliers referred for substantiated or suspicious activities during the previous 12-month period; (2) providers and suppliers who are currently either excluded under section 1128 of the Act or subject to a payment suspension pursuant to section 1862(o) or otherwise; (3) providers and suppliers who are revoked from Medicare, and (4) in the case the plan makes a referral via the portal concerning substantiated or suspicious activities of fraud, waste, or abuse of a provider or supplier, the Secretary shall notify the plan if the related providers or suppliers were subject to administrative action under title XI or XVIII for similar activities.

• The Secretary shall, through rulemaking, specify what constitutes substantiated or suspicious activities of fraud, waste, or abuse, using guidance such as that provided in the CMS Pub. 100–08, Medicare Program Integrity Manual (PIM), chapter 4, section 4.8. In section 4.8 of the PIM, CMS provides guidance to its Medicare program integrity contractors on the disposition of cases referred to law enforcement. Similar to what is stated in section 2008(d) of the SUPPORT Act, a fraud hotline tip without further evidence does not constitute sufficient evidence for substantiated fraud, waste, or abuse.

• On at least a quarterly basis, the Secretary must make available to the plans information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. The reports must include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders. This information must be anonymized data submitted by plans without identifying the source of such information.

The effective date for these provisions of section 6063(a) of the SUPPORT Act is beginning not later than 2 years after the date of enactment, or by October 24, 2020.

Furthermore, section 6063(b) of the SUPPORT Act, which amended section 1857(e) of the Act, requires MA organizations and Part D plan sponsors to submit to the Secretary, information on investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier related to fraud, and other actions taken by such plans, related to inappropriate prescribing of opioids. The Secretary shall, in consultation with stakeholders, establish a process under which MA organizations and Part D plan sponsors must submit this information. In addition the Secretary shall establish a definition of inappropriate prescribing, which will reflect the reporting of investigations and other corrective actions taken by MA organizations and Part D plan sponsors to address inappropriate prescribing of opioids and the types of information that must be submitted.

The effective date for these provisions of section 6063(b) of the SUPPORT Act is for plan years beginning on or after January 1, 2021.

b. Need for Additional Measures

Existing regulations for MA and Part D plan sponsors in §§ 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*) specify that plan sponsors should have procedures to voluntarily self-report potential fraud or misconduct related to the MA and Part D programs to CMS or its designee. (We note that § 422.503(b) generally outlines requirements that MA organizations must meet. Section 423.504(b) outlines conditions necessary to contract as a Part D plan sponsor.) Presently, MA organizations and Part D plan sponsors voluntarily report such data to CMS through either—(1) direct submissions to CMS, or (2) communication with the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC). Given the gravity of the nationwide opioid epidemic and the need for CMS and the plans to have as much information about potential and actual prescribing misbehavior as possible in order to halt such misbehavior, we believe that further regulatory action in this regard is warranted. Sections 2008 and 6063 of the SUPPORT Act provide the authority to establish regulations to implement a requirement for plans to report certain related data.

3. Proposed Provisions

Consistent with the foregoing discussion, we propose the following regulatory provisions to implement sections 2008 and 6063 of the SUPPORT Act. As explained, some of our proposals would modify or supplement existing regulations, while others would establish new regulatory paragraphs altogether. Existing (and our proposed) regulations related to Part C/MA are addressed in 42 CFR part 422; those pertaining to Part D are addressed in 42 CFR part 423. Regulations pertaining to or contained in other areas of title 42 will be noted as such.

a. Definitions

The definitions outlined below will be effective following the required statutory deadlines for each reporting piece described in the SUPPORT Act. Therefore, substantiated or suspicious activities of fraud, waste or abuse and fraud hotline time would be effective beginning October 24, 2020. Inappropriate prescribing of opioids and credible allegations of fraud would be effective beginning January 1, 2021.

(1) Substantiated or Suspicious Activities of Fraud, Waste, or Abuse

We indicated earlier that section 6063(a) of the SUPPORT Act added a new section 1859(i)(1) to the Act requiring the establishment of a regulatory definition of ''substantiated or suspicious activities of fraud, waste, or abuse,'' using guidance such as that in CMS Pub. 100–08, PIM, chapter 4, section. 4.8. To this end, we propose to add to §§ 422.500 and 423.4 a definition specifying that substantiated or suspicious activities of fraud, waste or abuse means and includes, but is not limited to allegations that a provider of services (including a prescriber) or supplier: Engaged in a pattern of improper billing; submitted improper claims with suspected knowledge of their falsity; submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or is

the subject of a fraud hotline tip verified by further evidence.

Consistent with the reference in section 6063(a) of the SUPPORT Act to chapter 4 of the PIM, our proposed definition largely mirrors that in section 4.8 of the PIM. We also believe that this definition is, importantly, broad enough to capture a wide variety of activities that could threaten Medicare beneficiaries and the Trust Funds. We solicit public comment on this definition.

(2) Inappropriate Prescribing of Opioids

Section 6063(b) of the SUPPORT Act, as mentioned previously, states the Secretary is required to establish: (1) A definition of inappropriate prescribing; and (2) a method for determining if a provider of services meets that definition. MA organizations and Part D Plan Sponsors must report actions they take related to inappropriate prescribing of opioids. We accordingly propose to add the following definition of inappropriate prescribing with respect to opioids. We propose to add this definition to §§ 422.500 and 423.4. We propose that inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D Plan Sponsors, there is an established pattern of potential fraud, waste and abuse related to prescribing of opioids, as reported by the Plan Sponsors. Plan Sponsors may consider any number of factors including, but not limited to the following: Documentation of a patient's medical condition; identified instances of patient harm or death; medical records, including claims (if available); concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm; levels of Morphine Milligram Equivalent (MME) dosages prescribed; absent clinical indication or documentation in the care management plan, or in a manner that may indicate diversion; State level prescription drug monitoring program (PDMP) data; geography, time and distance between a prescriber and the patient; refill frequency and factors associated with increased risk of opioid overdose.

We believe the many steps that CMS, the CDC, and HHS have taken in response to the nation's opioid crisis have had an overall positive impact on clinician prescribing patterns, resulting in safer and more conscientious opioid prescribing across clinician types and across the settings where beneficiaries receive treatment for pain, and have also resulted in heightened public awareness of the risks associated with opioid medications. Recent HHS guidance [40] for example, highlights the importance of judicious opioid prescribing that minimizes risk and; urges collaborative, measured approaches to opioid dose escalation, dose reduction, and discontinuation; furthermore, a 2019 HHS Task Force report [41] outlines best practices for multimodal approaches to pain care. In this definition, we recognize that there are legitimate clinical scenarios that may necessitate a higher level of opioid prescribing based on the clinician's professional judgement, including, the beneficiary's clinical indications and characteristics, whether the prescription is for an initial versus a subsequent dose, clinical setting in which the beneficiary is being treated, and various other factors. We welcome public comments on specific populations or diagnoses that could be excluded for purposes of this definition, such as cancer, hospice, and/or sickle cell patients. Based upon widely accepted principles of statistical analysis and taking into account clinical considerations mentioned previously, CMS may consider certain statistical deviations to be instances of inappropriate prescribing of opioids. We also welcome evidence from clinical experts regarding evidence based guidelines for opioid prescribing across clinical specialties and care settings that could be considered to develop meaningful and appropriate outlier methodologies. Therefore, we propose that inappropriate prescribing of opioids should be based on an established pattern as previously described in this section utilizing many parameters.

We solicit public comment on other reasonable measures of inappropriate prescribing of opioids.

(3) Credible Allegation of Fraud

Somewhat similar to section 6063(a) of the SUPPORT Act, section 2008(d) of the SUPPORT Act states that a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud. The term ''credible allegation of fraud'' is currently defined at §§ 405.370 and 455.2 (which, respectively, apply to Medicare and Medicaid) as an allegation from any source including, but not limited to the following: (1) Fraud hotline complaints; (2) claims data mining; and (3) patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability, and, in the case of § 455.2, the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.

To address this section 2008(d) of the SUPPORT Act requirement, we propose to revise the term ''credible allegation of fraud'' in §§ 405.370 and 455.2 as follows. We propose that the existing version of paragraph (1) in both §§ 405.370 and 455.2 would be amended to state ''Fraud hotline tips verified by further evidence.'' The existing version of paragraph (2) and (3) would remain unchanged. Similarly, we propose to add in § 423.4 a definition of credible allegation of fraud stating that a credible allegation of fraud is an allegation from any source including, but not limited to: Fraud hotline tips verified by further evidence; claims data mining; patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability. In the case of § 423.4, examples of claims data mining would include, but are not limited to, prescription drug events and encounter data mining. We solicit public comment on this definition.

(4) Fraud Hotline Tip

Sections 2008(d) and 6063(a) of the SUPPORT Act require the Secretary to define a fraud hotline tip. To this end, we propose to add to §§ 405.370, 422.500, 423.4, and 455.2 a plain language definition of this term. We propose that a fraud hotline tip would be defined as a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for that purpose, such as the federal government's HHS Office of the Inspector General (OIG) Hotline or a health plan's fraud hotline. This definition is intended to be broad enough to describe mechanisms such as the federal government's HHS OIG Hotline or a commercial health plan's fraud hotline. Many private plans, which have their own fraud reporting hotlines, participate as plan sponsors in Medicare Part D and this definition would seek to reflect their processes for reporting information on potential fraud, waste and abuse. We solicit public comment on this definition.

[40] ''HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics'' found at *https://www.hhs.gov/opioids/sites/default/files/2019-10/8-Page%20version__HHS%20Guidance%20for%20Dosage%20Reduction%20or%20Discontinuation%20of%20Opioids.pdf.*

[41] *https://www.hhs.gov/ash/advisory-committees/pain/index.html.*

b. Reporting

(1) Vehicle for Reporting

We plan to utilize a module within the HPMS as the program integrity portal for information collection and dissemination. The portal would serve as the core repository for the data addressed in sections 2008 and 6063 of the SUPPORT Act. Such data and the regular submission and dissemination of this important information would, in our view, strengthen CMS' ability to oversee plan sponsors' efforts to maintain an effective fraud, waste, and abuse program. We further believe that data sharing via use of a portal would, in conjunction with our proposals, help accomplish the following objectives in our efforts to alleviate the opioid epidemic:

- Enable CMS to perform data analysis to identify fraud schemes.
- Facilitate transparency among CMS and plan sponsors through the exchange of information.
- Provide better information and education to plan sponsors on potential fraud, waste, and abuse issues, thus enabling plan sponsors to investigate and take action based on such data.
- Improve fraud detection across the Medicare program, accordingly allowing for increased recovery of taxpayer funds and enrollee expenditures (for example, premiums, co-insurance, other plan cost sharing).
- Provide more effective support, including leads, to plan sponsors and law enforcement.
- Increase beneficiary safety through increased oversight measures.

(2) Type of Data To Be Reported by Plans

Sections 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*), as noted, state that plan sponsors should have procedures to voluntarily self-report potential fraud or misconduct related to the MA and Part D programs, respectively, to CMS or its designee. To conform to the aforementioned requirements of sections 2008(a) and (b) and section 6063(b) of the SUPPORT Act, we propose to add new regulatory language, effective beginning in 2021, in parts 422 and 423 as stated throughout this section.

First, we propose new language at §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) to include the new provisions. We propose that the new §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) would state that the MA organization or Part D plan sponsor, respectively, must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

- Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act; and
- Any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan. Second, we propose that new §§ 422.503(b)(4)(vi)(G)(*5*) and 423.504(b)(4)(vi)(G)(*5*) would require the data referenced in proposed §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) to be submitted via the program integrity portal. We propose that MA organizations and Part D plan sponsors would have to submit the data elements, specified below, in the portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by plan sponsors; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data elements, as applicable, are as follows:

- Date of Referral.
- Part C or Part D Issue.
- Complainant Name.
- Complainant Phone.
- Complainant Fax.
- Complainant Email.
- Complainant Organization Name.
- Complainant Address.
- Complainant City.
- Complainant State.
- Complainant Zip.
- Plan Name/Contract Number.
- Plan Tracking Number.
- Parent Organization.
- Pharmacy Benefit Manager.
- Beneficiary Name.
- Beneficiary Phone.
- Beneficiary Health Insurance Claim Number (HICN).
- Beneficiary Medicare Beneficiary Identifier (MBI).
- Beneficiary Address.
- Beneficiary City.
- Beneficiary State.
- Beneficiary Zip.
- Beneficiary Date of Birth (DOB).
- Beneficiary Primary language.
- Beneficiary requires Special Accommodations. If Yes, Describe.
- Beneficiary Medicare Plan Name.
- Beneficiary Member ID Number.
- Whether the Beneficiary is a Subject.
- Did the complainant contact the beneficiary? If Yes, is there a Report of the Contact?
- Subject Name.
- Subject Tax Identification Number (TIN).
- Does the Subject have Multiple TIN's? If Yes, provide.
- Subject NPI.
- Subject DEA Number.
- Subject Medicare Provider Number.
- Subject Business.
- Subject Phone Number.
- Subject Address.
- Subject City.
- Subject State.
- Subject Zip.
- Subject Business or Specialty Description.
- Secondary Subject Name.
- Secondary Subject Tax Identification Number (TIN).
- Does the Secondary Subject have Multiple TIN's? If Yes, provide.
- Secondary Subject NPI.
- Secondary Subject DEA Number.
- Secondary Subject Medicare Provider Number.
- Secondary Subject Business.
- Secondary Subject Phone Number.
- Secondary Subject Address.
- Secondary Subject City.
- Secondary Subject State.
- Secondary Subject Zip.
- Secondary Subject Business or Specialty Description.
- Complaint Prior MEDIC Case Number.
- Period of Review.
- Complaint Potential Medicare Exposure.
- Whether Medical Records are Available.
- Whether Medical Records were Reviewed.
- Whether the submission has been Referred to Law Enforcement. Submission Accepted? If so, provide Date Accepted.
- What Law Enforcement Agency(ies) has it been Referred to.
- Whether HPMS Analytics and Investigations Collaboration Environment for Fraud, Waste, and Abuse (AICE–FWA) was Used.
- Whether the submission has indicated Patient Harm or Potential Patient Harm.

• Whether the submission has been Referred. If so, provide Date Accepted.
• What Agency was it Referred to.
• Description of Allegations/Plan Sponsor Findings.

We note that the requirement for reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies under § 422.503(b)(4)(vi)(G)(*4*) would only apply to Medicare Part C in the context of Medicare Advantage Prescription Drug Plans (MA–PD plans). We believe this information is necessary to enable CMS to fully and completely understand the identity of the applicable party, the specific behavior involved, and the status of the action. We solicit public comment on these proposed requirements

(3) Timing of Plan Sponsor's Reporting

We propose in new §§ 422.503(b)(4)(vi)(G)(*6*)(*i*) and 423.504(b)(4)(vi)(G)(*6*)(*i*) that MA organizations and Part D plan sponsors would be required to notify the Secretary, or its designee of a payment suspension described in §§ 422.503(b)(4)(vi)(G)(*4*)(*i*) and 423.504(b)(4)(vi)(G)(*4*)(*i*) 14 days prior to implementation of the payment suspension. This timeframe will allow CMS to provide our law enforcement partners sufficient notice of a payment suspension to be implemented that may impact an ongoing investigation into the subject. We propose in the new §§ 422.503(b)(4)(vi)(G)(*6*)(*ii*) and 423.504(b)(4)(vi)(G)(*6*)(*ii*) that plans would be required to submit the information described in §§ 422.503(b)(4)(vi)(G)(*4*)(*ii*) and 423.504(b)(4)(vi)(G)(*4*)(*ii*) no later than January 15, April 15, July 15, and October 15 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. We propose that plans would be required to submit information beginning in 2021. For the first reporting period (January 15, 2021), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31). We believe that quarterly updates would be frequent enough to ensure that the portal contains accurate and recent data while giving plans sufficient time to furnish said information. We solicit public comment on the proposed timing of reporting by plans.

(4) Requirements and Timing of CMS' Reports

As mentioned earlier in this proposed rule, section 6063(a) of the SUPPORT Act requires the Secretary make available to the plans, not less frequently than quarterly, information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. The reports must include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders. Moreover, the information must be anonymized data submitted by plans without identifying the source of such information.

Section 6063 of the SUPPORT Act requires the Secretary provide reports no less frequently than quarterly. Consistent with this requirement, we propose in the new §§ 422.503(b)(4)(vi)(G)(*7*)(*i*) through (*iv*) and 423.504(b)(4)(vi)(G)(*7*)(*i*) through (*iv*) that CMS will provide MA organizations and Part D plan sponsors with data report(s) or links to data no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. We propose that CMS would provide this information beginning in 2021. For the first quarterly report (April 15, 2021), the report will reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 15, 2021. Similar to the timing requirements related to new §§ 422.503(b)(4)(vi)(G)(*6*)(*ii*) and 423.504(b)(4)(vi)(G)(*6*)(*ii*), we believe that quarterly updates would strike a suitable balance between the need for frequently updated information while giving CMS time to review and analyze this data in preparation for complying with new §§ 422.503(b)(4)(vi)(G)(*4*) through (*7*) and 423.504(b)(4)(vi)(G)(*4*) through (*7*). We solicit public comment on the proposed timing of CMS dissemination of reports to plans.

IV. Implementation of Certain Provisions of the 21st Century Cures Act

A. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

Section 4001 of the Balanced Budget Act of 1997 (hereinafter referred to as the BBA of 1997) added sections 1851 through 1859 to the Act establishing Part C of the Medicare program known originally as ''Medicare + Choice'' and later as ''Medicare Advantage (MA).'' As enacted, section 1851 of the Act provided that every individual entitled to Medicare Part A and enrolled under Part B, except for individuals with end stage renal disease (ESRD), could elect to receive benefits through an MA plan. The statute further permitted that, in the event that an individual developed ESRD while enrolled in an MA plan or in a health plan offered by the MA organization, he or she could remain in that MA plan or could elect to enroll in another health plan offered by that organization. These requirements were codified at § 422.50(a)(2) in the initial implementing regulations for the Part C program published in 1998 (63 FR 35071).

Section 1851 of the Act was subsequently amended several times to expand coverage of ESRD beneficiaries in MA plans.

• Section 620 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (hereinafter referred to as BIPA), established a one-time opportunity for individuals, medically determined to have ESRD, whose enrollment in an MA plan was terminated or discontinued after December 31, 1998, to enroll in another MA plan. The exception, codified in our regulations at § 422.50(a)(2)(ii) (68 FR 50855), was effective December 14, 2000, but was retroactive, to include individuals whose enrollment in an MA plan was terminated involuntarily on or after December 31, 1998.

• Section 231 of the MMA gave the Secretary authority to waive section 1851(a)(3)(B) of the Act, which precludes beneficiaries with ESRD from enrolling in MA plans. Under this authority, CMS undertook rulemaking to allow individuals with ESRD to join an MA special needs plan. This was codified at §§ 422.50(a)(2)(iii) and 422.52(c) (70 FR 4715) and was effective for the 2006 plan year.

In 2016, paragraph (a) of section 17006 of the Cures Act further amended section 1851 of the Act to remove the prohibition for beneficiaries with ESRD from enrolling in an MA plan. This change is effective for plan years beginning on or after January 1, 2021. (Please see sections IV.B. and IV.C. of this proposed rule for further changes established by section 17006 of the Cures Act.) To implement these changes in eligibility for MA plan enrollment made by the Cures Act, we propose the following amendments:

• Section 422.50(a)(2) would be revised to specify that the prohibition of beneficiaries with ESRD from enrolling in MA plans (and associated exemptions) is only applicable for coverage prior to January 1, 2021. Because of this limit on the prohibition

to plan years before 2021, the regulatory prohibition on enrollment in an MA plan by a beneficiary with ESRD will not apply to future periods. The exceptions to that prohibition would be similarly limited as the exceptions would no longer be necessary after January 1, 2021.

- Section 422.52(c) would be revised to specify that CMS authority to waive the enrollment prohibition in § 422.50(a)(2) to permit ESRD beneficiaries to enroll in a special needs plan would also only be applicable for plan years prior to 2021. Because there will be no additional limitations on enrollment by beneficiaries with ESRD beginning 2021, this waiver authority is unnecessary for that period.
- Section 422.110(b) would be revised to specify that the exception to the anti-discrimination requirement, which was adopted to account for the prohibition on MA enrollment by beneficiaries who have ESRD, is only applicable for plan years prior to 2021.

We considered whether § 422.66(d)(1), which requires MA organizations to accept enrollment in their MA plans by newly eligible Medicare beneficiaries who are seamlessly converting from health plan coverage offered by the MA organization and who are otherwise eligible for the MA plan, would also need to be amended to implement the eligibility changes made by the Cures Act. Section 422.66(d)(1) already provides that this right to seamlessly convert to an MA plan in the circumstances outlined in the regulation applies regardless whether the individual has ESRD. Therefore, we do not believe that any amendment to the regulation is necessary to ensure that the Cures Act change in MA eligibility is implemented. We solicit comment on this issue.

As noted previously in this rule, the changes mandated by the Cures Act do not take effect until the 2021 plan year. As such, individuals entitled to Medicare Part A and enrolled under Part B, and medically determined to have ESRD, are not eligible to choose to receive their coverage and benefits through an MA plan prior to plan year 2021, subject to the limited exceptions reflected in the current regulation text.

B. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322)

The MA organization is generally responsible for furnishing or providing coverage of all Medicare Part A and Part B benefits, excluding hospice, for its enrollees. The Medicare FFS program does not pay health care providers for furnishing these benefits to such enrollees. Section 1851(i) of the Act generally provides that, subject to specific exceptions, CMS pays only the MA organization for the provision of Medicare-covered benefits to a Medicare beneficiary who has elected to enroll in an MA plan. There are specific, statutory exceptions to this general rule in the statute, such as authority in section 1853(h) of the Act for FFS Medicare payment for Medicare-covered hospice services that an MA plan is prohibited by statute from covering. Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude from the list of items or services an MA plan is required to cover for an MA enrollee coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs will be covered under the original Medicare FFS program, pursuant to an amendment by section 17006(c)(2) of the Cures Act to section 1851(i) of the Act. As amended, section 1851(i)(3) of the Act authorizes FFS Medicare payment for the expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act. We are proposing conforming regulatory changes to reflect the revision to the statute.

Specifically, we propose to revise § 422.322, which describes the source of payment and effect of MA plan election on payment for Medicare-covered benefits. Paragraphs (b) and (c) of § 422.322 generally track the statutory requirements that, subject to specific exceptions, CMS payment to MA organizations is in lieu of the amounts that would otherwise be payable under the original Medicare FFS program for Medicare-covered benefits furnished to an MA enrollee and are the only payment by the government for those Medicare-covered services. Consistent with the amendments to sections 1851(i) and 1852(a)(1)(B)(i) of the Act, we are proposing to amend § 422.322 to add a new paragraph (d) to reflect that expenses for organ acquisitions for kidney transplants are an exception to the terms outlined in paragraphs (b) and (c), and will be covered by original Medicare. Our proposed new paragraph (d) generally tracks how section 17006(c) of the Cures Act amends section 1851(i)(3) of the Act.

The Cures Act does not provide for Medicare FFS coverage of organ acquisition costs for kidney transplants incurred by PACE participants. Therefore, PACE organizations must continue to cover organ acquisition costs for kidney transplants, consistent with the requirement described in section 1894(b)(1)(A)(i) of the Act that PACE organizations provide all Medicare-covered items and services. Accordingly, CMS will continue to include the costs for kidney acquisitions in PACE payment rates.

C. Exclusion of Kidney Acquisition Costs From Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Section 17006(b) of the Cures Act amended section 1853 of the Act to require that the Secretary's estimate of standardized costs for payments for organ acquisitions for kidney transplants be excluded from Medicare Advantage (MA) benchmarks and capitation rates, effective January 1, 2021. As amended, section 1853(k)(5) of the Act provides for the exclusion from the applicable amount and section 1853(n)(2) provides for the exclusion from the specified amount of the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under the Medicare statute (including expenses covered under section 1881(d) of the Act). As discussed in greater detail in the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes Final Rule (hereinafter referred to as the April 2011 final rule) (76 FR 21431, 21484 through 21485) and the annual Advance Notices and Rate Announcements starting with Payment Year 2012,[42] the applicable amount and the specified amount are used in the calculation of the MA benchmarks and capitation rates. We are proposing to revise the relevant regulations to reflect these amendments.

Specifically, we propose to revise § 422.258, which describes the calculation of MA benchmarks. Under section 1853(n)(1)(B) of the Act and § 422.258(d) of the regulations, for 2012 and subsequent years, the MA benchmark for a payment area for a year is equal to the amount specified in section 1853(n)(2) of the Act (that is, the ''specified amount''), but cannot exceed the applicable amount as described in 1853(n)(4) and § 422.258(d)(2). Prior to enactment of the Cures Act, section 1853(n)(2)(A) of the Act described the specified amount as the product of the base payment amount for an area for a year (adjusted to take into account the

[42] The Advance Notice and Rate Announcement for each year are available online at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

phase-out in the indirect costs of medical education from capitation rates) and the applicable percentage for the area and year. The base payment amount is, for years after 2012, the average FFS expenditure amount specified in § 422.306(b)(2). Section 17006(b)(2)(A) of the Cures Act amended section 1853(n)(2)(A)(i) of the Act to require that, for 2021 and subsequent years, the base payment amount used to calculate the specified amount must also be adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants from the capitation rate. We are proposing to make conforming amendments to paragraphs (d)(3), (5), and (6) of § 422.258. As amended, paragraph (d)(3) will specify that for 2021 and subsequent years, the base payment amount used to calculate the specified amount is required to be adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants. Also, as amended, paragraphs (d)(5) and (6) will specify that the average FFS expenditure amount used to determine the applicable percentage is adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants. To make these amendments, we propose to insert references to the adjustment made under § 422.306(d) to modify the various references to the base payment amount in paragraphs (d)(3) and (5), (d)(5)(i) and (ii), and (d)(6).

We also propose to amend § 422.306 by revising the introductory text and adding a new paragraph (d). Proposed paragraph (d) would describe the required adjustment, beginning for 2021, to exclude the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d) of the Act) in the area for the year. By operation of § 422.258(d)(2), the applicable amount is established by reference to § 422.306, and the rules there for calculation of MA annual capitation rates. By adding § 422.306(d), we would implement the new language in section 1853(k)(5) of the Act (added by section 17006(b)(1)(B) of the Cures Act) to require the adjustment to exclude payments for organ acquisitions for kidney transplants. We request comment whether these proposed revisions to §§ 422.258(d) and 422.306 adequately implement the statutory changes made by section 17006 of the Cures Act to require exclusion of the costs of kidney acquisition from the applicable amount and the specified amount for purposes of setting MA benchmarks and capitation rates.

Per section 1853(a)(1)(H) of the Act, CMS is required to establish separate rates of payment to an MA organization for individuals with end stage renal disease (ESRD) who are enrolled in a plan offered by that organization. This special rule for ESRD payment rates is codified in the regulations at 42 CFR 422.304(c). Since the Cures Act requires FFS Medicare payment for kidney acquisition costs for all MA enrollees, including MA enrollees with ESRD, we propose to apply the exclusion of kidney acquisition costs to the ESRD payment rates. As § 422.304(c) does not prescribe the specific methodology CMS must use to determine the separate rates of payment for ESRD enrollees described in section 1853(a)(1)(H) of the Act, the exclusion of kidney acquisition costs from ESRD rates does not require regulatory amendment. CMS will address the methodology for excluding kidney acquisition costs from MA benchmarks (including the MA ESRD state rates) in the 2021 Advance Notice and Rate Announcement. Section 1894(d)(2) of the Act requires that PACE capitation amounts be based upon MA payment rates established under section 1853 of the Act and adjusted to take into account the comparative frailty of PACE enrollees and such other factors as the Secretary determines to be appropriate. While capitated payments made to PACE organizations are based on the applicable amount under section 1853(k)(1) of the Act, CMS will include the costs for kidney acquisitions in PACE rates. Because PACE organizations are required to cover all Medicare-covered items and services under section 1894(b)(1)(A)(i) of the Act, including organ acquisition costs for kidney transplants, CMS will include kidney acquisition costs in PACE payment rates, including PACE ESRD rates. This approach is consistent with how PACE organizations have historically been paid for kidney acquisition costs for PACE enrollees.

V. Enhancements to the Part C and D Programs

A. Reinsurance Exceptions (§ 422.3)

Section 1855(b) of the Act requires MA organizations to assume full financial risk on a prospective basis for the provision of basic benefits (and, for plan years before 2006, additional benefits required under section 1854 of the Act) furnished to MA plan enrollees, subject to the exceptions listed in the statute at section 1855(b)(1)–(4) of the Act. The exception at section 1855(b)(1) of the Act states that an MA organization may obtain insurance or make arrangements for the cost of providing to any enrolled member such services the aggregate value of which exceeds a per-enrollee aggregate level established by the Secretary. Section 1855(b)(1) of the Act describes stop loss insurance arrangements but we are not using those terms in the regulation in order to be specific in describing the form of the arrangement. Section 1855(b)(1) of the Act permits an MA organization to obtain insurance or make other arrangements under which the MA organization bears less than full financial risk for the costs of providing basic benefits for an individual enrollee that exceed a certain threshold. For the reasons discussed in this section of this proposed rule, we are proposing to implement, at a new § 422.3, the exception at section 1855(b)(1) of the Act and establish in regulation options to use insurance for costs beyond a specified threshold. We are proposing that an MA organization may obtain insurance (that is, reinsurance) or make other arrangements for the cost of providing basic benefits to an individual enrollee the aggregate value of which exceeds $10,000 during a contract year or, alternatively, such costs may be shared proportionately on a first dollar basis, the value of which is calculated on an actuarially equivalent basis to the cost of the insurance for costs that exceed $10,000 in a contract year. We also propose that if the MA organization chooses to purchase pro rata coverage that provides first dollar coverage, the price of that coverage cannot exceed the cost of the option of purchasing stop loss insurance for enrollee health care costs that exceed a threshold of $10,000 in a contract year. The statutory exceptions at section 1855(b)(2)–(4) of the Act still apply. This proposal serves to establish in regulation the threshold described in section 1855(b)(1) of the Act.

Because we interpret section 1855(b) of the Act as requiring an MA organization to remain at full financial risk for basic benefits, subject to the exceptions listed in subsections (b)(1) through (b)(4), we are proposing that the limits in proposed § 422.3 apply for purposes of insuring (or making other arrangements) for costs of providing basic benefits and therefore do not apply to supplemental benefits offered by MA organizations. We are implementing the exception at section 1855(b)((1) of the Act because concerns were raised that absent the implementation of specific standards by CMS under section 1855(b)(1) of the Act

there was ambiguity about the legal basis of MA organizations sharing risk through reinsurance. A number of MA organizations expressed concern to CMS about this legal uncertainty as they have utilized reinsurance within the MA program. Therefore, we are proposing to implement section 1855(b)(1) of the Act to formally establish reinsurance standards for the MA program and remove any uncertainty on the permitted utilization of reinsurance.

Under this proposed implementation of the exception at section 1855(b)(1) of the Act, MA organizations which are voluntarily choosing to purchase insurance to limit their exposure to enrollee medical losses will have two options. In the first option, an MA organization could purchase insurance that would stop losses for the MA organization for individual plan enrollees when an individual enrollee's covered costs for basic benefits exceed $10,000 during a contract year. Stated another way, the MA organization could have insurance for costs that exceed $10,000 for covering or furnishing basic benefits to an individual plan enrollee in the contract year. In the second option, an MA organization could purchase pro rata insurance coverage that would provide first dollar coverage provided that the value of the insured risk is actuarially equivalent to costs that exceed $10,000 and the insurance coverage is priced at an actuarial value not to exceed the cost of purchasing the stop loss insurance for medical expenses exceeding $10,000 per member per year. Specifically, the cost to the MA organization in purchasing first dollar pro rata insurance cannot exceed the cost to the MA organization of purchasing $10,000 per member per year stop loss insurance.

Based on discussions with the National Association of Insurance Commissioners (NAIC) and previous 2018 Call Letter comments we have received, CMS recognizes that the use of insurance by health care insurers is a common and long standing market practice for both commercial health insurers and MA organizations and that the practice serves to reduce financial exposure to changes in health care costs, helps manage capital requirements, and allows health care insurers to grow enrollment. Based on our discussions with the NAIC and earlier discussion with the industry it is our understanding that MA organizations located in areas with fewer beneficiary choices (for example, rural, underserved areas) may particularly benefit from using reinsurance because of how it provides financial stability for the MA organization, which in turn can lead to enhanced competition and consumer choice, especially in small and mid-sized market areas. Insuring part of the risk assumed under an MA plan is important for smaller MA organizations to compete with larger organizations that can independently finance their operations. We recognize that some may see hazards in excessive reinsurance to the extent that the direct health insurer (here, the MA organization) might pass a large share of their risk and premium through insurance and that the MA organization could be viewed as no longer possessing the primary responsibility for furnishing the health care services. While the statute identifies the category of risk for which an MA organization may seek insurance or other arrangements (such as, in section 1855(b)(1) of the Act, the cost of providing to any enrolled member such services the aggregate value of which exceeds an established threshold), it is in the context of a mandate that MA organizations assume full financial risk on a prospective basis for providing basic benefit to enrollees. Therefore, we are cognizant of the need to ensure that MA organizations are not transferring all the risk of providing services to enrollees to a third party that is not under contract with CMS. We seek to balance these different interests in setting the threshold for the individual stop loss insurance coverage authorized by the statute.

The $10,000 threshold we are proposing has its roots in our review of the Conference Report for the BBA of 1997 (H.R. Conf. Rep. 105–217) and the difference between the House bill and the Senate amendment on the threshold at which a Part C plan could reinsure per-enrollee costs. The Conference Report indicates that the House bill tracked existing language in section 1876(b)(2)(D)(i) of the Act in using a $5,000 per year threshold while the Senate amendment provided for an amount established by the agency with an annual adjustment using the Consumer Price Index-Urban (CPI–U) for the 12-month period ending with June of the previous year. The conference agreement was to adopt the language in section 1855(b)(1) of the Act that remains today: A threshold established by the agency from time to time. To develop the $10,000 threshold we are proposing, we started with the amount of $5,000 identified in the Conference Report and used the following methodology: We multiplied the amount identified in the Conference Report ($5,000) by the increase in the CPI–U. Our policy choice was heavily influenced by the description in the Conference Report of the Senate amendment: ''the applicable amount of insurance for 1998 is the amount established by the Secretary and for 1999 and any succeeding year, is the amount in effect for the previous year increased by the percentage change in the CPI-urban for the 12-month period ending with June of the previous year.'' In updating the threshold this way, we rounded the amount for each year to the nearest whole dollar. Actual CPI–U values through June 2019 were used to perform these calculations. After 2019, the CPI–U values are estimated using the Congressional Budget Office's August 2019 report: An Update to the Economic Outlook: 2019 to 2029.

Based on our scan of the market and current practices of commercial health insurers, in selecting the $10,000 threshold for stop loss insurance we believe the level of risk transfer we have proposed is reasonable and consistent with supporting robust competition in Medicare Advantage. We believe the proposed level of risk transfer is acceptable given that CMS closely monitors MA organizations in terms of their administration of their MA plans, and specifically their timely provision of medically necessary health care services to enrollees and their overall financial solvency. CMS has a direct contract with each MA organization and despite any insurance arrangements, the MA organization remains accountable to CMS for ensuring timely access for enrollees to medically necessary Medicare covered services. In addition, CMS through its regional offices, plan audits, review of enrollee appeals and stakeholder letters closely monitors the performance of MA organizations and intervenes whenever it has evidence an MA organization is not meeting its contractual obligations. Also, any insurance arrangement used by MA organizations is subject to state insurance regulation and oversight regarding solvency because section 1856(b)(3) of the Act does not preempt those laws or provide that CMS regulation supersedes them. It is also our understanding that the NAIC model laws (Model 785); NAIC Credit for Reinsurance Regulation (Model 786); and the NAIC Life and Health Reinsurance Agreements Model Regulation (Model 791) have been substantially adopted by all states. We believe CMS oversight along with the states' oversight of financial solvency substantially ensures that CMS will be able to intervene on a timely basis when an MA organization is experiencing solvency problems or is not meeting its obligation to appropriately furnish its

enrollees with benefits covered under the MA plan.

Notwithstanding our rationale for proposing this specific threshold, we recognize that the reinsurance marketplace is complex and evolving. Therefore, we solicit comments regarding our proposed reinsurance regulation generally and the specific threshold proposed; we are particularly interested in comments whether the $10,000 threshold is a reasonable level and if the flexibility we are proposing for MA organizations in permitting insurance or other arrangements that are actuarially equivalent to a $10,000 threshold is sufficient to serve the goals outlined here. In addition, we welcome comments that provide additional information about insurance or other arrangements for addressing the risk of costs that exceed specific thresholds on an individual enrollee basis.

Additionally, CMS wishes to clarify what we consider to be an MA organization for purposes of this statute and is proposing to broaden our interpretation to include parent organizations. The result of that would be to evaluate compliance with section 1855(b) of the Act and proposed § 422.3 at the parent organization level, such that risk sharing or allocations of losses and costs among wholly-owned subsidiaries would not be evaluated. Therefore, we are seeking comment on whether CMS should consider a parent organization to be part of an MA organization for purposes of section 1855(b) of the Act or whether CMS should consider a parent organizations to be a separate entity from an MA organization.

B. Out-of-Network Telehealth at Plan Option

On April 16, 2019, CMS finalized requirements for MA plans offering additional telehealth benefits (ATBs).[43] Section 50323 of the BBA of 2018 created a new subsection (m) of section 1852 of the Act, authorizing MA plans to offer ATBs to enrollees starting in plan year 2020 and treat ATBs as basic benefits. In the April 2019 final rule, we finalized a new regulation at § 422.135 to implement that authority. As part of the parameters for the provision of ATBs, we finalized a requirement, at § 422.135(d), that MA plans furnishing ATBs only do so using contracted providers. The regulation specifically provides that benefits furnished by a non-contracted provider through electronic exchange may only be covered by an MA plan as a supplemental benefit.

We finalized the proposal at § 422.135(d) to require that all MA plan types, including preferred provider organizations (PPOs), use only contracted providers to provide MA additional telehealth benefits. In the April 2019 final rule, CMS adopted a policy that services furnished by non-contracted providers through electronic exchange are not MA ATBs. We explained that limiting service delivery of MA ATBs to contracted providers offers MA enrollees access to these covered services in a manner consistent with the statute because plans would have more control over how and when services are furnished. In the April 2019 final rule, we took the position that limiting MA ATBs to contracted providers will ensure additional oversight of providers' performance, thereby increasing plans' ability to provide these benefits. In response to commenters' recommendation that CMS allow PPOs to provide ATBs through contracted and non-contracted providers, we clarified that if a PPO furnishes MA ATBs consistent with the requirements at § 422.135, then the PPO plan requirement at § 422.4(a)(1)(v) (that the PPO must furnish all services both in-network and out-of-network) will not apply to the MA additional telehealth benefits and all other benefits covered by the PPO must be covered on both an in-network and out-of-network basis. In other words, a PPO plan is not required to furnish its MA additional telehealth benefits out-of-network, as is the case for all other plan-covered services. However, a PPO plan may cover—as a supplemental benefit—telehealth services that are furnished out-of-network.

Although we took the position that limiting MA ATBs to contracted providers will ensure additional oversight of providers' performance in the April 2019 final rule, CMS is also considering whether limiting MA ATBs to contracted providers may unnecessarily limit the ability of MA plans to furnish ATBs. If CMS revises § 422.135(d) to allow all plan types to offer ATBs through non-contracted providers, CMS would leverage existing oversight programs, which include monitoring beneficiary complaints, organization determinations, and appeals related to MA ATBs. CMS has regularly scheduled meetings with the Part C Independent Review Entity (IRE) contractor; during these meetings, CMS and the IRE contractor identify and evaluate systemic problems with coverage decisions that rise to the level of the IRE. We would continue to hold plans accountable for ensuring sufficient oversight of medically necessary Medicare covered items and services such as MA ATBs through CMS's oversight activities and believe that we have the means to do that through these monitoring and oversight policies.

The statute does not prohibit MA plans' use of non-contracted providers to deliver ATBs. Therefore, CMS is considering whether to revise § 422.135 to permit ATBs to be provided by non-contracted providers in cases where the non-contracted providers satisfy ATB requirements set forth in the April 2019 final rule. CMS believes requiring non-contracted and contracted providers to meet the same ATB requirements will ensure ATBs are delivered in a manner consistent with the statute and plans will have necessary control over how and when services are furnished. We solicit comment whether § 422.135(d) should be revised to allow all MA plan types, including PPOs, to offer ATBs through non-contracted providers and treat them as basic benefits under MA.

C. Supplemental Benefits, Including Reductions in Cost Sharing (§ 422.102)

In the Medicare Program; Establishment of the Medicare Advantage Program Final Rule, published in the **Federal Register** on January 28, 2005 (hereinafter referred to as the January 2005 final rule) (70 FR 4588, 4617), CMS established that an MA plan could reduce cost sharing below the actuarial value specified in section 1854(e)(4)(B) of the Act only as a mandatory supplemental benefit and codified that policy at § 422.102(a)(4). In order to clarify the scope of section 1854(e)(4)(A) of the Act, we are proposing to amend § 422.102(a)(4) and add new rules at § 422.102(a)(5) and (a)(6)(i) and (ii) to further clarify the different circumstances in which an MA plan may reduce cost sharing for covered items and services as a mandatory supplemental benefit and to specifically authorize certain flexibility in the mechanisms by which an MA plan may make reductions in cost sharing available.

Currently, reductions in cost sharing are an allowable supplemental benefit in Medicare Advantage (MA) and may include:

- Reductions in the cost-sharing for Parts A and B benefits compared to the actuarially equivalent package of Parts A and B benefits; and

[43] Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021. Retrieved at: *https://www.federalregister.gov/documents/2019/04/16/2019-06822/medicare-and-medicaid-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare.*

• Reductions in cost-sharing for Part C supplemental benefits, for example provided for specific services for enrollees that meet specific medical criteria, such that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same and enjoy the same access to these targeted benefits.

We propose to codify regulation text to clarify that reductions in cost sharing for (1) Part A and B benefits and (2) covered items and services that are not basic benefits are allowable supplemental benefits but may only be offered as mandatory supplemental benefits at § 422.102(a)(4) and (5). We propose to revise the current language at § 422.102(a)(4) by inserting the phrase ''for Part A and B benefits'' after the cite to section 1854(e)(4)(A) of the Act and to add a new paragraph (a)(5) to specify that reduced cost sharing may be applied to items and services that are not basic benefits; for both categories, the reduction of cost sharing may only be provided as a mandatory supplemental benefit.

MA plans currently have options in how they may choose to structure mandatory supplemental benefits that are in the form of cost sharing reductions. For example, MA organizations may offer, as a supplemental benefit, a reimbursement or a debit card to reduce cost sharing towards plan covered services or to provide coverage of 100 percent of the cost of covered items. For instance, enrollees may be given a debit card with a dollar amount that can be used towards cost sharing for plan covered services. MA plans may also decide to offer, as a supplemental benefit, a reduction in cost through a maximum allowance. An MA plan may establish a dollar amount of coverage that may be used to reduce cost sharing towards plan covered services and subject to a plan-established annual limit; enrollees can ''spend'' the allowance on cost sharing for whichever covered benefits the enrollee chooses. In both scenarios, MA plans are expected to administer the benefit in a manner that ensures the debit card and/or allowance can only be used towards plan-covered services. We are proposing new regulation text, at § 422.102(a)(6)(i) and (ii), to codify these flexibilities in how reductions in cost sharing are offered. These flexibilities are only for Part C supplemental benefits, as defined in proposed § 422.102(c) and discussed in section VI.F. Of this proposed rule. Therefore, cost sharing for Part D drugs is not included in these flexibilities.

As proposed, the flexibilities identified here are permitted only as a mandatory supplemental benefit which is why we are proposing to codify them in § 422.102(a). Further, this proposed flexibility is only for items and services that are identified in the MA plan's bid and marketing and communication materials as covered benefits, which is why the proposed regulation text uses the terms ''covered benefits'' and ''coverage of items and services.'' Thus, MA plans would not be able to offer use of a debit card for purchase of items or services that are not covered. This is consistent with current guidance in Chapter 4 of the Medicare Managed Care Manual under section 40.3 that allows debit cards to be used for plan-covered over-the-counter items under the conditions that the card is exclusively linked to the OTC covered items and has a dollar limit tied to the benefit maximum. We recognize that a debit card could be utilized as a reimbursement mechanism or as a means for the MA plan to make its payment for an item or service; in either case, the use of the card is tied to coverage of the benefit. Like all other coverage, the flexibilities proposed here are limited to the specific plan year; therefore, this authority to use debit cards or a basket of benefits up to a set value from which an enrollee can choose cannot be rolled over into subsequent years. We have proposed specific text in paragraph (a)(6) limiting these forms of supplemental benefits to the specific plan year to emphasize that rolling over benefits to the following plan year is not permitted.

For both benefit options, as previously described, MA plans have the flexibility to establish a maximum plan benefit coverage amount for supplemental benefits or a combined amount that includes multiple supplemental benefits, such as a combined maximum plan benefit coverage amount that applies to dental and vision benefits. Plans may not offer reimbursement, including use of a debit card to pay for supplemental benefits that are not covered by the plan. Reductions in cost sharing as a supplemental benefit are subject to an annual limit that the enrollee can ''spend'' on cost sharing for whichever covered benefits the enrollee chooses. Plans may use a receipt-based reimbursement system or provide the dollar amount on a debit card (linked to an appropriate merchant and item/service codes) so that the enrollee may pay the cost sharing at the point of service. This provision codifies already existing guidance and practices and therefore is not expected to have additional impact above current operating expenses. Additionally, this provision amends definitions and therefore does not impose any collection of information requirements.

D. Referral/Finder's Fees (§§ 422.2274 and 423.2274)

In the Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule, published in the **Federal Register** on May 23, 2014 (79 FR 29960), CMS codified rules in §§ 422.2274(h) and 423.2274(h) for MA organizations and Part D plans to pay agents and brokers for referrals of beneficiaries for enrollment, also known as finder's fees. In the proposed language, we are clarifying our longstanding intent that compensation is on a per-enrollment basis. Since referral fees are part of compensation, organizations may not pay independent agents more than regulatory limits. Because referral fees are already incorporated into compensation, limiting the amount of a referral fee has no impact on the statutory requirement of an agent enrolling a beneficiary in the plan that best meets their health care needs. With respect to captive and employed agents, who only sell for one organization, the referral fees also have no impact given the organization sets rates of pay, nor is there a statutory steerage impact.

Therefore, we propose to remove §§ 422.2274(h) and 423.2274(h). As currently codified at §§ 422.2274(b) and 423.2274(b), compensation for initial enrollments may not exceed the fair market value and compensation for renewal enrollments may not exceed 50 percent of the fair market value. Compensation is defined in the same current regulation, at paragraph (a), as all monetary or non-monetary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes or awards, or referral or finder fees. By eliminating the individual referral fee limit, we are restructuring the regulation to only provide for referral fees within the scope of Fair Market Value (FMV). Our proposal clarifies that MA organizations and Part D plans have the ability to compensate agents for referrals provided the total dollar amount does not exceed FMV. We believe that the primary value for this proposed additional flexibility is in connection with independent agents, as we believe that for captive and employed agents, referral/finder fees do not play a factor in making sure the agent enrolls the beneficiary in the best plan, since captive and employed agents

only sell for one organization. We therefore propose to eliminate the current specific limit on finder or referral fees that is codified at paragraph (h). Currently, the definition of compensation already includes referral or finder fees, so the result of this specific proposal would be an overall limit on compensation for initial and renewal enrollments, which includes finder or referral fees. In section VI.H. of this proposed rule, we also propose additional changes for §§ 422.2274(g) and 423.2274(g) regarding agent and broker compensation for Part C and Part D enrollments. Under those proposals, the definition of compensation continues to include finder or referral fees, so the limits on compensation continue to include finder or referral fees. We solicit comment on whether removing the limit on referral/finder's fees would generate concerns such as those discussed in the 2010 Call Letter for MA organizations issued March 30, 2009, CMS's October 19, 2011, memo entitled ''Excessive Referral Fees for Enrollments,'' or the ''Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' final rule that codified referral/finder's fees limits in regulation.

E. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

1. Introduction

In the April 2018 final rule, CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 83 FR 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 83 FR 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and give advance notice regarding enhancements to the Part C and D Star Ratings program. Under those regulations, CMS must propose through rulemaking any future changes to the methodology for calculating the ratings, addition of new measures, and substantive changes to the measures. Sections 422.164(e) and 423.184(e) provide authority and a mechanism for the removal of measures for specific reasons (low statistical reliability and when the clinical guidelines associated with the measure change such that the specifications are no longer believed to align with positive health outcomes). Generally, removal of a measure for other reasons would also occur through rulemaking. In the 2020 Call Letter, CMS announced the removal of the Adult Body Mass Index Assessment (Part C), Appeals Auto-Forward (Part D), and Appeals Upheld (Part D) measures due to low statistical reliability starting with the 2020 measurement year and associated 2022 Star Ratings following the rules codified at §§ 422.164(e) and 423.184(e). The collection of Part D Timeliness Monitoring Project (TMP) data was also stopped for the 2020 measurement year since it was used to validate the two Part D appeals measures. In the April 2019 final rule, CMS amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to update the methodology for calculating cut points for non-Consumer Assessment of Healthcare Providers and Systems (non-CAHPS) measures by adding mean resampling and guardrails, codify a policy to adjust Star Ratings for disasters, and finalize some measure updates.

At this time, we are proposing to further increase the stability of cut points by modifying the cut point methodology for non-CAHPS measures through direct removal of outliers. We are also proposing to increase the weight of patient experience/complaints and access measures, remove the Rheumatoid Arthritis Management (Part C) measure from the Star Ratings because the measure steward is retiring the measure from the HEDIS measurement set, implement substantive updates to the specifications of the Health Outcomes Survey (HOS) outcome measures, add two new Part C measures to the Star Ratings program, clarify the rules around consolidations when data are missing due to data integrity concerns, and add several technical clarifications. We are also proposing to codify additional existing rules for calculating MA Quality Bonus Payment (QBP) ratings. Unless otherwise stated, these changes would apply (that is, data would be collected and performance measured) for the 2021 measurement period and the 2023 Star Ratings.

2. Definitions (§ 422.252)

We propose to amend the definition at § 422.252 for new MA plans by clarifying how we apply the definition. We are proposing to modify the definition as follows: *New MA plan* means a plan that meets the following: (1) Is offered under a new MA contract; and (2) is offered under an MA contract that is held by a parent organization defined at § 422.2 that has not had an MA contract in the prior 3 years. For purposes of this definition, the parent organization is identified as of April of the calendar year before the payment year to which the final QBP rating applies, and contracts associated with that parent organization are also evaluated using contracts in existence as of April of the 3 calendar years before the payment year to which the final QBP rating applies. Under our current policy, we identify the parent organization for each MA contract in April of each year and then whether any MA contracts have been held by that parent organization in the immediately preceding 3 years to determine if the parent organization meets the 3 year standard. For example, if a parent organization is listed for an MA contract in April 2019, and that parent organization does not have any other MA contracts in April 2019, April 2018, or 2017, the plans under the MA contract would be considered new MA plans for 2020 QBP purposes.

3. Measure-Level Star Ratings (§§ 422.166(a), 423.186(a))

Over the past 2 years, we have codified and refined the methodology for calculating the Star Ratings from the performance scores for non-CAHPS measures. At §§ 422.166(a) and 423.186(a), we initially codified the historical methodology for calculating Star Ratings at the measure level in the April 2018 final rule. The methodology for non-CAHPS measures employs a hierarchical clustering algorithm to identify the gaps that exist within the distribution of the measure-specific scores to create groups (clusters) that are then used to identify the cut points. The Star Ratings categories are designed such that the scores in the same Star Ratings category are as similar as possible and the scores in different Star Ratings categories are as different as possible. The current methodology uses only data from the most recent Star Ratings year; therefore, the cut points are sensitive to changes in performance from 1 year to the next.

The primary goal of any cut point methodology is to disaggregate the distribution of scores into discrete categories or groups such that each grouping accurately reflects true performance. The current MA Star Ratings methodology converts measure-specific scores to measure-level Star Ratings so as to categorize the most similar scores within the same measure-level Star Rating while maximizing the differences across measure-level Star Ratings. We solicited comments 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 Proposed Rule (hereinafter referred to as the November 2017 proposed rule) regarding the approach to convert non-CAHPS measure scores to measure-level Star Ratings (82 FR 56397 through 56399). We requested input on the desirable attributes of cut points and recommendations to achieve the suggested characteristics in the Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Benefit, Programs for All-inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 Proposed Rule (hereinafter referred to as the November 2018 proposed rule). In addition, we requested that commenters either suggest alternative cut point methodologies or provide feedback on several options detailed in the November 2018 proposed rule, such as setting the cut points by using a moving average, using the mean of the 2 or 3 most recent years of data, or restricting the size of the change in the cut points from 1 year to the next.

The commenters identified several desirable attributes for cut points that included stability, predictability, and attenuation of the influence of outliers; commenters also suggested restricting movement of cut points from 1 year to the next and recommended that CMS either pre-announce cut points before the plan preview period or pre-determine cut points before the start of the measurement period. In the April 2018 final rule (83 FR 16567), we expressed appreciation for our stakeholders' feedback and stated our intent to use it to guide the development of an enhanced methodology while maintaining the intent of the cut point methodology to accurately reflect true performance.

Using the feedback from the comments we received in response to the November 2018 proposed rule, we considered enhancements to the methodology that would increase the stability and predictability of the cut points and finalized in the April 2019 final rule two enhancements to the historical methodology. In the April 2019 final rule, we amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to add mean resampling of the current year's data to the current clustering algorithm to attenuate the effect of outliers; we also added measure-specific caps in both directions to provide guardrails so that the measure-threshold-specific cut points do not increase or decrease more than the cap from 1 year to the next. Some commenters to the November 2018 proposed rule believed mean resampling would not be sufficient to address outliers and expressed support for directly removing outliers before clustering. We did not finalize an approach for directly removing outliers in the April 2019 final rule since the public did not have an opportunity to comment on a specific approach.

As we stated in the April 2019 final rule in response to public comments on this topic, we evaluated two options to address direct removal of outliers—trimming and Tukey outer fence outlier deletion. Under trimming, all contracts with scores below the 1st percentile or above the 99th percentile are removed prior to clustering. Although trimming is a simple way to remove extreme values, it removes scores below the 1st percentile or above the 99th percentile regardless of whether the scores are true outliers. This means in cases when true outliers are between the 1st and 99th percentile, they would not be removed by trimming, and in cases when the distribution of scores is skewed, scores that are not true outliers would be trimmed.

Tukey outer fence outlier deletion is a standard statistical method. Tukey outer fence outliers are sometimes called Whisker outliers. Under this methodology, outliers are defined as measure scores below a certain point (first quartile $-$ 3.0 $\times$ (third quartile $-$ first quartile)) or above a certain point (third quartile + 3.0 $\times$ (third quartile $-$ first quartile)). The Tukey outer fence outlier deletion will remove all outliers based on the previous definition and will not remove any cases that are not identified as outliers. Values identified by Tukey outer fence outlier deletion would be removed prior to clustering. If Tukey outer fence outlier deletion and a 5 percent guardrail had been implemented for the 2018 Star Ratings, 2 percent of MA–PD contracts would have seen their Star Rating increase by half a star, 16 percent would have decreased by half a star, and one contract would have decreased by 1 star. For PDP contracts, 2 percent would have increased by half a star, and 18 percent would have decreased by half a star. This simulation of the impact of Tukey outlier deletion also takes into account the removal of the two Part D appeals measures (Appeals Auto-Forward and Appeals Upheld) and the Part C measure Adult BMI Assessment in the simulations, because these measures will be removed starting with the 2022 Star Ratings. In general, there tend to be more outliers on the lower end of measure scores. As a result, the 1 to 2 star thresholds often increased in the simulations when outliers were removed compared to the other thresholds which were not as impacted.

The effect of Tukey outlier deletion would create a savings of $808.9 million for 2024, increasing to $1,449.2 million by 2030. Given the significant drawbacks of trimming, we are proposing to add Tukey outer fence outlier deletion to the clustering methodology for non-CAHPS measures. We request commenter feedback on Tukey outer fence outlier deletion as an additional step prior to hierarchal clustering. In the first year that this would be implemented, the prior year's thresholds would be rerun, including mean resampling and Tukey outer fence deletion so that the guardrails would be applied such that there is consistency between the years. We propose to amend §§ 422.162 and 423.182 to add a definition of the outlier methodology and amend §§ 422.166(a)(2) and 423.186(a)(2) to apply the outlier deletion using that methodology prior to applying mean resampling with hierarchal clustering. We welcome comments on this proposal.

4. Contract Consolidations (§§ 422.162(b)(3), 423.182(b)(3))

The process for calculating the measure scores for contracts that consolidate is specified as a series of steps at §§ 422.162(b)(3) and 423.182(b)(3). We propose to add a rule to account for instances when the measure score is missing from the consumed or surviving contract(s) due to a data integrity issue as described at §§ 422.164(g)(1)(i) and (ii) and 423.184(g)(1)(i) and (ii). CMS proposes to assign a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score. These rules would apply for contract consolidations approved on or after January 1, 2021. First, we propose minor technical changes to the regulation text in §§ 422.162(b)(3)(iv)(A) and (B) and 423.182(b)(3)(ii)(A) and (B) to improve the clarity of the regulation text. Second, we propose to redesignate the current regulation text (with the technical changes) as new paragraphs (b)(3)(iv)(A)(*1*) and (b)(3)(iv)(B)(*1*) and (b)(3)(ii)(A)(*1*) and (b)(3)(ii)(B)(*1*) of these regulations and to codify this new rule for contract consolidations approved on or after January 1, 2021 as §§ 422.162(b)(3)(iv)(A)(*2*) and (b)(3)(iv)(B)(*2*) and 423.182(b)(3)(ii)(A)(*2*) and (b)(3)(ii)(B)(*2*). We welcome comments on this proposal. We also propose an additional rule at §§ 422.164(g)(1)(iii)(A) and 423.184(g)(1)(iii)(A) to address how the Timeliness Monitoring Project

(TMP) or audit data are handled when two or more contracts consolidate. We propose to add that the TMP or audit data will be combined for the consumed and surviving contracts before carrying out the methodology as provided in paragraphs B through N (for Part C) and paragraphs B through L (for Part D). These rules would apply for contract consolidations approved on or after January 1, 2021. We propose to redesignate the current regulation text as new paragraphs (g)(1)(iii)(A)(*1*) and (g)(1)(ii)(A)(*1*) of these regulations and to codify this new rule for contract consolidations on or after January 1, 2021 as paragraphs (g)(1)(iii)(A)(*2*) and (g)(1)(ii)(A)(*2*). We welcome comments on this proposal.

5. Adding, Updating, and Removing Measures (§§ 422.164, 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedure for adding, updating, and removing measures for the Star Ratings program. Due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and specifications) adopted for the MA and Part D Star Ratings Program (83 FR 16537). CMS lists the measures used for the Star Ratings each year in the Technical Notes or similar guidance document with publication of the Star Ratings. In this rule, CMS is proposing measure changes to the Star Ratings program for performance periods beginning on or after January 1, 2021.

a. Proposed Measure Removal

CMS proposes to remove the Rheumatoid Arthritis Management measure from the Part C Star Ratings for the 2021 measurement year and the 2023 Star Ratings. The measure steward, NCQA, is retiring this measure from the HEDIS measurement set for the 2021 measurement year due to multiple concerns. For example, there are concerns that the performance on the measure may not reflect the rate at which members get anti-rheumatic drug therapy because sometimes these medications are covered by Patient Assistance Programs, which do not generate claims. In terms of the measure construction, the measure assesses only if members received a disease-modifying anti-rheumatic drug once during the measurement year, rather than assessing if members remain adherent to the medication. Additionally, it is unclear, based on the evidence, whether patients in remission should remain on these medications. Since NCQA plans to retire this measure from the HEDIS measurement set, CMS proposes to remove it starting with the 2023 Star Ratings. We welcome comments on this proposal.

b. Proposed Measure Updates

(1) Updates to the Improving or Maintaining Physical Health Measure and Improving or Maintaining Mental Health Measure From the HOS (Part C).

In accordance with § 422.164(d)(2), we are proposing substantive updates to two measures from the Medicare Health Outcomes Survey (HOS): The Improving or Maintaining Physical Health (PCS) measure and Improving or Maintaining Mental Health (MCS) measure.

First, we are proposing to change the case-mix adjustment for the measures. Case-mix adjustment (CMA) is critical to measuring and comparing longitudinal changes in the physical and mental health of beneficiaries across MA contracts through the PCS and MCS measures. To ensure fair and comparable contract-level scores, it is important to account for differences in beneficiary characteristics across contracts for these two measures. CMS proposes to modify the current approach for adjusting for differences in the case-mix of enrollees across contracts. The proposed approach would improve the case-mix model performance and simplify the implementation and interpretation of case-mix results when particular case-mix variables, such as household income, are missing. The current method for handling missing case-mix variables results in a reduced number of case-mix variables used for a beneficiary because it does not use any of the case-mix variables in a group of adjusters if one is missing from the group (see Medicare Part C & D Star Ratings Technical Notes, Attachment A for a full description of the current HOS case-mix methodology). This ''all-or-nothing'' approach for each group of adjusters may not be as efficient as alternative approaches for handling missing case-mix adjusters. Under the proposed change, when an adjuster is missing for a beneficiary, it would be replaced with the mean value for that adjuster for other beneficiaries in the same contract who also supply data for the PCS/MCS measures. This proposed approach has been used for the Medicare Advantage and Prescription Drug Plan CAHPS surveys for many years (see the 2020 Medicare Part C & D Star Ratings Technical Notes Attachment A for a description of the CAHPS case-mix methodology). In simulation models, this approach either outperformed the current approach for predicting outcomes or matched the current approach. The proposed approach is also easier to implement than the current approach because replacing the missing adjuster values with the contract mean scores for those adjusters rather than deleting the grouping of adjusters is less burdensome because it involves fewer steps and is easier to replicate and understand.

Second, we are proposing to increase the minimum required denominator from 30 to 100 for the two measures. The proposed increase to the minimum denominator would bring these measures into alignment with the denominator requirements for the HEDIS measures that come from the HOS survey and increase the reliability for these measures compared to the current reporting threshold of 30. We welcome comments on these proposals.

(2) Statin Use in Persons With Diabetes (Part D)

In the 2019 Call Letter, we proposed and finalized the addition of the Statin Use in Persons with Diabetes (SUPD) measure to the 2019 Star Ratings with a weight of 1 as a first year measure, then to have an increased weight of 3 as an intermediate outcome measure, starting with the 2020 Star Ratings. CMS did not increase the weight of this measure in the 2020 Star Ratings in response to the majority of comments to the Draft 2020 Call Letter opposing CMS's categorization of the measure as an intermediate outcome measure. The commenters presented a number of reasons for reclassifying the SUPD measure as a process measure, and we generally agree. For example, commenters noted that the Part C Statin Therapy for Patients with Cardiovascular Disease measure is similar to the SUPD and is a process measure. Also, commented pointed out that the SUPD measure specifications require two diabetes medication fills to qualify for the denominator, while only a single fill of a statin drug is required to be counted in the numerator. Commenters believed that this does not indicate a level of medication compliance needed to categorize it as an intermediate outcome measure. Furthermore, in a Frequently Asked Question (FAQ), the Pharmacy Quality Alliance clarified that ''The PQA SUPD measure is classified as a process measure. This aligns with the NQF definition for process measures, as prescribing a statin is a ''step that should be followed to provide good care'' rather than an outcome of such

care. [44] The FAQ can be found at *https://www.pqaalliance.org/measures-overview#supd.*

We finalized the SUPD measure with the intermediate outcome classification in the April 2019 final rule for the 2021 Star Ratings but no longer believe that is the appropriate classification. We propose to modify the classification of the SUPD measure category from an intermediate outcome classification to be a process measure, starting with the 2023 Star Ratings. This aligns with CMS's definition in the April 2019 final rule that process measures capture the health care services provided to beneficiaries which can assist in maintaining, monitoring, or improving their health status. We welcome comments on this proposal.

c. Proposed Measure Additions

As discussed in the April 2018 final rule (83 FR 16440), CMS stated that we anticipate that new measures will be added over time. Sections 422.164(c)(3) and (4) and 423.184(c)(3) and (4) provide that new measures would be reported on the display page for a minimum of 2 years before being added to the Star Ratings program; and new Star Ratings measures will be proposed and finalized through rulemaking. CMS is working with NCQA to expand efforts to better evaluate a plan's success at effectively transitioning care from a clinical setting to home. In the 2019 Call Letter, CMS discussed two potential new Part C measures and finalized these two measures in the 2020 Call Letter. CMS is proposing to add the HEDIS Transitions of Care and the HEDIS Follow-up after Emergency Department Visit for Patients with Multiple Chronic Conditions measures to the 2023 Star Ratings covering the contract year 2021 Performance Period. We are planning to display these new Part C measures on the display page for 3 years prior to adding them to the Star Ratings program, starting with the 2020 display page.

Since the Part C and D measures are now proposed and finalized through rulemaking, going forward we intend to follow the pre-rulemaking process that is used in other CMS programs. Section 3014 of the Affordable Care Act created a new section 1890A of the Social Security Act, which requires that HHS establish a federal pre-rulemaking process for the selection of quality and efficiency measures for use by HHS. HHS is required to convene multi-stakeholder groups to provide consensus-based input for the annual Measures under Consideration List. Both of these proposed measures were submitted through the Measures under Consideration process and were reviewed by the Measure Applications Partnership which is a multi-stakeholder partnership that provides recommendations to HHS on the selection of quality and efficiency measures for CMS programs.

(1) Transitions of Care (Part C)

The HEDIS Transitions of Care measure is the percent of discharges for members 18 years or older who have each of the four indicators during the measurement year: (1) notification of inpatient admission and discharge; (2) receipt of discharge information; (3) patient engagement after inpatient discharge; and (4) medication reconciliation post discharge.

Based on stakeholder input, NCQA is considering making a few non-substantive measure specification changes. The first considered change, for all measure indicators, is to broaden the forms of communications from one outpatient medical record to other forms of communication such as admission, discharge, and transfer record feeds, health information exchanges, and shared electronic medical records. The second is to change the notifications and receipts from 'on the day of admission or discharge or the following day' to 'on the day of admission or discharge or within the following two calendar days.' A third is to change one of the six criteria of the Receipt of Discharge Information indicator from 'instructions to the primary care providers or ongoing care provider for patient care' to 'instructions for patient care post-discharge.' If these updates are implemented we believe all of these changes are non-substantive since they add additional tests that would meet the numerator requirements as described at § 422.164(d)(1)(iv)(A); add alternative data sources as described at § 422.164(d)(1)(v); and do not change the population covered by the measure.

The intent of this measure is to improve the quality of care transitions from an inpatient setting to home, as effective transitioning will help reduce hospital readmissions, costs, and adverse events. The Transitions of Care measure excludes members in hospice and is based on the number of discharges, not members. We are proposing to add this measure to the Star Ratings in 2023 covering the contract year 2021 measurement period.

(2) Follow-Up After Emergency Department Visit for Patients With Multiple Chronic Conditions (Part C)

CMS is proposing to add a new HEDIS measure assessing follow-up care provided after an emergency department (ED) visit for patients with multiple chronic conditions. This measure is the percentage of ED visits for members 18 years and older who have high-risk multiple chronic conditions who had a follow-up service within 7 days of the ED visit between January 1 and December 24 of the measurement year. The measure is based on ED visits, not members. Eligible members must have two or more of the following chronic conditions: Chronic obstructive pulmonary disease (COPD) and asthma; Alzheimer's disease and related disorders; chronic kidney disease; depression; heart failure; acute myocardial infarction; atrial fibrillation; and stroke and transient ischemic attack. The following meet the criteria to qualify as a follow-up service for purposes of the measure: An outpatient visit (with or without telehealth modifier); a behavioral health visit; a telephone visit; transitional care management services; case management visits; and complex care management. Patients with multiple chronic conditions are more likely to have complex care needs, and follow-up after an acute event, like an ED visit, can help prevent the development of more severe complications. We are proposing to add this measure to the 2023 Star Ratings covering the contract year 2021 measurement period.

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[44] Process measures: These types of measures focus on whether actions that have been shown to benefit patients have been followed. Examples include: Whether patients with diabetes receive HbA1c testing during the measurement period; whether adolescents have received recommended immunizations; or whether stroke patients have received clot-busting medications in a timely manner.

TABLE 3: PROPOSED NEW AND REVISED INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2021

The measure descriptions listed in this table are high-level descriptions. The Star Ratings measure specifications supporting document, *Medicare Part C & D Star Ratings Technical Notes*, provides detailed specifications for each measure. Detailed specifications include, where appropriate, more specific identification of a measure's: (1) numerator, (2) denominator, (3) calculation, (4) timeframe, (5) case-mix adjustment, and (6) exclusions. The Technical Notes document is updated annually. In addition, where appropriate, the Data Source descriptions listed in this table reference the technical manuals of the measure stewards. The annual Star Ratings are produced in the fall of the prior year. For example, Star Ratings for the year 2020 are produced in the fall of 2019. If a measurement period is listed as 'the calendar year 2 years prior to the Star Ratings year' and the Star Ratings year is 2020, the measurement period is referencing the 1/1/2018-12/31/2018 period.

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Ratings	Reporting Requirements by Contract Type
Part C Measure								
Transitions of Care (TRC)	Percentage of discharges for members 18 years of age and older who had each of the following: 1) notification of admission and post-discharge: 2) receipt of discharge information, 3) patient engagement, and 4) medication reconciliation.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	Not Available	Clustering	MA-PD and MA-only
Follow-up after ED Visit for Patients with Multiple	Percentage of emergency department (ED) visits for members 18 years and older who have multiple high-risk	Managing Chronic (Long	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the	Not Available	Clustering	MA-PD and MA-only

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Ratings	Reporting Requirements by Contract Type
Chronic Conditions (FMC)	chronic conditions who had a follow-up service within 7 days of the ED visit. Eligible members must have two or more of the following chronic conditions: COPD and asthma; Alzheimer's disease and related disorders; chronic kidney disease; depression; heart failure; acute myocardial infarction; atrial fibrillation; and stroke and transient ischemic attack.	Term) Conditions			Star Ratings year			
Part D Measure								
Statin Use in Persons with Diabetes (SUPD)	Percent of the number of plan members 40-75 years old who were dispensed at least two diabetes medication fills and received a statin medication fill.	Drug Safety and Accuracy of Drug Pricing	Process Measure Weight of 1	Prescription Drug Event (PDE) data	The calendar year 2 years prior to the Star Ratings year	#2712	Clustering	MA-PD and PDP

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We welcome comments on these proposals.

6. Measure Weights (§§ 422.166(e), 423.186(e))

As finalized in the April 2018 final rule, beginning with the 2021 Star Ratings, §§ 422.166(e)(1)(iii) and (iv) and 423.186(e)(1)(iii) and (iv) provide the weight of 2 for both patient experience/complaints and access measures. We stated in the April 2018 final rule (83 FR 16575–16576) that given the importance of hearing the voice of patients when evaluating the quality of care provided, CMS intends to further increase the weight of patient experience/complaints and access measures in the future. The measures include the patient experience of care measures collected through the CAHPS survey, Members Choosing to Leave the Plan, Appeals, Call Center, and Complaints measures. The majority of the measures impacted by the proposed weight change are the CAHPS measures that focus on critical aspects of care from the perspective of patients such as access and care coordination issues. The experience of care measures focus on matters that patients themselves say are important to them and for which they are the best and/or only source of information.

The proposed increase in the weight does not impact the assignment of stars at the measure level, just the calculation of the overall and summary ratings, and will not impact the distribution of stars which varies for each of these measures. The statistical reliability of the CAHPS measures is high, exceeding standards for quality measurement so that higher star categories correspond to meaningfully better performance (generally, reliabilities of 0.7 or more are considered high for a quality measure).[45] The inter-unit reliability of the CAHPS measures range from 0.7638 for Customer Service to 0.9215 for Rating of Health Plan measure. The reliability for the other measures is as follows: Care Coordination is 0.8155, Getting Appointments and Care Quickly is 0.9059, Getting Needed Care is 0.8543, Getting Needed Prescription Drugs is 0.7895, Rating of Drug Plan is 0.8937, and Rating of Health Care Quality is 0.8263.

CMS has pledged to put patients first and to empower patients to work with their providers to make health care decisions that are best for them. To best meet the needs of beneficiaries, CMS believes we must listen to their perceptions of care, as well as ensure that they have access to needed care. Thus, CMS proposes to modify §§ 422.166(e) and 423.186(e) at paragraphs (e)(1)(iii) and (iv) to increase the weight of patient experience/complaints and access measures to 4 to further emphasize the importance of patient experience/complaints and access issues. If both Tukey outlier deletion and increasing the weight of patient experience/complaints and access measures are adopted, the net savings would be $368.1 million for 2024, increasing to $999.4 million for 2030.

7. Extreme and Uncontrollable Circumstances (§§ 422.166(i), 423.186(i))

As we have gained more experience with disasters and applying the disaster policy over the last couple of years, we are soliciting additional feedback on the disaster policy for contracts impacted across multiple years. As we stated in the April 2019 final rule, we are concerned about looking back too many years for contracts affected by disasters multiple years in a row; we are also concerned about including too many measurement periods in 1 year of Star Ratings. We also must consider operational feasibility, because using different thresholds for contracts affected by disasters in different ways would be very complicated for administration and for providing the necessary transparency to MA organizations, Part D plan sponsors, and beneficiaries who use and rely on the Star Ratings. We must balance these concerns about using older data with concerns about using data based on performance that has been impacted by consecutive disasters.

In striking a balance, we finalized in the April 2019 final rule a policy starting with the 2022 Star Ratings for contracts with at least 25 percent of enrollees in FEMA-designated Individual Assistance areas that were affected by disasters that began in 1 year and were also affected by disasters that began in the previous year. Such multiple year-affected contracts will receive the higher of the current year's Star Rating or what the previous year's Star Rating would have been in the absence of any adjustments that took into account the effects of the previous year's disaster for each measure. For example, if a multiple year-affected contract reverts to the 2021 Star Rating on a given measure in the 2022 Star Ratings, the 2021 Star Rating is not used in determining the 2023 Star Rating; rather, the 2023 Star Rating is compared to what the 2022 Star Rating would have been absent any disaster adjustments.

The rule for treatment of multiple year-affected contracts was established to limit the age of data that will be carried forward into the Star Ratings. We use the measure score associated with the year with the higher measure Star Rating regardless of whether the score is higher or lower that year. We finalized this policy to address when contracts are affected by separate extreme and uncontrollable circumstances that occur in successive years for the adjustments to CAHPS, HOS, HEDIS, and other measures. The provisions at §§ 422.166(i)(2)(v), (i)(3)(v), (i)(4)(vi), and (i)(6)(iv) and 423.186(i)(2)(v) and (i)(4)(iv) include this rule for how ratings for these measures are adjusted in these circumstances. We solicit comment on this policy and whether further adjustments are necessary.

In addition, the regulation we finalized to govern adjustments to a contract's Star Rating based on extreme and uncontrollable circumstances includes a provision to address when an affected contract has missing data. This provision was finalized at §§ 422.166(i)(8) and 423.186(i)(6) and provides that for an affected contract that has missing data in the current or previous year, the final measure rating comes from the current year unless an exemption described elsewhere in the regulation applies. We propose to modify §§ 422.166(i)(8) and 423.186(i)(6) to add new text at the end of the current regulation text to clarify that missing data includes data where there is a data integrity issue as defined at § 422.164(g)(1) and 423.184(g)(1). Under this proposal, when there is a data integrity issue in the current or previous year, the final measure rating comes from the current year.

8. Quality Bonus Payment Rules

The Affordable Care Act amended sections 1853(n) and 1853(o) of the Act to require CMS to make quality bonus payments (QBPs) to Medicare Advantage (MA) organizations that achieve at least 4 stars in a 5-star Quality Rating system. The Affordable Care Act also amended section 1854(b)(1)(C) of the Act to change the share of savings that MA organizations must provide to enrollees as the beneficiary rebate, mandating that the level of rebate is tied to the level of an MA organization's Quality Bonus Payment (QBP) rating. As a result, beginning in 2012, quality as measured by the 5-star Quality Rating System directly affected the monthly payment amount MA organizations receive from CMS. At the time the QBPs were implemented, CMS codified at § 422.260

[45] *https://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR653.pdf.*

an administrative review process available to MA organizations for payment determinations based on the quality bonuses. Historically, every November CMS has released the preliminary QBP ratings for MA contracts to review their ratings and to submit an appeal if they believe there is a calculation error or incorrect data are used as described at § 422.260(c).

In the April 2018 final rule, we codified at § 422.160(b)(2) that the ratings calculated and assigned under this subpart are used to provide quality ratings on a 5-star rating system used in determining QBPs and rebate retention allowances. Historically, the QBP rating rules have been announced through the Advance Notice and Rate Announcement since section 1853(b) of the Act authorizes an advance notice and rate announcement to solicit comment for proposed changes and announce changes to the MA payment methodology. As we have over the last couple of years codified in regulation the methodology for the Star Ratings, we are also proposing to clarify the rules around assigning QBP ratings, codify the rules around assigning QBP ratings for new contracts under existing parent organizations, and amend the definition of new MA plan that is codified at § 422.252 by clarifying how we apply the definition. Our proposal would codify current policy (for how we have historically assigned QBP ratings) without any changes.

Historically, for contracts that receive a numeric Star Rating, the final QBP rating released in April for the following contract year would be the contract's highest rating as defined at § 422.162(a). Section 422.260(a) states that the QBP determinations are made based on the overall rating for MA–PDs and the Part C summary rating for MA-only contracts. For further clarification, we are proposing to add language at § 422.162(b)(4) stating that for contracts that receive a numeric Star Rating, the final QBP rating is released in April of each year for the following contract year and that the QBP rating is the contract's highest rating, as that term is defined at § 422.162(a). We also propose to clarify in the regulation text that QBP rating is the contract's highest rating from the Star Ratings published by CMS in October of the calendar year that is 2 years before the contract year to which the QBP rating applies. For example, the 2020 QBPs were released in April 2019 and based on the Star Ratings published in October 2018. For MA contracts that offer Part D, the QBP rating would be the numeric overall Star Rating. For MA contracts that do not offer Part D (MA-only, MSA, and some PFFS contracts), the QBP rating would be the numeric Part C summary rating. We also propose adding language at § 422.160(b)(2)(ii) clarifying that the contract QBP rating is applied to each plan benefit package under the contract.

If a contract does not have sufficient data to calculate and assign Star Ratings for a given year because it is a new MA plan or low enrollment contract, § 422.166(d)(2)(v) provides the rules for assigning a QBP rating. That regulation references the definitions at § 422.252. We propose to amend the definition at § 422.252 for new MA plans by clarifying how we apply the definition as follows: *New MA plan* means a plan that meets the following: (1) Is offered under a new MA contract; and (2) is offered under an MA contract that is held by a parent organization defined at § 422.2 that has not had an MA contract in the prior 3 years.

We also propose to add rules at § 422.166(d)(2)(vi) for contracts that do not have sufficient data to calculate and assign ratings and do not meet the definition of low enrollment or new MA plans at § 422.252. Our proposal would codify the policy that has been in place since the 2012 Rate Announcement: any new contract under an existing parent organization that has had MA contract(s) with CMS in the previous 3 years receives an enrollment-weighted average of the Star Ratings earned by the parent organization's existing MA contracts. We intend for this policy to continue uninterrupted so that the calculation of QBPs remains stable and transparent to stakeholders.

We propose to add at § 422.166(d)(2)(vi)(A) that any new contract under an existing parent organization that has other MA contracts with numeric Star Ratings in November (when the preliminary QBP ratings are calculated for the contract year that begins 14 months later) would be assigned the enrollment-weighted average of the highest Star Rating of all other MA contracts under the parent organization that will be active as of April the following year. The Star Ratings used in this calculation would be the rounded stars (to the whole or half star) that are publicly displayed. For example, for the 2021 QBPs, for any new contracts under an existing parent organization, we would apply this rule as follows:

(i) We identify the parent organization of the new contract in November 2019.

(ii) We identify the MA contracts held by that parent organization in November 2019, when the preliminary 2021 QBP ratings are posted for review. For preliminary QBP ratings, we use the numeric Star Ratings for those MA contracts that were held by the parent organization in November 2019 that we anticipate to still be in existence and held by that parent organization in April 2020.

(iii) Using the enrollment in those other MA contracts as of November 2019, we calculate the enrollment-weighted average of the highest Star Rating(s) of those MA contracts.

(iv) In April 2020, we update the enrollment-weighted average rating based on any changes to the parent organization of existing contracts, using the November 2019 enrollment in the contracts. The enrollment-weighted average rating would include the ratings of any contract(s) that the parent organization acquired since November 2019. This enrollment-weighted average would be used as the 2021 QBP rating for the new MA contract under the parent organization for payment in 2021. This final QBP rating would be released to the MA organization for the new contract in April of 2020.

We propose to add at § 422.166(d)(2)(vi)(B) that if a new contract is under a parent organization that does not have any other MA contracts with numeric Star Ratings in November, CMS would look at the MA Star Ratings for the previous 3 years. The QBP rating would be the enrollment-weighted average of the MA contracts' highest Star Ratings from the most recent year that had been rated for that parent organization. For example, if in November 2019 there are no other MA contracts under the parent organization with numeric 2020 Star Ratings, we would go back first to the 2019 Star Ratings and then the 2018 Star Ratings. If there were MA contract(s) in the parent organization with Star Ratings in any of the previous 3 years, the QBP rating would be the enrollment-weighted average of the MA contracts' highest Star Ratings from the most recent year rated. The Star Ratings used in this calculation would be the rounded stars (to the whole or half star) that are publicly reported at some point on *www.medicare.gov.*

For example, for the 2021 QBPs, for any new contract(s) under a parent organization that has no MA contracts in November 2019, we would apply this rule as follows:

(i) We identify the MA contracts held by that parent organization in November 2018. If the parent organization had other MA contracts in November 2018, we use the numeric Star Ratings issued in October 2018 for those MA contracts that were held by the parent organization in November 2018.

(ii) Using the enrollment in those other MA contracts as of November

2018, we would calculate the enrollment-weighted average of the highest Star Rating(s) of those MA contracts.

(iii) This enrollment-weighted average would be used as the 2021 QBP rating for the new MA contract for that parent organization, for payment in 2021. This final QBP rating would be released to the MA organization for the new contract in April of 2020.

For the 2021 QBPs, for any new contract(s) under a parent organization that has no MA contracts in November 2018 and 2019, we would apply this rule as follows:

(i) We identify the MA contracts held by that parent organization in November 2017. If the parent organization had other MA contracts in November 2017, we use the numeric Star Ratings for those MA contracts that were held by the parent organization in November 2017.

(ii) Using the enrollment in those other MA contracts as of November 2017, we calculate the enrollment-weighted average of the highest Star Rating(s) of those MA contracts.

(iii) This would be used as the 2021 QBP rating for the new MA contract for payment in 2021. This final QBP rating would be released to the MA organization for the new contract in April of 2020.

If there were no MA contract(s) in the parent organization with numeric Star Ratings in the previous 3 years, the contract is rated as a new MA plan in accordance with § 422.258 (for QBP purposes) and § 422.166(d)(2)(v) (for other purposes).

We propose the rules for calculating the enrollment-weighted average and addressing changes in parent organizations in paragraphs (d)(2)(iv)(C) through (E). We propose to add at § 422.166(d)(2)(vi)(C) that the enrollment used in the enrollment-weighted calculations is the November enrollment in the year the Star Ratings are released. The enrollment data are currently posted publicly at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/index.html.*

We also propose at § 422.166(d)(2)(vi)(D) that the QBP ratings would be updated for any changes in a contract's parent organization prior to the release of the final QBP ratings in April of each year. The same rules described at § 422.166(d)(2)(vi)(A), (B), and (C) would be applied to the new contract using the new parent organization information. For example, for the 2021 QBPs, in April 2020 when the final QBP ratings are released, the enrollment-weighted average rating would include the ratings of any MA contract(s) that the parent organization acquired since November 2019. Thus, if a parent organization buys an existing contract it would be included in the enrollment-weighted average. We are also proposing at § 422.166(d)(2)(vi)(E) to codify our current practice that once the QBP ratings are finalized in April of each year for the following contract year, no additional parent organization changes are possible for QBP purposes.

We welcome comments on this proposal.

F. Permitting a Second, ''Preferred'', Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

1. Overview and Summary

Section 1860D–2(b)(2) of the Act, which establishes the parameters of the Part D program's Defined Standard benefit, allows for alternative benefit designs that are actuarially equivalent to the Defined Standard, including the use of tiered formularies. Although not required, Part D sponsors are permitted to include a specialty tier in their plan design. Use of a specialty tier provides the opportunity for Part D sponsors to manage high-cost drugs apart from tiers that have less expensive drugs.

CMS's policy for the specialty tier has aimed to strike the appropriate balance between plan flexibility and Part D enrollee access to drugs, consistent with our statutory authority. Section 1860D–2(b) of the Act requires that a plan design be actuarially equivalent to the Defined Standard benefit. Permitting tiering exceptions to allow Part D enrollees to obtain drugs on specialty tiers at a lower cost sharing applicable to non-specialty tiers could result in increased Part D premiums as well as increased cost sharing for non-specialty tiers. In other words, the ability to get lower cost sharing on specialty drugs through these kinds of exceptions means that costs would have to go up elsewhere—such as by increasing the cost-sharing on generic drug tiers—in order to keep the benefit design actuarially equivalent. Section 1860D–4(g)(2) of the Act grants CMS authority to establish guidelines under which Part D enrollees may request exceptions to tiered cost-sharing structures. Accordingly, we have developed a minimum dollar-per-month threshold amount to determine which drugs are eligible, based on relative high cost, for inclusion on the specialty tier,[46] and implemented a regulation (most recently § 423.578(a)(6)(iii)) permitting Part D sponsors to exempt drugs placed on the specialty tier from their tiering exceptions process. To prevent discriminatory formulary structures, in particular to protect Part D enrollees with certain disease types that are treated only by specialty tier-eligible drugs, our guidance[47] has set the maximum allowable cost sharing for drugs on the specialty tier between 25 and 33 percent coinsurance (25/33 percent).

We have not previously permitted Part D sponsors to structure their plans with more than one specialty tier. Pointing to factors such as the introduction of biosimilar biological products to the market[48] and recent higher pricing of some generic drugs relative to brand drug costs, some stakeholders requested that we reconsider this policy. They posited, for instance, that creating an additional specialty tier could improve the ability of Part D sponsors to negotiate with pharmaceutical manufacturers to help lower the prices of high-cost Part D drugs. Moreover, in its June 2016 Report to Congress (available at *http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf*), the Medicare Payment Advisory Commission (MedPAC) suggested that having two specialty tiers with differential cost sharing could potentially encourage the use of lower-cost biosimilar (or interchangeable, when available) biological products and encourage competition among existing specialty Part D drugs. More recently, some commenters on our Draft 2020 Call Letter (available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2020Advance.html*) took the

[46] See, for instance, Draft 2020 Call Letter, pages 178–179 (available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2020Part2.pdf*), and Final 2020 Call Letter, page 208 (available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf*).

[47] See section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf* and page 21 of the 2020 Bid Submission User Manual, Chapter 7: Plan Benefit Package Rx Drugs Section. The Bid Submission User Manual for 2020 is available at the following pathway after logging into the Health Plan Management System (HPMS): Plan Bids > Bid Submission > Contract Year 2020 > View Documentation > Bid Submission User Manual.

[48] See the April 2018 final rule for more background on biosimilar biological products (83 FR 16610).

opportunity to advocate for a second specialty tier.

Improving Part D enrollee access to needed drugs and lowering drug costs are central goals for CMS. Accordingly, in the hopes of providing flexibility that will promote these goals, we propose to allow Part D sponsors to establish up to two specialty tiers and design an exceptions process that exempts Part D drugs on these tiers from tiering exceptions to non-specialty tiers. Under our proposal, Part D sponsors would have the flexibility to determine which Part D drugs are placed on either specialty tier, subject to the ingredient cost threshold established according to the methodology we are proposing and the requirements of the CMS formulary review and approval process under § 423.120(b)(2). To maintain Part D enrollee protections, we are proposing to codify a maximum allowable cost sharing that would apply to a single specialty tier, or, if a Part D sponsor has a plan with two specialty tiers, to the higher cost-sharing specialty tier. Further, we propose to require that if a Part D sponsor has a plan with two specialty tiers, one must be a ''preferred'' tier that offers lower cost sharing than the higher cost sharing tier, which is subject to the proposed maximum allowable specialty-tier cost sharing. We note that we are not proposing any revisions to § 423.578(c)(3)(ii), which requires Part D sponsors to provide coverage for a drug for which a tiering exception was approved at the cost sharing that applies to the preferred alternative. We are proposing that the exemption from tiering exceptions for specialty tier drugs, at § 423.578(a)(6)(iii), would apply only to tiering exceptions to non-specialty tiers (meaning, when the tiering exception request is for the specialty tier drug to be covered at a cost-sharing level that applies to a non-specialty tier). Under our proposal, we would require Part D sponsors to permit tiering exception requests for drugs on the higher cost-sharing specialty tier to the lower cost-sharing specialty tier.

To improve transparency, we propose to codify current methodologies for cost sharing and calculations relative to the specialty tier, with some modifications. First, we propose to codify a maximum allowable cost sharing permitted for the specialty tiers of between 25 percent and 33 percent, depending on whether the plan includes a deductible, as described further in section V.F.4. of this proposed rule. We also propose to determine the specialty-tier cost threshold—meaning whether the drug has costs high enough to qualify for specialty tier placement—based on a 30-day equivalent supply. Additionally, we propose to base the determination of the specialty-tier cost threshold on the ingredient cost reported on the PDE. This would be a change from our current policy, which uses the negotiated price reflected on the PDE. Under our proposal, the specialty-tier cost threshold would apply to both specialty tiers. To respond to comments on our Draft 2020 Call Letter requesting that the specialty-tier cost threshold be increased regularly, we also propose to maintain a specialty-tier cost threshold that is set at a level that, in general, reflects Part D drugs with monthly ingredient costs that are in the top one percent of all monthly ingredient costs, as described further in section V.F.6. of this proposed rule. We propose to adjust the threshold, in an increment of not less than ten percent, rounded to the nearest $10, when an annual analysis of PDEs shows that recalibration of the specialty-tier cost threshold is necessary to continue to reflect only Part D drugs with the top one percent of monthly ingredient costs. We propose to annually determine whether the adjustment would be triggered and announce the specialty-tier cost threshold.

2. A Second, ''Preferred'', Specialty Tier

Placement on the specialty tier can play an important role in maintaining lower drug prices. Non-preferred brand or other non-preferred, non-specialty tiers frequently have cost sharing equal to as much as 50 percent coinsurance. This means that Part D enrollees would pay considerably more after application of coinsurance for a high-cost drug if it appeared on a non-preferred tier with, for instance, 50 percent cost sharing as opposed to placement on the specialty tier, which (as discussed later) has been subject to lower cost sharing requirements. For this reason we reject the suggestion of some commenters on our Draft 2020 Call Letter that we eliminate the specialty tier altogether. To the opposite effect, as noted previously, other stakeholders, including MedPAC, have recommended we permit Part D sponsors to create a second specialty tier. Stakeholders favoring this approach have posited that this change would: (1) Improve the ability of Part D sponsors and pharmacy benefit managers (PBMs) to negotiate better rebates with manufacturers by enabling them to establish a preferred specialty tier that distinguishes between high-cost drugs and effectively encourages the use of preferred specialty drugs; (2) reduce costs for Part D enrollees, not only through direct cost-sharing savings associated with a lower-cost, ''preferred'' specialty tier, but also through the lowered premiums for all Part D enrollees that could result from better rebates on specialty tier drugs; and (3) reduce costs to CMS directly through lower drug costs because lower cost sharing would delay a Part D enrollee's entry into the catastrophic phase of the benefit in which the government is responsible for 80 percent of the costs.

Consistent with CMS' ongoing efforts to implement new strategies that can help lower drug prices and increase competition, CMS now proposes to permit Part D sponsors to have up to two specialty tiers by permitting a new preferred specialty tier. However, driven by ongoing concerns over actuarial equivalence and discriminatory benefit designs, in order to strike the appropriate balance between plan flexibility and Part D enrollee access, CMS must also carefully weigh the following factors: (1) Tiering exceptions between the two specialty tiers or to other, non-specialty tiers; (2) the maximum allowable cost sharing for each specialty tier; and (3) tier composition (that is, the selection of Part D drugs for each specialty tier). The proposed regulatory text to allow up to two specialty tiers (which reflects CMS' consideration of these factors) and other related proposals are discussed in the following sections of this preamble.

3. Tiering Exceptions and Two Specialty Tiers

Section 1860D–4(g)(2) of the Act specifies that a beneficiary enrolled in a Part D plan offering a prescription drug benefit for Part D drugs through the use of a tiered formulary may request an exception to the Part D sponsor's tiered cost-sharing structure. Additionally, Part D sponsors are required under this section to create an exceptions process to handle such requests, consistent with guidelines established by CMS (see section 40.5.1 of Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, available at *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf*). However, section 1860D–4(g)(2) of the Act did not require tiering exceptions in every case, and even indicated that tiering exceptions might not be covered in every instance, by recognizing that non-preferred Part D drugs ''could be'' covered at the cost sharing applicable to preferred Part D drugs.

As noted earlier, the requirement that Part D plans be actuarially equivalent to

the Defined Standard benefit means that if Part D sponsors were required to permit Part D enrollees to obtain drugs on specialty tiers at non-specialty tier cost sharing, Part D sponsors might need to increase premiums and cost sharing for non-specialty tiers. To avoid such increased costs, in the Medicare Program; Medicare Prescription Drug Benefit Final Rule (hereinafter referred to as the January 2005 final rule, 70 FR 4193), CMS finalized § 423.578(a)(7), which provided that Part D sponsors with a tier for very high cost and unique items (in other words, a specialty tier), such as genomic and biotech products, could exempt such drugs from its tiering exception process (70 FR 4353).

In CMS's April 2018 final rule, CMS revised and redesignated § 423.578(a)(7) as new § 423.578(a)(6)(iii) to specify that if a Part D sponsor maintains a specialty tier, the Part D sponsor may design its exception process so that Part D drugs and biological products on the specialty tier are not eligible for a tiering exception. While the current policy does not require that Part D sponsors use a specialty tier that is exempt from tiering exceptions, we are aware that nearly all do.

Section 1860D–4(g)(2) of the Act stipulates that under an exception, a non-preferred Part D drug could be covered under the terms applicable for preferred Part D drugs if the prescribing provider determines that the preferred Part D drug for treatment of the same condition would not be as effective for the Part D enrollee, would have adverse effects for the Part D enrollee, or both. Thus, the statutory basis for approval of tiering exceptions requests is the presence of (a) clinically appropriate therapeutic alternative drug(s) or biological product(s) on a lower cost-sharing tier of the plan's formulary. Therefore, even if a Part D sponsor permitted tiering exceptions for Part D drugs on the specialty tier, tiering exceptions requests would not be approvable if the plan's formulary did not include any clinically appropriate therapeutic alternative Part D drugs on a lower cost-sharing tier. For example, suppose that reference biological product ''Biologic A'' and another biological product in the same class, ''Biologic B'' are both on the specialty tier with no clinically appropriate therapeutic alternative on a lower cost-sharing tier. If the Part D enrollee's prescriber were to write for Biologic A, and the prescriber were to request a tiering exception, because Biologic B, the clinically appropriate therapeutic alternative, is on the same tier as Biologic A, and not a lower cost-sharing tier, the tiering exception request would be denied. For further explanation of tiering exceptions requirements, please see § 423.578(a)(6).

Permitting Part D sponsors to exempt Part D drugs on a higher cost-sharing specialty tier from any tiering exceptions, even to a preferred specialty tier, would improve Part D sponsors' ability to negotiate better rebates. Nevertheless, unlike our justification for allowing Part D plans to exempt a specialty tier from tiering exceptions to lower cost non-specialty tiers, permitting tiering exceptions from the higher cost-sharing, specialty tier to the preferred specialty tier is less likely to lead to increased premiums or cost sharing to meet actuarial requirements because we are proposing to apply the same cost threshold to both specialty tiers. Our current belief is that improved negotiation alone is not sufficient to justify permitting Part D sponsors to exempt drugs on the higher cost-sharing, specialty tier from requests for tiering exceptions to the preferred specialty tier cost sharing. While as currently proposed, CMS would not require Part D sponsors to permit tiering exceptions from either specialty tier to lower, non-specialty tiers, our proposal would not change current regulations that require Part D sponsors to cover drugs for which a tiering exception was approved at the cost-sharing level that applies to the preferred alternative(s). This would mean that Part D sponsors would be required to permit tiering exceptions for Part D drugs from the higher cost-sharing, specialty tier to the preferred specialty tier if tiering exceptions requirements are met (for instance, when a Part D enrollee cannot take an applicable therapeutic alternative on the preferred specialty tier). Specifically, CMS proposes to amend § 423.578(a)(6)(iii) to specify that if a Part D sponsor maintains up to two specialty tiers, the Part D sponsor may design its exception process so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers. Consequently, the existing policy at § 423.578(c)(3)(ii) would require Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing, specialty tier that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier. While CMS would not require Part D sponsors to permit tiering exceptions to non-specialty tiers for Part D drugs on a specialty tier, nothing precludes a Part D sponsor from doing so, insofar as their plan benefit design remains actuarially equivalent to the Defined Standard benefit.

Alternatively, CMS could continue to permit Part D sponsors to exempt drugs on either specialty tier from tiering exceptions, as is provided under current regulations. We do not believe maintaining the current exemption would be discriminatory in light of CMS's proposal, discussed in the next section, to set a maximum allowable cost sharing (that is, 25/33 percent) for the higher cost-sharing, specialty tier and to also require the preferred specialty tier to have cost sharing below that maximum. If the proposed maximum allowable cost sharing is finalized, Part D enrollees would pay no more for a drug on either specialty tier than is the case under our current policy. And, as noted previously, maintaining the current exemption from tiering exceptions for all drugs on a specialty tier could allow Part D sponsors to negotiate better rebates. On the other hand, our proposal to require Part D sponsors with two specialty tiers to permit tiering exceptions from the higher-cost sharing to the lower-cost sharing, preferred specialty tier would provide a Part D enrollee protection when there is a therapeutic alternative on the preferred specialty tier that the Part D enrollee is unable to take. Accordingly, we invite comment on the benefits or drawbacks of maintaining the current policy under § 423.578(a)(6)(iii) that, if we were to finalize our proposal to permit Part D sponsors to have up to two specialty tiers, would apply to permit Part D sponsors to exempt drugs on a specialty tier from the tiering exceptions process altogether.

CMS notes that, as part of our proposed change at § 423.578(a)(6)(iii), we have proposed a technical change to remove the phrase ''and biological products.'' While the specialty tier usually includes biological products, in the context of the Part D program, biological products already are included in the definition of a Part D drug at § 423.100. Therefore the phrase ''Part D drugs and biological products'' is redundant and potentially misleading. Consequently, we propose to remove the phrase ''and biological products.''

To summarize, we are proposing to amend § 423.578(a)(6)(iii) to: (1) Reflect the possibility of a second specialty tier, permitting Part D sponsors to design their exception processes so that Part D drugs on the specialty tier(s) are not eligible for a tiering exception to non-specialty tiers and (2) remove the phrase ''and biological products.'' Additionally, we are proposing to maintain the existing policy at § 423.578(c)(3)(ii),

thereby requiring Part D sponsors to permit tiering exceptions between their two specialty tiers to provide coverage for the approved Part D drug on the higher cost-sharing specialty tier that applies to preferred alternative Part D drugs on the lower cost-sharing, preferred specialty tier. Additionally, if we finalize our proposal to permit Part D sponsors to maintain up to two specialty tiers, we solicit comment on maintaining the existing policy at § 423.578(a)(6)(iii), thereby permitting Part D sponsors to exempt drugs on either specialty tier from the tiering exceptions process altogether.

4. Maximum Allowable Cost Sharing and Two Specialty Tiers

At the start of the Part D program, when CMS provided Part D sponsors the option to exempt specialty tiers from the exceptions process, we remained concerned that removing this option for the specialty tier could potentially be discriminatory for Part D enrollees with certain diseases only treated by specialty tier-eligible drugs, and thus in conflict with the statutory directive under section 1860D–11(e)(2)(D) of the Act that CMS disapprove any ''design of the plan and its benefits (including any formulary and tiered formulary structure) that are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.'' Using this authority, CMS aligned the cost-sharing limit for Part D drugs on the specialty tier with the Defined Standard benefit at section 1860D–2(b)(2)(A) of the Act. Consequently, CMS established a ''25/33 percent'' maximum allowable cost sharing for the specialty tier, meaning that we would approve cost sharing for the specialty tier of no more than 25 percent coinsurance after the standard deductible and before the initial coverage limit (ICL), or up to 33 percent coinsurance for plans with decreased or no deductible under alternative prescription drug coverage designs and before the ICL. In other words, under actuarially equivalent alternative prescription drug coverage designs, CMS allows the maximum allowable cost sharing for the specialty tier to be between 25 and 33 percent coinsurance if the Part D plan has a decreased deductible, such that the maximum allowable cost sharing equates to 25 percent coinsurance plus the standard deductible. CMS derived the maximum allowable cost sharing of 33 percent coinsurance for plans with no deductible under alternative prescription drug coverage by adding the allowable deductible to the 25 percent maximum allowable cost sharing between the deductible and initial coverage limit (ICL) and dividing the resultant value by the ICL.

For example, in 2006, under the Defined Standard benefit, the maximum deductible was $250, and the ICL was $2250. The maximum allowable cost sharing between the deductible and the ICL was 25 percent coinsurance. (This example uses contract year 2006 numbers for simplicity, but the concepts presented still apply to current guidance.)

$2250 ICL − $250 deductible = $2000 difference × 0.25 = $500 maximum allowable cost sharing after the deductible and before the ICL for specialty tier drugs in plans with the standard deductible.

$500 maximum (previous calculation) + $250 deductible = $750. Therefore, the maximum coinsurance before the ICL for specialty tier drugs in plans with no deductible is $750 divided by the $2250 ICL = 0.33, or 33 percent coinsurance.

Plans with deductibles between $0 and $250 were permitted to have maximum allowable cost sharing for specialty tier drugs between the deductible and the ICL of between $500 and $750 (that is, coinsurance between 25 and 33 percent) provided that such cost sharing added to the deductible was $750. For example, using contract year 2006 numbers, if the deductible was $100, the maximum coinsurance that the plan could charge for specialty tier drugs between the deductible and the ICL would have been approximately 30 percent:

$750 − $100 deductible = $650 maximum allowable cost sharing (that is, $650 + $100 = $750). Therefore the maximum coinsurance between the $100 deductible and the $2250 ICL ≈ 0.30, or 30 percent coinsurance; that is, $650 divided by $2150 ≈ 0.30, or 30 percent. (This 30 percent represents mathematical rounding from the actual calculated value.)

Because section 1860D–2(b)(2) of the Act requires that plan benefit designs be actuarially equivalent to the Defined Standard benefit, the cost sharing for high-cost drugs would likely increase without the use of a specialty tier. This is because often the specialty tier has lower cost sharing than non-preferred brand or other non-preferred, non-specialty tier, which frequently have cost sharing as much as 50 percent coinsurance. Additionally, many specialty tier-eligible Part D drugs, particularly biological products, often do not have viable alternatives on lower-cost tiers. Our proposal to codify a maximum allowable cost sharing for the specialty tier equal to the cost sharing for the Defined Standard benefit plus the cost of any deductible would ensure Part D enrollees still pay no more than the Defined Standard cost sharing for high-cost drugs placed on a specialty tier.

Although CMS is proposing to allow Part D sponsors to have up to two specialty tiers, CMS notes that the currently available tier model structures already allow Part D sponsors to negotiate rebates and distinguish their preferred high-cost Part D drugs by placing them on the preferred brand tier as opposed to the specialty tier, and placing less preferred agents on the specialty tier. Such distinction could potentially drive the same rebates as two specialty tiers; however, Part D sponsors have told CMS they are reluctant to take such an approach because of the availability of tiering exceptions for the non-specialty tiers, which could increase costs in lower, non-specialty tiers in order to achieve actuarial equivalence. We believe this concern is addressed by our proposal (discussed previously) to permit Part D sponsors to exempt Part D drugs on either or both specialty tiers from exceptions to lower, non-specialty tiers.

Additionally, while CMS is sensitive and trying to be responsive to the volatility of the specialty drug market by proposing to allow Part D sponsors to have up to two specialty tiers, CMS remains concerned about whether this proposal will actually achieve the potential benefits to the Part D program and Part D enrollees asserted by stakeholders in support of two specialty tiers. As discussed previously, those stakeholders contend that permitting two specialty tiers will reduce Part D enrollee cost sharing for specialty Part D drugs. However, this would be true only for Part D drugs on the lower cost-sharing, preferred specialty tier, and only if the lower cost-sharing, preferred specialty tier cost sharing were set lower than 25/33 percent.

When requesting a second specialty tier, some Part D sponsors and PBMs have told CMS they would need to charge more than 25/33 percent for the higher cost-sharing specialty tier. However, if CMS were to permit Part D sponsors to charge more than 25/33 percent for the higher cost-sharing, specialty tier, the cost sharing for drugs in the higher cost-sharing, specialty tier would likely be higher than if there were only one specialty tier. We appreciate that permitting Part D sponsors to increase cost sharing over current limits might lead to negotiations for better rebates, which could result in savings to Part D enrollees offered through, for instance, lower costs on some Part D drugs in the preferred

specialty tier or lower premiums. However, in the absence of evidence to the contrary, it appears to us that if we were to permit Part D sponsors to charge higher percentages than is currently the case, Part D enrollees who need Part D drugs on the higher cost-sharing specialty tier will pay more, and possibly significantly more, than they currently do for those drugs given that specialty tiers by definition offer high-cost drugs, unless they happen to be taking those Part D drugs whose costs are lowered due to better rebates. In other words, we remain concerned about Part D enrollee protections and do not want improved rebates on some Part D drugs to come at the expense of those Part D enrollees who could already be paying, as proposed, as much as a 33 percent coinsurance on the highest-costing drugs. Moreover, because Part D enrollees who use high-cost Part D drugs progress quickly through the benefit, some Part D enrollees' entry into the catastrophic phase of the benefit may be advanced faster if the higher cost-sharing, specialty tier were to have a maximum allowable cost sharing that is higher than 25/33 percent. Therefore, it is unclear to CMS, in the aggregate, how much a second specialty tier would save the government if the second specialty tier was allowed to have a higher cost sharing than the current 25/33 percent.

In addition, while a second specialty tier might improve Part D sponsors' ability to negotiate better rebates, CMS also has concerns regarding actuarial equivalence and discriminatory plan design with a second, higher cost-sharing, specialty tier with cost sharing higher than the 25/33 percent that is currently permitted. If CMS were to allow a maximum allowable cost sharing for the higher cost-sharing, specialty tier above the 25/33 percent that is currently permitted, Part D enrollees whose Part D drugs are placed on the higher cost-sharing, specialty tier could see their out-of-pocket (OOP) costs increase above the Defined Standard cost-sharing amount, yet still be exempt from tiering exceptions. CMS is concerned that the disproportionate impact on Part D enrollees who take Part D drugs on the higher cost-sharing, specialty tier runs a greater risk of discriminatory plan design. Additionally, while it is generally allowable for plans to use tier placement to steer Part D enrollees toward preferred agents, CMS would have to develop additional formulary checks to prevent discrimination against those Part D enrollees who require Part D drugs on the higher cost-sharing, specialty tier, and those additional formulary checks would limit the ability of plans to negotiate for tier placement between the two specialty tiers.

We propose to set a maximum allowable cost sharing for a single specialty tier or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier as follows: (1) For plans with the full deductible provided for in the Defined Standard benefit, 25 percent coinsurance; (2) for plans with no deductible, 33 percent coinsurance; and (3) for plans with a deductible that is greater than $0 and less than the deductible provided for in the Defined Standard benefit, a coinsurance percentage that is determined by subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL) under section 1860D–2(b)(3) of the Act, dividing the difference by the difference between the ICL and the plan's deductible, and rounding to the nearest one percent. We propose to require that a plan's second specialty tier, if any, must have a maximum allowable cost sharing that is less than the maximum allowable cost sharing of the higher cost-sharing, specialty tier. For example, if a Part D sponsor establishes a cost sharing of 25 percent on its higher-cost sharing specialty tier, the Part D sponsor would need to set the cost sharing for the preferred specialty tier at any amount lower than 25 percent. Similarly, if a Part D sponsor establishes a cost sharing of 33 percent on its higher specialty tier (permitted if the plan has no deductible, as discussed previously), the Part D sponsor would need to set the cost sharing for the preferred specialty tier at any amount lower than 33 percent. To encourage the flexibility and with the belief that we might not be able to anticipate every variation Part D sponsors might plan, we are not proposing to require a minimum difference between the cost-sharing levels of the higher cost-sharing, specialty tier and a lower cost-sharing, preferred specialty tier that would apply to Part D sponsors choosing to provide two specialty tiers. As we have generally seen, for example, in relation to our policy recommending a threshold of $20 for the generic tier and ''less than $20'' for the preferred generic tier,[49] we believe it would be unlikely that Part D sponsors would take the trouble to create two different tiers and then establish an inconsequential differential. That said, we would, of course, reexamine this policy if we were to finalize this provision and thereafter find that not requiring a minimum difference between the cost-sharing levels of the two specialty tiers was creating problems. And we solicit comment as to whether to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier, including suggestions on requiring a minimum difference between the cost-sharing levels of the two specialty tiers that can provide maximum flexibility and anticipate varied approaches that Part D sponsors might take. Lastly, nothing in our proposal would prohibit Part D sponsors from offering less than the maximum allowable cost sharing on either tier as long as the preferred specialty tier has lower cost sharing than the higher cost-sharing, specialty tier.

As mentioned previously, CMS has ongoing concerns that offering a lower cost-sharing, preferred specialty tier below the current 25/33 percent maximum could, in theory, lead to increased costs in lower, non-specialty tiers in order to achieve actuarial equivalence. However, because these increases in costs would be spread across the overall plan design, we believe the overall impact on Part D enrollees, would be less impactful than the increase on individual Part D enrollee cost sharing were we to permit a maximum allowable cost sharing for the specialty tier above what is currently permitted (25/33 percent). Although CMS is concerned about offsetting increases to lower, non-specialty tiers, the 25/33 percent maximum allowable cost sharing that we are proposing is based upon the Defined Standard benefit cost sharing and therefore would provide is an important Part D enrollee protection to prevent discriminatory benefit structures. Consequently, CMS believes this approach would strike the appropriate balance between Part D sponsor flexibility and Part D enrollee access. CMS would monitor bids to assess the impact of this proposed policy.

In summary, CMS proposes to add a new paragraph at § 423.104(d)(2)(iv)(D) to specify that a Part D plan may maintain up to two specialty tiers. Further, CMS proposes to set a maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing, specialty tier by adding paragraphs (d)(2)(iv)(D)(*1*), (*2*), and (*3*) which provide: (1) 25 Percent coinsurance for plans with the full deductible provided under the Defined Standard benefit; (2) 33 percent

[49] See page 212 of the Final 2020 Call Letter, available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

coinsurance for plans with no deductible; and (3) for plans with a deductible that is greater than $0 and less than the deductible provided under the Defined Standard benefit, a coinsurance percentage that is between 25 and 33 percent, determined by subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL), dividing this difference by the difference between the ICL and the plan's deductible, then rounding to the nearest one percent.

We solicit comment on this approach. CMS is also interested in and seeks comments on plan benefit designs with two specialty tiers if we were to permit the higher cost-sharing, specialty tier to have a higher coinsurance than what we have proposed. Specifically, CMS is interested in comments that discuss whether permitting a coinsurance higher than 25/33 percent would be discriminatory.

Additionally, we note that the deductible applies to all tiers, and is not limited to, nor borne solely by, Part D enrollees taking Part D drugs on the specialty tier. Therefore, it is unclear that we should continue to differentiate the specialty tier from the other tiers on the basis of the deductible. Accordingly, we are also considering adopting a maximum allowable cost sharing of 25 percent for any specialty tier, regardless of whether the plan has a deductible. We solicit comment on alternative approaches of using a maximum allowable cost sharing of 25 percent coinsurance regardless of whether there is a deductible.

To summarize, we are proposing to add a new paragraph at § 423.104(d)(2)(iv)(D) to: (1) Specify that a Part D plan may maintain up to two specialty tiers; and (2) set a maximum allowable cost sharing of 25/33 percent for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing specialty tier. We are also proposing to allow Part D sponsors to set the cost sharing for the preferred specialty tier at any amount lower than that of the higher cost-sharing, specialty tier. Additionally, we solicit comment on actuarial equivalence and the potential for discriminatory effects plan designs with two specialty tiers if we were to permit: (1) The higher cost-sharing, specialty tier to have a higher coinsurance than the 25/33 percent maximum allowable cost sharing we have proposed; or (2) a maximum allowable cost sharing of 25 percent without regard to deductible. Finally, we also solicit comment as to whether to set a numeric or other differential in cost sharing between a specialty tier and any preferred specialty tier.

5. Tier Composition and Two Specialty Tiers

A few commenters on the Draft 2020 Call Letter suggested that we should create a lower cost specialty tier for generic drugs and biosimilar biological products, and that such a tier should be limited to only such products. We decline to propose such a policy. First, we wish to provide maximum flexibility to Part D sponsors that might find, for instance, that a brand-name Part D drug costs less with a rebate than a generic equivalent or corresponding biosimilar (or interchangeable, when available) biological product. Moreover, generic drugs and biosimilar (or interchangeable, when available) biological products that meet the specialty-tier cost threshold may not always be the lowest-priced product. Second, nothing in our proposal would prohibit Part D sponsors from setting up such parameters should they choose (provided they meet all other requirements, including the proposed maximum allowable cost sharing). Therefore, in order to provide more flexibility for plans to generate potential savings through benefit design and manufacturer negotiations, CMS is not proposing to prescribe which Part D drugs may go on either specialty tier. However, such placement will be subject to the requirements of the CMS formulary review and approval process under § 423.120(b)(2). Additionally, consistent with our current policy, CMS will continue to evaluate formulary change requests involving biosimilar (or interchangeable, when available) biological products on the specialty tiers on a case-by-case basis to ensure they continue to meet the requirements of the CMS formulary review and approval process. (See § 423.120(b)(5).)

CMS solicits comment on whether Part D sponsors should restrict the lower cost-sharing, preferred specialty tier to only generic drugs and biosimilar (or interchangeable, when available) biological products while also placing them along with any other Part D drugs meeting the specialty-tier cost threshold on the higher cost-sharing specialty tier. In other words, either brand or generic drugs and biosimilar (or interchangeable, when available) biological products would be placed on the higher cost-sharing specialty tier, but only generic drugs and biosimilar (or interchangeable, when available) biological products would be placed on the preferred specialty tier. CMS is particularly interested in comments that discuss what impact such a policy would have on non-specialty tiers.

6. Codifying the Specialty-Tier Cost Threshold Methodology

To effectuate the specialty tier, it was necessary to determine which Part D drugs could be placed on a specialty tier. Consequently, we developed a minimum dollar-per-month threshold amount to determine which Part D drugs are eligible, based on relative high cost, for inclusion on the specialty tier. CMS has sought comment on both this methodology used to establish the specialty-tier cost threshold and the resultant value of the specialty-tier cost threshold when publishing the annual Draft Call Letter. Most recently, commenters on the Draft 2020 Call Letter were largely supportive of having a methodology in place to annually evaluate and adjust the specialty-tier cost threshold, as appropriate. While some commenters wanted to maintain the current level (and others wanted to eliminate the specialty tier or reduce its cost sharing), there was broad support to regularly increase the specialty-tier cost threshold. Some comments asked for annual increases, while others wanted us to tie increases to the specialty-tier cost threshold to drug inflation, or benefit parameters. As we will detail later in this discussion, we are proposing to codify, with some modifications, the same outlier PDE analysis we have historically used. Our proposed annual methodology would account for rising drug costs, as well as any potential changes in utilization. By identifying the top one percent of 30-day equivalent PDEs, our proposal aims to create a specialty-tier cost threshold that is representative of outlier claims for the highest-cost drugs. By using PDEs, the proposed analysis would also reflect the fact that the numbers of Part D enrollees filling prescriptions for high-cost drugs as a percentage of all drug claims may vary from year to year. Given the general support for regular increases in the specialty-tier cost threshold, we propose to make adjustments to the specialty-tier cost threshold based on a specific methodology, as discussed later in this section.

Beginning in 2007, CMS established the specialty-tier cost threshold at $500 per month [50] based on identifying outlier claims (that is, the top one percent of claims having the highest negotiated prices as reported on the PDE, adjusted, as described in this

[50] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/CY07FormularyGuidance.pdf.*

section of this proposed rule, for 30-day equivalent supplies) and increased the threshold to $600 beginning in contract year 2008. The specialty-tier cost threshold remained at $600 per month from contract years 2008 through 2016.[51] [52] In the 2016 analysis for contract year 2017 (using contract year 2015 PDE data), the number of claims for 30 day-equivalent supplies with negotiated prices meeting the existing $600 per month cost threshold exceeded one percent. This, coupled with the significant increase in the cost of Part D drugs since the last adjustment (in 2008), supported an increase in the specialty-tier cost threshold for contract year 2017. To adjust the specialty-tier cost threshold, CMS applied the annual percentage increase used in the Part D benefit parameter updates (that is, 11.75 percent for contract year 2017) to the $600 threshold. This increase in the specialty-tier cost threshold (that is, $70.50), rounded to the nearest $10 increment (that is, $70), was sufficient to reestablish the one percent outlier threshold for PDEs having negotiated prices for 30-day equivalent supplies greater than the threshold. Since contract year 2017, the specialty-tier cost threshold has been $670 per month.

In our April 2018 final rule, we defined specialty tier in regulation at § 423.560 to mean a formulary cost-sharing tier dedicated to very high-cost Part D drugs and biological products that exceed a cost threshold established by the Secretary (83 FR 16509). To improve transparency, we propose to codify current methodologies for calculations relative to the specialty tier, with some changes. As noted previously, it was necessary to establish the composition of a specialty tier in order to effectuate specialty tier exceptions and anti-discrimination policies. Under § 423.560, only very high-cost drugs and biological products that meet or exceed a cost threshold established by the Secretary may be placed on a plan's specialty tier (for example, a negotiated price of or exceeding $670 per month for coverage year 2020). Current guidance at section 30.2.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual describes these high-cost drugs and biological products as those having Part D sponsor-negotiated prices that exceed a dollar-per-month amount established by CMS in the annual Call Letter, which has noted the historical use of a threshold under which approximately 99 percent of monthly PDEs adjusted for 30-day equivalent supplies have been below the specialty-tier cost threshold.

In setting the specialty-tier cost threshold, CMS has historically analyzed prescription drug event (PDE) data for the plan year that ended 12 months before the applicable plan year (for example, CMS used contract year 2017 PDE data to determine the cost threshold for contract year 2019). First, CMS has calculated the number of 30-day equivalent supplies reported on each PDE. We have considered a 30-day equivalent supply to be any days' supply, as reported on each PDE, of less than or equal to 34 days. Thus, a PDE with a 34-days' supply has been considered one 30-day equivalent supply. (This reflects the fact that a full supply of medication for a Part D enrollee could equal less than a month's supply, or reflect manufacturer packaging. For instance, we did not want to triple the cost of a 10-day course of antibiotics to determine the 30-day equivalent supply because that would overstate the Part D enrollee's cost for the full prescription). If the days' supply on the PDE is greater than 34, the 30-day equivalent supply is equal to the PDE's days' supply divided by 30. Thus, for example, a PDE with a 90-day supply has been considered as three 30-day equivalent supplies. Similarly, a PDE with a drug that has been dispensed in a package containing a 45-days' supply has been considered as 1.5 30-day equivalent supplies. This includes long-acting drugs, including, but not limited to long-acting injections. For example, a single injection that is considered to be a 90-days' supply has been considered as three 30-day equivalent supplies.

After determining the number of 30-day equivalent supplies for each PDE, we have calculated the 30-day equivalent negotiated price for the PDE by dividing the PDE's negotiated price by the number of 30-day equivalent supplies reflected on the PDE. Thus, for example, if the PDE is for a 90-days' supply and has a negotiated price of $810, that PDE contains three 30-day equivalent supplies, and the 30-day equivalent negotiated price is $270.

Next, taking into consideration the 30-day equivalent negotiated prices for all Part D drugs for which PDE data are available, CMS has identified the PDEs with 30-day equivalent negotiated prices that reflect the top 1 percent of 30 day-equivalent negotiated prices, and has maintained the specialty-tier cost threshold at an amount that corresponds to the lowest 30-day equivalent negotiated price that is within the top one percent of all 30-day equivalent negotiated prices.

We note that this process may result in dose specificity of eligibility for placement on the specialty tier, such that one strength of a Part D drug may be eligible but another strength may not. For example, suppose that Part D drug X is available as tablets in strengths of 10mg, 20mg, and 30mg taken once daily with 30-day equivalent negotiated prices of $300, $600, and $900, respectively. The 30mg tablets, because their 30-day equivalent negotiated price exceeds the specialty-tier cost threshold, are eligible for placement on the specialty tier, but the 10mg and 20mg tablets are not, because their 30-day equivalent negotiated prices do not exceed the specialty-tier cost threshold.

We believe our existing policy to set the specialty-tier cost threshold such that only the top one percent of 30-day equivalent negotiated prices would exceed it is consistent with the purpose of the specialty tier—that is, that only the highest-cost Part D drugs are eligible for placement on the specialty tier. For this reason, we propose to codify a similar process to adjust and rank PDE data as the basis for determining the specialty-tier cost threshold, as described in this section of this proposed rule. Specifically, instead of 30-day equivalent negotiated prices, we propose to determine the 30-day equivalent ingredient cost to set the specialty tier-cost threshold in the same manner as we have historically done, as described previously in this section.

In addition, to maintain stability in the specialty-tier cost threshold, we propose to set the specialty-tier cost threshold for contract year 2021 to reflect the top 1 percent of 30-day equivalent ingredient costs, at an amount that corresponds to the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs. We also propose to undertake an analysis of 30-day equivalent ingredient costs annually, and to increase the specialty-tier cost threshold for a plan year only if CMS determines that no less than a ten percent increase in the specialty-tier cost threshold, before rounding to the nearest $10 increment, is needed to reestablish the specialty-tier cost threshold that reflects the top one percent of 30-day equivalent ingredient costs.

As a hypothetical example, suppose that, in 2020, when analyzing contract year 2019 PDE data for contract year 2021, CMS finds that more than one percent of PDEs have 30-day equivalent ingredient costs that exceed the contract year 2020 specialty-tier cost threshold of

[51] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2017.pdf.*

[52] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf.*

$670. Further, suppose that CMS finds that one percent of the PDEs have 30-day equivalent ingredient costs that exceed $685. This $15 difference represents a 2.24 percent increase over the $670 specialty-tier cost threshold. Under our proposed methodology, we would not increase the specialty-tier cost threshold for contract year 2021.

However, if we suppose that, instead of $685, CMS finds that one percent of the PDEs have 30-day equivalent ingredient costs that exceed $753, then in this scenario, the $83 change represents a 12.39 percent increase over the $670 specialty-tier cost threshold. Under our proposed methodology, because this would be a change of more than 10 percent, we would set the specialty-tier cost threshold for contract year 2021 at $750 which is the nearest $10 increment to $753.

We solicit comment on this proposal. Because CMS notes that rounding down, as in the previous example, would technically cause the new specialty-tier cost threshold to account for very slightly more than one percent of 30 day-equivalent ingredient costs, we are also considering the alternative that CMS would always round up to the next $10 increment. Using the previous example, CMS would have set the threshold for contract year 2021 at $760 instead of $750. This alternative would: (a) Better ensure that the new specialty-tier cost threshold actually reflects the top one percent of claims adjusted for 30-day equivalent supplies, and (b) provide more stability, to the specialty-tier cost threshold, that is, it will theoretically not need to be changed as frequently, because rounding down will always result in a specialty-tier cost threshold that would include more than the top one percent of 30-day equivalent ingredient costs. We do not expect that this alternative would significantly impact the number of Part D drugs that would meet our proposed specialty-tier cost threshold. We solicit comment on this alternative approach to rounding and could finalize an amended version of our proposed language at § 423.104(d)(2)(B) to reflect such alternative. We propose to annually determine whether the adjustment would be triggered using the proposed methodology, and if it is, we would apply the proposed methodology to determine the new specialty-tier cost threshold, which we would announce via an HPMS memorandum or a comparable guidance document. Finally, we propose for contract year 2021 that we would apply our proposed methodology to the contract year 2020 specialty-tier cost threshold of $670, and if a change to the methodology based on comments received on this proposed rule would result in a change to that threshold, we will announce the new specialty-tier cost threshold in the final rule.

CMS has concerns regarding the use of negotiated prices of drugs, as the term is currently defined in § 423.100, in the determination of the specialty-tier cost threshold, because the negotiated prices include all pharmacy payment adjustments except those contingent amounts that cannot reasonably be determined at the point-of-sale. For this reason, negotiated prices typically do not reflect any performance-based pharmacy price concessions that lower the price a Part D sponsor ultimately pays for a drug. Negotiated prices in the PDE record are composed of ingredient cost, administration fee (when applicable), dispensing fee, and sales tax (when applicable). Administration fees, dispensing fees, and sales tax are highly variable. Therefore, because the ingredient cost has fewer variables than the negotiated price, the ingredient cost represents the most transparent, least complex, and most predictable of all the components of negotiated price upon which to base the determination of the specialty-tier cost threshold. Consequently, as noted previously, we propose to use the ingredient costs associated with 30-day equivalent supplies when we determine the specialty-tier cost threshold according to the methodology proposed earlier in this preamble. We do not expect that this change would significantly affect the number of Part D drugs meeting the specialty-tier cost threshold because the ingredient cost generally accounts for most of the negotiated price; however we are proposing this change to use the ingredient cost in order to ensure that we are using the most predictable of all the components of the negotiated price upon which to base the specialty- tier cost threshold.

Using the methodology proposed in this proposed rule and contract year 2019 PDE data that CMS has to date, the specialty-tier cost threshold for contract year 2021 would be $780 as a 30-day equivalent ingredient cost. To determine this proposed threshold, we analyzed 2.2 billion PDEs, and determined the lowest 30-day equivalent ingredient cost that is within the top one percent of all 30-day equivalent ingredient costs to be $780, which did not require rounding. Therefore, we are proposing to increase the specialty-tier cost threshold to $780 (as a 30-day equivalent *ingredient cost*) for contract year 2021 from the previous $670 (as a 30-day equivalent *negotiated price*). While this change will impact the specific dollar threshold amount for specialty-tier eligibility, the specialty-tier cost threshold still accounts for the top 1 percent of all claims, as adjusted for 30-day equivalent supplies. Due to the increased costs of prescription drugs since the previous $670 specialty-tier cost threshold was set several years ago, the top 1 percent of all claims, as adjusted for 30-day equivalent supplies, cost more, on average. Moreover, we estimate that the change from using negotiated price to using ingredient cost only will result in fewer than 20 drugs not meeting the $780 30-day equivalent ingredient cost specialty-tier cost threshold that would have if we continued to use the 30-day equivalent negotiated price.

Additionally, consistent with current guidance in section 30.2.4 in Chapter 6 of the Medicare Prescription Drug Benefit Manual, CMS considers claims history in reviewing the placement of Part D drugs on Part D sponsors' specialty tiers. Consequently, CMS proposes to codify current guidance that a Part D drug will be eligible for placement on a specialty tier if the majority of a Part D sponsor's claims for that Part D drug, when adjusted for 30-day equivalent supplies, exceed the specialty-tier cost threshold. However, for Part D drugs newly approved by the Food and Drug Administration (FDA) for which Part D sponsors would have little or no claims data because such drugs have only recently become available on the market, we propose to permit Part D sponsors to estimate the 30-day equivalent ingredient cost portion of their negotiated prices based on the maximum dose specified in the FDA-approved labeling and taking into account dose optimization, when applicable for products that are available in multiple strengths. If, based on their estimated 30-day equivalent ingredient cost, the newly FDA-approved Part D drug is anticipated to exceed the specialty-tier cost threshold most of the time (that is, more than 50 percent of the time), we would allow Part D sponsors to place such drug on a specialty tier. Finally, such placement would be subject to CMS review and approval as part of our formulary review and approval process.

CMS proposes to add paragraphs (d)(2)(iv)(A), (B), and (C) to § 423.104 and to cross reference this section in our proposed revised definition of specialty tiers, which we are proposing to move to § 423.104, as described later in this section. Specifically, we propose in paragraph (d)(2)(iv)(A) to described in paragraphs (d)(2)(iv)(A)(*1*) through (*4*) the manner by which CMS sets the specialty-tier cost threshold, and further, to describe in paragraph

(d)(2)(iv)(A)(*5*) a Part D drug's eligibility for placement on the specialty tier. We propose that paragraph (d)(2)(iv)(A)(*1*) would specify that CMS uses PDE data, and further, uses the ingredient cost reflected on the PDE to determine the ingredient costs in dollars for 30-day equivalent supplies of drugs. We propose that paragraph (d)(2)(iv)(A)(*2*) would specify how CMS determines 30-day equivalent supplies from PDE data, such that if the days' supply reported on a PDE is less than or equal to 34, the number of 30-day equivalent supplies equals one, and if the days' supply reported on a PDE is greater than 34, the number of 30-day equivalent supplies is equal to the number of days' supply reported on the PDE divided by 30. We propose that paragraph (d)(2)(iv)(A)(*3*) would specify that CMS then determines the amount that equals the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs reflected in the PDE data. Further, proposed paragraph (d)(2)(iv)(A)(*4*) would specify that, except as provided in proposed paragraph (B), the amount determined in paragraph (d)(2)(iv)(A)(*3*) is the specialty-tier cost threshold for the plan year. Proposed paragraph (d)(2)(iv)(A)(*5*) would specify that, except for newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, CMS will approve the placement of a Part D drug on a specialty tiers when that Part D sponsor's claims data from the plan year that ended 12 months prior to the applicable plan year demonstrate that greater than 50 percent of the Part D sponsor's PDEs for a given Part D drug, when adjusted for 30-day equivalent supplies, have ingredient costs for 30-day equivalent supplies that exceed the specialty-tier cost threshold.

We propose in paragraph (d)(2)(iv)(B) to describe the methodology CMS will use to increase the specialty-tier cost threshold. Specifically, we propose to increase the specialty-tier cost threshold for a plan year only if the amount determined by proposed paragraph (d)(2)(iv)(A)(*3*) for a plan year is at least ten percent above the specialty-tier cost threshold for the prior plan year. CMS proposes that if an increase is made, CMS would round the amount determined in proposed paragraph (d)(2)(iv)(A)(*3*) to the nearest $10. That amount would be the specialty-tier cost threshold for the applicable plan year.

Finally, CMS proposes paragraph (d)(2)(iv)(C) to specify that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year.

As mentioned previously, to align the definition of specialty tier with our proposal to allow Part D sponsors to have up to two specialty tiers, CMS first proposes to move the definition of specialty tier from § 423.560 to appear in § 423.104(d)(2)(iv) as part of a proposed new section on specialty tiers that also includes the methodology for determining the specialty tier cost-thresholds and maximum allowable cost sharing. (We also propose to revise § 423.560 and § 423.578(a)(6)(iii) to cross reference the placement of that definition in § 423.104(d)(2)(iv).) Additionally, CMS proposes to amend the definition of specialty tier to reflect our proposal to allow Part D sponsors to have up to two specialty tiers. With respect to the phrase ''and biological products,'' for the reasons discussed in the previous section of this preamble, (specifically, that biological products are already are included in the definition of a Part D drug at § 423.100), CMS is also proposing a technical change to the definition of specialty tier to remove the phrase ''and biological products.'' Therefore, CMS proposes to define specialty tier at § 423.104(d)(2)(iv) to mean a formulary cost-sharing tier dedicated to high-cost Part D drugs with ingredient costs for a 30-day equivalent supply (as described in § 423.104(d)(2)(iv)(A)(*2*)) that are greater than the specialty-tier cost threshold specified in § 423.104(d)(2)(iv)(A).

To summarize, we are proposing to: (1) Amend the definition of specialty tier at § 423.560 and move it to § 423.104(d)(2)(iv); (2) amend § 423.578(a)(6)(iii) to cross reference placement of the definition of specialty tier at § 423.104(d)(2)(iv); (3) add new paragraph (d)(2)(iv)(A) which describes, in (d)(2)(iv)(A)(*1*) through (*4*), the manner by which CMS sets the specialty-tier cost threshold, and in (d)(2)(iv)(A)(*5*), a Part D drug's eligibility for placement on the specialty tier; (4) add new paragraph (d)(2)(iv)(B), which describes the methodology CMS will use to increase the specialty-tier cost threshold; and (5) add new paragraph (d)(2)(iv)(C), which specifies that the determination of the specialty-tier cost threshold for a plan year is based on PDE data from the plan year that ended 12 months prior to the beginning of the applicable plan year. We solicit comment on specifying at the proposed new § 423.104(d)(2)(iv)(B) that we would round *up* to the nearest $10 increment.

G. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

Section 101 of the MMA requires the adoption of Part D E-Prescribing (eRx) standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage Prescription Drug Plans (MA–PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority.

Prescribers and dispensers who electronically transmit and receive prescription and certain other information for Part D-covered drugs prescribed for Medicare Part D eligible individuals, directly or through an intermediary, are required to comply with any applicable standards that are in effect. For a further discussion of the statutory basis for this proposed rule and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. of the February 4, 2005, Medicare Program; E-Prescribing and the Prescription Drug Program Proposed Rule (70 FR 6256).

In accordance with our regulations at § 423.160(b)(1), (2), and (5), CMS' Part D eRx program requires that Part D sponsors support the use of the adopted standards when electronically conveying prescription and formulary and benefit information regarding Part D-covered drugs prescribed to Part D-eligible individuals between plans, prescribers, and dispensers.

We utilized several rounds of rulemaking to update the Part D e-prescribing program. Most recently, in the May 2019 Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses Final Rule (84 FR 23832) (hereinafter referred to as the May 2019 final rule), we required that Part D plans support a prescriber electronic real-time benefit tool capable of integrating with at least one e-prescribing or electronic health record (EHR) system. The prescriber RTBT must provide its enrollees with complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives and utilization management requirements). This ''prescriber RTBT'' electronic transaction requirement will become effective January 1, 2021, and is expected to enhance medication adherence and lower overall drug costs by providing Part D prescribers information in real time when lower-cost alternative drugs are available.

The SCRIPT and the NCPDP Formulary and Benefits standards have already become critical components of the Part D program, and we believe the recently finalized prescriber RTBT requirement at § 423.160(b)(7) will do the same by enhancing the electronic communication of prescription-related information between plans and prescribers under the Part D benefit program. While these requirements will empower prescribers, we also believe it is important to empower patients with information like that which will be included in the prescriber RTBT and give them the ability to access this information either at their computer or using a mobile device. We now propose to adopt at § 423.128(d) a requirement that Part D sponsors implement a beneficiary RTBT that would allow enrollees to view accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information, effective January 1, 2022, so as to allow both prescriber and patient to consider potential cost differences when choosing a medication that best meets the patient's medical and financial needs. Each system response value would be required to present real-time values for the patient's cost-sharing information and clinically appropriate formulary alternatives, where appropriate. This requirement would include the formulary status of clinically appropriate formulary alternatives, including any utilization management requirements, such as step therapy, quantity limits, and prior authorization, applicable to each alternative medication. We're also proposing to add § 423.128(d)(1)(vi) to require that plans make this information available to enrollees via their customer service call center. The goal of this requirement is help ensure that the beneficiary RTBT information is available to enrollees without computer or smartphone access.

We believe that January 1, 2022 is an appropriate deadline for this proposal, since it would give plans adequate time to implement the proposal while still helping ensure that enrollees have access to this information in a timely manner. We welcome comments on this proposal, including the feasibility for plans to meet the proposed January 1, 2022 deadline or whether this proposal should be finalized effective January 1, 2021 in order to align with the prescriber RTBT effective date.

We also welcome comments on the need for the beneficiary RTBT when Part D plans will be required to support the prescriber RTBT by January 1, 2021. For instance, we would like to understand the beneficiary interest in such a tool compared to provider interest. We also would like to understand whether a beneficiary RTBT is a less complicated, therefore more likely utilized tool, than a prescriber RTBT.

As we stated in our April 16, 2018 final rule adopting version 2017071 of the SCRIPT standard for various Part D e-prescribing transactions (see 83 FR 16440), we believe that patient-specific coverage information at the point of prescribing would enable the prescriber and patient to collaborate in selecting a medication based on clinical appropriateness, coverage, and cost. In order to fully realize this benefit, however, we believe that it is important to afford the patient direct access to this formulary and benefit information so they need not depend on their prescribers pulling up the information to empower their discussions with those prescribers as to medication options.

Section 1860D–12(b)(3)(D) of the Act authorizes additional contract terms not inconsistent with the Part D statute. Under this authority, we are proposing to require Part D sponsors to offer a patient RTBT because we believe that it is appropriate to require that the formulary and benefit information be provided to enrollees in real time. Enrollees should have continuous access to this information, since drug pricing information is so dynamic.

Based on our research, we believe that the process that Part D sponsors will have to follow in order to implement a prescriber RTBT would establish a foundation from which a beneficiary RTBT could be implemented for use by enrollees, since the required information and information culling process is substantially similar. As discussed in our May 2019 final rule, implementation of an effective prescriber RTBT requires that plans review formulary medications to determine which alternatives may exist and whether those alternatives could save the beneficiary money through reduced cost sharing if deemed clinically appropriate by the practitioner. As discussed in our May 2019 final rule, analysis needed when developing the formulary and benefit information necessary to implement prescriber RTBTs would also include cataloging any existing drug-specific utilization requirements such as prior authorization (PA) or step therapy. Specifically, the plan's prescriber RTBT system will require integration with at least one prescriber's e-Prescribing (eRx) system or electronic health record (EHR) to provide complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information to the prescriber in real time for assessing coverage under the Part D plan (§ 423.160(b)(7)). Such information must include enrollee cost-sharing information, clinically appropriate formulary alternatives, when available, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug. Once the Part D sponsor has developed the information necessary to implement the prescriber RTBT, the list of formulary alternatives and utilization requirements could also be used to implement a beneficiary RTBT.

We believe that sharing this kind of formulary and benefit information would allow enrollees to take an active role in their health care decisions, which we believe would yield greater medication adherence. In our May 2019 final rule (see 84 FR 23832), we cited evidence suggesting that reducing medication cost yields benefits in increased patient medication adherence. Evidence indicated that increased medication out-of-pocket costs was associated with adverse non-medication related outcomes such as additional medical costs, office visits, hospitalizations, and other adverse events. Given that patient cost is such a determinant of adherence, allowing the patient greater access to drug cost information, independent of their prescriber, should improve medication adherence. Further, research shows that when patients play an active role in their health care decisions the result is increased patient knowledge, satisfaction, adherence with treatment and improved outcomes.[53] Although not all patients will chose to actively participate in treatment decisions, interactive discussions between patients and physicians are correlated with improved patient satisfaction with their health care provider.[54]

We believe that bringing all of these benefits to Part D enrollees is especially important, in light of the fact that the Medicare population is becoming increasingly comfortable with technology. According to a 2017 Pew Research Center study, some groups of seniors, particularly those who are younger, report ''owning and using various technologies at rates similar to adults under the age of 65''[55] and also characterized ''82 percent of 65- to 69-year-olds as internet users'' and found

[53] See *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1855272/*.

[54] See *https://www.ncbi.nlm.nih.gov/pubmed/11021677/*.

[55] Report is accessible at *https://www.pewinternet.org/2017/05/17/technology-use-among-seniors/*.

that 40 percent of seniors now own smartphones, ''more than double the share that did so in 2013''. As more seniors use computers and smart phones in their daily lives, they may use electronic means to research information about their prescription medications. CMS believes that the Part D program must move to accommodate those enrollees by enhancing the way that digital technologies are used in the Part D e-prescribing context. We are aware that some Part D plans have already created beneficiary portals.

The intent of this proposal is to ensure that enrollees have access to formulary and benefit information while giving plans latitude to determine how to meet this beneficiary need. We encourage Part D sponsors to explore whether a beneficiary RTBT function could be added to existing beneficiary portals with the intent of giving enrollee access to a variety of drug plan services through a single secure portal. Alternatively, if this provision is finalized, Part D plans could also create dedicated beneficiary RTBTs for use on a computer or smart phone or create a new patient portal for this purpose. We propose to allow for either of these solutions.

When developing their solutions, Part D Plans should also be mindful of ensuring their compliance with their current non-discrimination responsibilities and obligations, particularly to individuals who are deaf, hard of hearing, or blind, or who have other sensory or manual impairments.[56] Plans should be mindful of complying with current regulations at 28 CFR 36.303 45 CFR 84, 92.4, and 92.202. In addition, should this proposal be finalized, Part D Plans should ensure that beneficiaries without computer or smart phone access can retrieve the same formulary and benefits information available on the beneficiary RTBT via calling the Plan's call center. We believe that this is important to help guarantee that all Part D enrollees have equal access to the information on the beneficiary RTBT.

Currently, enrollees in Part D can use a number of tools to access prescription drug information for their particular plan, but the tools do not offer the advantages of a beneficiary RTBT. Blue Button 2.0 is an application programming interface that provides traditional Medicare beneficiaries with cost and beneficiary information after those expenses are incurred. By contrast, the beneficiary RTBT would provide the information before the expenses are incurred, so that beneficiaries and prescribers can have meaningful conversations about their medications before choosing the most appropriate medication. The Medicare Plan Finder (MPF) (*https://www.medicare.gov/find-a-plan/questions/home.aspx*) is a web tool that is available to the public. The web tool allows beneficiaries to make informed choices about enrolling in Part D plans by comparing coverage options based on the plans' benefit package (PBP), premium, formulary, pharmacy, and pricing data. Beneficiaries also use the MPF to evaluate their estimated annual out-of-pocket drug costs at the selected pharmacies from those pharmacies available in their area. These tools are powered by the data Part D sponsors submit to CMS and its contractors. In addition, the web tool also shows the plans' Star Ratings, which can be used by beneficiaries to evaluate quality and performance of available plans.

Part D plan enrollees can also access helpful information by viewing plan websites, which contain their current plan formularies, including the drug tiers and any PA requirements. Enrollees can use these tools to predict cost sharing for the medication selected.

Although the aforementioned tools are helpful, neither the MPF nor plan websites identify drug-specific formulary alternatives for enrollees, nor can they provide beneficiary-specific PA information. For example, a plan may have a PA requirement on a drug and that requirement would be listed on the online formulary and in MPF. However, if a PA request for a drug for a particular beneficiary has already been approved and additional PA is not required for that enrollee, he or she could not ascertain that information unless they call the plan. Similarly, as beneficiary costs vary depending upon the benefit phase, the costs included on MPF and plan websites may not accurately reflect beneficiary-specific out-of-pocket costs based on the applicable phase of the benefit phase that the beneficiary is in at that point in time. Although we are proposing that plans can use similar formulary and benefit information to implement both a prescriber and a beneficiary RTBT, we recognize that there would be inherent differences in the way that each real time benefit tool will be used, and each tool raises different concerns. First, the end user of the beneficiary RTBT would be the beneficiary, and since the data would not be passed on from the beneficiary RTBT to another system, we believe that the information released would have to be information that is understandable to the average patient and that can be of use to them in their interactions with their provider, whereas the information from the prescriber RTBT would be information that is understandable to prescribers. Second, there are not any different standards available for a beneficiary tool, since plans can use their own portals or computer applications for the beneficiary RTBT, and a standard is only required when information flows to another system. We invite comment on these issues.

We understand that, generally, most enrollees may not have the clinical background required to accurately discern the clinical appropriateness of the alternatives that would be presented to a prescriber using an RTBT. We realize that there may be occasions where certain drugs, for example certain antibiotics which are ''drugs of last resort'' that are typically reserved for instances in which the patient is found to have certain drug-resistant infections, or instances in which side-effects are such that a given prescription would not typically be selected in the absence of countervailing risks that would justify risking such side-effects, or instances in which there would be interactions with other drugs already used by the beneficiary that would contra-indicate prescribing a given drug. In these and other clinically appropriate instances, we believe it may be appropriate to omit certain drugs from what is presented to the user of a beneficiary RTBT. Furthermore, where there are many potential prescriptions that could be presented to the beneficiary through an RTBT for a given condition, and those drugs fall exclusively in a small number of classes or categories of drugs, it may be appropriate to allow the RTBT to present those classes or categories rather than requiring the listing of every medication for that condition as it may be overly burdensome for Part D sponsors to do otherwise, and confusing for enrollees. Thus, in order to address these and other clinically appropriate scenarios, we propose that Part D sponsors would be permitted to have their Pharmacy and Therapeutics (P & T) committees evaluate whether certain medications should be excluded from the beneficiary RTBT. P & T committees should exclude medications from the beneficiary RTBT if any of the following criteria are met: (1) The only formulary alternatives would have significant negative side effects for most enrollees and the drug would not typically be a practitioner's first choice for treating a given condition due to those side effects, (2) for cases where medications

[56] These responsibilities and obligations include compliance with Title VI of the Civil Rights Act of 1964, sections 504 and 508 of the Rehabilitation Act, the Age Discrimination Act, and section 1557 of the Affordable Care Act.

are considered to be ''drugs of last resort,'' (3) instances in which there would be interactions with other drugs already used by the beneficiary that would contra-indicate prescribing a given drug, or (4) other clinically-appropriate instances.

We propose to allow these exceptions to what should be provided to beneficiary RTBTs, since we believe that it will help ensure that beneficiaries have reasonable access to information about the viable alternatives for treating their conditions which will increase transparency about drug alternatives over what is currently available, while addressing what we believe are reasonable policy concerns about the potential ill-effects of providing unfiltered information to consumers. We note that this would only be appropriate in limited circumstances. In order to provide the most appropriate decision support to beneficiaries, we propose at this time to defer to plans and their medical professionals to choose which medication options should be presented in the beneficiary RTBT, but we would monitor for improper use of this discretion, and would propose changes if this discretion is found to be abused. Alternatives must only be excluded based only on clinical appropriateness, not based on any cost implications to the beneficiary or plan. By contrast, prescriber RTBTs must show all medication alternatives, since prescribers have the ability to discern which medications can appropriately treat the specific issues and what their side effects could be.

Should this proposal be finalized, if plans do not populate the beneficiary RTBT with all options, Part D plans would be required to indicate to the Part D enrollee that not all potential medication options are included and the rationale for why not all options were included. Although we recognize that in some cases information presented through RTBT would thereby differ for beneficiaries and providers, we believe that the provider would be positioned to explain the differences if they are brought to the providers' attention. We propose that the fact that a beneficiary received a curated listing of options would need to be prominently shown in the human-readable output of the technology used by the beneficiary to access the formulary and benefit information, such as on the screen viewed through a patient portal or computer application or the print out generated using such portal or application.

However, we want to clarify that the data that we are proposing to require be provided in the beneficiary RTBT must be patient-specific, clinically appropriate, timely, and accurate, and must be devoid of commercial purposes that would adversely impact the intended functionality of promoting cost-effective beneficiary and prescriber selections of drugs. Such improper commercial purposes would include the presentation of advertising in the beneficiary RTBT, outputs that are intended to promote choices based on the commercial interests of the part D sponsor rather than the beneficiary's best interests, or the promotion of medications or refills based on the rebates that would be received. We also would consider it a best practice, should the proposal be finalized, for beneficiary RTBTs to include cost-sharing amounts for medications if purchased at a pharmacy selected by the beneficiary, provided the pharmacy is in the plan's network. Sponsors would also be allowed to provide cost data for alternative pharmacies in the plan's network. However, due to concerns with enrollees being improperly steered to different pharmacies, we are not proposing to require that beneficiary RTBTs include pharmacy-specific cost sharing information.

In order to support maximum transparency, CMS also encourages plans to show each drug's negotiated price (as defined in § 423.100) in the beneficiary RTBTs in addition to the requirement to reflect the beneficiary's out-of-pocket cost information at the beneficiary's currently chosen pharmacy. Alternatively, if the beneficiary RTBT does not show the negotiated price, we would encourage plans to provide additional cost data comparing the beneficiary and plan cost comparisons for each drug and its alternatives. For example, if Drug A has beneficiary cost sharing of $10 and the plan pays $100, and Drug B also has a beneficiary cost sharing of $10 but the plan only pays $90, the beneficiary RTBT would reflect a difference of $0 for cost sharing and −$10 in comparative plan cost for Drug B. Providing data such as negotiated price or comparative plan costs would provide beneficiaries with a better understanding of the price differences between alternative drugs and could help provide beneficiaries with information on potential clinically appropriate alternatives that could steer a discussion with their clinician and provide the biggest savings to the beneficiary and potentially lower Part D costs overall. Although we encourage the inclusion of the negotiated price and other comparative information in the beneficiary RTBT, we are not proposing to require the inclusion of such information at this time. We are also not proposing this requirement at this time because we don't have research that shows learning the payer's rate will effect beneficiary choice if there is no effect on their payment amount. However, we solicit comment on this proposal.

To summarize, we propose that each Part D sponsor implement a beneficiary real time benefit tool that will allow enrollees to view a plan-defined subset of the information included in the prescriber RTBT, which includes accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including enrollee cost-sharing information, clinically appropriate formulary alternatives, subject to the aforementioned exceptions, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug), no later than January 1, 2022. Plans are encouraged, but would not be required, to include the negotiated price. Plans could meet this proposed requirement by using existing or new secure patient portals, or an application or other technology. We seek feedback on this proposal, including if any further limitations should be imposed, what type of information should be included in the beneficiary RTBT, and the value of this tool being in the hands of the beneficiary and the prescriber.

In addition, in order to encourage enrollees to use the beneficiary RTBT, we propose to allow plans to offer rewards and incentives (RI) to their enrollees who use the tool. We propose to define use, for purposes of permitted RI, to mean logging onto either the portal or application or calling the plan's call center to ask for this information, without regard to whether the enrollee engages in a discussion with his or her prescriber or obtains or switches to any medication in response to such use. In other words, we propose that plans who choose to offer RI must offer it to all plan enrollees who use the tool or seek to access this information via phone and must not make RI contingent upon the medical diagnosis or the type of medication a beneficiary is taking, or upon the enrollee switching medications.

In addition, we prohibit any enrollee remuneration under the guise of RI, which includes waivers of copayments and deductible amounts and transfers of items or services for free. We also prohibit plans from offering any cash or monetary donations, under the guise of RI. However, we do allow for the use of

gift cards, as long as they are not cash equivalents and do not encourage enrollees to further patronize the plan or any of the plan's corporate affiliates. CMS considers gift cards to be used like cash, for example, a VISA or Amazon gift card, to be a ''cash equivalent.'' Cash equivalents also may include, for example, instruments convertible to cash or widely accepted on the same basis as cash, such as checks and debit cards. This means that gas cards or restaurant gift cards would be permitted. However, a gift card that can be used for goods or services purchased from the plan would be prohibited, since that could incentivize enrollment in plans that could provide gift cards that enrollees could use at pharmacies or retail stores owned by their plan, rather than at a third-party establishment owned by a different company.

In addition, we seek to minimize risks of violations of the Federal anti-kickback statute and compromising the integrity of the program.

We also propose that the RI be of nominal value, which OIG guidance specifies as no more than $15 per login or $75 in the aggregate annually, in accordance with OIG guidance.[57] We also propose that the member can receive a RI for no more than one login per month. Should this proposal be finalized, this expense would have to be included as an administrative expense in the bids of Part D sponsors. We would prohibit it from being considered a drug cost. We seek comments on these limitations and on how we can ensure that these RIs will not be indirectly provided or funded by pharmaceutical manufacturers. We also seek comments on safeguards to mitigate risks of fraud and abuse with respect to these incentives.

MA–PDs are already permitted to offer rewards and incentives for Part C benefits under our regulation at § 422.134, which permits plans to offer health-driven rewards and incentives that are designed to encourage enrollees to participate in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources. We propose to adopt Part C's ban at § 422.134(b) on discrimination for Part D RI that plans offer to encourage the use of the beneficiary RTBT. We therefore propose to require that if a plan offers RI, it must be available to all of the plan's enrollees that log into the plan's portal or call the plan's call center, regardless of the enrollee's race, national origin, gender, disability, chronic disease, health status, or basis prohibited by any applicable law.

Our statutory authority to allow RI for beneficiary RTBT stems from section 1860D–4(c)(1)(A) of the Act, which requires Part D sponsors to have in place, directly or through appropriate arrangements, a cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate. We believe that an RI program for beneficiary RTBTs could be part of the plan's effective UM program, since they help inform and remind Part D enrollees about their utilization management requirements for their medications and provide them with alternatives that may be more appropriate for enrollees' individual health and budgetary needs. As a result, we believe that this provision would fall under the utilization management provisions of the Act. Previously, CMS has solicited comment from Part D sponsors about whether allowing rewards and incentives in Part D would be beneficial.[58] Specifically, we asked for input on the kinds of RI Program(s) Part D sponsors would propose to offer enrollees, the level of incentives Part D sponsors believe would be necessary to achieve positive outcomes for beneficiaries, such as medication adherence, and how to mitigate any concerns about a sponsor potentially selecting healthier beneficiaries for rewards. Commenters expressed interest in allowing for RI under Part D, and offered a variety of different suggestions about the types of rewards to incent enrollees. However, we did not receive suggestions about how to mitigate concerns about sponsors potentially selecting healthier beneficiaries for rewards.

Over the past several years, plans and vendors have written CMS to express their interest in allowing RI under Part D. In addition, CMS has obtained additional information demonstrating that RI can positively impact beneficiaries' health-related choices by increasing medication adherence and encouraging beneficiaries to choose lower-cost alternative medications.[59] [60] [61] [62] Since the objectives of the beneficiary RTBT so closely align with these goals, we believe that allowing Part D plans to offer RI for beneficiary RTBT usage would further incentivize beneficiaries to use the RTBT, while providing CMS the opportunity to further review the impact of RI under Part D by examining the differences in costs and beneficiary behavior between plans that use RI versus plans that do not. We propose to add this provision to our regulations at § 423.128 by amending paragraph (d) to add paragraphs (a)(4) and (5). Paragraph (a)(4) would address the beneficiary RTBT and paragraph (a)(5) would address the rewards and incentives for use of the beneficiary RTBT. We believe that this proposal fits under § 423.128, since it is consistent with the requirements under that provision to increase transparency to Part D enrollees. We believe that this new tool would enhance the existing disclosures by providing another means for Part D enrollees to access the information.

H. Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

Section 1860D–12(b)(3)(D) of the Act provides broad authority for the Secretary to add terms to the contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary with information as the Secretary may find necessary and appropriate. Pursuant to our statutory authority, we codified these information collection requirements for Part D sponsors in regulation at § 423.514.

Section 423.514(a) requires each Part D sponsor to have a procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, statistics indicating the following: (1) The cost of its operations; (2) the patterns of utilization of its services; (3) the availability, accessibility, and acceptability of its services; (4) information demonstrating it has a fiscally sound operation; and (5) other matters as required by CMS.

[57] *Office of Inspector General Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries*, Office of Inspector General (2016).

[58] See the 2014 Call Letter, available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Announcement2014.pdf.*

[59] *The Effectiveness of Financial Incentives for Health Behaviour Change: Systematic Review and Meta-Analysis Giles EL, Robalino S, McColl E, Sniehotta FF, Adams J (2014) The Effectiveness of Financial Incentives for Health Behavior Change: Systematic Review and Meta-Analysis.* PLOS ONE 9(3): e90347. *https://doi.org/10.1371/journal.pone.0090347.*

[60] *Personal financial incentives for changing habitual health-related behaviors: A systematic review and meta-analysis.* Mantzari, Eleni, et al. *Preventive medicine* 75 (2015): 75–85.

[61] *Acceptability of financial incentives for health behavior change to public health policymakers: A qualitative study*, Giles, Sniehotta, et al. *BMC Public Health* (2016).

[62] *A Simulation Modeling Framework to Optimize Programs Using Financial Incentives to Motivate Health Behavior Change* Basu, Kiernan *Medical Decision Making* (2016).

We established the Part D reporting requirements to monitor the prescription drug benefit to ensure a safe, consistent and fair experience for beneficiaries purchasing medication through the Part D prescription drug program. These data have successfully enabled us to respond to questions about the Part D program and to identify Part D sponsors that are not operating in an equitable manner in regard to their respective enrollees and not in compliance with specific contractual terms required by the Medicare Part D program. Consistent with § 423.514(a), the reporting requirements program requires Part D sponsors to report a set of performance measures either annually or quarterly providing an element of transparency to the Part D program as many of the performance measures' results are made public. Over time we have added or retired reporting requirements and any corresponding data elements as our needs to evaluate the program evolved. New reporting sections and changes to the data elements are proposed for public comment in the **Federal Register** and approved through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process. The current Part D reporting requirements (OMB 0938–0992) may be accessed at: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html*.

We propose to amend the regulatory language at § 423.514(a) to establish a requirement for Part D sponsors to disclose to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreement. Collecting pharmacy performance measures used to determine whether a financial reward or penalty is incurred by a pharmacy after the point-of-sale (POS) will enable CMS at a minimum to better understand the extent to which the measures are applied, whether it be uniformly or specific to pharmacy type. This effort may also explain if there is a pharmacy performance problem, as pharmacy price concessions (financial penalties incurred) after the POS have continued to grow annually. Knowledge of the industry's pharmacy performance measures would also provide transparency to the process and likely confirm or dispel the idea that many of the measures may not provide appropriate metrics across all types of pharmacies. Given the growing use of pharmacy performance measures in determining the final cost of a drug under Part D and the impact of these recoupment practices on the amount a beneficiary pays for a Part D drug at the POS, we believe this information to be essential if there is to be predictable reimbursement for pharmacies and cost sharing for beneficiaries.

Once collected, CMS would publish the list of pharmacy performance measures to increase public transparency. The public would benefit from the release of this information because pharmacy services are expanding, and therefore, it is imperative to measure the care provided. Quality measures can document a pharmacy's contribution to value-based care and incentivize high quality care. We believe collecting this information is the right thing to do for patients and our healthcare system. Standardized pharmacy measures bring value and relevance to patient care and cost management. In addition, this supports collaboration and consensus within the pharmacy industry. Collected data elements would be limited to those necessary to identify and understand each measure and how it is applied by pharmacy type, if applicable and may include:

- Name of the performance measure
- Performance calculation methodology
- Success/failure threshold(s)
- Financial implications of success/failure to achieve threshold(s)
- Pharmacy appeal requirements; and
- Method of payment of collection

We may also consider collecting retrospective information on the number of pharmacies by pharmacy type, if applicable that achieved established success/failure thresholds and average scores or other statistics for each measure. If this proposal is finalized, the actual Part D reporting requirements data elements (consistent with our adopted standard), timeline, and method of submission would then be proposed through the OMB PRA process after publication of the final rule. We normally seek comment on a new information collection and its associated burden through rulemaking, however, we believe the best approach is to have the industry first begin to develop, test and achieve a consensus on the measures themselves, via a measure developer. Then, we would provide an opportunity for the industry to comment on more specific data collection instruments via notices in the **Federal Register**. This encourages collaboration and consensus within the industry and promotes alignment across the pharmacies and plans. We would also have the opportunity to gather initial feedback on the actual data elements in response to this proposal.

We encourage the industry to continue to work together on developing a set of pharmacy performance measures through a consensus process and Part D sponsors to adopt such measures to ensure standardization, transparency and fairness. We also encourage Part D sponsors to use a third party, independent organization that is free of conflict of interest to assess pharmacy performance on such measures (including data aggregation, development of measure thresholds and cut points, and definition of applicable pharmacy types for each measure). We are aware that the Pharmacy Quality Alliance (PQA), a measure developer, hosted a consensus building workshop in early 2019 and hosted an all-member webinar in late August 2019 to share the results of the workshop to build consensus across pharmacy, plan, PBM, and other stakeholders to create a standard set of feasible, valid, and reliable measures that could be used in plan-pharmacy agreements in Medicare Part D. The participants reached consensus on an approach to prioritize the development of measures in the short, medium, and long term. The PQA plans to re-specify certain plan-level measures at the pharmacy-level and to create new pharmacy-level measures. The short term pharmacy-level measure specifications and testing may be complete in early 2020 for the 2021 contract year. We are encouraged by the progress being made by the industry to establish a consensus set of pharmacy performance measures and encourage the industry to keep us apprised of their efforts in this area.

We recommend that pharmacy performance measures established for use in Part D adhere to the following principles. The measures should—

- Improve medication use and outcomes for the beneficiaries served;
- Be specified at the right level of attribution and appropriate level of comparison considering pharmacy type;
- Factor in both pharmacy accountability and drug plan performance goals;
- Have clear specifications and be established prior to the measurement period;
- Be reliable, transparent and fair; and
- Use threshold minimums if appropriate.

In the future, CMS may develop measures to consider for use in the Part D Star Ratings that, for example, assess Part D plan sponsors' uptake of a standard set of pharmacy performance measures or that evaluate the percent of high-performing pharmacies in the sponsors' pharmacy network.

We solicit comment on the principles that Part D pharmacy performance measures should adhere to, including potential burden or hardship of performance measures on small, independent, and/or rural pharmacies, and recommendations for potential Part D Star Ratings metrics related to these measures. Finally, we solicit comment on the data elements, timeline, and method of submission for the reporting of pharmacy performance measures.

I. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

1. Background

Section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amended section 1857(e) of the Act to add a medical loss ratio (MLR) requirement to Medicare Part C (MA program). An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. In the May 2013 Medicare MLR final rule, which codified the MLR requirements for Part C MA organizations and Part D sponsors (including organizations offering cost plans that offer the Part D benefit) in the regulations at 42 CFR part 422, subpart X and part 423, subpart X. In the April 2018 final rule (83 FR 16440), we changed certain aspects of the MLR calculation and revised the reporting requirements.

For contracts for 2014 and later, MA organizations and Part D sponsors are required to report their MLRs and are subject to financial and other sanctions for a failure to meet the statutory requirement that they have an MLR of at least 85 percent (see §§ 422.2410 and 423.2410). The statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination. The minimum MLR requirement creates incentives for MA organizations and Part D sponsors to reduce administrative costs, such as marketing costs, profits, and other uses of the funds earned by plan sponsors, and helps to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health and drug plans.

This proposed rule sets forth our proposed changes to the incurred claims portion of the MLR numerator for MA contracts. We are also proposing to codify the current definitions of partial, full, and non-credibility and the credibility factors for MA and Part D contracts, and to add a deductible factor for MA MSA contracts.

2. Regulatory Changes to Incurred Claims (§ 422.2420)

Section 422.2420(a) of the regulations sets forth a high-level definition of the MLR as the ratio of the numerator, defined in paragraph (b), to the denominator, defined in paragraph (c). In general, MA costs are in the numerator and revenues are in the denominator. Section 422.2420(b)(1) identifies the three components of the MLR numerator for MA contracts that are not MSA contracts: (1) Incurred claims (as defined in paragraphs (b)(2) through (4)); (2) the amount of the reduction, if any, in the Part B premium for all MA plan enrollees under the contract for the contract year; and (3) expenditures under the contract for activities that improve health care quality, which are described in detail at § 422.2430. For MA MSA contracts, the three components of the MLR numerator are (1) incurred claims (as defined in paragraphs (b)(2) through (4)); (2) expenditures under the contract for activities that improve health care quality; and (3) the amount of the deposit into the Medicare savings account for MSA enrollees. Our proposal is to revise the regulation text regarding the incurred claims portion of the numerator.

Under current § 422.2420(b)(2)(i), incurred claims include direct claims that the MA organization pays to providers (including under capitation contracts) for covered services (described at paragraph (a)(2) of that section) that are provided to all enrollees under the contract. Section 422.2 defines a ''provider'' for purposes of the MA regulations as any individual or entity that is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the state, or to deliver those services if such licensing or certification is required by State law and regulation. Per § 422.2420(a)(2), ''covered services'' are the benefits defined at § 422.100(c): basic benefits, mandatory supplemental benefits, and optional supplemental benefits.

As explained in greater detail in sections II.A. and VI.F. of this proposed rule, CMS is proposing to revise the regulations at § 422.100 to codify subregulatory guidance and statutory changes that have expanded the types of supplemental benefits that MA plans may include in their plan benefit packages (PBPs). The proposed amendment to § 422.100(c)(2) would codify CMS's longstanding interpretation of the statute to require a supplemental benefit to be an item or service (1) that is primarily health related, such that the benefit diagnoses, compensates for physical impairments or acts to ameliorate the functional or psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization; (2) for which the MA organization incurs a non-zero direct medical cost; and (3) that is not covered by Medicare Parts A, B, or D. In the contract year (CY) 2019 Call Letter, issued on April 2, 2018, CMS announced that we reinterpreted the scope of the ''primarily health related'' supplemental benefit definition. Under this reinterpretation, to be considered ''primarily health related,'' a supplemental benefit must focus directly on an enrollee's health care needs and should be recommended by a licensed medical professional as part of a health care plan, but it need not be directly provided by one. As part of proposed § 422.100(c)(2), to account for the types of supplemental benefits that may be offered under the policy changes addressed in sections II.A. and VI.F. of this proposed rule, CMS is also proposing specific provisions to address permissible supplemental benefits that are not primarily health related and for which the non-zero direct cost incurred must be a non-administrative direct cost (if it is not a medical cost).

In proposed § 422.102(f), we are proposing to codify regulation text implementing amendments made by the BBA of 2018 to section 1852(a)(3) of the Act to expand the types of supplemental benefits that may be offered to chronically ill enrollees, starting in contract year 2020. Under paragraph (D) of section 1852(a)(3) of the Act, as added by the BBA of 2018, MA organizations may provide SSBCI that are not primarily health related to chronically ill enrollees, as long as the item or service has the reasonable expectation to improve or maintain the chronically ill enrollee's health or overall function.

Under § 422.2420(b)(2)(i) of the MA MLR regulations, incurred claims in the MLR numerator include direct claims paid *to providers* for covered services furnished to all enrollees under an MA contract. The amendment to section 1852(a)(3)(D) of the Act has expanded the types of supplemental benefits that can be ''covered services'' under an MA plan. The proposal to implement that change at § 422.102(f) and the continuation of our policy for establishing what it means for a benefit

to be primarily health related both mean that permissible supplemental benefits might include items and services that would not typically be furnished by an individual or entity that is a ''provider'' as defined at § 422.2. A provider, as defined in § 422.2, is an individual or entity engaged in the delivery of health care services and who is licensed or certified by the State to engage in that activity in the State. To ensure that amounts that an MA organization pays for covered services to individuals or entities that are not health care providers are included in incurred claims under current § 422.2420(b)(2)(i), we propose to amend the regulation to remove the specification that incurred claims are payments to providers for covered services.

If incurred claims do not include amounts an MA organization pays to individuals or entities that are not providers for supplemental benefits, including SSBCI, under current rules these expenditures could still potentially be included in the MLR numerator as expenditures related to quality improvement activities (QIAs). To be considered QIA-related expenditures under § 422.2430, the benefit must be an activity that falls into one or more of the categories listed in paragraph (a)(2) of that section, and it must be designed for the purposes listed in paragraph (a)(3): (1) To improve health quality; (2) to increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results; (3) to be directed toward individual enrollees, specific groups of enrollees, or other populations as long as enrollees do not incur additional costs for population-based activities; and (4) to be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations. Although we believe that supplemental benefits that meet the expanded ''primarily health related'' standard at proposed § 422.100(c)(2)(ii)(A) and non-primarily health related SSBCI described at proposed § 422.102(f) could potentially qualify as QIAs under § 422.2430, whether a particular benefit met all of the requirements of that regulation would need to be determined on a case-by-case basis. With our proposal, this case-by-case determination would no longer be necessary for services that are covered under the plan benefit package offered by an MA plan pursuant to the statute and regulations governing the MA program; all expenditures for covered services would be included in the incurred claims portion of the MLR numerator.

We believe that including in the MLR numerator amounts MA organizations spend on supplemental benefits that meet the ''primarily health related standard'' at proposed § 422.100(c)(2)(ii)(A) and on non-primarily health related SSBCI under proposed § 422.102(f) is consistent with the purpose of the MA MLR requirement. As explained in the May 2013 Medicare MLR final rule adopting the MLR regulations (78 FR 31284), the MLR requirement creates an incentive for MA organizations to reduce administrative costs such as marketing costs, profits, and other uses of plan revenues, and to help ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans.

In order to ensure that the MLR numerator includes amounts MA organizations spend on supplemental benefits that are ''primarily health related'' under proposed § 422.100(c)(2)(ii)(A) and on non-primarily health related SSBCI under proposed § 422.102(f), we propose to modify the regulation at § 422.2420(b)(2)(i) to remove the specification that incurred claims are direct claims that an MA organization pays *to providers* for covered services provided to all enrollees under the contract. We also propose to remove the specification that incurred claims include payments under capitation contracts *with physicians.* Finally, we propose to replace the phrase ''direct claims,'' which customarily refers to billing invoices providers submit to payers for reimbursement, with the general term ''amounts.'' As amended, § 422.2420(b)(2)(i) would include in incurred claims all amounts that an MA organization pays (including under capitation contracts) for covered services, regardless of whether the recipient of the payment is a provider as defined in § 422.2. Including in incurred claims amounts spent on these expanded supplemental benefits, as proposed, avoids creating uncertainty over whether payments for such services could otherwise be included in the MLR numerator (for example, as QIA-related expenditures), and it is consistent with our determination in the May 2013 Medicare MLR final rule (78 FR 31289) that incurred claims should reflect the benefit design under the contract.

3. Codifying Current Definitions of Partial, Full, and Non-Credibility and Credibility Factors (§§ 422.2440 and 423.2440)

The regulations at §§ 422.2440 and 423.2440 provide for the application of a credibility adjustment to the medical loss ratios (MLRs) of certain MA and Part D contracts with relatively low enrollment. A credibility adjustment is a method to address the impact of claims variability on the experience of smaller contracts by adjusting the MLR upward. As discussed in the February 23, 2013 Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (78 FR 12428, 12438) (hereinafter referred to as the ''February 2013 Medicare MLR proposed rule''), for contracts with fewer members, random variations in the claims experience of enrollees could cause a contract's reported MLR to be considerably below or above the statutory requirement in any particular year, even though the MA organization or Part D sponsor estimated in good faith that the combination of the projected revenues and projected claims would produce an MLR that meets the statutory 85 percent minimum MLR requirement. The MLR credibility adjustments address the effect of this random variation by increasing the MLR of smaller contracts, thereby reducing the probability that such contracts will fail to meet the minimum MLR requirement simply because of random claims variability.

Whether a contract receives a credibility adjustment depends on the extent to which the contract has credible experience. A contract with credible experience is one that covers a sufficient number of beneficiaries for its experience to be statistically valid. A contract with fully credible experience has sufficient data to expect that the statistical variation in the reported MLR is within a reasonably small margin of error and will not receive a credibility adjustment under §§ 422.2440(b) and 423.2440(b). A contract has non-credible experience if it has so few beneficiaries that it lacks valid data to determine whether the contract meets the MLR requirement. Under §§ 422.2440(c) and 423.2440(c), a contract with non-credible experience is not subject to sanctions for failure to meet the 85 percent MLR requirement. A contract has partially credible experience if it exceeds the enrollment threshold for non-credible experience but does not have a sufficient number of enrollees for its experience to be fully credible. For contracts with partially credible

experience, a credibility adjustment adds additional percentage points to the MLR in recognition of the statistical unreliability of the underlying data.

In the May 2013 Medicare MLR final rule (78 FR 31284, 31295–96), CMS published the definitions of partial, full, and non-credibility and the credibility factors for partially credible MA and Part D contracts for contract year 2014. The factors appear in proposed Table 1 to § 422.2440 and proposed Table 1 to § 423.2440. Consistent with that final rule and regulations at §§ 422.2440 and 423.2440, for contract years 2015 through 2020, we have finalized through the annual Advance Notice and Rate Announcement process the continued use of these definitions and credibility factors.

We believe that the definitions of partial, full, and non-credibility and the credibility factors published in the May 2013 Medicare MLR final rule continue to appropriately address the effect of random claims variability on the MLRs of low enrollment MA and Part D contracts. However, we believe that it is more consistent with the policy and principles articulated in Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (October 9, 2019) that we define and publish the definitions of partial, full, and non-credibility and the credibility factors in the **Federal Register**, and that we codify these definitions and factors in the Code of Federal Regulations, as opposed to defining and publishing these terms and factors through the annual Advance Notice and Rate Announcement process. Therefore, we are proposing to amend the regulations at §§ 422.2440 and 423.2440 to codify in regulation text the definitions of partial, full, and non-credibility and the credibility factors that CMS published in the May 2013 Medicare MLR final rule (78 FR 31296). First, we propose to amend paragraph (d) of §§ 422.2440 and 423.2440 by removing the current text (which states that CMS will define and publish definitions of partial, full, and non-credibility and the credibility factors through the annual Advance Notice and Rate Announcement process) and adding new paragraphs (d)(1) through (3) to specify ranges for the number of member months at which a contract's experience is, respectively, partially credible, fully credible, or non-credible. We propose that the number of member months at which a contract's experience is defined as partially credible, fully credible, or non-credible be the same as the values that were used define each of those terms in the May 2013 Medicare MLR final rule. Thus, for MA contracts, we propose that a contract is partially credible if it has at least 2,400 member months and fewer than or equal to 180,000 member months, fully credible if it has more than 180,000 member months, and non-credible if it has fewer than 2,400 member months. For Part D contracts, we propose that a contract is partially credible if it has at least 4,800 member months and fewer than or equal to 360,000 member months, fully credible if it has more than 360,000 member months, and non-credible if it has fewer than 4,800 member months. We propose to amend paragraphs (a), (b), and (c) of both §§ 422.2440 and 423.2440 by removing the text which provides that CMS determines whether a contract's experience is partially credible, fully credible, or non-credible, respectively, and by adding new language specifying that partially credible experience is defined at (d)(1), fully credible experience is defined at (d)(2), and non-credible experience is defined at (d)(3).

At § 422.2440, we propose to add new paragraph (e) to address the credibility adjustment for partially credible contracts. We propose at paragraph (e)(1) that, for partially credible MA contracts other than MSA contracts, the credibility adjustment is the base credibility factor determined under proposed paragraph (f). At proposed paragraph (f), we propose to specify that the base credibility factor for a partially credible MA contract is determined based on the number of member months and the factors in proposed Table 1 to § 422.2440. Proposed paragraph (f) also states the rules for using proposed Table 1 to § 422.2440 to identify the base credibility factor: (i) When the number of member months for a partially credible MA contract exactly matches the amount in the ''Member months'' column in proposed Table 1 to § 422.2440, the value associated with that number of member months is the base credibility factor; and (ii) the base credibility factor for a number of member months between the values shown in proposed Table 1 to § 422.2440 is determined by linear interpolation.

At § 423.2440, we propose to add new paragraph (e), which provides that for partially credible Part D contracts, the applicable credibility adjustment is determined based on the number of member months and the factors in proposed Table 1 to § 423.2440. Proposed paragraph (e) states the rules for using proposed Table 1 to § 423.2440 to identify the base credibility factor: (1) When the number of member months used to determine credibility exactly matches a member month category listed in proposed Table 1 to § 423.2440, the value associated with that number of member months is the credibility adjustment; and (ii) the credibility adjustment for a number of member months between the values shown in proposed Table 1 to § 423.2440 is determined by linear interpolation.

To illustrate linear interpolation, if the number of member months for an MA contract falls between two values in proposed Table 1 to § 422.2440, the base credibility factor would be calculated by first determining where, by percentage of the difference between those two values, the number of member months falls. Thus, if an MA contract has 10,000 member months, its number of member months falls 66.7 percent of the way between 6,000 and 12,000 (equal to $(10{,}000 - 6{,}000) \div (12{,}000 - 6{,}000)$). This percentage is multiplied by the difference between the base credibility factors corresponding to the number of member months in proposed Table 1 to § 422.2440; $0.667 * (0.053 - 0.037) = 0.011$. To find the base credibility factor, this amount is subtracted from the factor corresponding to the lower number of member months in proposed Table 1 to § 422.2440. Thus, $0.053 - 0.011$ is equal to 0.042, or 4.2 percent, which is the base credibility factor for an MA contract with 10,000 member months.

4. Deductible Factor for MA Medical Savings Account (MSA) Contracts (§ 422.2440)

We are proposing to include in the MLR calculation an additional adjustment factor for MA medical savings account (MSA) contracts that receive an MLR credibility adjustment. Specifically, we are proposing that the credibility adjustment for partially credible MA MSA contracts will be calculated by multiplying the applicable base credibility factor in proposed Table 1 to § 422.2440 by a ''deductible factor.'' This additional adjustment for MA MSAs is intended to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles, with high cost or outlier claims representing a larger portion of the overall claims experience of plans with high deductibles. As a result, a contract with a high average deductible is more likely to report a low MLR than is a contract with the same number of enrollees but with a low average deductible. As under the commercial MLR rules, the proposed deductible-based adjustment would only apply to contracts that receive a credibility adjustment due to low enrollment. We believe that a

contract with experience that is fully credible has sufficient data to expect that the statistical variation in the reported MLR is within a reasonably small margin of error, regardless of the deductible level.

As explained in the February 2013 Medicare MLR proposed rule (78 FR 12428), CMS used the MLR rules that apply to issuers of employer group and individual market private insurance (referred to hereafter as the ''commercial MLR rules'') as a reference point for developing the MLR rules for MA and Part D (referred to hereafter as the ''Medicare MLR rules''). We sought to align the commercial and Medicare MLR rules in order to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes, including by Medicare beneficiaries. However, we recognized that some areas of the commercial MLR rules would need to be revised to fit the unique characteristics of the MA and Part D programs. One way in which the Medicare MLR rules currently deviate from the commercial rules is the omission of a deductible-based adjustment to the Medicare MLR calculation. The rationale given in the February 2013 Medicare MLR proposed rule for omitting a deductible factor from the Medicare MLR calculation was that Medicare deductibles were more confined than deductibles in the commercial market, and that we believed that the limited range of Medicare cost sharing did not prompt the need for such an adjustment (78 FR 12439).

Although we continue to believe that deductibles for most MA and Part D contracts are too low to necessitate the adoption of a deductible factor for all contracts, we now recognize that the February 2013 Medicare MLR proposed rule's rationale for excluding a deductible factor from the Medicare MLR calculation did not adequately take into account the specific characteristics of MA MSA plans, which tend to have much higher deductibles than other MA plan types. (For contract year 2020, the average deductible is $454 for MA plans (excluding MA MSAs) and $6,000 for MA MSAs.) We note that, under the commercial MLR regulations at 45 CFR part 158, a deductible factor applies to the credibility adjustment of issuers of employer group and private health insurance plans that have an average deductible of $2,500 or higher. For contract year 2020, all MA MSAs have deductibles in excess of $2,500. These significantly higher deductibles in MSA plans cause MA MSA contracts to have more variability in their claims experience relative to MA contracts with the same number of enrollees but lower deductibles. To the extent that this variability in claims experience and its potential impact on the MLR calculation has deterred MA organizations from offering an MSA product, the proposed addition of a deductible factor to the MLR calculation for MA MSAs would serve to encourage the offering of MA MSA plans by eliminating the current inconsistency in how the commercial and Medicare MLR rules take into account the greater variability of claims experience under health insurance policies with high deductibles.

The proposal to add a deductible factor to the MLR calculation for MA MSA contracts also aligns with the directive in Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors (October 3, 2019) for the Secretary to take actions that ''encourage innovative MA benefit structures and plan designs, *including through changes in regulations and guidance that reduce barriers to obtaining Medicare Medical Savings Accounts . . . .*'' (emphasis added). Currently, for many Medicare beneficiaries, the greatest barrier to enrolling in an MA MSA is the lack of MA MSA plans in the beneficiary's area of residence. For contract year 2020, MA MSA plans are only available in 27 states and the District of Columbia. The omission of a deductible-based adjustment from the current Medicare MLR regulations could contribute to the limited availability of MA MSAs for Medicare beneficiaries because the greater variability in the MLR for contracts with high average deductibles—and the resulting higher risk of a potential remittance to CMS or sanctions under § 422.2410—could dissuade MA organizations from offering plans of this type. We believe that, if the proposed change is finalized, MA organizations would be less likely to be deterred from offering MA MSAs out of concern that the MA MSA contract would be at risk of failing to meet the MLR requirement due to random variations in claims experience.

We propose to adopt the same deductible factors that apply under the commercial MLR regulations at 45 CFR part 158. As noted in the Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act Interim Final Rule (75 FR 74864, 74881–82, published December 1, 2010), the commercial deductible factors were based on an actuarial analysis of anticipated claims experience in the commercial market by actuarial consultants to the National Association of Insurance Commissioners (NAIC). Our preference is to use Medicare data to develop the deductible factors that apply to MA MSAs, and we are working to assess how to use Medicare data for this purpose. We believe that the commercial deductible factors are suitable for adjusting MSA MLRs in the absence of Medicare-specific deductible factors because the commercial factors are designed to take into account the variability in claims experience resulting from similarly high deductibles. In order to advance the use of MSAs in the MA program, we are proposing to apply the commercial deductible factors in the MLR calculation for MA MSAs. We intend to assess the feasibility of developing deductible factors using Medicare data. We solicit comment on whether and how Medicare data should be used to evaluate whether the difference in variability between MLRs for MSA plans and non-MSA plans necessitates the use of Medicare-specific deductible factors, as well as how Medicare data could be used to develop Medicare-specific deductible factors. We also solicit comment on whether and how the proposed deductible factors should be adjusted to account for any unique features of the Medicare MLR rules (for example, the inclusion of the MA MSA deposit amount in the Medicare MLR numerator and denominator), or to reflect any differences between the commercial and Medicare MLR rules (such as the commercial rules' lower minimum MLR requirement for small group and individual health insurance plans (80 percent, compared to the Medicare rules' 85 percent MLR requirement for all contracts)). We solicit comment on potential consequences of the application of a deductible factor to the MLR calculation for MA MSA contracts, such as impacts on benefits for enrollees in MSA plans.

We propose new § 422.2440(e)(2) to specify that the credibility adjustment for an MA MSA contract will be the base credibility factor determined under proposed paragraph (f), multiplied by the deductible factor determined under proposed paragraph (g). At proposed paragraph (g), we specify that the applicable deductible factor for an MA MSA contract will be based on the enrollment-weighted average deductible for all MSA plans under the contract, where the deductible for each plan under the contract is weighted by the plan's portion of the total number of member months for all plans under the contract during the contract year for

which the MLR is being calculated. (We note that all MA plans under an MA MSA contract must be MSA plans, and MSA plans may only be offered under MSA contracts.) When the weighted average deductible for a contract exactly matches the amount in the ''Weighted average deductible'' column in proposed Table 2 to § 422.2440, the value associated with that weighted average deductible is the deductible factor. The deductible factor for a weighted average deductible between the values shown in proposed Table 2 to § 422.2440 is determined by linear interpolation.

To illustrate calculation of the credibility adjustment for a partially credible MA MSA contract, if enrollment under an MA MSA totals 24,000 member months, the base credibility factor in proposed Table 1 to § 422.2440 is 2.6 percent. If the contract's weighted average deductible is $5,000, the deductible factor in proposed Table 2 to § 422.2440 is 1.402. The credibility adjustment is calculated by multiplying the base credibility factor by the deductible factor; 0.026 * 1.402 = 0.036. Thus, the credibility adjustment is 3.6 percent.

If an MA MSA contract has a weighted average deductible that falls between two values in proposed Table 2 to § 422.2440, the deductible factor is calculated by first determining where, by percentage of the difference between those two values, the weighted average deductible falls. Thus, if an MA MSA has a weighted average deductible of $8,000, its weighted average deductible falls 60 percent of the way between $5,000 and $10,000 (equal to ($8,000 − $5,000) ÷ ($10,000 − $5,000)). This percentage is multiplied by the difference between the deductible factors corresponding to the weighted average deductibles in proposed Table 2 to § 422.2440; 0.60 * (1.736 − 1.402) = 0.200. To find the deductible factor, this amount is added to the factor corresponding to the lower weighted average deductible in proposed Table 2 to § 422.2440. Thus, 1.402 + 0.2 is equal to 1.602, which is the deductible factor for a weighted average deductible of $8,000.

J. Dismissal and Withdrawal of Medicare Part C Organization Determination and Reconsideration and Part D Coverage Determination and Redetermination Requests (§§ 422.568, 422.570, 422.582, 422.584, 422.590, 422.592, 422.631, 422.633, 423.568, 423.570, 423.582, 423.584, and 423.600)

We are proposing regulations for withdrawing or dismissing Part C organization determination and reconsideration requests and Part D coverage determination and redetermination requests. We are also proposing regulations for withdrawing or dismissing Part C and Part D independent review entity (IRE) reconsiderations. A withdrawal of a request is when the party that initiated the request voluntarily decides that a decision on their request is no longer needed, and the party communicates that desire to the plan to stop consideration of the request for determination (or reconsideration). A dismissal of a request is when a plan decides to stop consideration of a request before issuing a decision. The effect of both a withdrawal and a dismissal is that the plan does not proceed with making a substantive decision on the merits of the coverage request.

Under § 422.562(d)(1), which provides that unless subpart M provides otherwise, and subject to specific exclusions set forth in paragraph (d)(2), the regulations in part 405 (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) apply to MA cases to the extent they are appropriate. Given that the dismissal requirements in § 405.952 apply to withdrawal or dismissal of a request for a redetermination (which is the first level of appeal in the Medicare fee-for-service (FFS) program), we believe the applicability of those provisions is generally limited to Part C plan level reconsiderations but not to initial organization determinations. In addition, we believe the requirements at § 405.972 are generally applicable to withdrawal or dismissal of a reconsideration by the independent review entity under the provisions of § 422.562(d)(1). For Part D requests, the regulations at part 423, subpart U, apply to cases reviewed by the Office of Medicare Hearings and Appeals (OMHA) and the Appeals Council. Currently, the Part D withdrawal and dismissal procedures applicable to Part D plan sponsors is communicated through sub-regulatory guidance.

In the absence of Part C and Part D regulations related to withdrawal and dismissal of requests that are under consideration at the plan level, we have observed through plan audits and inquiries that MA organizations and Part D plan sponsors utilize § 405.952 as a guide for handling the withdrawal and dismissal of initial requests for coverage (that is, organization determinations and coverage determinations) and plan level appeals from those decisions (that is., reconsiderations). Based on the number of inquiries CMS has received regarding withdrawal and dismissal of Part C organization determinations and reconsiderations and Part D coverage determinations and redeterminations, we are proposing rules that would apply when these procedural actions are taken. These proposals would codify what we believe to be the current practices related to dismissal of Part C organization determination and reconsideration requests and Part D coverage determination and reconsideration requests, including those applicable to the Part C and Part D IRE. The proposals would also apply to requests for integrated organization determinations and reconsiderations at §§ 422.631 and 422.633. The proposals specifically address under what circumstances it would be appropriate to dismiss a coverage request or appeal at the plan or IRE level. We are also proposing rules for how a party may request to withdraw their coverage request or appeal at the plan or IRE level. The proposed requirements would be consistent across both Part C and Part D and would be as follows:

- In proposed new §§ 422.568(g), 422.631(e), and 423.568(i), we are proposing to permit a plan to dismiss a request for the initial plan level decision (that is, organization determination, integrated organization determination or coverage determination) when any of the following apply—

++ The individual or entity making the request is not permitted to request an organization determination or coverage determination.

++ The plan determines that the individual or entity making the request failed to make a valid request for an organization determination or coverage determination.

++ The enrollee dies while the request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the organization determination or coverage determination; we note that we interpret having a financial interest in the case as having financial liability for the item(s) or service(s) underlying the coverage request.

++ The individual or entity who requested the review submits a timely written request for withdrawal of their request for an organization determination or coverage determination with the plan.

- In proposed §§ 422.570(g) and 423.570(f), we are proposing to permit a plan to dismiss an expedited organization determination or coverage determination, consistent with the proposed requirements at §§ 422.568

and 423.568, respectively. Applicability of these procedures to expedited integrated coverage determinations is described in proposed § 422.631(e).

• In proposed §§ 422.582(f), 422.633(h), and 423.582(e), we are proposing to permit a plan to dismiss (either entirely or as to any stated issue) a request for the second plan level decision (that is, reconsideration, integrated reconsideration or redetermination) when any of the following apply—

++ The individual or entity making the request is not a proper party to the reconsideration, integrated reconsideration, or redetermination under the applicable regulation; we mean this to authorize dismissal when the individual or entity making the request is not permitted to request a reconsideration, integrated reconsideration, or redetermination.

++ When the plan determines the party failed to make a valid request for a reconsideration, an integrated reconsideration, or a redetermination that substantially complies with the applicable regulation for making a valid request for reconsideration or redetermination.

++ When the party fails to file the reconsideration, integrated reconsideration or redetermination request within the proper filing time frame in accordance with the applicable regulation.

++ When the enrollee dies while the reconsideration or redetermination is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the reconsideration or redetermination. We interpret having a financial interest in the case as having financial liability for the item(s) or service(s) underlying the coverage request.

++ When the individual or entity submits a timely written request to withdraw their request for a reconsideration or redetermination.

• At new § 422.584(g), we are proposing to permit a plan to dismiss an expedited reconsideration using virtually identical language as for the proposed requirements at § 422.582. At new § 423.584(f), we are proposing to permit a plan to dismiss an expedited redetermination by cross referencing § 423.582. Applicability of these procedures to expedited integrated coverage determinations is described in proposed § 422.633(h).

• At new §§ 422.592(d) and 423.600(g), we are proposing to permit the Part C and Part D IRE to dismiss a request when any of the following apply—

++ The individual or entity is not a proper party under § 422.578(c) in the case of a Part C reconsideration or is not permitted to request a reconsideration by the IRE under § 423.600(a) in the case of a Part D reconsideration.

++ The independent entity determines the party failed to make out a valid request for a reconsideration that substantially complies with the applicable regulation.

++ When the enrollee dies while the reconsideration request is pending and the enrollee's spouse or estate has no remaining financial interest in the case and no other individual or entity with a financial interest in the case wishes to pursue the reconsideration. We interpret having a financial interest in the case as having financial liability for the item(s) or service(s) underlying the coverage.

++ When the individual or entity submits with the independent review entity a timely written request for a withdrawal of the reconsideration.

• In proposed §§ 422.568(h), 422.582(g), 422.592(e), 422.631(f), 422.633(i), 423.568(j), 423.582(f), and 423.600(h) we are proposing that written notice of the dismissal must be delivered to the parties (either mailed or otherwise transmitted) to inform them of the action; this would include the individual or entity who made the request. The notice must include certain information, as appropriate, including applicable appeal rights (that is, request to vacate dismissal, review of the dismissal).

• In proposed §§ 422.568(i), 422.582(h), 422.592(f), 422.631(g), 422.633(j), 423.568(k), 423.582(g), and 423.600(i), we are proposing that a dismissal may be vacated by the entity that issued the dismissal (that is, MA organizations, applicable integrated plans, Part D plan sponsors, and the IRE) if good cause for doing so is established within 6 months of the date of the date of the dismissal.

• In proposed §§ 422.568(j), 422.631(h), and 423.568(l), we are proposing that the dismissal of the organization determination or coverage determination is binding unless it is vacated by the MA organization, applicable integrated plan, or Part D plan sponsor, as applicable.

• At new §§ 422.582(i), 422.633(k), and 423.582(h), we are proposing that the dismissal of the reconsideration or redetermination is binding unless the enrollee or other valid party requests review by the IRE or the dismissal is vacated under the applicable regulation.

• At new §§ 422.592(g) and 423.600(j), we are proposing that a dismissal by the IRE is binding and not subject to further review unless a party meets the amount in controversy threshold requirements necessary for the right to a review by an administrative law judge or attorney adjudicator and the party files a proper request for review with the Office of Medicare Hearings and Appeals as outlined in §§ 422.600, 422.602, and 423.600(j), as applicable.

• At new §§ 422.568(k), 422.592(h), 422.631(i), 422.633(g), 423.568(m), and 423.600(f), we are proposing that a party that makes a request may withdraw its request at any time before the decision is issued by filing a written request for withdrawal. Each proposed regulation paragraph identifies the entity (that is, the MA organization, the applicable integrated plan, or the Part D plan) with which the request for withdrawal must be filed.

We are also proposing a change that applies to Part C only, given that the current rules do not include a process for an enrollee or other party to request IRE review of an MA organization's reconsideration. Specifically, we are proposing to add a new paragraph (h) to § 422.590 that would give the enrollee or another party to the reconsideration the right to request review by the independent entity of an MA organization's dismissal of a request for a reconsideration in accordance with §§ 422.582(f) and 422.584(g). We believe this proposed language is necessary because there is currently no process specified in regulation for an MA enrollee or another party to request review by the independent entity of an MA organization's reconsideration. We are also proposing at new paragraph (h) of § 422.590 that a request for review of such a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the MA organization's dismissal notice. Under existing rules at § 422.590(a)(2), (b)(2), (c)(2), (d), (e)(5), and (g),[63] if the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a reconsideration (or no later than the expiration of an applicable extension). These regulations that require a case to be automatically sent to the independent entity do not

[63] We note that § 422.590 was extensively amended by the April 2019 final rule, effective January 1, 2020.

apply in the case of a dismissal of a request for a reconsideration because the MA organization is not making a substantive decision on the merits of the request. In other words, if the MA organization dismisses a reconsideration request, this does not constitute an affirmation of an adverse organization determination decision and, therefore, the case is not subject to being automatically forwarded to the independent entity. Under the current process established through an HPMS memo issued September 10, 2013 and effective January 1, 2014, MA organizations dismiss reconsideration requests, when appropriate, and provide notice of the dismissal, including informing enrollees and other parties of the opportunity to request that the independent entity review the dismissal. The proposal to add a new paragraph (h) to § 422.590 seeks to establish in regulation the right of enrollees and other parties to request review by the independent entity of the MA organization's dismissal of a request for a reconsideration in accordance with §§ 422.582(f) and 422.584(g).

As a corollary to this proposal, we are also proposing to revise paragraph (a) of § 422.592 to state that, consistent with proposed § 422.590(h), the independent entity is responsible for reviewing MA organization dismissals of reconsideration requests. Further, we are proposing a new paragraph (i) at § 422.592 to state that the independent entity's decision regarding an MA organization's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review. Under this proposal, if the independent entity determines that the MA organization's dismissal was in error, the independent entity would vacate the dismissal and remand the case to the plan for reconsideration. In such cases, the MA organization must accept the remand from the independent entity and consider the substance of the reconsideration request. Again, this proposal is consistent with existing guidance on the processing of dismissals of requests for an MA organization reconsideration and should be familiar to MA organizations and the independent review entity.

We are also proposing a change that applies to Part D only, given that the current rules do not include a process for enrollees to request IRE review of plan sponsor dismissals of redetermination requests. Under existing rules at § 423.600(a), an enrollee may request reconsideration from the IRE of a plan sponsor's redetermination, but there is no existing regulatory mechanism for an enrollee to seek IRE review if a plan takes the procedural action of dismissing a redetermination request.

We are proposing to add a new paragraph (f) at § 423.582 to establish in regulation the right of enrollees and other parties to request review by the independent entity of the Part D plan sponsor's dismissal of a request for a redetermination. As a corollary to this proposal, we are also proposing to add paragraph (j) at § 423.590 to state that, consistent with proposed § 423.584(f), an enrollee can request review of a Part D plan sponsor's dismissal of a redetermination request by the independent entity. Further, we are proposing a new paragraph (k) at § 423.600 to state that if the independent entity determines that the Part D plan sponsor's dismissal was in error, the independent entity would reverse the dismissal and remand the case to the plan for a redetermination on the merits of the case. We believe this proposed language is necessary because there is currently no process specified in regulation for a Part D enrollee or another party to request review by the independent entity of a Part D plan sponsor's dismissal.

Although creating a process for enrollees to request IRE review of a Part D plan sponsor dismissal of redetermination request is not simply codifying current practice, we have not included a Regulatory Impact Analysis for this provision in the Collection of Information section because this change is technical in nature, but seek comment on this assumption. It aligns language for Part C and Part D. For the reasons given in the next paragraph, we believe it will have no impact.

Plan dismissals in Part D are different than plan dismissals in Part C. In Part C, a plan may dismiss an organization determination request for a number of reasons. However, Part D plan level dismissals tend to be purely administrative (for example, pertaining to a lack of proper submission). For that reason, the number of plan level dismissals in Part D is much lower than in Part C. Additionally, because Part D dismissals are administrative, in most cases it will be more prudent and expeditious for a party to resubmit their coverage determination request with the correct information than to request independent review of the dismissal. Requesting independent review of a dismissal will add increased paperwork and time. Therefore, while it is important to have parity and consistency between the regulations in FFF, Part C and Part D, we do not believe there will be many, if any, requests for independent review of Part D plan level dismissals.

These proposed rules generally mirror the current FFS rules at §§ 405.952 and 405.972 to the extent we believe is appropriate. We believe it is appropriate to base these proposed rules on the existing FFS rules related to withdrawal and dismissal of requests given the applicability, to the extent appropriate, of those rules to Part C per § 422.562(d)(1), as well as the observed current practices of both MA organizations and Part D plan sponsors. We believe that codification of these procedures will reduce confusion and promote consistent and proper handling of withdrawals and dismissals. Furthermore, we believe these proposals will be beneficial to enrollees because there will be clarity and consistency in how plans process these actions. We are not scoring this provision in the Regulatory Impact Analysis section since it codifies existing guidance, but seek comment on this assumption. We believe all stakeholders are already following the current guidance. We are also not scoring this provision in the Collection of Information section since the filing of an appeal is an information collection associated with an administrative action pertaining to specific individuals or entities and thus exempt from Paperwork Reduction Act requirements under 5 CFR 1320.4(a)(2) and (c). We welcome comments on these proposals.

We believe that the proposed addition of parallel provisions regarding dismissals and withdrawals to the integrated organization determination and integrated reconsideration procedures at §§ 422.631 and 422.633 also reflect current D–SNP operations. We seek comment, however, on whether these rules could create inconsistencies with any state-specific Medicaid procedures pertaining to dismissals or withdrawals. We note that under § 422.629(c), states have the ability through their contracts with D–SNPs to require more stringent beneficiary protections regarding timeframes and notices. We encourage commenters to consider if any Medicaid-related inconsistencies could be addressed through such contractual language and to submit comments on this topic.

We also request comment whether additional clarification or regulatory changes are necessary to ensure smooth operations for MA organizations, applicable integrated plans, or Part D plans in connection with implementing this proposal or if additional beneficiary protections need to be addressed. We believe that this proposal would streamline and standardize processes

while empowering beneficiaries in these plans to take steps to withdraw their appeals when they like. Further, by clarifying the authority for plans and IREs to dismiss coverage requests and appeals where there is no longer a financial interest for any enrollee or where the minimum standards for the content and timing of a request are not met, we hope to minimize administrative burden for plans.

K. Methodology for Increasing Civil Money Penalties (CMPs) (§§ 422.760 and 423.760)

CMS may impose civil money penalties (CMPs) on MA organizations and Part D sponsors for certain regulatory offenses, as described in subpart O of 42 CFR parts 422 and 423. Sections 1857(g)(3)(A) and 1860D–12(b)(3)(E) of the Act provides CMS with the ability to impose CMPs of up to $25,000 per determination (determinations are those which could otherwise support contract termination, pursuant to § 422.509 or § 423.510), as adjusted annually under 45 CFR part 102, when the deficiency on which the determination is based adversely affects or has the substantial likelihood of adversely affecting an individual covered under the organization's contract. The current regulations mirror the statute with respect to the amount of the penalty that CMS may impose for a per determination (contract level) penalty. Additionally as specified in §§ 422.760(b)(2) and 423.760(b)(2) CMS is permitted to impose CMPs of up to $25,000, as adjusted annually under 45 CFR part 102, for each Part D enrollee directly adversely affected or with a substantial likelihood of being adversely affected by a deficiency.

CMS has the authority to issue a CMP up to the maximum amount permitted under regulation, as adjusted annually [64] for each affected enrollee or per determination. The statute and the existing regulations afford the agency wide discretion to calculate CMPs. CMS does not apply the maximum penalty amount authorized under regulation, in all instances because the penalty amounts under the current CMP calculation methodology are sufficient to encourage compliance with CMS rules. On December 15, 2016, CMS released on its website, the first public CMP calculation methodology for calculating CMPs for MA organizations and Part D sponsors starting with referrals received in 2017. On March 15, 2019, CMS released for comment a proposed CMP calculation methodology on its website that revised some portions of the methodology released in December 2016. Subsequently, on June 21, 2019, CMS finalized the revised CMP calculation methodology document, made it available on its website, and applied it to CMPs issued starting with referrals received in contract year 2019 and beyond. CMS also indicated in the revised June 2019 CMP calculation methodology that CMS would memorialize the approach to increase minimum penalty amounts in regulation, which is specified in this proposal.[65]

CMS calculates the CMP amount for each deficiency by applying a standard formula. Under the standard formula, CMS applies a standard penalty amount (based on whether the deficiency should be calculated on a per enrollee or per determination basis) to the deficiency, and adjusts it for any factors that contributed to the deficiency (that is, aggravating factors). If the penalty for a deficiency is calculated on a per determination basis pursuant to §§ 422.760(b)(1) and 423.760(b)(1), the penalty amount is multiplied by the number of affected contracts. If a penalty for a deficiency is calculated on a per enrollee basis pursuant to §§ 422.760(b)(2) and 423.760(b)(2), the penalty amount is multiplied by the number of affected enrollees.

The Federal Civil Penalties Inflation Adjustment Act Improvement Act of 2015 (Sec. 701 of Pub. L. 114–74) requires agencies to adjust the maximum CMP amounts for inflation annually. The Office of Management and Budget (OMB) releases the cost-of-living multiplier agencies must use to calculate penalty increases for the following year.[66] CMS, however, has the discretion to set CMP amounts below the maximum amount required by law. CMS proposes increasing the per determination and per enrollee standard minimum penalty amounts and associated aggravating factors by multiplying the standard minimum penalty amounts by the cost-of-living multiplier published annually by OMB.[67]

CMS proposes to update the minimum penalty and aggravating factor amounts no more often than every 3 years. Historically, CMS has audited Part C and D organizations on a three-year audit cycle. Therefore, CMS proposes to update penalty amounts consistent with this schedule in an effort to subject organizations audited within the same audit cycle to the same penalty amounts. When the standard penalty amount is updated, CMS proposes to increase the penalty amounts that would have been applied if CMS had multiplied the standard penalty amounts by the cost-of-living multiplier each year during the preceding 3-year period. CMS also proposes to track the accrual of the standard penalty and aggravating factor penalty amounts and announce them on an annual basis. CMS proposes to codify this minimum penalty adjustment process by adding a new paragraph (b)(3) to §§ 422.760 and 423.760, and redesignating current paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5).

VI. Codifying Existing Part C and D Program Policy

A. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101)

Section 1852(b)(1) of the Act prohibits discrimination by MA organizations on the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. Under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act, CMS added §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3), effective for coverage in 2011, to require all MA plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)) to establish limits on enrollee out-of-pocket cost sharing for Parts A and B services that do not exceed the annual limits established by CMS (75 FR 19709–11). We note that MA EGWPs must follow all relevant MA regulations and guidance unless CMS has

[64] Per the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which amended the Federal Civil Penalties Inflation Adjustment Act of 1990, the maximum monetary penalty amount applicable to 42 CFR 422.760(b), 423.760(b), and 460.46(a)(4) will be published annually in 45 CFR part 102. Pursuant to § 417.500(c), the amounts of civil money penalties that can be imposed for Medicare Cost Plans are governed by section 1876(i)(6)(B) and (C) of the Act, not by the provisions in part 422. Section 1876 solely references per determination calculations for Medicare Cost Plans. Therefore, the maximum monetary penalty amount applicable is the same as § 422.760(b)(1).

[65] See the ''Downloads'' section of the following CMS web page for the 2019 CMP Methodology and 2019 CMP Methodology Comments Responses Document: *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcementActions-.*

[66] See OMB Memorandum M–19–04 for the 2019 inflation adjustment multiplier. Available at: *https://www.whitehouse.gov/wp-content/uploads/2017/11/m_19_04.pdf.*

[67] Per OMB Memoranda M–19–04, *Implementation of Penalty Inflation Adjustments for 2019, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,* published December 14, 2018, the cost-of-living adjustment multiplier for 2019 is 1.02522.

specifically waived a requirement under its 1867(i) statutory authority. Section 1858(b)(2) of the Act requires a limit on in-network and out-of-pocket expenses for enrollees in Regional Preferred Provider Organization (RPPO) MA plans. In addition, MA Local PPO (LPPO) plans, under § 422.100(f)(5), and RPPO plans, under section 1858(b)(2) of the Act and § 422.101(d)(3), are required to have two maximum out-of-pocket (MOOP) limits (also called catastrophic limits) established by CMS annually, including (a) an in-network and (b) a total catastrophic (combined) limit that includes both in-network and out-of-network items and services covered under Parts A and B. Relying on the same authority, we are proposing amendments to the regulations at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to specify how these MOOP limits will be set for 2022 and subsequent years. In addition, our proposals here take into account statutory changes that are relevant to how CMS sets benefit category cost sharing limits. As discussed in section IV.A. of this proposed rule, section 17006 of the Cures Act amended section 1851(a)(3) of the Act to allow Medicare eligible beneficiaries with diagnoses of end-stage renal disease (ESRD) to choose a MA plan for Medicare coverage starting January 1, 2021, without the limits on such enrollment that currently apply.

CMS proposes to modify the regulations at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to establish a methodology for setting the MOOP limits that takes into account how Medicare beneficiaries with diagnoses of ESRD will have greater access to MA plan coverage beginning with contract year 2021. Specifically, CMS proposes a multiyear transition that incorporates ESRD costs into the methodology for setting the MOOP limits. In addition, CMS proposes to provide additional transparency on how CMS determines up to three MOOP limits for local and regional plans by codifying the methodology for how MOOP limits will be set at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3). This proposal, in combination with section VI.B. of this proposed rule, aims to address potential stakeholder concerns regarding this program change and provide MA organizations with cost sharing flexibilities as an incentive to encourage more favorable benefit designs for beneficiaries. As noted in the 2020 Final Call Letter, CMS has an established policy of affording MA plans greater flexibility in establishing cost sharing for Part A and B benefits (that is, basic benefits) by adopting a lower, voluntary MOOP limit than is available to plans that adopt the higher, mandatory MOOP limit. In contract year 2020, CMS provided this flexibility, on varying levels, for a number of benefit categories. CMS expects adopting greater benefit design flexibilities will incentivize competition and result in greater access to MA plans with lower MOOP or cost sharing limits for enrollees. Codifying the flexibilities in regulation in advance of the 2022 and subsequent contract years to which they will apply will provide a measure of transparency and stability for the MA program and, we believe, encourage MA organizations to develop plan designs to take advantage of the flexibilities. In addition, we discuss potential factors that could trigger future rulemaking for determining MOOP limits.

Currently, local and regional PPO plans are required to have two MOOP limits consistent with maximum thresholds established by CMS, including (a) an in-network and (b) a catastrophic (combined) limit that includes both in-network and out-of-network items and services covered under Parts A and B. HMO–POS plans may offer out-of-network benefits as supplemental benefits, but are not required to have these services contribute to the in-network MOOP limit or to a combined in- and out-of-network MOOP limit. Although the MOOP limits apply to Parts A and B benefits, an MA organization can apply the MOOP limit to supplemental benefits as well. MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee (that is, cost sharing includes deductibles, coinsurance, and copayments, pursuant to § 422.2) and to alert enrollees and contracted providers when the MOOP limit is reached.

As stated in the April 2018 final rule, CMS currently sets MOOP limits based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare Fee-for-Service (FFS). The Office of the Actuary (OACT) conducts an annual analysis to help CMS determine the MOOP limits using the most recent complete year's data and by projecting cost sharing using trend factors, such as enrollment changes and enrollment shifts between MA and original Medicare. The OACT bases its projections on actual claims data for Parts A and B benefits from the National Claims History files. Setting MOOP limits for 2020 was based on current regulation text at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) authorizing CMS to set MOOP limits to strike a balance between limiting costs to enrollees and changes in benefits, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages. The current mandatory MOOP limit represents approximately the 95th percentile of projected beneficiary out-of-pocket spending for the year to which the MOOP limit will apply. Stated differently, using the contract year 2020 MOOP limits as examples, 5 percent of Medicare FFS beneficiaries are expected to incur approximately $6,700 or more in Parts A and B deductibles, copayments, and coinsurance; the current voluntary MOOP limit of $3,400 represents approximately the 85th percentile of projected Medicare FFS out-of-pocket costs.

A strict application of the thresholds at the 95th and 85th percentile to set the MOOP limits since adoption of the MOOP regulations would have resulted in MOOP limits for MA LPPO and RPPO plans fluctuating from year-to-year. Therefore, CMS exercised discretion in order to maintain stable MOOP limits from year-to-year, when the established MOOP limits were approximately equal to the appropriate percentile. CMS took this approach in an effort to avoid enrollee confusion, allow MA plans to provide stable benefit packages year over year, and not discourage MA organizations from adopting the lower voluntary MOOP limit because of fluctuations in the amount.

MA plans may establish MOOP limits that are lower than the CMS-established maximum amounts. We currently consider any MOOP limit within the $0–$3,400 range as a voluntary MOOP and any MOOP limit within the $3,401–$6,700 range as a mandatory MOOP limit. The in-network MOOP limit dictates the combined MOOP range for PPOs (that is, PPOs are not permitted to offer a combined MOOP limit within the mandatory range, while having an in-network MOOP limit within the voluntary range). The combined MOOP limit for PPOs is calculated by multiplying the respective in-network MOOP limits by 1.5 for the relevant year and rounding to the nearest or lower $50 increment, similar to the proposal in paragraph (f)(4)(iii), if necessary.[68] Thus, the voluntary combined MOOP limit for PPOs in contract year 2020 was calculated as $3,400 × 1.5 = $5,100 (that is, an MA plan that establishes a dollar

[1] CMS. ''Benefits Policy and Operations Guidance Regarding Bid Submissions; Duplicative and Low Enrollment Plans; Cost Sharing Standards; General Benefits Policy Issues; and Plan Benefits Package (PBP) Reminders for Contract Year (CY) 2011'' (2010). Retrieved from *http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/downloads/dfb_policymemo04610final.pdf.*

limit within the $0–$5,100 range is using a lower, voluntary combined MOOP limit). Similarly, the mandatory combined MOOP limit for PPOs in contract year 2020 was calculated as $6,700 × 1.5 = $10,050, rounded down to the nearest $100 ($10,000) and MA plans that establish a dollar limit within the $5,101–$10,000 range are using a mandatory combined MOOP limit.

CMS currently affords greater flexibility in establishing Parts A and B cost sharing to MA plans that adopt a lower, voluntary MOOP limit (including PPO plans with a combined MOOP limit in the voluntary range) than is available to plans that adopt the higher, mandatory MOOP limit. The percentage of eligible Medicare beneficiaries with access to an MA plan (excluding employer and dual eligible special needs plans) offering a voluntary MOOP limit has decreased from 97.7 percent in contract year 2011 to 81.8 percent in contract year 2019. This has resulted in the percentage of total enrollees in a voluntary MOOP plan decreasing from 51 percent in contract year 2011 to 26 percent in contract year 2019.

We intend to continue use of more than one MOOP limit and are proposing, beginning with coverage for the 2022 contract year, to (1) establish explicit authority for up to three MOOP limits, including the current mandatory and voluntary MOOP limits and a third, intermediate MOOP limit; (2) codify the methodology for setting MOOP limits, and (3) adjust the methodology to take into account how the MA eligibility for Medicare beneficiaries is changing to remove the current limits on MA enrollment for Medicare eligible beneficiaries with diagnoses of ESRD. We believe that implementing more than two levels of MOOP and cost sharing limits will encourage plan offerings that result in more favorable benefit designs for beneficiaries. For example, increased access to plans with MOOP limits below the mandatory MOOP limit or lower cost sharing. We will monitor whether this change results in beneficiaries having access to plan offerings with MOOP limits below the mandatory MOOP limit or lower cost sharing over time and may consider additional changes through future rulemaking. By codifying the methodology for how these MOOP limits will be set, we are increasing the level of transparency for these policies and providing more stability and predictability to the MA program; MA organizations will have greater knowledge about how the MOOP limits are set and ability to anticipate where the MOOP limits will be in future years. For that reason, our proposal codifies our current practice with some revisions. In addition, as discussed in section VI.B. of this proposed rule, we are proposing to codify specific cost sharing limits and flexibility tied to use of the intermediate and lower voluntary MOOP limits by MA plans.

Under our proposal, we would substantially revise and restructure §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3). In the proposed revisions to these regulations, we are using the term ''basic benefits'' instead of referring to Medicare Part A and Part B benefits because the term ''basic benefits'' is now defined in § 422.100(c). We believe using the shorter, defined term increases the clarity and readability of the regulation. The proposed regulation text for these paragraphs avoids duplicate language where possible. We propose to codify the rules for setting the MOOP limits at § 422.100(f)(4). Currently, the same MOOP limits apply to MA local plans and to in-network limits for MA local and regional PPO plans. Therefore, we are proposing that § 422.101(d)(2), which imposes the MOOP limit for in-network MA regional plans, be revised to cross-reference the MOOP limits set for MA local plans at § 422.100(f)(4). Currently, the same MOOP limits apply to combined in-network and out-of-network out-of-pocket cost sharing for MA LPPO and RPPO plans and we intend to continue that policy. Therefore, we are proposing to use a cross-reference providing that the same MOOP limits apply under both § 422.100(f)(5) (for MA local PPOs) and § 422.101(d)(3) (for MA regional plans) for combined in-network and out-of-network cost sharing. By using these cross-references, we intend to clarify how certain MOOP limits are the same and to avoid repetitive regulation text. We are proposing to amend § 422.100(f)(4) to state the general rule that, except as provided in paragraph (f)(5), MA local plans must establish MOOP limits for basic benefits; as in the current regulation, proposed paragraph (f)(5) would address how the MOOP limits apply to the out-of-network coverage provided by local PPO plans. We also propose to include in §§ 422.100(f)(5) and 422.101(d)(2) the rules for PPOs in establishing in-network and combined (or catastrophic) MOOP limits. Finally, our proposal would codify in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) the responsibility MA organizations have to track enrolled beneficiaries' out-of-pocket spending and to alert enrollees and contracted providers when the MOOP limit is reached. This is implicit in how a MOOP limit works, but we believe codifying these responsibilities emphasizes for MA organizations that these requirements are integral to administration of basic benefits.

As proposed, paragraph (f)(4) authorizes CMS, for 2022 and subsequent years, to set up to three MOOP limits using projections of beneficiary spending that are based on the most recent, complete Medicare FFS data. We would codify the current practice of setting the MOOP limits based on a percentile of projected Medicare FFS beneficiary out-of-pocket spending. Under this proposal, we would set up to three MOOP limits: The lower MOOP limit, the intermediate MOOP limit, and the mandatory MOOP limit. CMS uses these terms (lower, intermediate, and mandatory) in referencing MOOP limits instead of only ''voluntary'' and ''mandatory'' MOOP limits. As proposed, paragraph (f)(4) would also impose general rules for setting the MOOP limits. We are proposing to codify in § 422.100(f)(4)(ii) the current rule for using ranges to identify the type of MOOP limit an MA plan has established and applying that rule to the three types of MOOP limit. A mandatory MOOP limit is any dollar limit that is above the intermediate MOOP limit and at or below the mandatory MOOP limit threshold established each year. The intermediate MOOP limit is any dollar limit that is above the lower MOOP limit and at or below the intermediate MOOP limit threshold established each year. The lower MOOP limit is any dollar limit that is between $0.00 and up to and including the lower MOOP limit threshold established each year. As proposed in paragraph (f)(4)(iii), each MOOP limit would be rounded to the nearest whole $50 increment. Further, in cases where the MOOP limit is projected to be exactly in between two $50 increments, CMS would round to the lower $50 increment (for example, $7,125 would be rounded to $7,100) to protect beneficiaries from higher increases in costs by rounding down whenever possible.

We propose to codify in paragraphs § 422.100(f)(4)(iv), (v), and (vi) the rules for establishing the MOOP limits for contract year 2022, 2023, 2024, and for 2025 and subsequent years. In effect, the MOOP limits for contract year 2022 would be a recalibration of the MA MOOP limits to using a methodology that is adjusted from current practice. For contract year 2022, we propose to set the MOOP limits as follows:

(A) The mandatory MOOP limit is set at the 95th percentile of projected

Medicare FFS beneficiary out-of-pocket spending.

(B) The intermediate MOOP is set at the numeric midpoint of mandatory and lower MOOP limits.

(C) The lower MOOP limit is set at the 85th percentile of projected Medicare FFS beneficiary out-of-pocket spending.

These MOOP limits would be set subject to the rounding rules in paragraph (f)(4)(iii). Under our proposal, CMS would use projections for the applicable contract year of out-of-pocket expenditures for Medicare FFS beneficiaries that are based on the most recent, complete Medicare FFS data that incorporates a percentage of the costs incurred by beneficiaries with diagnoses of ESRD, using the ESRD cost transition schedule proposed in paragraph (f)(4)(vii). We explain in detail that transition schedule and the data we propose to use for setting MOOP limits later in this section of the proposed rule.

For future contract years, we propose to set the MOOP limits using a methodology that takes into account the amount of change from the prior year's MOOP limits in a way that minimizes disruption and change for enrollees and plans. Our proposed methodology is designed to allow plans to provide stable benefit packages year over year by minimizing MOOP limit fluctuations unless a consistent pattern of increasing or decreasing costs emerges over time. Again, these MOOP limits would be set subject to the rounding rules and using projections based on the most recent, complete Medicare FFS data that incorporates a percentage of the costs incurred by beneficiaries with diagnoses of ESRD, using the transition schedule in paragraph (f)(4)(vii).

To set the mandatory and lower MOOP limits for contract years 2023 and 2024 or, if later, until the end of the ESRD cost transition we would follow these steps:

- Review OACT projections of out-of-pocket spending for the applicable year that is based on updated Medicare FFS data, including all spending regardless of ESRD diagnoses;
- Compare the applicable year's projection of the 95th percentile and 85th percentiles to the prior year's projections;
- Determine if the prior year's projection for the 95th percentile and 85th percentile are within a range, above or below, of two percentiles of the applicable percentile in that updatedprojection. For example, for the contract year 2023 mandatory MOOP limit, we would determine if the contract year 2022 95th percentile projection is between or equal to the 93rd and 97th percentiles of the projections for 2023 out-of-pocket expenditures;
- If the prior year's 95th and 85th percentile projections are between or equal to the two percentile range above or below, we would continue the ESRD cost transition schedule proposed in paragraph (f)(4)(vii) for one or both of the MOOP limits;
- If one or both of the prior year's 95th and 85th percentile projections are not within that range, we would increase or decrease one or both of the MOOP limits up to 10 percent of the prior year's MOOP limit annually until the MOOP limit reaches the projected 95th percentile for the applicable year, subject to the rounding rules as proposed in paragraph (f)(4)(iii). For example, if the dollar amount needed to be transitioned represents 15 percent, then 10 percent would be addressed during the first year, while any remaining amount would be addressed during the second year, if applicable based on updated data projections from the OACT. During this period of time we would delay implementation of the next step in the ESRD cost transition schedule proposed in paragraph (f)(4)(vii). The ESRD cost transition schedule would resume at the rate that was scheduled to occur once the prior year's projected 95th and 85th percentile remains within the range of two percentiles above or below the projected 95th percentile for the upcoming contract year. For example, for the contract year 2023 mandatory MOOP limit, if the 2023 projected 95th percentile corresponds to the projected 98th percentile for contract year 2022 out-of-pocket expenditures, we would set the contract year 2023 mandatory MOOP by: Increasing the contract year 2022 mandatory MOOP limit by up to 10 percent and rounding as proposed in paragraph (f)(4)(iii); and
- The intermediate MOOP limit would be set by either maintaining it as the prior year's intermediate MOOP limit (if the mandatory and lower MOOP limits are not changed) or updating it to the new numerical midpoint of the mandatory and lower MOOP limits, and rounding as proposed in paragraph (f)(4)(iii). We propose regulation text to implement this process for setting the mandatory, intermediate, and lower MOOP limits at § 422.100(f)(4)(v), with paragraphs (f)(4)(v)(A), (B) and (C) addressing the mandatory, intermediate, and lower MOOP limits respectively.

For contract year 2025 or following the ESRD cost transition schedule proposed in paragraph (f)(4)(vii) and for subsequent years, we propose to include in the methodology a means to take into account trends that are consistent for three years. The proposed regulation text includes ''or following the ESRD cost transition'' to clarify that the ESRD cost transition schedule may end in 2025 or extend longer due to our proposals for how we would handle any sudden increases or decreases in costs. For example, if for contract year 2023, the projected 95th percentile amount represents the 98th percentile from the prior year's (contract year 2022) projections, then we would only increase the MOOP limit for contract year 2023 by up to 10 percent of the prior year's MOOP amount and extend the ESRD cost transition schedule past 2025 by the number of years it takes until the upcoming year's projected 95th percentile amount was within two percentiles above or below the prior year's projection of the 95th percentile. We propose the methodology for the mandatory and lower MOOP limits for contract year 2025 or following the ESRD cost transition schedule as follows: the prior year's corresponding MOOP limit is maintained for the upcoming contract year if: (1) The prior year's MOOP limit amount is within the range of two percentiles above or below the projected 95th or 85th percentile of Medicare FFS beneficiary out-of-pocket spending incurred by beneficiaries with and without diagnoses of ESRD and (2) the projected 95th or 85th percentile did not increase or decrease for three consecutive years in a row. If the prior year's corresponding MOOP limit is not maintained because either (1) or (2) occur, CMS increases or decreases the MOOP limit by up to 10 percent of the prior year's MOOP amount annually until the MOOP limit reaches the projected applicable percentile for the applicable year, based on the most recent, complete data projections from the OACT. The intermediate MOOP limit would be set by either maintaining it as the prior year's intermediate MOOP limit (if the mandatory and lower MOOPs are not changed) or updating it to the new numerical midpoint of the mandatory and lower MOOP limits, and rounding as proposed in paragraph (f)(4)(iii). We propose regulation text to implement this process for setting the mandatory, intermediate, and lower MOOP limits for contract year 2025 or following the data transition schedule and subsequent years at § 422.100(f)(4)(vi), with paragraphs (f)(4)(vi)(A), (B), and (C) addressing the mandatory, intermediate, and lower MOOP limits respectively.

This approach aims to allow plans to provide stable benefit packages year over year by minimizing MOOP limit

fluctuations unless a consistent pattern of increasing or decreasing costs emerges over time. We solicit comment on this approach in light of our goal of avoiding enrollee confusion and maintaining stable benefit packages. We also solicit comments whether our proposed regulation text adequately and clearly specifies the methodology that will be used to set the MOOP limits each year. We intend to issue annual guidance applying these rules, sufficiently in advance of the bid deadline so that MA organizations know and understand the MOOP limits for the upcoming year.

We would continue the current policy of setting the combined MOOP limits (that is, the MOOP limits that cover in-network and out-of-network benefits) for PPOs by multiplying the respective in-network MOOP limits by 1.5 for the relevant year and rounding as proposed in paragraph (f)(4)(iii) if necessary. We propose to codify this rule for MA regional plans in § 422.101(d)(3) and to cross-reference that rule for MA local PPOs in § 422.100(f)(5)(i).

Because of the change in eligibility requirements for MA plans regarding beneficiaries with diagnoses of ESRD, we believe that it is appropriate that the data we use to set the MOOP limits also reflect the out-of-pocket expenditures of such beneficiaries. We therefore propose to codify rules for what data CMS would use to set the MOOP limits that are consistent with current practice, but revised to take into account costs incurred by beneficiaries with diagnoses of ESRD. CMS currently sets MOOP limits using projected Medicare FFS beneficiary out-of-pocket spending for the upcoming year, which are based on a beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare FFS, excluding all costs for beneficiaries with ESRD. For example, for contract year 2020 MOOP limits, we used projected out-of-pocket costs for Medicare FFS beneficiaries (excluding out-of-pocket costs from beneficiaries with diagnoses of ESRD) from the OACT, based on the most recent complete Medicare data (from 2018). We excluded the costs for individuals with diagnoses of ESRD because of the limits on when and how a Medicare beneficiary with diagnoses of ESRD could enroll in an MA plan under section 1851(a) of the Act. Under the current enrollment limitations, in contract year 2018, 0.6 percent of the MA enrollee population, or approximately 121,000 beneficiaries, have diagnoses of ESRD, using CMS data.[69]

As discussed in section IV.A. of this proposed rule, section 1851(a)(3) of the Act, as amended by the Cures Act, will allow Medicare beneficiaries with diagnoses of ESRD to enroll in MA plans beyond current enrollment limitations, beginning in contract year 2021. CMS expects this change will result in Medicare beneficiaries with diagnoses of ESRD to begin transitioning to or choosing MA plans in greater numbers than what has happened so far (in light of the prior limitations under section 1851(a) of the Act). To ensure that the MOOP limits take into account out-of-pocket costs for beneficiaries with diagnoses of ESRD, we propose a multi-year transition from our current practice of excluding all costs incurred by beneficiaries with diagnoses of ESRD to including all related costs into the Medicare FFS data that is used to set the MOOP limits. We propose to codify the transition schedule at § 422.100(f)(4)(vii).

We propose to factor in a percentage of the difference between the projected costs that are based on, first, data for beneficiaries without diagnoses of ESRD and second, based on data that includes beneficiaries with diagnoses of ESRD. We propose to use the term ''ESRD cost differential'' to refer to the difference between: (1) Projected out-of-pocket costs for beneficiaries using Medicare FFS data excluding the costs incurred by beneficiaries with ESRD diagnoses for contract year 2021 and (2) the projected out-of-pocket costs for all beneficiaries using Medicare FFS data (including the costs incurred by beneficiaries with ESRD diagnoses) for each year of the ESRD cost transition. We propose a specific schedule for factoring in a percentage of the ESRD cost differential annually until 2024 or, if later, the final year of the transition and beyond. As shown in Table 11, for MOOP limits for years after contract year 2022, CMS proposes to incorporate an additional 20 percent of the ESRD cost differential, as it is updated calculated each year using the most recent, complete data projections from the OACT, until contract year 2024 or the final year of transition. Table 11 shows MOOP limits calculated following these proposed rules and transition schedule, but using the data available at this time, to illustrate the impact of factoring in greater portions of the ESRD cost differential. In the final year of the transition, 100 percent of the costs incurred by beneficiaries with diagnoses of ESRD would be integrated into the most recent, complete Medicare FFS data that is used to project and determine MOOP limits.

For the 2021 contract year, the projected costs incurred by beneficiaries without ESRD diagnoses for the 95th percentile is $7,175 and for the 85th percentile is $3,360. Each year, we would compare the 95th and 85th percentiles of the projected out-of-pocket costs for all Medicare FFS beneficiaries for the upcoming year to these dollar amounts to calculate the ESRD cost differential for that year. We therefore propose to identify these dollar amounts in the regulation text defining the ESRD cost differential. Using the most recent, complete Medicare FFS data without costs incurred by beneficiaries with diagnoses of ESRD, the 95th percentile is projected to be $7,175 in contract year 2021, compared to $8,174 with related ESRD costs, a difference of $999. This is the same type of comparison we will complete each year based on complete and updated data projections provided by the OACT. Table 11 illustrates the MOOP limits set using these proposed rules and is based on projections using 2018 data. For example, for the 2022 contract year, we would take 60% of the ESRD cost differential ($599.40) and add it to the projected 95th percentile without ESRD costs to align with the proposed transition schedule, which equals $7,774.40. This rounds to $7,750; this means the mandatory MOOP limit range would be $5,601 (because the intermediate MOOP would be $5,600) through $7,750, as reflected in Table 11.

CMS developed this approach in consultation with the OACT to take into account the likely increase in enrollment of beneficiaries with diagnoses of ESRD in MA while ensuring that there is not a significant and sudden shift in the MOOP limits in any given year. CMS and the OACT do not expect 100 percent of Medicare beneficiaries with diagnoses of ESRD will enroll in the MA program immediately after the current enrollment limitations are lifted and as such, CMS is not proposing to integrate 100 percent of the costs within one contract year. Our goal is to strike a balance between potential increases in plan costs and enrollee cost sharing or premiums by scheduling adjustments to the MOOP limits to reflect a reasonable transition of ESRD beneficiaries into the MA program. Further, using a scheduled transition will allow MA organizations to plan for the change and mitigate sudden changes in MOOP limits, benefit

[69] *See page 14 from the 2020 Rate Notice and Final Call Letter, retrieved from https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

designs, and premiums that could be disruptive to enrollees and MA organizations. CMS's goal in the MOOP and Cost Sharing proposals in this proposed rule is to provide predictable and transparent MOOP limit and cost sharing standards and to set limits at a level that should not result in significant new costs for MA plans or enrollees. We solicit comment on whether the transition schedule proposed at 422.100(f)(4)(vii) aligns best to this goal or if the transition should be structured differently in terms of annual percentage of ESRD cost differential transition (for example, 50 percent in 2022, 70 percent in 2023 or, if later, the next year of transition, and 100 percent in the final year of transition).

Using the most recent, complete Medicare FFS data available at this time (2018 data), the OACT projected the out-of-pocket costs for Medicare FFS beneficiaries. CMS developed Table 4 for illustrative purposes to show how the most recently available projections of the 95th and 85th percentiles along with our proposed methodology results in mandatory, intermediate, and lower MOOP limits for in-network basic benefits for contract years 2022 through 2024. CMS also developed Table 5 to show the current projections of combined MOOP limits for in-network and out-of-network basic benefits based on our proposed methodology (that is, multiplying the respective in-network MOOP limits by 1.5 for the relevant year). Overall, Table 4 and Table 5 illustrate examples of potential MOOP limits that integrate the ESRD cost differential over multiple years (60 percent by 2022, 80 percent for 2023 or, if later, the next year of transition, and 100 percent for 2024 or the final year of transition) and include application of the rounding rules as proposed in paragraph (f)(4)(iii). These are only illustrative MOOP limits for contract years 2022 through 2024 to show the potential impact of our proposal for incorporating the out-of-pocket costs of FFS beneficiaries with diagnoses of ESRD into the most recent, complete Medicare FFS data we currently have to set the MOOP limits. We expect these numbers will change when we receive the next year's projections from the OACT and CMS will update the MOOP limits using the methodology decided upon in the final rule. We intend to apply the revised regulations each year to calculate the MOOP limits and to publish the annual MOOP limits with a description of how the regulation standard is applied (that is, the methodology used) through Health Plan Management System (HPMS) memoranda issued prior to bid submission each year.

TABLE 4—ILLUSTRATIVE EXAMPLE OF IN-NETWORK MOOP LIMITS BASED ON MOST RECENT MEDICARE FFS DATA PROJECTIONS

MOOP limit	Approximate original Medicare percentile	Contract year 2022	Contract year 2023	Contract year 2024
Mandatory	95t	$5,601 to $7,750	$5,701 to $7,950	$5,801 to $8,150.
Intermediate	Approximate numeric midpoint*	$3,451 to $5,600	$3,501 to $5,700	$3,501 to $5,800.
Lower	85th	$0 to $3,450	$0 to $3,500	$0 to $3,500.

*The intermediate MOOP limit would be based on the mandatory MOOP limit, less approximately 50 percent of the numeric difference between the mandatory and lower MOOP limits.

TABLE 5—ILLUSTRATIVE EXAMPLE OF COMBINED MOOP LIMITS FOR LPPO AND CATASTROPHIC (MOOP) LIMITS FOR RPPO PLANS BASED ON MOST RECENT MEDICARE FFS DATA PROJECTIONS

MOOP limit*	Contract year 2022	Contract year 2023	Contract year 2024
Mandatory	$8,401 to $11,600	$8,551 to $11,900	$8,701 to $12,200.
Intermediate	$5,151 to $8,400	$5,251 to $8,550	$5,251 to $8,700.
Lower	$0 to $5,150	$0 to $5,250	$0 to $5,250.

*Combined MOOP limits are calculated by multiplying the respective MOOP limits by 1.5 for the relevant year.

Under our proposal, we intend to explain how we apply the methodology we have proposed to codify at §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) and the resulting MOOP limits for each year on a timely basis through HPMS memoranda. We solicit comment whether we should codify a specific rule requiring CMS to issue such subregulatory guidance applying the methodology in these regulations by a specific date each year.

CMS also seeks comments and suggestions on whether additional regulation text or restructuring of §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) is needed to achieve CMS's goal of providing additional transparency on how CMS will: (1) Set up to three in-network and out-of-network MOOP limits for local and regional MA plans; (2) transition ESRD costs into MOOP limit calculations; and (3) calculate MOOP limits during and after completion of the transition of data about cost sharing expenses for beneficiaries with diagnoses of ESRD.

B. Service Category Cost Sharing Limits for Medicare Parts A and B Services and per Member per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)

Section 1852 of the Act imposes a number of requirements that apply to the cost sharing and benefit design of MA plans. First, section 1852(a)(1)(B) of the Act provides that the MA organization must cover the benefits under Parts A and B (that is, basic benefits as defined in § 422.100(c)) with cost sharing that is the same or at least actuarially equivalent to cost sharing in original Medicare; this is repeated in a bid requirement under section 1854(e)(4) of the Act. We have addressed and implemented that requirement in several regulations, including §§ 422.101(e), 422.102(a)(4), and 422.254(b)(4). Second, section 1852(a)(1)(B) of the Act also imposes particular constraints on the cost sharing for specific benefits, which have been implemented in § 422.100(j) for MA plans and extended to cost plans under § 417.454(e); the statute explicitly authorizes CMS to add to the list of items and services for which MA cost sharing may not exceed the cost sharing levels in original Medicare. Third, section 1852(b)(1) of the Act prohibits discrimination by MA organizations on

the basis of health status-related factors and directs that CMS may not approve an MA plan if CMS determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals. The requirements under §§ 422.100(f)(4) and (5) that impose MOOP limits on local MA plans are based on this anti-discrimination provision and align with the statutory catastrophic limits imposed on regional MA plans under section 1858(b) of the Act. Section 422.100(f)(6) provides that cost sharing must not be discriminatory and CMS has issued guidance addressing discriminatory cost sharing, as applied to specific benefits and to categories of benefits, in the annual Call Letter and in Chapter 4 of the Medicare Managed Care Manual (MMCM) under this regulation. Establishing limits on cost sharing for covered services is an important way to ensure that the cost sharing aspect of a plan design does not discriminate against or discourage enrollment in an MA plan by beneficiaries who have high health care needs.

Currently, CMS annually analyzes Medicare program data to interpret and apply the various cost sharing limits from these authorities and to publish guidance on MA cost sharing limits in the annual Call Letter. The relevant Medicare data includes the most recent, complete Medicare FFS data, including cost and utilization data and MA patient utilization information from MA encounter data. CMS sets cost sharing limits based on analyses of and projections from this data and then reviews cost sharing established by MA organizations to determine compliance with the cost sharing limits and requirements established in the statute and regulations, as interpreted and implemented in sub-regulatory guidance, including Chapter 4 from the MMCM. The cost sharing limits set by CMS reflect a combination of outpatient visits and inpatient utilization scenarios based on length of stays typically used by average to sicker patients. CMS uses multiple inpatient utilization scenarios to guard against MA organizations setting inpatient cost sharing amounts in a manner that is potentially discriminatory. Review parameters are also established for frequently used professional services, such as primary and specialty care services. We are proposing to codify our current (and in many cases, long-standing) practice and methodology for interpreting and applying the limits on MA cost sharing, with some modifications.

In using the most recent, complete Medicare FFS data for developing and applying the reviews of MA cost sharing, CMS excludes the costs for individuals with diagnoses of ESRD because of the current restrictions on when and how a Medicare beneficiary with diagnoses of ESRD could enroll in an MA plan under section 1851(a) of the Act. In contract year 2018, 0.6 percent of the MA enrollee population, or approximately 121,000 beneficiaries, have ESRD based on the statutory definition and CMS data.[70] As discussed in more detail in section IV.A. of this proposed rule, section 17006 of the Cures Act has amended the Medicare statute to allow Medicare beneficiaries with diagnoses of ESRD to enroll in MA plans beginning in contract year 2021. CMS expects this change will result in Medicare beneficiaries with diagnoses of ESRD beginning to transition to, or choosing, MA plans in greater numbers than they do currently, but the rate of transition is currently unknown. Given the potential increase in enrollment of beneficiaries with diagnoses of ESRD in MA, the OACT has conducted an analysis to determine the impact of including all costs incurred by beneficiaries with diagnoses of ESRD into the most recent, complete Medicare FFS data CMS uses to project future out-of-pocket expenditures to establish cost sharing standards and limits. Based on the most recent analyses and projections, adding in ESRD costs affects MA cost sharing limits for inpatient hospital acute length of stay scenarios, with the longer length of stay scenarios being the most affected. As discussed in section VI.A. of this proposed rule, CMS is proposing, at § 422.100(f)(4)(vii), a schedule for incorporating use of the most recent, complete Medicare FFS data for beneficiaries with diagnoses of ESRD into the data used to set MOOP limits. The proposal here to codify, with some updates and changes, the current process for establishing non-discriminatory cost sharing limits similarly takes into account data about out-of-pocket expenditures for beneficiaries with diagnoses of ESRD. In addition, CMS is proposing to provide additional transparency on how updates are made to inpatient hospital acute and psychiatric length of stay scenarios in conjunction with the ESRD cost transition, as described in the 2020 Final Call Letter for contract year 2021. CMS also proposes to codify the methodology used to set the standards for MA cost sharing for professional services and for inpatient hospital acute and psychiatric services at § 422.100(f)(6). Under our proposal, an MA plan must have cost sharing that does not exceed the standards set each year using the methodology in paragraph (f)(6). The limits in proposed § 422.100(f)(6) would be in addition to other limits on cost sharing that apply to MA plans. We are also proposing, at § 422.100(j), that MA plans must not impose cost sharing that exceeds original Medicare for certain specific benefits and for certain categories of benefits on a per member per month actuarially equivalent basis. Our proposal would also set specific cost sharing requirements for emergency services (including post-stabilization service) and urgently needed services, which would be codified in § 422.113(b)(2)(v) and (vi).

CMS is committed to encouraging plan offerings with more favorable MOOP and cost sharing limits. Accordingly, CMS is proposing to modify the regulations at §§ 422.100(f)(6) and 422.113(b)(2)(v) and (vi) to establish a range of cost sharing limits for benefits furnished on an in-network basis based on the MOOP limit established by the MA plan. Increasing the flexibility MA organizations have in setting cost sharing limits based on more favorable MOOP limits should incentivize more favorable benefit designs for MA enrollees.

In addition, this proposal for amending §§ 422.100(f)(6) and (j) and 422.113(b)(2) implements safeguards to ensure MA enrollees are not subject to discriminatory benefits or discriminatory costs for basic benefits. These safeguards include codifying a longstanding interpretation of the current anti-discrimination provision that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who need those services. Specifically, CMS proposes to codify at § 422.100(f)(6)(i)(A) that MA plans may not pay less than 50 percent of the total MA plan financial liability, regardless of the MOOP limit established, for basic benefits that are provided in-network and out-of-network that are not explicitly proposed in the cost sharing standards at § 422.100(f)(6). This proposal as a whole, in combination with the MOOP proposal in section VI.A. of this proposed rule, aims to provide MA organizations incentives to offer plans with favorable benefit designs for beneficiaries. Under sections 1854(a)(1)(A) and 1860D–11(b) of the Act, initial bid submissions for all MA organizations are due the first Monday

[70] *See page 14 from the 2020 Rate Notice and Final Call Letter, retrieved from https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

in June and shall be in a form and manner specified by the Secretary. Organizations may design their plan benefits as they see fit so long as they satisfy Medicare coverage requirements, including applicable MA regulations. MA organizations typically offer benefits with lower cost sharing amounts than the limits published in the annual Call Letter; we believe this is due to multiple factors, including the principles and incentives inherent in managed care, effective negotiations between organizations and providers, and competition. CMS also reminds organizations that they also must comply with applicable Federal civil rights laws that prohibit discrimination on the basis of race, national origin, gender, disability, chronic disease, health status, or other prohibited basis including section 1557 of the Affordable Care Act, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975. None of the proposed regulations under this rule limit application of such anti-discrimination requirements.

1. General Non-Discriminatory Cost Sharing Limits (§§ 422.100(f)(6))

We are proposing to codify in § 422.100(f)(6) a set of general rules for cost sharing for basic benefits. We use the term ''basic benefits'' as defined in § 422.100(c) to mean items and services (other than hospice care and, beginning 2021, coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at § 422.135. Under our proposal, the rules in § 422.100(f)(6) must be followed by MA plans in addition to other regulatory and statutory requirements for cost sharing. MA organizations have the option to charge either coinsurance or a copayment for most benefit category benefits, which the proposed regulation text makes clear. Under our proposal, the MA plan cannot exceed the coinsurance or copayment limit for benefit category standards established by CMS using the various rules in the regulation.

We are proposing to codify our longstanding interpretation of the anti-discrimination provisions that payment of less than 50 percent of the total MA plan financial liability discriminates against enrollees who have high health needs and discourages enrollment in the plan by such beneficiaries. We recognize that it is difficult to set a cost sharing limit for every possible benefit and believe that this catch-all rule, which has been longstanding policy used in our review of bids, is an important beneficiary protection. This rule would apply regardless of the MOOP limit established and regardless whether the basic benefit is furnished in-network or out-of-network, to protect beneficiaries regardless of the MA plan or MOOP limit they choose. As used in the proposed regulation text, the term ''total MA plan financial liability'' means the total payment paid and includes both the enrollee cost sharing and the MA organization's payment. Specifically, CMS proposes to codify at § 422.100(f)(6)(i) that MA plans may not pay less than 50 percent of the total MA plan financial liability, regardless of the MOOP limit established, for in-network benefits and out-of-network benefits for which a cost sharing limit is not otherwise specified in proposed paragraph (f)(6), inclusive of basic benefits. In order to clarify this policy, we are also proposing in paragraphs (f)(6)(i)(B) and (C) how this rule would apply when coinsurance or copayment structures are used. Under our proposal, if the MA plan uses copayments, the copayment for an out-of-network benefit cannot exceed 50 percent of the average Medicare FFS allowable cost for that service area and the copayment for in-network benefits cannot exceed 50 percent of the average contracted rate of that benefit (item or service); if the MA plan uses coinsurance, then the coinsurance cannot exceed 50 percent.

We are also proposing general rules to govern how CMS would set copayment limits under this proposal. Proposed paragraph (f)(6)(ii)(A) provides that CMS rounds to the nearest whole $5 increment for professional services and nearest whole $1 for inpatient acute and psychiatric and skilled nursing facility cost sharing limits. Proposed paragraph (f)(6)(B) provides that for all cases in which the copayment limit is projected to be exactly between two increments, CMS rounds to the lower dollar amount. This rounding rule codifies for the most part current policy but with slight modification to protect beneficiaries from higher increases in costs by rounding down whenever possible.

In proposed paragraph (f)(6)(iii), we would codify rules to give MA plans flexibility in setting cost sharing for professional services, including primary care services, physician specialist services, partial hospitalization, and rehabilitation services. The proposed flexibility is in many respects the same as the flexibility we currently provide for MA plans that use the lower, voluntary MOOP limit, but with modifications to account for our proposal to set up to three MOOP limits each year. Proposed new § 422.100(f)(6)(iii)(A) provides that an MA plan may not establish cost sharing that exceeds the limits set under paragraph (f)(6)(iii) for basic benefits that are professional services furnished in-network (that is, by contracted providers). Proposed new § 422.100(f)(6)(iii)(B) specifies the data that CMS would use in applying the methodology in paragraph (f)(6)(iii) to set the cost sharing limits: Projections of out-of-pocket costs representing beneficiaries with and without diagnoses of ESRD based on the most recent, complete Medicare FFS data for basic benefits that are professional services. Proposed new § 422.100(f)(6)(iii)(C) outlines the method for setting the cost sharing limits for professional services each year and clarifies that the resulting limits (specified as dollar amounts) are subject to the rounding rules in paragraph (f)(6)(ii). The cost sharing limits would vary based on the type of MOOP limit used by the MA plan and would be as follows:

(1) Mandatory MOOP limit: 30 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 70 percent of the total MA plan financial liability.

(2) Intermediate MOOP limit: 40 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 60 percent of the total MA plan financial liability.

(3) Lower MOOP limit: 50 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 50 percent of the total MA plan financial liability. We are proposing that the MA plan must pay a specific percentage of the total financial liability for professional services to align with the range of flexibility each MOOP limit provides. By specifying this in regulation, we are ensuring that there is a clear increase in MA organization financial responsibility for professional services if they choose a mandatory MOOP limit rather than a lower or intermediate MOOP limit. We arrived at the specified percentages discussed previously by assigning the highest coinsurance amount that was not discriminatory (50%) to the lowest MOOP limit; and 30% coinsurance (which is most closely related to limits stated in the CY 2020 Call Letter) to the mandatory MOOP limit, to balance the beneficiary incentives for each type of MOOP limit. Then, we established the midpoint (40%) for the intermediate MOOP limit. These coinsurance percentages also result in reasonable differences between expected copayment limits for each of the MOOP

limits. Overall, we aim to prevent discrimination by setting these limits to serve as caps to how much financial responsibility the MA organization can transfer to enrollees for professional services. Accordingly, 422.100(f)(6) clarifies that MA organizations cannot disproportionally increase cost sharing for specific benefit categories beyond the specified percentages. To set the actuarially equivalent values each year, CMS would work with the OACT to establish copayment limits that are approximately equal to the identified coinsurance percentage limit based on projections of the most recent, complete Medicare FFS data that includes 100 percent of the out-of-pocket costs representing all beneficiaries with and without diagnoses of ESRD.

We propose to base the approximate actuarially equivalent copayment limits for primary care, physician specialties, mental health specialty services, and physical and speech therapy on the most recent, complete Medicare FFS average cost data (including 100 percent of the out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD), weighted by utilization by the applicable provider specialty types for each service category. We believe that using an average that is weighted by specialty type utilization is consistent with developing the actuarially equivalent copayment for the coinsurance percentage specified in proposed § 422.100(f)(6)(iii). We solicit comment on whether our regulation text should be further revised on this point. The applicable provider specialty types include:

A. Primary Care: Family Practice; General Practice; Internal Medicine
B. Physician Specialties: Cardiology; Geriatrics; Gastroenterology; Nephrology; Otolaryngology (ENT)
C. Mental Health Specialty Services: Clinical Psychologist; Licensed Clinical Social Worker; Psychiatry
D. Physical and Speech Therapy: Physical Medicine and Rehabilitation; Speech-language Pathologists

We propose to base the approximate actuarially equivalent copayment limits for psychiatric services, occupational therapy, and chiropractic care on the most recent, complete Medicare FFS cost data from a single, most applicable provider specialty. Respectively, this includes Psychiatry, Occupational Therapist, and Chiropractor. We solicit comment on whether other provider specialty types should inform our proposed actuarially equivalent copayment limits for the various professional services. We direct readers to Table 4 for an illustration of how cost sharing limits would be developed based on the most recent, complete data projected to the applicable contract year for professional services, emergency services/post stabilization care, and urgent care.

CMS issued guidance in Chapter 4, section 50.1 ''Guidance on Acceptable Cost-sharing'' of the MMCM that cost sharing should appear to MA enrollees consistent with MA disclosure requirements at § 422.111(b)(2). Section 422.111(b)(2) requires MA plans to clearly and accurately disclose benefits and cost sharing. Accordingly, MA plans must identify (and charge) the enrollee's entire cost sharing responsibility as a single copay (if using copayment rather than coinsurance) even if the MA plan has differential cost sharing that varies by facility setting or contracted arrangements that involves separate payments to facilities (or settings) and providers. We are aware of situations where a facility or setting charges a separate amount from the health care provider that actually furnishes covered services, such as an emergency department fee and a fee for the emergency room physician. In such situations, those fees should be combined (bundled) into the cost sharing amount for that particular place of service and be clearly reflected as a total copayment in appropriate materials distributed to beneficiaries. We believe that this current guidance is an appropriate interpretation of § 422.111 but solicit comment on whether the existing regulations are sufficiently clear or if clarification in the regulation text would be helpful to avoid potential confusion on how MA plans should bundle copayments.

2. Cost Sharing Limits for Inpatient Hospital Acute and Psychiatric Services (§ 422.100(f)(6)(iv))

Since contract year 2011, CMS has annually announced the maximum cost sharing permitted for inpatient length of stay scenarios for both acute and psychiatric care. For each length of stay scenario, CMS set cost sharing limits based on a percentage of estimated Medicare FFS cost sharing projected to the applicable contract year. The OACT conducts an annual analysis of the most recent, complete Medicare FFS data, and uses that data to project costs for the Part A deductible and Part B costs based on the length of stay scenarios and the setting of the inpatient stay (acute or psychiatric), to help determine the inpatient hospital acute and psychiatric cost sharing limit amounts. CMS compares the cost sharing for an MA enrollee under the plan design for each bid to the projected Medicare FFS cost sharing in each scenario; for MA plans with the mandatory MOOP limit, the cost sharing limit is 100 percent of the Medicare FFS cost sharing for the applicable scenario and for MA plans using the lower, voluntary MOOP limit, it is 125 percent of the Medicare FFS cost sharing. If an MA plan's cost sharing exceeds the applicable limit for any of the length of stay scenarios, CMS considers the MA plans' cost sharing as discriminatory under current § 422.100. We are proposing new § 422.100(f)(6)(iv)(A) through (D) to codify this longstanding policy for the cost sharing established by an MA plan for inpatient acute and psychiatric services, with modifications to take into account cost sharing expenditures for beneficiaries with diagnoses of ESRD in setting the limits and to set a limit for MA plans that use the intermediate MOOP limit. Under proposed paragraph (f)(6)(iv)(A), an MA plan is required to have cost sharing for inpatient acute and psychiatric benefits that do not exceed the limits set in § 422.100(f)(6)(iv). Our proposal aims to provide transparency on how CMS will set the thresholds with which MA cost sharing must comply for inpatient hospital acute and psychiatric benefits. In reviewing bids, we will evaluate MA cost sharing to determine whether it complies with the limits set under this proposed new regulation text.

We propose that the cost sharing limits are set for each of the seven inpatient stay scenarios for which cost sharing would apply under original Medicare. The inpatient hospital acute stay scenarios are for 3 days, 6 days, 10 days, and 60 days and the psychiatric inpatient hospital stay scenarios are for 8 days, 15 days, and 60 days. Most of these are the same scenarios used in the contract year 2020 Call Letter and in previous years. Cost sharing limits for each of the seven inpatient hospital length of stay scenarios incorporates the estimated Medicare FFS inpatient Part A deductible and Part B professional costs. Plans may vary cost sharing for different admitting health conditions, providers, or services provided, but overall benefit cost sharing must satisfy the limits established by CMS. We identify these length of stay scenarios in proposed paragraph (f)(6)(iv)(B). Proposed paragraph (f)(6)(iv)(C) describes the data CMS would use for establishing the Medicare FFS out-of-pocket costs for each scenario. CMS would use projected out-of-pocket costs and utilization data based on the most recent, complete Medicare FFS data that factors in out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD

on the transition schedule described in paragraphs (f)(4)(vii)(A) through (D) and may also use patient utilization information from MA encounter data. For purposes of setting these cost sharing limits, the Medicare FFS data that factors in the ESRD cost differential would not include the exceptions for the MOOP limit calculations that are described at § 422.100(f)(4)(v)(A) and (C). In essence, the exceptions relate to how the ESRD cost transition would be delayed if the prior year's projected 95th or 85th percentile (including costs incurred by all Medicare FFS beneficiaries with and without diagnoses of ESRD) is two percentiles above or below the projected 95th or 85th percentile for the upcoming contract year. This exception is not relevant for setting inpatient cost sharing limits as our methodology does not utilize percentiles to establish length of stay scenario limits.

OACT conducted an analysis to help determine the impact of including all costs incurred by beneficiaries with diagnoses of ESRD into the most recent, complete Medicare FFS data used to establish cost sharing standards. This analysis found adding in related ESRD costs affects inpatient hospital acute cost sharing limits. For example, in contract year 2021 the inpatient hospital acute 60 day limit without ESRD costs for MA plans that establish a mandatory MOOP limit is projected to be $4,645 and with 100 percent of ESRD costs increases to $5,073. This is an increase of $428, due to increased Part B professional fees ($3,169 for 60 days without ESRD costs and $3,597 with 100 percent of ESRD costs). The projected Part A deductible of $1,476 stays the same in both calculations. Although costs incurred by beneficiaries with diagnoses of ESRD costs are not expected to impact inpatient hospital psychiatric standards based on current projections, we are proposing to update the methodology to consider ESRD costs for all inpatient hospital acute and psychiatric standards. Specifically, CMS proposes to integrate approximately 60 percent of the difference between Medicare FFS costs incurred by all beneficiaries (including those with diagnoses of ESRD) and the costs excluding beneficiaries with diagnoses of ESRD into the data used to set the inpatient hospital acute and psychiatric cost sharing limits for contract year 2022. After contract year 2022, CMS will incorporate an additional 20 percent of costs incurred by beneficiaries with diagnoses of ESRD each year until contract year 2024, when CMS will integrate 100 percent of the costs incurred by beneficiaries with diagnoses of ESRD into the most recent, complete Medicare FFS data that is used to determine inpatient hospital acute and psychiatric cost sharing limits. This is the same as the proposed transition schedule of ESRD costs into MOOP limit calculations discussed in section VI.A. of this proposed rule. Accordingly, we cross-reference that transition at § 422.100(f)(6)(iv)(C) to avoid repetitive regulation text.

We will apply the transition of ESRD costs across all existing and new inpatient hospital length of stay scenarios. Specifically, we propose to add a 3-day length of stay scenario for acute stays and an 8-day length of stay scenario for psychiatric care to the scenarios we have used for the past several years. The proposed 3-day and 8-day stay scenarios for inpatient hospital acute and psychiatric standards were determined based on Medicare FFS data and informed by patient utilization information from MA encounter data. For example, the analysis of Medicare FFS 2015–2017 claims data indicates that 3 days was the median length of stay within an inpatient hospital acute setting. CMS also reviewed patient utilization during the same 2015–2017 time period using MA encounter data and noted the median length of stay was about the same for MA enrollees. Based on the combined data, we believe the addition of a 3-day length of stay cost sharing limit is an appropriate addition to our existing inpatient hospital acute cost sharing standards (6 days, 10 days, and 60 days). CMS completed similar analyses regarding psychiatric stays and is, therefore, proposing to add an 8-day length of stay scenario to the existing psychiatric length of stay scenarios (15 days and 60 days) used in the past.

Finally, in paragraph (f)(6)(iv)(D), we are proposing specific cost sharing limits for inpatient acute and psychiatric stays that are tied to the type of MOOP limit used by the MA plan. These limits are stated as percentages of the FFS costs for each length of stay scenario:

(1) Mandatory MOOP limit: Cost sharing must not exceed 100 percent of estimated Medicare Fee-for-Service cost sharing, including the Part A deductible and related Part B costs.

(2) Intermediate MOOP limit: Cost sharing must not exceed the numeric mid-point between the cost sharing limits for the mandatory and lower MOOP limits.

(3) Lower MOOP limit: Cost sharing must not exceed 125 percent of estimated Medicare Fee-for-Service cost sharing, including the Part A deductible and related Part B costs. Consistent with existing policy, for inpatient acute 60 day length of stays, MA plans that establish a lower MOOP limit have the flexibility to set cost sharing above 125 percent of estimated Medicare Fee-for-Service cost sharing as long as the total cost sharing for the inpatient benefit does not exceed the MOOP limit or cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis.

This proposal would continue the established percentage of estimated Medicare FFS cost sharing for the mandatory and lower MOOP limits (100 percent and 125 percent respectively) to determine inpatient hospital acute and psychiatric cost sharing limits. Using the rule proposed for paragraph (f)(6)(ii)(A), all inpatient hospital acute and psychiatric cost sharing limits would be rounded to the nearest or lower whole $1 increment. Our proposal for limits on the cost sharing an MA plan uses for inpatient acute and psychiatric services aligns with our current practice (with some modifications, as discussed) and will provide benefit design stability for MA plans. CMS would continue to publish acceptable inpatient hospital acute and psychiatric cost sharing limits and a description of how the regulation standard is applied (that is, the methodology used) through subregulatory means, such as Health Plan Management System (HPMS) memoranda, issued prior to bid submission each year.

Table 4 is based on the most recent, complete Medicare FFS data available and then projected to contract years 2022 through 2024 to provide an illustrative example of how CMS would apply our proposals related to inpatient hospital acute standards for the 10-day length of stay scenario. As such, the limits for contract years 2022 through 2024 in Table 4 are illustrations only. The actual cost sharing limits developed under the rules we are proposing would change each year as OACT will update Part A deductible, Part B professional costs, and Medicare FFS cost assumptions annually prior to bid submission; the actual cost sharing limits for these future years, applying the final rules, could increase or decrease accordingly. In developing Table 4, we calculated the proposed contract year 2022 inpatient hospital acute 10-day length of stay scenario cost sharing limit for a MA plan that establishes a mandatory MOOP limit ($2,242 in Table 4) as follows:

(i) Add the projected Part B professional costs per day, up to a 10-day inpatient acute hospital stay. The

first day Part B professional costs are $251.00, followed by, $77.00, $49.00, $47.00, $50.00, and $245.00 for the next five days combined. This totals to $719.00 for a 10-day stay, regardless of the health condition initiating the hospitalization.

(ii) Add the $719.00 subtotal of projected Part B professional costs to the projected Part A deductible ($1,476.00) which equals $2,195.00.

(iii) Add 60 percent of the ESRD cost differential ($46.80) to the sum of Part A and B costs ($2,195.00) which equals $2,241.80.

(iv) Round that sum ($2,241.80) to the nearest whole dollar which equals, $2,242.00.

TABLE 4—ILLUSTRATIVE EXAMPLE OF COST SHARING LIMITS BASED ON CURRENT MEDICARE FFS DATA FOR INPATIENT HOSPITAL ACUTE 10-DAY LENGTH OF STAY SCENARIO

MOOP limit	Percent of estimated medicare FFS cost sharing	Contract year 2022	Contract year 2023	Contract year 2024
Mandatory	100	$2,242	$2,257	$2,273
Intermediate	Approximate numeric midpoint*	2,522	2,540	2,557
Lower	125	2,802	2,822	2,841

*The intermediate MOOP limit would be based on the related mandatory MOOP cost sharing limit, less approximately 50 percent of the numeric difference between the mandatory and voluntary MOOP cost sharing limits.

We expect to publish the annual inpatient hospital acute and psychiatric limits with a description of how the regulation standard is applied (that is, the methodology used) through HPMS memos issued prior to bid submission each year. We solicit comment on whether additional regulation text is necessary to establish when those memos should be released. We also refer readers to Table 8, which includes the proposed inpatient hospital acute and psychiatric cost sharing limits (for all length of stay scenarios) using the methodology we have proposed in § 422.100(f)(6)(iv). These are only projections of potential inpatient hospital acute and psychiatric cost sharing limits for contract years 2022 through 2024 to illustrate the potential impact of our proposal for incorporating the out-of-pocket costs of Medicare FFS beneficiaries with diagnoses of ESRD into the most recent, complete Medicare FFS data used to set the MA inpatient hospital acute and psychiatric limits. We intend to apply the proposed revised regulations each year to calculate the inpatient hospital acute and psychiatric limits.

CMS requests comments and suggestions on its application and implementation of this proposal for these cost sharing standards. CMS also seeks comments and suggestions on whether additional regulation text or restructuring of § 422.100(f)(6)(iv) is needed to achieve CMS's goal of providing additional transparency on how CMS will: (1) Develop the seven length of stay scenarios for inpatient hospital acute and psychiatric services; (2) transition ESRD costs into inpatient hospital acute and psychiatric limit calculations; and (3) calculate inpatient hospital acute and psychiatric limits after the ESRD cost transition is complete.

3. Basic Benefits for Skilled Nursing Facilities (SNFs), Outpatient, and Professional Services Subject to Cost Sharing Limits (§§ 422.100(j))

We are also proposing to codify and adopt specific cost sharing limits for certain benefits (by individual service and by category) that are based on a comparison to the cost sharing applicable in the Medicare FFS program. For example, the cost sharing limit for days 21–100 in a SNF is calculated by taking one eighth of the projected Part A deductible for the applicable contract year. In addition, the cost sharing limit for days 1 to 20 in a SNF is set at $0 for MA plans that establish a mandatory MOOP limit and MA plans that establish a lower or intermediate MOOP limit are permitted nominal cost sharing limits to align with Medicare FFS and balance incentives for the various types of MOOP limits. In codifying the current policy and in proposing to add new limits, we are relying on both section 1852(a)(1)(B)(iv)(IV) and section 1852(b) of the Act. Section 1852(a)(1)(B)(iv)(IV) of the Act explicitly authorizes the Secretary to identify services that the Secretary determines appropriate (including services that the Secretary determines require a high level of predictability and transparency for beneficiaries) to be subject to a cost sharing limit that is tied to the cost sharing imposed for those services under original Medicare. We have traditionally relied on how higher cost sharing for these benefits discriminates against the enrollees who need these services in establishing limits in the past. Charging higher cost sharing for specific services discriminates against and discourages enrollment by beneficiaries with a health status that requires those services.

Following the discussion is a detailed chart (Table 5) which illustrate the cost sharing limits based on the methodology proposed for contract year 2022, similar to the chart CMS included in the annual Call Letter in past years. Table 5 is based on applying the rules we have proposed in §§ 422.100(f)(6) and (j)(1) and (2) and 422.113(b)(2)(v) and (vi).

a. Range of Cost Sharing Limits for Certain Outpatient and Professional Services

As noted in the 2020 Final Call Letter, CMS has an established policy of affording MA plans greater flexibility in establishing Parts A and B cost sharing when the MA plan adopts a lower, voluntary MOOP limit; less flexibility is available to plans that adopt the higher, mandatory MOOP limit. In contract year 2020, CMS provided this flexibility, on varying levels, for a number of service categories. For example, service categories where we have allowed greater cost sharing flexibility included the first 20 days of a stay at a SNF, emergency care/post stabilization care, home health, and all categories of durable medical equipment (DME).

CMS developed this proposal to provide MA organizations with benefit design flexibilities and to balance beneficiary incentives for each type of MOOP. Accordingly, CMS is proposing to modify the regulation at § 422.100(f)(6) to establish a range of cost sharing limits based upon the MOOP limit established by the MA plan for specific basic benefits (as defined in § 422.100(c)(1)) offered on an in-network basis.

CMS proposes to add § 422.100(f)(6)(iii) to specify that for basic benefits that are professional services furnished in-network, MA plans may have greater flexibility in setting cost sharing based on the MOOP

limit they establish. In our proposal for paragraph (f)(6)(iii), discussed in detail at section VI.B.1. of this proposed rule, we address the type of data that will be used to set cost sharing limits for those professional services and, in proposed paragraphs (f)(6)(iii)(C)(*1*), (*2*), and (*3*) to specify the maximum cost sharing limit based on the MOOP limit established by the MA plan. In addition to those cost sharing limits, we are also proposing to amend § 422.100(j) to impose cost sharing limits for specific benefits and specific categories of benefits that are based on the cost sharing used in original Medicare. Our proposal for § 422.100(j) also takes into account the MOOP type used by an MA plan to grant additional cost sharing flexibility to MA plans. Therefore, under our proposed rule as a whole, multiple standards will apply to the cost sharing for professional services and outpatient benefits. Table 5 in this section summarizes these proposals by illustrating the copayment limits that would be applicable to in-network cost sharing for basic benefits, using projections based on the most recent, complete data that is currently available.

CMS will, in its annual review of plan cost sharing, monitor both copayment amounts and coinsurance percentages. Although MA plans have the flexibility to establish cost sharing amounts as copayments or coinsurance, MA plans should keep in mind, when designing their cost sharing, that enrollees generally find copayment amounts more predictable and less confusing than coinsurance. Copayments are expected to reflect specific benefits identified within the PBP service category or a reasonable group of benefits or services provided. Some PBP service categories may identify specific benefits for which a unique copayment would apply (for example, category 7a includes primary care services), while other categories include a variety of services with different levels of costs which may reasonably have a range of copayments based on groups of similar services (for example, category 15 includes Part B drugs—other which covers a wide range of products and costs). We note that MA plans may establish one cost sharing amount for multiple visits provided during an episode of care (for example, several sessions of cardiac rehabilitation) as long as the overall (or total) cost sharing amount satisfies CMS standards. If the proposals for §§ 422.100(f)(6) and (j) and 422.113(b)(2)(v) and (vi) are finalized, contract year 2022 bids must reflect enrollee cost sharing for in-network services no greater than the amounts calculated using the rules in those regulations. For example, CMS would permit an MA plan that establishes a lower MOOP limit to establish up to 50 percent coinsurance or actuarial equivalent copayment for cardiac rehabilitation (a professional service for which cost sharing is subject to § 422100(f)(6)(iii)), and other services included in Table 5 where we do not propose a specific actuarially equivalent copayment limit. MA organizations have the option to charge either coinsurance or a copayment for most service category benefits.

b. Emergency and Urgently Needed Services (§ 422.113(b)(2)(v) and (vi))

Most of these proposals for limiting cost sharing for basic benefits use methodologies that permit CMS to annually update the dollar amount applicable to copayments while the coinsurance limits would remain at a specified percentage of the total MA plan financial liability. CMS believes a different approach for emergency services is appropriate, as our analyses with OACT find shifts in payment trends may affect emergency services costs more so than urgently needed services and encompass care for a more complex patient. In addition, CMS recognizes that MA plans are able to manage urgently needed services similar to professional services like primary and specialty care in a manner that may not be appropriate or applicable for emergency services. Accordingly, we propose to codify in existing regulation at § 422.113(b)(2)(v) that a maximum cost sharing limit permitted per visit for emergency services corresponds to the MOOP limit established by the MA plan. Our proposal also incorporates elements from the current rule at § 422.113(b)(2)(v), which requires MA organizations to limit cost sharing to enrollees for emergency services that is the lesser of what the enrollee would pay for the services if they were obtained through the MA organization or the amount CMS sets annually.

We are proposing, at § 422.113(b)(2)(v), effective for contract year 2022 and subsequent years, that the MA organization is financially responsible for emergency and urgently needed services with a dollar limit on emergency services including post-stabilization services costs for enrollees that is the lower of—

(A) The cost sharing established by the MA plan if the emergency services were provided through the MA organization; or

(B) A maximum cost sharing limit permitted per visit that corresponds to the MA plan MOOP limit as follows:

(1) $115 for MA plans with a mandatory MOOP limit.

(2) $130 for MA plans with an intermediate MOOP limit.

(3) $150 for MA plans with a lower MOOP limit.

To develop this proposal, CMS looked to the projected median total allowed amount for emergency services (including visit and related procedure costs) using the most recent, complete Medicare FFS data that includes 100 percent of the out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD. We propose to include 100 percent of ESRD costs instead of a gradual transition as the difference in median amounts without ESRD costs and with 100 percent of ESRD costs for contract year 2022 is only $4 ($759 versus $755). The proposal for the cost sharing limits for an MA plan with a mandatory MOOP limit and an MA plan with a lower MOOP limit are tied to the dollar figures that are 15 percent and 20 percent of that median cost, rounded to the nearest whole $5 increment. For example, we reached the mandatory MOOP limit amount by multiplying the projected median total allowed amount for emergency services/post stabilization care with 100 percent of ESRD costs ($755) by 15 percent, which equals $113.25. Then we rounded to the nearest whole $5 increment ($115). The proposed maximum cost sharing limits for MA plans with an intermediate MOOP limit is based on the numeric midpoint of the related cost sharing limits for MA plans with mandatory and lower MOOP limits, rounded to the nearest whole $5 increment. In consultation with the OACT, CMS determined that using the projected median allowed amounts from the most recent, complete Medicare FFS with 100 percent of related ESRD costs (versus projected average Medicare FFS allowed amounts) was more appropriate given the distribution of emergency services and shifts in payment trends. CMS will monitor trends and consider updating cost sharing limits for both urgently needed services and emergency services in future rulemaking based on emerging trends.

In addition, CMS believes it can be difficult for enrollees to differentiate emergency services from post-stabilization services and as such, proposes clarifying updates to the language within paragraph (b)(2)(v) to note that cost sharing limits for emergency services include post-stabilization service costs. We are also proposing to set cost sharing limits for

urgently needed services that are subject to § 422.113(b)(2)(vi). We believe that urgently needed services are most like professional services and therefore, are proposing that the same cost sharing limits for professional services under § 422.100 will apply to urgently needed services, regardless whether those urgently needed services are furnished in-network or out-of-network. We are not proposing any changes to § 422.113 regarding the MA organization's obligations to cover and pay for emergency services, post-stabilization services, and urgently needed services but only to codify specific cost sharing limits for those services.

c. Services No Greater Than Original Medicare

Section 1852(a)(1)(B) of the Act specifies that MA plans may not charge enrollees higher cost sharing than is charged under original Medicare for chemotherapy administration services (which we have implemented as including Part B—chemotherapy/radiation drugs integral to the treatment regimen), skilled nursing care, and renal dialysis services. This rule is currently implemented in §§ 417.454(e) (for cost plans) and 422.100(j) (for MA plans). We are proposing to restructure § 422.100(j) as part of codifying cost sharing limits for other services. Under our proposal, cost sharing standards for cost plans will remain the same. In our current interpretation and application of this requirement for skilled nursing care, we have addressed the first 20 days of a SNP stay differently than days 21 through 100. In Medicare FFS, there is no cost sharing for the first 20 days of a SNP stay. MA plans that establish a voluntary MOOP limit can establish per-day cost sharing for the first 20 days of a SNF stay, but the total cost sharing for the overall SNF benefit (that is, days 1 through 100) must be no higher than the actuarially equivalent cost sharing in original Medicare and the per-day cost sharing for days 21 through 100 must not be greater than the projected original Medicare SNF amount. MA plans that establish the higher, mandatory MOOP limit must establish $0 per-day cost sharing for the first 20 days of a SNF stay and the per-day cost sharing for days 21 through 100 must not be greater than the original Medicare SNF amount. Under our proposal for § 422.100(j)(1)(iii), the current rule for MA plans that use the higher, mandatory MOOP limit will remain the same; we are proposing to permit limited cost sharing for the first 20 days of SNF for MA plans that establish either the lower or intermediate MOOP limit beginning in contract year 2022.

We propose to add the following services to the requirement that cost sharing charged by an MA plan may not exceed cost sharing required under original Medicare: (1) Home health services (as defined in section 1861(m) of the Act) for MA plans that establish a mandatory or intermediate MOOP limit and (2) Durable medical equipment (DME). For home health services, we are also proposing that when the MA plan establishes the lower MOOP limit, the MA plan may have cost sharing up to 20 percent of the total MA plan financial liability. Under our proposal, the DME per-item or service cost sharing must not be greater than original Medicare for MA plans that establish a mandatory MOOP limit. For MA plans that establish a lower or intermediate MOOP limit, total cost sharing for all DME PBP service categories combined must not exceed original Medicare on a per member per month actuarially equivalent basis, but such MA plan may establish cost sharing for specific items of DME that exceed the cost sharing under original Medicare. In order to codify these changes at § 422.100(j), we are proposing to reorganize that paragraph with new text at paragraph (j)(1) to provide that for the basic benefits specified, an MA plan may not establish in-network cost sharing that exceeds the cost sharing required under original Medicare. We are proposing to re-designate existing paragraphs (j)(1) through (3) as (j)(1)(i) through (iii) and to add new paragraphs (j)(1)(iv) (for home health) and (v) (for DME).

d. In-Network Service Category Cost Sharing Requirements

To provide context for our proposal to establish the methodology to set the various cost sharing limits in proposed §§ 422.100(f)(6) and (j) and 422.113(b)(2)(v) and (vi), we provide illustrative cost sharing limits for contract year 2022 in Table 5 based on that methodology and projections of the most recent, complete Medicare FFS data. Table 5 illustrates the coinsurance and copayment standards that would apply only to in-network Parts A and B services (unless otherwise indicated in the table as an application of the rules proposed at §§ 422.100(f)(6)(i) and 422.113(b)(2)(v) and (vi)) for the corresponding type of combined MOOP limit a MA plan chooses to establish. These are only projections of potential cost sharing limits for contract year 2022 to illustrate the potential impact of our proposal. If the proposal for the various amendments to §§ 422.100(f) and (j) and 422.113(b)(2)(vi) regarding cost sharing limits are adopted, we will update these numbers on an annual basis to establish the specific cost sharing limits MA organizations would not be permitted to exceed in establishing their benefit designs. Consistent with our proposal at § 422.113(b)(2)(v), the cost sharing limits for emergency services would remain the same each year unless the regulation is amended. We intend to apply the proposed revised regulations each year to calculate the cost sharing limits unless otherwise stated. We expect to publish the annual inpatient hospital acute and psychiatric limits with a description of how the regulation standard is applied (that is, the methodology used) through HPMS memoranda issued prior to bid submission each year. Under our proposal, all standards and cost sharing are inclusive of applicable service category deductibles, copayments and coinsurance, but do not include plan level deductibles. These cost sharing limits are based on projections of the most recent, complete Medicare FFS data that includes 100 percent of the out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD for basic benefits that are professional services, emergency services/post stabilization care, and urgent care. We propose to include 100 percent of ESRD costs versus a transition of ESRD costs over time as there were no significant difference when including ESRD for any of the physician specialties based on projections of the most, recent complete Medicare FFS from the OACT. For the service categories with only coinsurance limits (that is, limits defined as not applicable (N/A)), and those with $0 or nominal limits (such as SNF), we note that the related ESRD costs are not applicable. For example, our methodology of setting the SNF cost sharing limit for days 21 to 100 only considers the projected Part A deductible from the most recent, complete Medicare FFS data which is not affected by beneficiaries with diagnoses of ESRD enrolling in MA.

In Table 5 we do not include approximate actuarially equivalent copayment limits for: Cardiac rehabilitation, intensive cardiac rehabilitation, pulmonary rehabilitation, supervised exercise therapy (SET) for symptomatic peripheral artery disease (PAD), partial hospitalization, home health, therapeutic radiological services, DME, dialysis, Part B Drugs Chemotherapy/Radiation Drugs, and Part B Drugs—Other. In general, we found these categories are subject to a higher variation in cost or unique provider contracting arrangements

which makes using Medicare FFS average or median cost data less applicable for developing a standardized actuarially equivalent copayment value. As such, in order to monitor and enforce compliance with these cost sharing requirements that are based on the contracted rates the MA plan uses for in-network services, MA organizations may be required to provide information to CMS demonstrating how contracted rates comply with the regulation standards we are proposing here at § 422.100(f)(6). We solicit comment whether an explicit regulatory provision should be added to require MA organizations to demonstrate compliance with these standards upon request by CMS; such demonstration would include providing CMS with information substantiating the contracted rates for basic benefits that are professional services for which CMS has not established an approximate actuarially equivalent copayment limits, and illustrating how the MA organization determined its cost sharing amounts.

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TABLE 5: ILLUSTRATIVE CONTRACT YEAR 2022 IN-NETWORK SERVICE CATEGORY COST SHARING LIMITS

Service Category	PBP Section B data entry field	Lower MOOP	Intermediate MOOP	Mandatory MOOP
Inpatient Hospital – Acute - 60 days	1a	N/A	$5,514	$4,902
Inpatient Hospital – Acute - 10 days	1a	$2,802	$2,522	$2,242
Inpatient Hospital – Acute - 6 days	1a	$2,536	$2,282	$2,029
Inpatient Hospital Acute – 3 days	1a	$2,339	$2,105	$1,872
Inpatient Hospital Psychiatric - 60 days[6]	1b	$3,408	$3,067	$2,726
Inpatient Hospital Psychiatric - 15 days[6]	1b	$2,339	$2,105	$1,871
Inpatient Hospital Psychiatric – 8 days[6]	1b	$2,173	$1,955	$1,738
Skilled Nursing Facility – First 20 Days [1,2]	2	$20	$10	$0
Skilled Nursing Facility – Days 21 through 100 [1,2,7]	2	$184/d	$184/d	$184/d
Cardiac Rehabilitation[5]	3	50%	40%	30%
Intensive Cardiac Rehabilitation[5]	3	50%	40%	30%
Pulmonary Rehabilitation[5]	3	50%	40%	30%
Supervised exercise therapy (SET) for Symptomatic peripheral artery disease (PAD)[5]	3	50%	40%	30%
Emergency Care/Post Stabilization Care[3]	4a	$150	$130	$115
Urgently Needed Services[3]	4b	50% / $55	40% / $45	30% / $35
Partial Hospitalization[5]	5	50%	40%	30%
Home Health	6a	20%[5]	$0	$0
Primary Care Physician	7a	50% / $55	40% / $45	30% / $35
Chiropractic Care	7b	50% / $25	40% / $20	30% / $15
Occupational Therapy	7c	50% / $60	40% / $45	30% / $35
Physician Specialist	7d	50% / $80	40% / $65	30% / $50
Mental Health Specialty Services	7e	50% / $65	40% / $55	30% / $40
Psychiatric Services	7h	50% / $65	40% / $50	30% / $40
Physical Therapy and Speech-language Pathology	7i	50% / $85	40% / $65	30% / $50
Therapeutic Radiological Services[5]	8b	20%	20%	20%
DME-Equipment	11a	N/A	N/A	20%[5]
DME-Prosthetics	11b	N/A	N/A	20%[5]
DME-Medical Supplies	11b	N/A	N/A	20%[5]

Service Category	PBP Section B data entry field	Lower MOOP	Intermediate MOOP	Mandatory MOOP
DME-Diabetes Monitoring Supplies	11c	N/A	N/A	20%[5]
DME-Diabetic Shoes or Inserts	11c	N/A	N/A	20%[5]
Dialysis Services[1,5]	12	20%	20%	20%
Part B Drugs Chemotherapy/Radiation Drugs[1,4, 5]	15	20%	20%	20%
Part B Drugs-Other[5]	15	50%	40%	30%

[1] MA plans and 1876 Cost Plans may not charge enrollees higher cost sharing than is charged under original Medicare for Part B chemotherapy/radiation drugs integral to the treatment regimen, skilled nursing care, and renal dialysis services (§ 417.454(e) and proposed § 422.100(j)(1)(i), (ii), and (iii)).

[2] MA plans that establish a lower and intermediate MOOP limit may have cost sharing for the first 20 days of a SNF stay (proposed § 422.100(j)(1)(iii)). The per-day cost sharing for days 21 through 100 must not be greater than the original Medicare SNF amount, proposed at § 422.100(j)(1)(iii)(A). Total cost sharing for the overall SNF benefit must be no higher than the actuarially equivalent cost sharing in original Medicare, pursuant to section1852(a)(1)(B), and proposed § 422.100(j)(1)(iii)(B).

[3] The dollar amount for Emergency Care/Post Stabilization Care and Urgently Needed Services included in the table represents the maximum cost sharing permitted per visit (copayment or coinsurance) under proposed § 422.113(b)(2)(v) and (vi).

[5] MA plans may set cost sharing limits that are actuarially equivalent to the coinsurance limits based on their contracted rates under proposed § 422.100(f)(6)(iii)(A).

[6] Inpatient hospital psychiatric standards will be updated for contract year 2022 to incorporate differences in Part A deductible and cost impacts for beneficiaries with diagnoses of ESRD.

[7] This SNF limit is based on the 1/8th of the projected contract year 2021 Part A deductible, which will be updated for 2022.

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MA organizations with benefit designs using a coinsurance or copayment amount for which we are not proposing to publish a specific threshold for cost sharing (for example, coinsurance for inpatient or copayment for durable medical equipment) must maintain documentation that clearly demonstrates how the coinsurance or copayment amount satisfies the regulatory requirements for each applicable plan. This is consistent with existing MA program monitoring and oversight for MA organizations to be able to demonstrate compliance with applicable program requirements. Cost sharing and other plan design elements remain subject as well to § 422.100(f)(2), which prohibits MA plans from designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. This documentation may be used to address potential beneficiary appeals, complaints, and/or general oversight activities performed by CMS. In addition, MA plans are required to attest when they submit their bid that their benefits will be offered in accordance with all applicable Medicare program authorizing statutes and regulations.

4. Per Member per Month Actuarial Equivalent (AE) Cost Sharing Limits for Basic Benefits (§ 422.100(j)(2))

Under the statute and current regulations, total MA cost sharing for Parts A and B services must not exceed cost sharing for those services in Medicare FFS on an actuarially equivalent basis and must not be discriminatory. In order to ensure that cost sharing is consistent with both §§ 422.254(b)(4) and 422.100(f)(2), and current § 422.100(f)(6), CMS has historically evaluated cost sharing limits on a per member per month actuarially equivalent basis for the following service categories: Inpatient hospital, SNF, DME, and Part B drugs.

In proposed § 422.100(j)(2), we propose a rule requiring that total cost sharing for all basic benefits covered by an MA plan, excluding out-of-network benefits covered by a regional MA plan, must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis. This provision implements section 1852(a)(1)(B) of the Act and the carve out of out-of-network benefits covered by a regional MA plan is to be consistent with section 1852(a)(1)(B)(ii) of the Act. CMS is also proposing to codify our existing policy regarding the specific benefit categories that MA plans must not exceed the cost sharing for those benefit categories in original Medicare on a per member per month actuarially equivalent basis in § 422.100(j)(2)(i). Consistent with existing policy, the services subject to this requirement under our proposal are: (A) Inpatient hospital acute and psychiatric services, defined as services provided during a covered stay in an inpatient facility during the period for which cost sharing would apply under original Medicare; (B) DME; (C) Drugs and biologics covered under Part B of original Medicare (including both chemotherapy/radiation drugs and other

drugs covered under Part B); and (D) Skilled nursing care, defined as services provided during a covered stay in a SNF during the period for which cost sharing would apply under original Medicare.

This proposal would ensure that MA plans with greater cost sharing flexibility in these categories are not designing benefits in a way that discriminates against enrollees with health status factors and conditions that require these services. Further, limiting cost sharing this way will ensure that enrollees with certain conditions or who are high utilizers of these basic benefits are not discouraged from enrolling in MA plans. We are therefore relying on our authority under section 1852(a)(1)(B)(iv) and 1852(a)(2) of the Act to codify these rules requiring MA cost sharing to be limited based on cost sharing in original Medicare. In addition, we believe that setting copayment limits through quantitative formulas (such as those used for our inpatient hospital acute and psychiatric standards) may be less appropriate for some categories, like DME and Part B drugs. Cost sharing for these services may be better evaluated for discrimination on an aggregate service category basis. These categories include items or services that significantly vary in costs and/or may be subject to provider contracting arrangements that makes it difficult and arbitrary for CMS to establish a specific copayment amount for the category as a whole as opposed to specific items and benefits.

We are also proposing, at § 422.100(j)(2)(ii) that CMS may extend flexibility for MA plans when evaluating actuarial equivalent cost sharing limits for those service categories to the extent that the per member per month cost sharing limit is actuarially justifiable based on generally accepted actuarial principles and supporting documentation included in the bid, provided that the cost sharing for specific services otherwise satisfies published cost sharing standards. We believe that this exception will apply in limited situations, such as when the MA plan uses capitated arrangements with provider groups, operate their own facilities, or other unique arrangements. This flexibility codifies and is consistent with current policy and practice.

This proposal aims to clarify how CMS uses the most relevant and appropriate information to determine whether specific cost sharing is discriminatory and to set standards and thresholds above which CMS believes cost sharing is discriminatory. Similar to current practice, CMS intends to use HPMS memoranda to communicate prior to bid submission its application of the regulation for future years, as appropriate. We solicit comment on the previously discussed proposals.

C. Plan Crosswalks for Medicare Advantage (MA) Plans and Cost Plans (§§ 417.496 and 422.530)

We are proposing to codify the current process and conditions under which MA organizations and 1876 cost plans can transfer their enrollees into the same plan or plan type from year to year when no other election has been made (this process is a ''plan crosswalk''), as well as when plans can transfer their enrollees to other plans of a different type offered by the same MA organization or cost plan (this is a ''crosswalk exception''). Our proposal defines plan crosswalks, codifies rules that protect a beneficiary's right to choose a plan, and specifies the circumstances under which MA organizations and cost plans may transfer beneficiaries into another plan of the same type offered by the MA organization or, in the case of cost plans, transfer enrollees from that cost plan benefit package to another plan benefit package (PBP) under the same contract. We generally use the terms ''plan'' and ''PBP'' interchangeably to refer to a specific plan offered under a contract. Specifically, the term PBP is used to describe the individual benefits packages that may be offered under a singular plan. Section 1851(c)(3)(B) of the Act provides for evergreen elections which are when an individual who has made an election is considered to have continued to make the same election until the individual makes a change to the election, or the MA plan is discontinued or no longer serves the area in which the individual resides. In many cases, our crosswalk policy is a mechanism for operationalizing these evergreen elections.

Section 1851 of the Act provides that Medicare beneficiaries who are entitled to Part A and enrolled in Part B may elect to receive benefits through enrollment in an MA plan of their choice and authorizes CMS to adopt the process, form and manner for making and changing enrollment elections. We are proposing to codify existing policy regarding crosswalks and crosswalk exceptions using this authority and our authority under sections 1856(b)(1) and 1857(e)(1) of the Act to adopt standards and contract terms for MA organizations. In furtherance of the beneficiary's right to choose and implementing evergreen elections, CMS is proposing to codify existing policy in new regulations at §§ 417.496 and 422.530 to define plan crosswalks, implement rules that protect a beneficiary's right to choose a plan, and describe allowable circumstances under which MA organizations may transfer beneficiaries from one of its MA plans into another of its MA plans or a cost contract may transfer beneficiaries from one of its plans into another of its cost plans. With respect to cost plans, we are proposing to codify existing enrollment policy related to the transfer of enrollees from an entity's cost plan to another cost plan, under the authority of section 1876(i)(3)(D) of the Act, which requires that cost contracts shall contain such other terms and conditions, not inconsistent with the statute, as the Secretary may find necessary and appropriate. Our proposal does not include rules for deeming enrollment from a cost plan to an MA plan under sections 1876(h)(5)(C) and 1851(c)(4) of the Act. The statute does not permit deeming of enrollees from cost plans to MA plans beyond contract year 2018.

We are also proposing, at § 422.530(d), the procedures that an MA organization must follow when submitting a crosswalk or a crosswalk exception request. An MA organization must submit all allowable crosswalks in writing through the bid submission process in HPMS by the bid submission deadline announced by CMS. Through the bid submission process, the MA organization may indicate if a crosswalk exception request is needed at that time, but the MA organization must request a crosswalk exception later through the crosswalk exception functionality in HPMS by the deadline announced by CMS. CMS verifies the exception request and notifies the requesting MA organization of the approval or denial of the request after the crosswalk exception deadline has expired. These exceptions must be submitted by the MA organization to ensure that plan benefit package (PBP) enrollment is allocated appropriately. We solicit comment on what, if any, additional procedures we should adopt for managing crosswalk exceptions.

CMS has developed extensive guidance addressing the transfer of enrollees from one PBP offered by an organization to another PBP offered by that organization under the same contract.[71] The guidance, applicable to MA organizations and cost plans, was developed in light of the ability of MA organizations and cost plans to revise their benefit offerings and PBPs from year to year. The transfer of enrollees

[71] Chapter 16b of the Medicare Managed Care Manual and Process for Requesting an HPMS Crosswalk Exception for Contract Year (CY) 2020 (released annually).

from one PBP to another under these circumstances serves to facilitate evergreen elections. MA organizations frequently make business decisions resulting in changes of their MA plans offered for enrollment in the following contract year. Each year, through the bid process for plan design and an application process for service area changes, MA organizations submit changes in coverage and cost sharing design for their MA plans. In addition, MA organizations have the ability to terminate existing plans and apply to offer new plans. While cost plan organizations may not offer new cost plans, they also may make changes in their benefit and cost sharing design and seek service area changes through an annual process. CMS has issued annual sub-regulatory guidance related to changes of this type for MA and cost plans to address how MA organizations and cost plans may transition enrollees from a plan that is terminating or changing its service area to another plan offered by the same organization. These transitions are useful to preserve beneficiary enrollment and are subject to a number of beneficiary protections. We are proposing to codify existing crosswalk policy to clearly identify the basic rules for plan crosswalks, including the parameters for allowable crosswalks, and formalize CMS's crosswalk exception review process. Crosswalk exceptions are specific circumstances where a crosswalk is not automatically authorized under our policies but CMS permits MA organizations and cost plans to transfer beneficiaries into another plan of the same type offered by the MA organization or cost plan after a review, provided that certain requirements are met. The crosswalk exceptions process would allow CMS to review and validate the existence of an exception, and then manually effectuate the transaction in our system. Crosswalk exceptions are not part of the standard, annual PBP renewal process. These new regulations would be codified at §§ 417.496 and 422.530 to govern, respectively, cost plans and MA organizations.

We are proposing, at §§ 417.496(a)(1) and 422.530(a)(1), to define a plan crosswalk as the movement of enrollees from one PBP to another PBP under the same contract between the MA or cost organization and CMS. MA and cost organizations complete these crosswalk transactions annually as part of the renewal process. Unlike MA plans, however, cost plans do not include different plan types such as PPOs, PFFS, and special needs plans, therefore in § 417.496(a)(2), we are not specifying, as we are for the MA section, that crosswalks from one plan type to another are prohibited.

In § 422.530(a)(5), we propose to define the types of MA plans that we consider different for purposes of crosswalk policy. We propose that health maintenance organizations, provider-sponsored organizations, and regional and local preferred provider organizations coordinated care plans are different plan types, even though they are all coordinated care plans. Additionally, we note here that the segmented plans are not a ''type'' of plan in MA and that crosswalks are permitted between segmented and non-segmented plans. We do not include in the cost plan crosswalk regulation that contract transactions related to plan types and policies such as segmentation and continuation, which are specific to MA contract transactions. The majority of crosswalks involve moving enrollees from one contract year plan to the corresponding plan for the following contract year. Therefore, enrollees are not required to make an enrollment election to remain enrolled in their chosen plan. In § 417.496(a)(2)(i), we are proposing to codify the general rule, that crosswalks are prohibited between different cost contracts and in § 417.496(a)(2)(ii), we are proposing to codify that crosswalks are prohibited between different cost plan IDs under a cost contract unless the crosswalk qualifies for an exception to this requirement. In § 417.496(c)(1)(i) and (ii) we propose to codify the exception that cost contracts terminating PBPs with optional supplemental benefits may transfer enrollees to another PBP with or without optional benefits under the same cost contract as long as enrollees who have Part A and B benefits only are not transferred to a PBP that includes Part D. In § 417.496(c)(1)(iii)(A), (B), and (C), we propose to codify that an enrollee in a terminating PBP that includes Part D may only be moved to a PBP that does not include Part D if the enrollee is notified in writing that she/he is losing Part D coverage, the options for obtaining Part D, and the implications of not getting Part D through some other means. In § 422.530(a)(2), we are proposing to codify the general rule that crosswalks are prohibited between different MA contracts or different plan types (for example, HMO to PPO). This means that crosswalks are only permitted between plans of the same type under the same contract. However, we are also proposing, in § 422.530(c), the limited circumstances in which CMS will allow a crosswalk transaction that does not comply with this general prohibition on crosswalks to different contracts. We include in § 422.530(a)(2) a reference to these ''exceptions'' permitted under paragraph (c). The exceptions we are proposing in § 422.530(c) apply to MA plans only as they pertain to MA policies so we are not proposing similar regulation text in § 417.496.

As most plan crosswalks are related to contract renewals and non-renewals, we are also proposing a general rule at § 422.530(a)(3) to require that MA plans must comply with renewal and nonrenewal rules in §§ 422.505 and 422.506 in order to be eligible to complete plan crosswalks. In § 417.496(a)(3), we are proposing that cost plans must comply with the renewal and non-renewals per §§ 417.490 and 417.492, in order to be eligible to complete plan crosswalks. In § 422.530(a)(4), we are proposing that enrollees must be eligible for enrollment under §§ 422.50 through 422.54 in order to be moved from PBP to another PBP.

In §§ 422.530(b) and 417.496(b), we propose to codify the existing crosswalk policy by specifying the circumstances under which a crosswalk is permitted so that an MA organization or cost plan may move enrollees into, respectively, another MA plan or cost plan. For MA plans, in proposed paragraph (b)(1), we address permissible crosswalks for all plan types and in proposed paragraph (b)(2), we address crosswalks that are permissible only for MA special needs plans (SNPs). We remind readers that the MA plan types are identified in § 422.4; therefore, we specified in § 422.530(a)(5) that the different types of coordinated care plans are considered different ''plan types'' for purposes of crosswalking policy. For cost plans, in proposed paragraph (b), we address permissible crosswalks for cost plans.

1. Cost Plans and All MA Plan Types

a. Renewal Plan

An MA or cost organization may continue to offer, that is, renew, a current PBP that retains all of the same service area for the following year; the renewing plan must retain the same PBP ID number as in the previous contract year. We are proposing to codify this as a permissible crosswalk in paragraph (b)(1)(i) for MA plans and § 417.496(b)(1) for Cost plans. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the MA or cost organization will not submit enrollment transactions to CMS for current enrollees but will transition all enrollees

from the current PBP to the new PBP with the same PBP ID number for the following year. New enrollees must complete enrollment requests, and the MA or cost organization will submit enrollment transactions to CMS for those new enrollees. Under §§ 422.111 and 417.427 current MA and cost enrollees of a renewed PBP, respectively, must receive an Annual Notice of Change (ANOC) notifying them of any changes to the renewing plan.

b. Consolidated Renewal Plan

MA and cost organizations may combine two or more PBPs offered under the same contract in the current contract year into a single renewal plan, as a plan consolidation. When the consolidation includes two or more complete PBPs being combined and no PBP being split among more than one PBP in the next contract year, the MA or cost organization is permitted to transition all enrollees in the combined plans under one PBP under that contract, with the same benefits in the following contract year; the resulting PBP must have the plan ID of one of the consolidated plans. We are proposing to codify this as a permissible crosswalk in §§ 417.496(b)(2) and 422.530(b)(1)(ii). Current enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the MA or cost organization does not submit enrollment transactions to CMS for those current enrollees. The renewal PBP ID is used to transition current enrollees of the plans being consolidated into the designated renewal plan. In operationalizing this crosswalk, the MA or Cost organization may need to submit updated data to CMS for the enrollees affected by the consolidation. New enrollees in the consolidated renewal plan must complete enrollment forms and the MA or cost organization must submit the enrollment transactions to CMS for those new enrollees. Under §§ 422.111 and 417.427 MA and Cost plans, respectively, are required to provide an ANOC to all current enrollees in the consolidated renewal plan.

c. Renewal Plan With a Service Area Expansion (SAE)

An MA or cost organization may continue to offer the same cost plan or local MA plan but expand the service area to include one or more additional counties for the following contract year. To expand the service area of its plan(s), an MA or cost organization must submit a service area expansion (SAE) application to CMS for review and approval; CMS treats service area expansions as applications subject to the rules in part 422, subpart K, and § 417.402. An MA or cost organization renewing a plan with a SAE must retain the renewed PBP's ID number in order for all current enrollees to remain enrolled in that plan the following contract year. Current enrollees of a PBP that is renewed with a SAE are not required to take any enrollment action, and the MA or cost organization does not submit enrollment transactions to CMS for those current enrollees but will transition all enrollees from the current PBP to the new PBP with the same PBP ID number for the following year. We are proposing to codify this as a permissible crosswalk in § 422.530(b)(1)(iii) for MA plans and § 417.496(b)(3) for cost plans. New enrollees must complete enrollment forms and the MA or cost organization must submit the enrollment transactions to CMS for those new enrollees. Under §§ 422.111 and 417.427 MA and cost plans, respectively, are required to provide an ANOC to all current enrollees of a renewed PBP with a SAE.

d. Renewal Plan With a Service Area Reduction

An MA organization offering a local MA plan may reduce the service area of a current contract year PBP; similarly, a cost organization may reduce the service area of a cost plan. This service area reduction (SAR) means that enrollees who were in the part of the service area being reduced will generally not be eligible to remain in the plan because of the residence requirement in §§ 417.422(b), 422.50(a)(3), and 422.54. We propose to address crosswalks that may occur in connection with a service area reduction in §§ 422.530(b)(1)(iv) and 417.496(b)(4). We are proposing that when there is a service area reduction for a plan, the MA organization or cost plan may only crosswalk the enrollees who reside in the remaining service area to the plan in the following contract year that links to a current contract year plan but only retains a portion of the prior service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area. MA organizations may have different options available to them in terms of notices and the ability to offer a continuation of enrollment under § 422.74(b)(3)(ii) depending on the other MA plans in the area at the time of the service area reduction. We are proposing regulation text to address the different scenarios.

In § 422.530(b)(1)(iv)(C), we propose that enrollees that are no longer in the service area of the MA or cost plan will be disenrolled at the end of the contract year and will need to elect another plan (or default to original Medicare). The MA or cost organization must submit disenrollment transactions to CMS for these enrollees. In addition, the MA or cost plan organization must send a Medigap guaranteed issue rights to the affected enrollees and a non-renewal notice to enrollees in the reduced portion of the service area that includes notification of special election period (SEP). We are also proposing to codify, at § 422.530(b)(1)(iv)(D) specific rules about what information may be provided by the MA organization about its other MA plan options in the area that will no longer be part of the service area of the continued plan. Per the marketing and communication regulations, we are proposing at §§ 422.2263(a) and 423.2263(a) and discussed elsewhere in this proposed rule, marketing information about other MA plan options offered by the MA organization for the prospective plan year can begin October 1 of each year for the following contract year.

2. Special Needs Plans (SNPs)

Under our current crosswalk policies, MA Special Needs Plans (SNPs) follow the general rules, which we propose to codify in § 422.530(b)(1), and are permitted additional flexibility for crosswalks in specific situations. We propose to codify regulation text to identify the additional crosswalks permitted for SNPs in § 422.530(b)(2). These additional scenarios vary based on the type of SNP. We reiterate that MA organizations may not crosswalk enrollees from one SNP type to a different SNP type, as that would constitute crosswalking into a different type of plan, which is prohibited by proposed § 422.530(a)(2).

(a) Chronic Condition SNPs (C–SNPs): We are proposing to codify four permissible crosswalks specific to C–SNPs at § 422.530(b)(2)(ii)(A) through (D). C–SNPs serve and are limited to enrolling special needs individuals who have a severe or disabling chronic condition(s) and would benefit from enrollment in a specialized MA plan. The MA organization offering the C–SNP may target one or more specific severe or disabling chronic conditions. When a C–SNP targets more than one severe or disabling chronic condition, we refer to that as a ''grouping'' and we have addressed groupings in guidance in Chapter 16b of the Medicare Managed Care Manual. These permissible crosswalks reflect the limitations on

eligibility for C–SNPs, as different C–SNPs serve different populations depending on the chronic condition(s) targeted for enrollment restriction.

A. Renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

B. Non-renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

C. Renewing C–SNP with a grouping that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping.

D. Non-renewing C–SNP in a grouping that is transitioning eligible enrollees into a different grouping C–SNP if the new grouping contains at least one condition that the prior plan contained.

(b) Institutional-SNPs:

We are proposing to codify five permissible crosswalks specific to I–SNPs at § 422.530(b)(2)(iii)(A) through (E). I–SNPs are limited to enrolling individuals who are institutionalized or institutionalized-equivalent, as those terms are defined in § 422.2. I–SNPs may limit their enrollment to either institutionalized or institutionalized-equivalent individuals or may enroll both categories of individuals. These permissible crosswalks reflect the enrollment limitations on I–SNPs.

A. Renewing Institutional SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

B. Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

C. Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.

D. Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.

E. Non-renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/Institutional Equivalent SNP.

(c) Dual Eligible-SNPs (D–SNPs):

We are not proposing to codify any permissible crosswalks specific to D–SNPs.

e. Exceptions

In some instances, crosswalk actions must be manually reviewed and entered by CMS staff. We call these *crosswalk exceptions.* We propose to codify at § 422.530(c) when CMS will approve a request for a crosswalk exception and permit crosswalks in situations that are not specified in § 422.530(b). These exceptions address certain unusual circumstances involving specific types of plans or contract activities. Under our proposal, only an exception specified in § 422.530(c) would be approved and recognized as an additional circumstance when a crosswalk is permitted. We propose the following exceptions to the limits on the crosswalk process:

1. When a non-network or partial network based private fee-for-service (PFFS) plan is transitioning to either a partial network or a full network PFFS plan, we are proposing to permit a crosswalk when CMS determines it is in the interest of beneficiaries. CMS will consider whether the risks to enrollees are such that they would be better served by remaining in the plan, whether there are other suitable managed care plans available, and whether the enrollees are particularly medically vulnerable, such as institutionalized enrollees. We anticipate that granting these exceptions would be extremely rare since in the great majority of instances enrollees have choices of multiple MA plans or Original Medicare and are able to exercise their choice. We are specifically proposing to restrict crosswalks between these network and non-network PFFS plans because the way enrollees will access health care services is significantly different in each of these plans. Section 1852(d)(5) of the Act establishes that in areas that are determined to be ''network areas'' PFFS plans can only operate by having a network of providers that meets CMS current network adequacy standards. The network based PFFS plan functions very much like a MA PPO plan in that there is a network of contracted providers through which enrollees can obtain Medicare covered services. In addition, an enrollee in a network based PFFS plan has the option of also going out-of-network for plan covered services though their cost sharing may be higher. However, in areas of the country that have determined to be non-network areas with respect to PFFS plans, the PFFS plan can operate without a network and enrollees must seek care from any willing provider under the non-network PFFS plans terms and conditions of payment. Because these two types of PFFS plans function very differently for enrollees obtaining covered health care services, we do not believe crosswalks should be generally permitted between these two types of PFFS plans.

2. When MA plans offered by two different MA organizations that share the same parent organization are consolidated such that the MA plans under separate contracts consolidated under one surviving contract, the enrollees from the consolidating plans may be moved to an MA plan under the surviving plan. As a result of the consolidation of contracts, enrollees from at least one of the PBPs are transitioned to another contract; therefore, CMS limits approval of these crosswalks to an exception because of the movement across different contracts. As part of reviewing a request for this crosswalk exception, CMS reviews the contract consolidation to ensure compliance with the change of ownership regulations (§§ 422.550 through 422.553).

3. Renewing D–SNP in a multi-state service area that is reducing its service area to accommodate a state contract in part of the service area. When a renewing D–SNP in a multi-state service area reduces its service area to accommodate state contracting efforts in the service area, we are proposing to permit a crosswalk exception at § 422.530(c)(3). Under this proposed crosswalk exception, enrollees who are no longer in the service area would be moved into one or more new or renewing D–SNPs in their service area, when CMS determines it is necessary to accommodate changes to D–SNP state contracts.

4. Renewing D–SNP that transitions eligible enrollees into another D–SNP. We propose a crosswalk exception at § 422.530(c)(4) for circumstances where an MA organization renews a D–SNP for the upcoming contract year, but has another available new or renewing D–SNP for the upcoming contract year, and the two D–SNPs are offered to different populations. An MA organization may change—or as part of state contracting, may be required to change—a D–SNP's eligibility criteria for the upcoming contract year. As a result, some current enrollees may no longer be eligible for their current D–SNP. However, the MA organization may have a new or renewing D–SNP in the same service area with eligibility requirements that can accommodate the enrollees who are no longer eligible for their current D–SNP. In such cases, CMS may determine it is in the best interests to current enrollees who are no longer eligible for their D–SNP to allow such a crosswalk exception.

5. Renewing C–SNP with a grouping that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping. This crosswalk exception differs from

the allowable crosswalk in § 422.530(b)(2)(i)(B) because it is a renewing C–SNP and not a non-renewing C–SNP. A crosswalk exception is required in order for CMS to identify which enrollees are moving from the renewing plan C–SNP to the other C–SNP. In a non-renewing C–SNP, all enrollees would be crosswalked to another plan or disenrolled.

CMS crosswalk policies are designed to protect the rights of enrollees to make a choice about the plan from which they wish to receive Medicare benefits while facilitating how section 1851(c)(3)(B) of the Act requires evergreen elections. This proposal would codify policies and standards CMS has implemented that allow MA and Cost organizations the flexibility to make business decisions about the benefit and cost sharing design of a plan while preserving the rights of beneficiaries to make informed choices about their health care coverage. We invite comments about codifying our existing plan crosswalk policies.

D. Medicare Advantage (MA) Change of Ownership Limited to the Medicare Book of Business (§ 422.550)

Section 1857 of the Act requires each MA organization to have a contract with CMS in order to offer an MA plan. Section 1857(e)(1) of the Act authorizes the adoption of additional contract terms that are consistent with the statute and that the Secretary finds are necessary and appropriate. Consistent with this authority, at the beginning of the Part C program we implemented contracting regulations in § 422.550 which provide for the novation of an MA contract in the event of a change of ownership involving an MA organization. (63 FR 35106) Under the regulations, codified at §§ 422.550 through 422.553, the execution of a novation agreement is required when an MA organization is acquired or when it no longer is able or desires to continue to participate in the MA program and wants to transfer its ownership to a different entity. When an MA organization is no longer able or willing to participate in the MA program, a change of ownership can provide both the holder of the contract and CMS with an opportunity to transfer the ownership of the contract to a different entity with little or no disruption to enrolled beneficiaries. In this instance, CMS would agree to a novation of the existing MA contract because it promotes the efficient and effective administration of the MA program.

We propose to revise § 422.550 by adding a new paragraph at § 422.550(f) to restrict the situations in which CMS will agree to an MA contract novation to those transfers involving the selling of the organization's entire line of MA business, which would include all MA contracts held by the legal entity that is identified as the MA organization. It has been long-standing policy in the MA program that CMS will only recognize the sale or transfer of a legal entity's entire MA line, or book of business, consisting of all MA contracts held by the MA organization because we believe that allowing the sale of just one contract (when the MA organization has more than one MA contract) or pieces of a single contract can have a negative impact on beneficiary election rights. The proposed change would codify existing policy and also create more consistency in regulations between the Part D program and the MA program as stated in § 423.551(g).

This policy has not been applied in cases where contracts are transferred among subsidiaries of the same parent organization. We do not wish to interfere with an MA organization's (or parent organization's) ability to decide its corporate structure or contractual arrangements with its subsidiaries. Therefore, we are also proposing, at § 422.550(f)(1) an exception to the proposed limit for changes of ownership to only when the entire MA book of business is being transferred; that exception would be when the sale or transfer is of a full contract between wholly owned subsidiaries of the same parent organization.

We are proposing to codify explicitly in § 422.550(f)(2) that CMS will not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries, groups of beneficiaries enrolled in a plan benefit package, or one MA contract if the organization holds more than one MA contract. We reiterate that we believe that allowing the sale of just one contract (when the MA organization has more than one MA contract) or pieces of a single contract can have a negative impact on beneficiary election rights.

E. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

Section 1852(d)(1)(A) of the Act establishes that an organization offering an MA plan may select the providers from whom the benefits under the plan are provided so long as the organization makes such benefits available and accessible with reasonable promptness to each individual electing the plan within the plan service area. This is generally implemented at § 422.112(a), which provides that a coordinated care plan must maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served. In the April 15, 2010, Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program Final Rule (75 FR 19691), CMS added criteria at § 422.112(a)(10) for determining whether an MA plan network is adequate and meets the statutory standard by codifying that MA plans must have networks that are consistent with the prevailing community pattern of health care delivery in the service area. The regulation provides that CMS will consider factors that make up the community patterns of health care, which CMS will use as a benchmark in evaluating MA plan networks, and lists certain examples of those factors in § 422.112(a)(10)(i) through (v). CMS explained in the October 22, 2009, Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (74 FR 54644) that it would develop an automated system for reviewing network adequacy based on the elements that define community patterns of health care delivery and that we would define through subregulatory guidance how CMS would operationalize these factors.

Since that time, CMS has routinely provided subregulatory guidance to MA organizations that defines how CMS measures and assesses network adequacy.[72] We built the Network Management Module (NMM) in HPMS to facilitate automated reviews of plan networks and to annually transmit information to MA plans about provider/facility specialty types that are subject to specific network adequacy standards, maximum time and distance standards, minimum number requirements, and other critical information needed for the network adequacy reviews. The NMM also gave existing MA organizations and new applicants to the MA program the opportunity to routinely test their networks against our standards. Currently, CMS requires that organizations contract with a sufficient number of specified providers/facilities to ensure that 90 percent of the beneficiaries have access to at least one provider/facility of each specialty type within the published maximum time and distance standards. CMS updates and refines the data and information that feed into network adequacy

[72] *See* ''Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance''—*https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/index.*

measures and CMS performs analyses as needed. It is important that CMS ensure that MA organizations maintain an adequate network of contracted providers that are capable of providing medically necessary covered services to beneficiaries, both to ensure compliance with section 1851(d) of the Act and to protect beneficiaries. The network adequacy rules protect beneficiaries by ensuring that most, it not all, of the beneficiaries enrolled in a plan have access to providers within a reasonable time and distance from where the beneficiaries reside.

We propose to codify existing network adequacy standards to provide MA organizations with a greater understanding of how CMS measures and assesses network adequacy. We propose to codify in § 422.116 the list of provider and facility specialty types subject to network adequacy reviews, county type designations and ratios, maximum time and distance standards, minimum number requirements, and exceptions. The proposed regulation would also address CMS's annual publishing of the Provider Supply file and Health Service Delivery (HSD) reference file to release updated numbers and maximums for these standards in subsequent years. We also propose to modify our current network adequacy policy to further account for access needs in all counties, including rural counties, and to take into account the impact of telehealth providers in contracted networks. Section 1876(c)(4) of the Act imposes similar requirements for cost plans offered under section 1876 of the Act to make Medicare-covered services available and accessible to each enrollee with reasonable promptness when medically necessary. Under this authority, we are also proposing to amend § 417.416(e) to require 1876 cost organizations to also comply with the network adequacy standards described in proposed § 422.116.

We propose in § 422.116(a) that each network-based MA plan demonstrate that it has an adequate contracted provider network that is sufficient to provide access to medically necessary covered services consistent with standards in section 1851(d) of the Act, the regulations at §§ 422.112(a) and 422.114(a), and the rules in new § 422.116. Under our proposal, an MA plan would demonstrate its compliance as part of our triennial evaluation using the adequacy standards identified in § 422.116. In addition, we are proposing that, when required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year. We anticipate that we would require such attestation in the MA organization's application or contract for a given year but we might require the attestation when performing other network adequacy reviews, such as when there is a significant change in the MA plan's provider network.

We are proposing to cross-reference § 422.114(a)(3)(ii) to identify the network-based plan types that would be subject to these network adequacy requirements. Network-based MA plans include all coordinated care plans in § 422.4(a)(1), network-based MA private-fee-for-service (PFFS) plans in § 422.4(a)(3), and 1876 cost organizations. Generally, network-based MA medical savings account (MSA) plans are considered coordinated care plans in accordance with § 422.4(a)(1)(iii)(D), which includes ''other network plans'' as a type of coordinated care plan. However, since MSA plans do not require contracted networks, we propose to exclude MSA plans from the requirements in § 422.116. By cross-referencing § 422.114(a)(3)(ii), our proposal would carve out an MA regional plan that meets access requirements substantially through deemed contracting, so local and regional PFFS plans operating in CMS defined network areas must meet CMS network adequacy requirements at § 422.116 under our proposal.

We are also proposing, at paragraph (a)(2), to codify the general rule underlying § 422.116 that an MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility specialty type, with each contract provider type within maximum time and distance of at least one beneficiary in order to count toward the minimum number. Under our proposal, the minimum number criteria and the time and distance criteria vary by the county type. We propose to establish the specific provider and facility types; county types; specific time and distance standards by county designation; and specific minimum provider number requirements in paragraphs (b), (c), (d) and (e), respectively, of § 422.116. Regardless of whether CMS evaluates a plan's network against the access and adequacy standards in a given year, a plan's network must meet these standards and will be held to full compliance with the standards. At paragraphs (a)(3) through (4), we are proposing to codify additional general rules about the network adequacy requirements in this section. At paragraph (a)(3), we propose general rules for which provider types are not counted in evaluating network adequacy; we discuss this specific proposal in connection with proposed paragraph (b). In paragraph (a)(4), we are proposing to codify certain administrative practices we have instituted over the past several years. Specifically, we propose to codify that CMS will annually update and make available Health Service Delivery (HSD) reference files in advance of our review of plan networks. These HSD files contain the minimum provider and facility number requirements, minimum provider ratios, and the minimum time and distance standards. We are also proposing to codify that CMS will annually update and make available a Provider Supply file that identifies available providers and facilities with office locations and specialty types. The Provider Supply file is updated annually based on information from the Integrated Data Repository (IDR), which has comprehensive claims data, as well as information from public sources. CMS may also update the Provider Supply file based on findings from validation of provider information.

We propose to codify at § 422.116(b) the list of provider and facility specialty types that have been subject to CMS network adequacy standards in the past, as not all specialty types are included in network adequacy reviews. The proposed regulation text identifies the 27 provider specialty types and 14 facility specialty types that are currently used in the evaluation of network adequacy in each service area. CMS has identified these provider and facility specialty types as critical to providing services based on review of Medicare FFS) utilization patterns, utilization of provider/facility specialty types in Medicare FFS and managed care programs, and the clinical needs of Medicare beneficiaries. We propose to codify at § 422.116(a)(3) existing policy identifying provider and facility types that are not counted in evaluating network adequacy: Specialized, long-term care, and pediatric/children's hospitals and providers and facilities contracted with the organization only for its commercial, Medicaid, or other non-MA plans. In paragraph (a)(3), we also propose that hospital-based dialysis may count in network adequacy criteria for the facility type of Outpatient Dialysis. We clarify that primary care providers, the first provider specialty in our proposed list in paragraph (b)(1), are measured as a single specialty by combining provider specialty codes (001–006) in the HSD reference file. Otherwise, we believe that the list of

provider and facility types in proposed paragraphs (b)(1) and (2) are fairly self-explanatory.

Section 2005 of the SUPPORT Act establishes a new Medicare Part B benefit for OUD treatment services furnished by Opioid Treatment Programs (OTPs) on or after January 1, 2020. OTPs provide medication-assisted treatment for people diagnosed with an Opioid Use Disorder and must be certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and accredited by an independent, SAMHSA-approved accrediting body. We have not proposed to include OTPs as a facility type in § 422.116(b)(2) due to the newness of the benefit and we may consider adding OTPs to the facility type list in future proposals. However, we remind MA organizations that they are required to pay for medically necessary care from certified OTPs, regardless of the location of the OTP.

The lists of provider and facility specialty types that we have used in the network adequacy evaluations have seen very few changes over the past 5 years, so we believe that codifying the lists currently in use is appropriate. However, we expect that, from time to time, it may not be necessary to evaluate the number and accessibility of each of the 27 specialty and 14 facility types in a particular year. Therefore, we propose at § 422.116(b)(3) that CMS may remove a specialty or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file. For example, in the past CMS removed oral surgery from the HSD reference file, and replaced home health and durable medical equipment with an attestation in its application about the plan's network ensuring access to providers of these types. Under our proposed authority at § 422.116(a)(1) to require an MA plan to submit an attestation when required by CMS, we would require an MA organization to complete an attestation that it has an adequate network that provides the required access to and availability of provider specialty or facility types even where we do not evaluate access ourselves. Network adequacy criteria are measured for each individual specialty type and do not roll up into an aggregate score. Therefore, the removal of a specialty type from the network review will not affect the outcome of an MA plan's network review and use of an attestation in lieu of evaluation will permit us some necessary flexibility. In light of the lack of change to the list we have used over the past several years, we are not proposing any means for CMS to add new provider specialty or facility types to the network adequacy evaluation without additional rulemaking.

We propose at § 422.116(c) to codify our current policy regarding county designations. Network adequacy is assessed at the county level, and counties are classified into five county type designations: Large Metro, Metro, Micro, Rural, or CEAC (Counties with Extreme Access Considerations). These metrics provide the means by which the various network adequacy criteria are differentiated to represent large geographic variations across the United States and its territories. They are based on the population size and the population density of each county. We propose to codify at § 422.116(c) the five county type designations using population size and density parameters. We propose to codify the population size and density parameters in Table 6.

TABLE 6: POPULATION SIZE AND DENSITY PARAMETERS

COUNTY DESIGNATION	POPULATION	DENSITY
Large Metro	≥ 1,000,000	≥ 1,000/mi^2
	500,000 – 999,999	≥ 1,500/mi^2
	Any	≥ 5,000/mi^2
Metro	≥ 1,000,000	10 – 999.9/mi^2
	500,000 – 999,999	10 – 1,499.9/mi^2
	200,000 – 499,999	10 – 4,999.9/mi^2
	50,000 – 199,999	100 – 4,999.9/mi^2
	10,000 – 49,999	1,000 – 4,999.9/mi^2
Micro	50,000 – 199,999	10 – 99.9/mi^2
	10,000 – 49,999	50 – 999.9/mi^2
Rural	10,000 – 49,999	10 - 49.9/mi^2
	< 10,000	50 - 999.9/mi^2
CEAC	Any	< 10/mi^2

A county must meet both the population and density parameters for inclusion in a given county type designation. These parameters are consistent with those we have used in conducting network adequacy reviews in prior years. We have based the parameters on approaches used by the United States Census Bureau in its classification of ''urbanized areas'' and ''urban clusters,'' and by the Office of Management and Budget (OMB) in its classification of ''metropolitan'' and ''micropolitan.'' To calculate population density at the county level, we divided the latest county-level population [73] estimate by the land area [74] for that county. This county designation methodology was designed specifically for MA network adequacy and may not be appropriate for other purposes.

We propose in § 422.116(a)(2) that network adequacy is measured using both maximum time and distance standards and minimum number requirements that vary by county type. In § 422.116(d), we propose that CMS determines maximum time and distance

[73] United States Census Bureau. American Factfinder. Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2018: 2018 Population Estimates. Retrieved from: *https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2017_PEPANNRES&src=pt.*

[74] United States Census Bureau. American Factfinder. Population, Housing Units, Area, and Density: 2010—United States—County by State; and for Puerto Rico: 2010 Census Summary File 1. Retrieved from: *https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=DEC_10_SF1_GCTPH1.US05PR&prodType=table.*

standards by county type and specialty type and publishes these standards annually in the HSD Reference file. Maximum time and distance standards are set by county designation, referred to as the ''base'' time and distance standards, or by a process referred to as ''customization.'' We propose to codify the base time and distance standards by county designation that are in current practice with recent network reviews. See Table 7.

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TABLE 7: BASE TIME AND DISTANCE STANDARDS

	Large Metro		Metro		Micro		Rural		CEAC	
Provider/Facility Type	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**
Primary Care	10	5	15	10	30	20	40	30	70	60
Allergy and Immunology	30	15	45	30	80	60	90	75	125	110
Cardiology	20	10	30	20	50	35	75	60	95	85
Chiropractor	30	15	45	30	80	60	90	75	125	110
Dermatology	20	10	45	30	60	45	75	60	110	100
Endocrinology	30	15	60	40	100	75	110	90	145	130
ENT/Otolaryngology	30	15	45	30	80	60	90	75	125	110
Gastroenterology	20	10	45	30	60	45	75	60	110	100
General Surgery	20	10	30	20	50	35	75	60	95	85
Gynecology, OB/GYN	30	15	45	30	80	60	90	75	125	110
Infectious Diseases	30	15	60	40	100	75	110	90	145	130
Nephrology	30	15	45	30	80	60	90	75	125	110
Neurology	20	10	45	30	60	45	75	60	110	100
Neurosurgery	30	15	60	40	100	75	110	90	145	130
Oncology - Medical, Surgical	20	10	45	30	60	45	75	60	110	100
Oncology - Radiation/Radiation Oncology	30	15	60	40	100	75	110	90	145	130
Ophthalmology	20	10	30	20	50	35	75	60	95	85
Orthopedic Surgery	20	10	30	20	50	35	75	60	95	85
Physiatry, Rehabilitative Medicine	30	15	45	30	80	60	90	75	125	110
Plastic Surgery	30	15	60	40	100	75	110	90	145	130

	Large Metro		Metro		Micro		Rural		CEAC	
Provider/Facility Type	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**	**Max Time**	**Max Distance**
Podiatry	20	10	45	30	60	45	75	60	110	100
Psychiatry	20	10	45	30	60	45	75	60	110	100
Pulmonology	20	10	45	30	60	45	75	60	110	100
Rheumatology	30	15	60	40	100	75	110	90	145	130
Urology	20	10	45	30	60	45	75	60	110	100
Vascular Surgery	30	15	60	40	100	75	110	90	145	130
Cardiothoracic Surgery	30	15	60	40	100	75	110	90	145	130
Acute Inpatient Hospitals	20	10	45	30	80	60	75	60	110	100
Cardiac Surgery Program	30	15	60	40	160	120	145	120	155	140
Cardiac Catheterization Services	30	15	60	40	160	120	145	120	155	140
Critical Care Services – Intensive Care Units (ICU)	20	10	45	30	160	120	145	120	155	140
Outpatient Dialysis	20	10	45	30	65	50	55	50	100	90
Surgical Services (Outpatient or ASC)	20	10	45	30	80	60	75	60	110	100
Skilled Nursing Facilities	20	10	45	30	80	60	75	60	95	85
Diagnostic Radiology	20	10	45	30	80	60	75	60	110	100
Mammography	20	10	45	30	80	60	75	60	110	100
Physical Therapy	20	10	45	30	80	60	75	60	110	100
Occupational Therapy	20	10	45	30	80	60	75	60	110	100
Speech Therapy	20	10	45	30	80	60	75	60	110	100

	Large Metro		Metro		Micro		Rural		CEAC	
Provider/Facility Type	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance
Inpatient Psychiatric Facility Services	30	15	70	45	100	75	90	75	155	140
Outpatient Infusion/Chemotherapy	20	10	45	30	80	60	75	60	110	100

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CMS established the base time and distance standards proposed here by mapping the various specialty types' practice locations from the National Provider and Plan Enumeration System (NPPES) National Provider Identifier (NPI) file compared with Medicare beneficiary locations from CMS enrollment data. We then tested different options for combinations of beneficiary coverage percentages and maximum travel distances to determine what was feasible and practical for the majority of counties given the trade-off between beneficiary coverage and travel distance. The travel time standards were calculated according to the average driving speeds in each of the ZIP code types (urban, suburban, rural) that beneficiaries would traverse between their homes and the provider locations.

While the base time and distance criteria are not updated regularly, criteria for some specialty types within some county types have been updated over the past few years. These updates generally have been done to reflect a significant change in the supply of providers in an area, and when the new county designation methodology was implemented (that is, moving from classifying counties based on metropolitan statistical areas to the current county designations). In our current practice and under our proposal, the designation of each particular county is not static but is based on the application of specific population size and density standards. If a county designation changes as a particular type under the rules proposed in § 422.116(c), the time and distance standards for that county will also change, consistent with the standards we are proposing in § 422.116(d). In the annual HSD Reference File that CMS publishes, and would continue to publish under our proposal at paragraph (a)(4)(i), the county designation and applicable time and distance standards for each county will be identified for the applicable year.

CMS currently requires that organizations contract with a sufficient number of providers/facilities to ensure that 90 percent of the beneficiaries have access to at least one provider/facility of each specialty type within the published maximum time and distance standards. The location of a contracted provider specialty or facility is not required to be within the county or state boundaries to be considered within the time and distance standards.

In recent years, we have added flexibility to expand the time (in minutes) and distance (in miles) standards beyond the base standards, in cases where, due to a shortage of supply of providers or facilities, it is not possible to meet the base time and distance standards. We propose to codify this process at § 422.116(d)(3) and refer to it as ''customization.'' To customize distance standards, we use software to map provider location data from the Provider Supply file against the population distribution data in CMS's MA Medicare Sample Census.[75] For each specialty and county where there are insufficient providers within the base distance standard, we use mapping results to identify the distance at which 90% of the population would have access to at least one provider or facility in the applicable specialty type. The resulting distance is then rounded up to the next multiple of five (51.2 miles would be rounded up to 55 miles), and a multiplier specific to the county designation is applied to determine the analogous maximum time criterion. We request comment on our customization methodology and whether we should adjust factors in the distance calculation to achieve outcomes that are more equitable. For example, CMS could adjust the percentage of the population from 90%, or we could require more than one provider or facility to be within distance of the designated percentage of the population.

Customization of base criteria may be triggered based on information received through exception requests from plans, or from other sources, such as certificates of need (CON) from state departments of health. However, we propose that CMS may only use customization to increase time and distance standards from the base standards, and may not reduce time and distance standards below the base standards. CMS may consider relevant information when creating network adequacy standards in accordance with § 422.112(a)(10)(i)–(v), and therefore, we solicit comment from the industry on other sources of information that CMS should consider and how it would work within the structure of our network adequacy standards.

Historically, CMS has required that at least 90 percent of the beneficiaries residing in a particular county have access to at least one provider/facility of each specialty type within the published maximum time and distance standards for that county. In this rule, and in an effort to encourage more MA offerings in rural areas, we propose to reduce this percentage to 85 percent in Micro, Rural, and CEAC counties. In these generally ''rural'' counties, there is evidence of a lower supply of physicians, particularly specialists, compared to urban areas.[76] In order to account for this shortage, two state Medicaid programs that utilize network adequacy criteria have adjusted percentages in rural counties to require that standards be met for less than 100 percent of enrollees. New Jersey allows an 85 percent coverage requirement for primary care in ''non-urban counties''

[75] CMS built the MA Medicare Sample Census, which derives from information maintained by CMS on the residence of Medicare beneficiaries. CMS built the Sample Census to be an adequate representative sample of Medicare beneficiaries in each applicable county. This file is only available to CMS and is only utilized for the purposes of measuring network adequacy.

[76] Department of Health and Human Services, National Advisory Committee on Rural Health and Human Services (2018) ''Rural Health Insurance Market Challenges: Policy Brief and Recommendations.'' Retrieved April 3, 2019, from: *https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/rural/publications/2018-Rural-Health-Insurance-Market-Challenges.pdf.*

but 90 percent in urban counties.[77] Tennessee's Medicaid Managed Care program takes a slightly different approach, requiring that 60 percent of enrollees have access within 60 miles and 100 percent within 90 miles.[78] Additionally, the Part D program has a 90 percent retail pharmacy network coverage requirement in urban and suburban areas that drops to 70 percent for rural areas.[79] Further, our data indicates that existing failures in MA plans' meeting the time and distance standards frequently occur at the range between 80–89 percent of beneficiaries. As a result, we propose to adopt a similar change in our MA network adequacy approach to account for access challenges in Micro, Rural, and CEAC counties; we are proposing at § 422.116(d)(4)(i) to require that at least 85 percent of the beneficiaries have access to at least one provider/facility of each specialty type within the published time and distance standards in Micro, Rural, and CEAC counties. We estimate that approximately 14 percent of contracts (96 contracts) operating in these county designations will benefit from the reduced percentage and will no longer need to submit an exception request. We propose to codify the existing policy of using a 90 percent threshold for Large Metro and Metro counties in § 422.116(d)(4)(ii). We note that this specific proposal does not include a change from current policy requirements for a minimum number of provider specialties and facilities and that we are proposing, at paragraph (e), that MA plans will still be required to maintain contracts with a minimum number of providers in each county.

We also propose to give an MA plan a 10-percentage point credit towards the percentage of beneficiaries residing within the applicable time and distance standards for certain provider specialty types when the plan contracts with telehealth providers for those specified specialty types. For example, in a rural county where an MA plan must have 85 percent of beneficiaries residing within applicable time and distance standards, the MA plan will receive an additional 10 percentage points towards the 85 percent requirement should they contract with applicable telehealth providers under § 422.135. This is not currently part of the network adequacy evaluation, but we believe it is appropriate in light of the expanding coverage in the MA program of additional telehealth benefits. In the April 2019 final rule, we adopted § 422.135 to implement the option for MA plans to offer additional telehealth benefits as part of their coverage of basic benefits under section 1852(m) of the Act, as amended by section 50323 of the BBA of 2018. In that rulemaking, we solicited feedback from the industry concerning the impact, if any, that telehealth should have on network adequacy policies. We received thirty-five responses from stakeholders in managed care, provider, advocacy, and government sectors. While health plans clearly favored taking into account telehealth access while evaluating network adequacy, providers had more concerns that telehealth services could be used to replace in-person healthcare delivery. One commenter stated that it is imperative that beneficiaries continue to have the choice to access services in-person not only as a matter of preference, but to ensure those that do not have access to the required technologies aren't left without care. Section 1852(m)(4) of the Act and the regulation at § 422.135(c)(1) require that an enrollee in an MA plan offering additional telehealth benefits must retain the choice of receiving health care services in person rather than through electronic exchange (that is, as telehealth). With that in mind, and emphasizing the importance of maintaining an in-person network, we are not proposing any changes to how we currently calculate minimum provider requirements. Under our proposal, MA plans must still contract with a minimum number of providers for each specialty type. We believe this is imperative for MA plans to be able to provide in-person care when needed or when preferred by the beneficiary. However, contracting with telehealth providers as a supplement to an existing in-person contracted network will give enrollees more choices in how they receive health care. We believe it is important and appropriate to account for contracted telehealth providers in evaluating network adequacy consistent with reflecting how MA plans supplement, but do not replace, their in-person networks with telehealth providers. We are proposing, at § 422.116(d)(5) to provide a 10-percentage point credit towards the percentage of beneficiaries residing within time and distance standards for specific provider specialty types by county when the MA plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted network. Since additional telehealth benefits described at § 422.135 only apply to MA plans, cost plans will not be eligible for this 10-percentage point credit.

We believe a 10-percentage point credit is an appropriate amount that proportionately supplements a plan's percentage score because telehealth providers add value to a contracted provider network, but should not have the same level of significance or value as an in-person provider. Additionally, information from prior network adequacy reviews show that many failures in meeting time and distance standards occur in this 80–89% range. Therefore, our proposal for a 10-percentage point credit is significant enough to have an impact on MA plans and encourage the use of telehealth, and proportionate to the role that telehealth providers have in a contracted network. Further, we propose to apply this telehealth credit only to specific provider specialty types: Dermatology, psychiatry, neurology, otolaryngology and cardiology. We believe this limited approach will allow CMS to appropriately monitor the effectiveness of the proposal, while also allowing us to determine whether there may be access or quality of care impacts. As we discussed in the April 2019 final rule, additional telehealth benefits are monitored by CMS through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations will alert CMS to any issues with access to care and CMS may require MA organizations to address these matters if they arise.

CMS considered feedback from industry stakeholders, publicly available studies, and analyses of Medicare claims data for telehealth services in determining applicable provider specialty types. We considered not only the potential that telehealth has within a specialty type, but also the observed access challenges for provider specialty types over the years of our network adequacy reviews. CMS has observed that most MA plans do not have challenges meeting time and distance standards for primary care as compared to non-primary care provider specialty types. We also believe that it is critical to quality health care that Medicare beneficiaries have a primary care provider that they can visit in

[77] State of New Jersey Dept of Human Services. ''Contract Between State of New Jersey Department of Human Services Division of Medical Assistance and Health Services and _____, Contractor'' Sec. 4.8.8 ''Provider Network Requirements'' Retrieved April 5, 2019, from: *https://www.state.nj.us/humanservices/dmahs/info/resources/care/hmo-contract.pdf.*

[78] State of Tennessee, Department of Finance and Administration, Division of Health Care Finance and Administration, Division of TennCare (2019) ''Statewide Contract with Amendment 9—January 1, 2019'' Attachment IV. Retrieved April 3, 2019, from: *https://www.tn.gov/content/dam/tn/tenncare/documents/MCOStatewideContract.pdf.*

[79] Section 423.120(a)(1).

person and within a suitable time and distance. Therefore, despite the potential and prevalence of telehealth for furnishing primary care services, we do not believe that it is necessary to take telehealth access into account when measuring and setting minimum standards for access to primary care providers. CMS solicits comments on the appropriateness of the provider specialty types eligible for the telehealth credit and whether CMS should expand or limit this list to a different set of provider specialties.

CMS has received comments from providers and physician groups about the limitations of current network adequacy policies on dialysis treatment when performed in a hospital, at home, or in an outpatient facility. Some research suggests that home-based dialysis may offer advantages over in-center hemodialysis, including patient convenience, reduction in costs associated with dialysis, and potentially improved patient quality of life and blood pressure control with greater survival and fewer hospitalizations.[80] We recognize that there is more than one way to access medically necessary dialysis care and we want plans to exercise all of their options to best meet a beneficiary's health care needs. Therefore, we are considering several options about how to improve our proposal as it relates to measuring and setting minimum standards for access to dialysis services. We solicit comment on: (1) Whether CMS should remove outpatient dialysis from the list of facility types for which MA plans need to meet time and distance standards; (2) allowing plans to attest to providing medically necessary dialysis services in its contract application (as is current practice for DME, home health, and transplant services) instead of requiring each MA plan to meet time and distance standards for providers of these services; (3) allowing exceptions to time and distance standards if a plan is instead covering home dialysis for all enrollees who need these services; and (4) customizing time and distance standards for all dialysis facilities.

CMS has also received comments concerning patterns of provider consolidation and its impact on higher costs for patients. CMS has heard from stakeholders that providers in concentrated areas may leverage network adequacy requirements in order to negotiate prices well above Medicare FFS rates. We solicit comment on existing problems and behavior in non-rural, consolidated provider markets and recommendations that CMS could take to encourage more competition in these markets.

President Trump's Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors (October 3, 2019) calls for adjustments to network adequacy requirements to account for the competitiveness of state health care markets, including taking into account whether states maintain Certificate of Need (''CON'') laws or other anticompetitive restrictions. Many states began adopting CON laws in the 1960s and 1970s in part to promote resource savings and to prevent investments that could raise hospital costs.[81] A number of studies have found no evidence that CON programs have led to resource savings, and in some instances, may raise health care costs. In one study published in 2013, researchers studied whether states that dropped CON programs experienced changes in costs or reimbursements from coronary artery bypass graft surgery or percutaneous coronary interventions.[82] In this study, the cost savings from removing the CON requirements slightly exceeded the total fixed costs of new facilities that entered after deregulation. Another study published in 2016 concluded that there is no evidence that CON requirements limit health care price inflation and little evidence that they reduce health care spending.[83] It further concluded that CON laws are associated with higher per unit costs and higher total healthcare spending. Most relevant here, other studies suggest that the removal of these laws that serve as a barrier to entry into the market lead to greater access to providers and a redistribution of health care services to higher quality providers, improving the overall quality of health outcomes.[84]

As this research points out, CON laws restrict the supply and competition for healthcare services and increases costs. Therefore, CON laws adversely affect access in states and counties where they are in effect, including for MA organizations that operate in those areas. CMS pays MA organizations a capitated amount in each county for the provision of Medicare benefits based on the expected costs to provide benefits. When MA organizations must pay more for benefits, as the research demonstrates happens when there are fewer providers or facilities with which to contract, that reduces the access to benefits offered by MA organizations. In order to take into account the adverse effects that CON laws have on access, we propose in § 422.116(d)(6) to provide that MA organizations may receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed anti-competitive restrictions, that limit the number of providers or facilities in a county or state. As discussed below, under our proposal, where appropriate, CMS may instead address network adequacy by customizing base time and distance standards in States with CON laws. We believe this proposal is justified based on the studies cited previously that have shown that CON laws adversely affect competition and free market entry in states and that our network adequacy policy thus should provide for us to consider this factor when evaluating the adequacy of an MA organization's contracted network.

We propose to make this credit equal to and in addition to, if applicable, the telehealth credit (10 percentage points) discussed earlier in this proposal. We chose a 10-percentage point credit for CON laws for reasons similar to those that we selected the 10-percentage point credit for the telehealth specialties; that is information from prior network adequacy reviews show that many failures in meeting time and distance standards occur in the 80–89% range. Under our proposal, CMS may elect to grant this credit instead of customizing time and distance standards depending on a number of factors like the speed of implementing customized standards, operational and timing constraints, and the amount of work required to calculate customized time and distance standards. We solicit comment on additional criteria or factors we should consider when deciding whether to apply the 10-percentage point credit or customize time and distance standards in the impacted states or counties. Additionally, we solicit comment about what other actions CMS could take in markets with state CON laws.

We are also considering whether there are circumstances where a more limited

[80] Comparative Effectiveness of Home-Based Kidney Dialysis Versus In-Center or Other Outpatient Kidney Dialysis Locations—A Systematic Review [internet]: *https://www.ncbi.nlm.nih.gov/books/NBK344417/.*

[81] Daniel Sherman, ''The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis,'' *Federal Trade Commision,* January 1988.

[82] Vivian Ho, Meei-Hsiang Ku-Goto, ''State Deregulation and Medicare Costs for Acute Cardiac Care,'' *Med Care Res Rev.,* April 2013.

[83] Matthew D. Mitchell, ''Do Certificate-of-Need Laws Limit Spending?'' *Mercatus Working Paper,* Mercatus Center at George Mason University, Arlington, VA, September 2016.

[84] David M. Cutler, Robert S. Huckman, and Jonathan T. Kolstad, ''Input Constraints and the Efficiency of Entry: Lessons from Cardiac Surgery,'' *American Economic Journal: Economic Policy,* February 2010.

application of network adequacy flexibility might be more appropriate. We solicit comment as to how and under what circumstances we should refrain from applying the 10 percentage point credit, should mitigate the size of this credit, or other actions we might undertake to apply this flexibility in a more limited manner.

We are proposing to codify the current policy that MA plans must contract with a specified minimum number of each provider and facility specialty type in § 422.116(e). The MA plan must have a minimum number of in-person providers and facilities in each county for each specialty type specified in paragraph (b). We propose at § 422.116(e)(1) the general rules that the provider or facility must be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number requirement and cannot be a telehealth-only provider. We are also proposing to codify the methodology for establishing the minimum number requirements for specific contracted provider and facility specialty types per county. Under our proposal, CMS will use this methodology each year to determine and publish the updated minimum provider standards on an annual basis. Certain standards for the minimum number of providers are updated annually to account for changes in the Medicare population, MA market penetration, and county designations. Under our current policy and our proposal, the provider/facility must be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number requirements.

We proposed to codify our existing practice in § 422.116(e)(2)(iii) that all facilities, except for acute inpatient hospitals facilities, have a minimum number requirement of one. We are proposing to limit the methodology for establishing and changing the required minimum number standard to acute inpatient hospitals and other non-facility provider specialties. We propose the methodology at § 422.116(e)(3): CMS determines the minimum number requirement for all provider specialty types and Acute Inpatient Hospitals by multiplying the ''minimum ratio'' by the ''number of beneficiaries required to cover,'' dividing the resulting product by 1,000, and rounding up to the next whole number. The steps and components of the methodology are proposed in paragraphs (e)(3)(i) and (ii).

The Minimum Ratio is the number of providers required per 1,000 beneficiaries, and for Acute Inpatient Hospitals, the number of beds per 1,000 beneficiaries. CMS established minimum ratios in 2011 using a number of data sources, including, Medicare fee-for-service claims data, American Medical Association (AMA) and American Osteopathic Association (AOA) physician workforce data, US Census population data, National Ambulatory Medical Care Survey data, AMA data on physician productivity, and published literature. We propose to codify the Minimum Ratios at § 422.116(e)(3)(i) as shown in Table 8.

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TABLE 8: MINIMUM RATIOS

MINIMUM RATIO	LARGE METRO	METRO	MICRO	RURAL	CEAC
Primary Care	1.67	1.67	1.42	1.42	1.42
Allergy and Immunology	0.05	0.05	0.04	0.04	0.04
Cardiology	0.27	0.27	0.23	0.23	0.23
Chiropractor	0.10	0.10	0.09	0.09	0.09
Dermatology	0.16	0.16	0.14	0.14	0.14
Endocrinology	0.04	0.04	0.03	0.03	0.03
ENT/Otolaryngology	0.06	0.06	0.05	0.05	0.05
Gastroenterology	0.12	0.12	0.10	0.10	0.10
General Surgery	0.28	0.28	0.24	0.24	0.24
Gynecology, OB/GYN	0.04	0.04	0.03	0.03	0.03
Infectious Diseases	0.03	0.03	0.03	0.03	0.03
Nephrology	0.09	0.09	0.08	0.08	0.08
Neurology	0.12	0.12	0.10	0.10	0.10
Neurosurgery	0.01	0.01	0.01	0.01	0.01
Oncology - Medical, Surgical	0.19	0.19	0.16	0.16	0.16
Oncology - Radiation/Radiation Oncology	0.06	0.06	0.05	0.05	0.05
Ophthalmology	0.24	0.24	0.20	0.20	0.20
Orthopedic Surgery	0.20	0.20	0.17	0.17	0.17
Physiatry, Rehabilitative Medicine	0.04	0.04	0.03	0.03	0.03
Plastic Surgery	0.01	0.01	0.01	0.01	0.01

MINIMUM RATIO	LARGE METRO	METRO	MICRO	RURAL	CEAC
Podiatry	0.19	0.19	0.16	0.16	0.16
Psychiatry	0.14	0.14	0.12	0.12	0.12
Pulmonology	0.13	0.13	0.11	0.11	0.11
Rheumatology	0.07	0.07	0.06	0.06	0.06
Urology	0.12	0.12	0.10	0.10	0.10
Vascular Surgery	0.02	0.02	0.02	0.02	0.02
Cardiothoracic Surgery	0.01	0.01	0.01	0.01	0.01
Acute Inpatient Hospitals	12.2	12.2	12.2	12.2	12.2

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The Number of Beneficiaries Required to Cover is also calculated by CMS based on an established methodology. The Number of Beneficiaries Required to Cover is the minimum population that an MA plan's network should be able to serve and represents the potential number of beneficiaries an organization may serve within a county. We propose at § 422.116(e)(3)(ii)(A) that the Number of Beneficiaries Required to Cover is calculated by multiplying the ''95th Percentile Base Population Ratio'' times the total number of Medicare beneficiaries residing in a county. CMS uses its MA State/County Penetration data to calculate the total beneficiaries residing in a county. For counties with lower populations, and particularly for specialties with lower minimum ratios, the minimum number is usually one.

The 95th Percentile Base Population Ratio is calculated annually for each county type. Several years ago, CMS allowed MA organizations to provide their expected enrollment and then define their networks based on that number, but we later developed a more objective means to measure network adequacy for all MA plans consistently. The 95th Percentile Base Population Ratio is a fair and consistent enrollment estimate that can be applied to new and current plans. While it varies over time as MA market penetration and plan enrollment changes across markets, the 95th Percentile Base Population Ratio currently ranges between 0.073 and 0.145 depending on county type, indicating that MA plans are expected to have networks at least sufficient to cover between 7.3 percent (Large Metro) and 14.5 percent (CEAC) of the Medicare beneficiaries in the county. This ratio represents the proportion of Medicare beneficiaries enrolled in the 95th percentile MA plan (that is, 95% of plans have enrollment lower than this level).

To calculate the 95th Percentile Base Population Ratio, we use the List of PFFS Network Counties [85] to exclude PFFS plans in non-networked counties [86] from the calculation at the county type level. We use the MA State/County Penetration data [87] to determine the number of eligible Medicare beneficiaries in each county, and our Monthly MA Enrollment data [88] to determine enrollment at the contract ID and county level, including only enrollment in RPPO, LPPO, HMO, HMO/POS, healthcare prepayment plans under section 1833 of the Act, and network PFFS plan types. We calculate penetration at the contract ID and county level by dividing the number of enrollees for a given contract ID and county by the number of eligible beneficiaries in that county. Finally, we group counties by county designation to determine the 95th percentile of penetration among MA plans for each county type. We propose to codify the methodology for calculating the 95th Percentile Base Population Ratio at § 422.116(e)(3)(ii)(B).

Finally, we are also proposing to codify in paragraph (f) a process by which an MA plan may request and receive an exception from the network adequacy standards in § 422.116. CMS conducts network adequacy reviews through an automated process, but also allows for exceptions to that process when failures are detected in the submitted network. We propose to codify the exceptions process, the basis upon which an MA plan may request an exception, and the factors that CMS may consider when evaluating an MA organization's request for an exception to our network standards. An MA organization may request an exception when certain providers or facilities are not available for the MA organization to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type, and the MA organization has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care. For

[85] CMS. PFFS Plan Network Requirements. Retrieved from: *https://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/Network Requirements.html.*

[86] Non-networked counties in this context means there are not at least two networked plans operating in that county.

[87] CMS. MA State/County Penetration. Retrieved from: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/MA-State-County-Penetration.html.*

[88] CMS. Monthly MA Enrollment by State/County/Contract. Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-MA-Enrollment-by-State-County-Contract.html.*

example, certain providers/facilities may not be available for contracting when the provider has moved or retired, or when the provider/facility does not contract with any organizations or exclusively with another organization. The MA plan should contract with telehealth providers, mobile providers, or providers outside the time and distance standards, but accessible to most enrollees (or consistent with the local pattern of care) to qualify for an exception by CMS. In evaluating exception requests, CMS will consider: (i) Whether the current access to providers and facilities is different from the HSD reference and Provider Supply files for the year; (ii) whether there are other factors present, in accordance with § 422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and (iii) whether approval of the exception is in the best interests of beneficiaries.

Currently, CMS collects information for purposes of testing an MA organization's network adequacy in the PRA-approved collection titled, ''Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans, CMS–10636, OMB 0938—New.'' CMS relies on this collection of information to evaluate whether an MA organization maintains a network of appropriate providers and facilities that is sufficient to provide adequate access to covered services based on the needs of the population served. In the collection of information, CMS explains that organizations must comply with the current CMS network adequacy criteria posted in the HSD reference file on CMS's website and updated annually. Our proposal aims to formalize the use of criteria posted in the HSD reference file by codifying and explaining the standards and, where necessary, the formulas used to calculate network adequacy standards (that is, provider/facility types, maximum time and distance standards, minimum provider/facility numbers). CMS will continue to use the HSD reference file as a means to communicate these standards to MA organizations, and therefore, this proposal requires no changes to the collection of information needed for CMS to assess network adequacy. The proposed provisions would not impose any new or revised information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) or burden. Consequently, the provisions are not subject to the PRA.

We thank commenters in advance for their input on our proposed network adequacy policies.

F. Supplemental Benefit Requirements (§§ 422.100 and 422.102)

CMS has released guidance on supplemental benefits several times since April 2, 2018, including the 2019 Call Letter [89] and a subsequent HPMS memo [90] concerning the definition of 'primarily health related' with respect to supplemental benefits. Under a longstanding interpretation of the MA statute and regulations, CMS defines a mandatory or optional supplemental health care benefit as an item or service (1) not covered by original Medicare, (2) that is primarily health related, and (3) for which the plan must incur a non-zero direct medical cost. Only an item or service that meets all three conditions could be proposed as a supplemental benefit in a plan's PBP. We are proposing to codify this policy at § 422.102(c)(2)(ii) by setting forth these criteria as requirements that supplemental benefits must meet.

The current regulation text at § 422.100(c)(2) focuses on distinguishing between mandatory supplemental benefits and optional supplemental benefits. We are proposing to re-designate the substance of that current regulation text as new paragraphs (c)(2)(i)(A) and (B). We are proposing to codify our longstanding definition of supplemental benefits as three requirements that must be met by a supplemental benefit at paragraph (c)(2)(ii). In proposed paragraph (c)(2)(ii)(A), we would codify that a supplemental benefit must be primarily health related, using a standard discussed in more detail in this section of this proposed rule and with specific text to address SSBCI, discussed in more detail in section II.A. of this proposed rule. In proposed paragraph (c)(2)(ii)(B), we would codify that a MA organization must incur a non-zero direct medical cost in furnishing or covering the supplemental benefit to verify that the benefit is medically related, with specific text to address SSBCI, discussed in more detail in section II.A. of this proposed rule. Finally, in proposed paragraph (c)(2)(ii)(C), we would codify the requirement that the supplemental benefit is not covered by Medicare. By this, we mean that the supplemental benefit is not covered by Parts A, B or D. More generous or greater coverage of a Medicare Part A or Part B benefit—such as coverage of more inpatient days or coverage with lower cost sharing compared to Medicare—is a supplemental benefit. However, an MA plan may not cover a part D drug or reduce Part D cost sharing as an MA supplemental benefit. Under § 422.500, an MA plan that covers any Part D benefit must comply with the Part D regulations in part 423 and, therefore, must be a Part D sponsor of a Part D plan. In addition, § 422.266(b)(1) provides that an MA plan may use its rebates to buy down a Part D premium, including the premium for supplemental drug coverage described at § 423.104(f)(1)(ii).

1. Primarily Health Related

As discussed in the 2019 Call Letter and April 2018 HPMS memo, CMS currently interprets ''primarily health related'' as meaning that the item or service is used to diagnose, compensate for physical impairments, acts to ameliorate the functional/psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization. Using this interpretation, CMS has provided MA plans with flexibility in designing and offering supplemental benefits that may enhance beneficiaries' quality of life and improve health outcomes. We are proposing to codify this definition of a supplemental benefit at § 422.102(c)(2)(ii)(A).

Examples of supplemental benefits include: Dental, vision, adult day health services, home-based palliative care, in-home support services, support for caregivers of enrollees, stand-alone memory fitness, expanded home & bathroom safety devices & modifications, wearable items such as compression garments and fitness trackers, over-the-counter items, and expanded transportation. A supplemental benefit is not primarily health related under this definition if it is an item or service that is solely or primarily used for cosmetic, comfort, general use, or social determinant purposes. Also, to be primarily health related, the benefit must focus directly on an enrollee's health care needs and should be recommended by a licensed medical professional as part of a care plan, if not directly provided by one. Enrollees are not currently required to get physician orders for supplemental benefits (for example, OTC items) and requiring it now would impose new restrictions on MA plans and potentially cause large administrative burden and interruptions in care. Therefore, CMS

[89] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.*

[90] *https://hpms.cms.gov/hpms/upload_area/NewsArchive_MassEmail/000011202/HPMS%20Memo%20Primarily%20Health%20Related%204-27-18.pdf.*

uses the ''recommended'' standard as part of interpreting and applying this component of the definition of supplemental benefit. We note that supplemental benefits must also be medically appropriate to be primarily health related; if a service or item is not medically appropriate, it is not primarily health related. This is consistent as well with our longstanding guidance in Chapter 4, section 30.2, of the Medicare Managed Care Manual that supplemental benefits that extend Part A or Part B benefits must be medically necessary. We will continue our current interpretations and guidance in codifying existing policy on this issue.

We note that the BBA of 2018 amended section 1852(a)(3) of the Act to permit MA plans to offer additional supplemental benefits for chronically ill enrollees (SSBCI) in contract year 2020. We discuss implementation of that legislation in section II.A. of this proposed rule. The new legislation permits supplemental benefits that are not primarily health related, but limited these benefits to chronically ill enrollees, using a statutory definition. It added new supplemental benefit options for the chronically ill that are in addition to the existing supplemental benefit options available to all MA enrollees effective contract year 2020. The expansion of supplemental benefits for chronically ill enrollees does not affect the expanded scope of the primarily health related supplemental benefit standard discussed here because supplemental benefit standard requires more than just a reasonable expectation of improving overall health and instead requires supplemental benefits to address specific illnesses and/or injuries.

2. Uniformity Requirements

As explained in the April 2018 final rule (83 FR 16440, 16480–85), CMS determined that providing access to supplemental benefits that are tied to health status or disease state in a manner that ensures that similarly situated individuals are treated uniformly is consistent with the uniformity requirement in the MA regulations. We solicited comments on this reinterpretation and finalized it in that prior rulemaking. In response to those comments and our further consideration of this issue, we provided guidance to MA organizations in both the April 2018 final rule and a subsequent HPMS memo [91] released April 27, 2018. We are proposing now to codify this reinterpretation specifically in regulation text at § 422.100(d)(2)(i).

The regulatory requirement that MA plans provide uniform benefits implements both section 1852(d) of the Act, which requires that benefits under the MA plan are available and accessible to each enrollee in the plan, and section 1854(c) of the Act, which requires uniform premiums for each enrollee in the plan. Previously, we required MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. In 2018, in issuing a final rule and guidance for contract year 2019, we determined that these statutory provisions and the regulation at § 422.100(d) meant that we had the authority to permit MA organizations the ability to reduce cost sharing for certain covered benefits, including lower deductibles, and offer specific tailored supplemental benefits for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the medical criteria identified by the MA plan for the benefits) are treated the same. In addition, we stated that our interpretation means that there must be some nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state. We propose to redesignate (d)(2) as (d)(2)(i) and add new paragraph (d)(2)(ii) to specifically state that MA organizations may reduce cost sharing for certain covered benefits, including lower deductibles, and offer specific tailored supplemental benefits for enrollees that meet specific medical criteria, provided that similarly situated enrollees are treated the same and that there is some nexus between the health status or disease state and the tailored benefits. We review benefit designs to make sure that the overall impact is non-discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations. This provision codifies already existing guidance and practices and therefore is not expected to have additional impact above current operating expenses.

G. Rewards and Incentives Program Regulations for Part C Enrollees (§ 422.134 and Subpart V)

CMS authorized MA organizations, including those offering a Medicare Medical Savings Account (MSA) plan option, to offer rewards and incentives (R&I) programs in a regulation adopted in 2014 (79 FR 29956, May 23, 2014). We briefly review the history of that rulemaking and our policies and goals for authorizing R&I programs. We relied on our authority under sections 1856(b)(1) and 1857(e)(1) of the Act to adopt the regulation; in addition, several of the provisions of the regulation, such as the anti-discrimination requirement, were consistent with statutory provisions governing the MA program. We adopted the regulation that authorized Part C R&I programs for a number of reasons. In some cases, MA organizations wished to extend rewards and incentives already offered to their commercial members to their Medicare enrollees; and many MA organizations wished to sustain their current R&I programs as well as stay competitive with other MA organizations with comparable offerings. Further, there was some evidence to suggest that health-driven reward and incentive programs may lead to meaningful and sustained improvement enrollee health behaviors and outcomes.[92]

Over the years we have also been asked by many plans to clarify how to start an R&I program. Our experience has shown that most R&I programs fall into the following four areas:

(i) Specified use of plan benefits, for example, rewards provided for obtaining preventive benefits at specified intervals;

(ii) Following a specified program that promotes exercise and/or good nutrition;

(iii) Participating in specified programs that educate on health matters and/or self-management of nutrition and exercise;

(iv) Specified utilization of plan resources such as hotlines, patient portals, and similar items that facilitate promotion of health.

Having reviewed the history of the program, we next describe its current state. Over the past 5 years, MA R&I programs have grown. We have benefitted greatly from partnership with our stakeholders who continually provide fresh and innovative ideas. We continue to encourage MA organization flexibility in rewards and incentives that is nonetheless consistent with the basic protections and parameters in the current regulation. Over the past 5 years we have also received many inquiries about how the regulation applies to specific R&I programs, including questions about the types of rewards that may be offered, types of health related activities that may be rewarded, and targeting R&I programs to specific

[91] *https://hpms.cms.gov/hpms/upload_area/News Archive_MassEmail/000011207/HPMS%20Memo %20Uniformity%20Requirements%204-27-18.pdf.*

[92] Ali Shirvani-Mahdavi, Ph.D. & Melissa Haeffner Ph.D., *Rewarding Wellness: The Science Behind Effective Wellness Incentive Programs* (2014).

disease states. To address these questions and based on our experience implementing the current regulation, we are proposing to amend § 422.134 to codify the guidance we have given, unify principles governing MA rewards and incentive programs, clarify the requirements of the regulation, and clarify flexibilities available to MA organizations under the regulation.

Under our proposal, we would move the substance of current paragraph (a) to new paragraph (c)(1)(iii). New paragraph (c) deals with the requirements of the target activity and therefore the current paragraph (a) which enumerates three categories promoting improved health, preventing injuries and illness, and promoting efficient use of health care resources is moved to paragraph (c) since being health related is a requirement of the target activity. In this way the purposes and goals of R&I programs, to improve health incomes, is still mentioned in the regulatory text albeit as an attribute of target activities.

We are proposing a new paragraph (a) to define several terms used in § 422.134. We propose to define a ''Reward and Incentive program'' as a program offered by an MA organization which allows qualified individuals (as defined later in this section) to voluntarily perform target activities in exchange for which the plan provides reward items. This definition of R&I program replaces certain aspects of current paragraph (a). The health related requirements in current paragraph (a) are requirements on target activities (not on for example reward items) and hence these health-related requirements were moved and placed in new paragraph (c). We propose to define ''target activity'' as that activity for which the reward is provided to the enrollee by the MA plan. We propose to define the term ''reward item'' as the item furnished to an enrollee who performs a target activity as specified by the plan. Further, we propose to revise the regulation to explicitly provide that when referring to the entire R&I program offered by a plan (that is, the target activity, its reward, and any requirements) the following terms are synonymous: ''reward and incentive program,'' ''reward(s) program'', ''incentive program'', and ''R&I program''. We also propose to clarify that when referring to the particular items used as rewards the following terms are synonymous: ''reward(s)'', ''incentive(s)'', ''R&I'', and ''rewards and incentives''. Similarly, we propose that the terms ''reward item'' and ''incentive item'' are synonymous. We are also proposing a definition for the term ''qualifying individual'' as that term is used throughout proposed § 422.134. This term has different meanings depending on whether the context of the target activity is a plan-covered health benefit or not: (1) If the target activity is not a plan-covered benefit (for example adherence to a particular diet), the term means a plan enrollee who satisfies the plan criteria to participate in that target activity; and (2) If the target activity is a plan-covered benefit (for example obtaining a mammograms), the term means a plan enrollee who qualifies for the target activity and satisfies all plan criteria to participate in the target activity.

For clarity, we are proposing to reorganize the order and structure of how the regulation addresses the requirements for R&I programs. We are proposing to address the substance of current paragraph (b) regarding non-discrimination and current paragraph (c) regarding prohibitions and requirements in new text in the revised regulation. As part of our reorganization, we are proposing to address the requirements for target activities in paragraph (c) and the requirements for reward items in paragraph (d).

In paragraph (b) we propose to state that MA programs are allowed to offer R&I programs consistent with the requirements of the section. This allowance is in current paragraph (a). Since the majority of (a) has been moved to new paragraph (c) it is important to explicitly state the allowance for MA plans to offer R&I programs.

Proposed paragraph (c) sets forth the requirements for a target activity to be used in an R&I program; compliance with these requirements is necessary in order for the MA organization to provide a reward item to a qualifying individual for participating in the activity. We propose to organize paragraph (c) by whether the proposed standard is something the target activity must do (or meet) or is something the target activity must not do. Additionally, proposed paragraph (c) will incorporate the current health-related requirements of current paragraph (a), since, although health improvement is the goal of the R&I program, these health-requirements are requirements in target activities (not for example in reward items) and therefore should be listed in (c).

Proposed paragraph (c)(1)(i), requires the qualifying individual be directly involved and perform the target activity. CMS recognizes there is growing involvement of caregivers, such as immediate family, with enrollees. However, the purpose of R&I programs is to provide a way for plans to influence positive behavioral changes of qualifying individuals through the performance of target activity designed to achieve at least one of the stated goals under (c)(1)(iii). Therefore, under our proposal, the qualifying individual must perform the activity and not the caregiver or other third party individual. Similarly, we propose in paragraph (d)(1)(i) that the reward item must be a direct tangible benefit to the enrollee. This means that the reward item may not be offered to or for the benefit of caregivers or other third party individuals. For example, under these proposed provisions, an MA organization may not offer a gift card to caregiver (such as family members) that attend an educational class about services provided to enrollees.

We are proposing a new paragraph (c)(1)(ii) to require that a target activity must be specified, in detail, as to the level of completion needed in order to qualify for the reward item. We are proposing (c)(1)(ii) as a replacement for the current requirement (at paragraph (c)(1)(i)) that a reward be available only in connection with an entire service or activity as it has caused confusion and generated numerous inquiries over the past 5 years. The current formulation, ''entire'' activity, could be misread that a plan could not simultaneously reward both the completion of a multi-part activity and one of its components. That was not our original intent. Rather, the intent was to require specificity: If the plan only specified the entire activity then it could not reward completion of a component activity; but if the plan wanted to reward both the completion of the entire activity as well as one of its components (possibly with different rewards) then it could do so provided it specified in detail the level of completion needed in order to qualify for the reward item.

A typical application of this principle occurs with an R&I program rewarding multi-session health management classes (for example weight management). The proposed formulation allows the following: (1) An MA organization targets an 8 session weight management class and provides rewards to those enrollees who complete the entire 8 sessions; and (2) An MA organization targets an 8 session weight management class and provides a separate reward for each session enrollees attend. Both of these are permissible because of how the plan (or R&I program) defines the completed activity or what is an entire activity to be completed. To allow plan flexibility we are proposing to clarify that an MA organization must specify, in detail, the

level of completion of a target activity in order for the qualifying individual to receive the reward item. Each scenario discussed previously would be permissible under our proposal provided the MA organization has clearly indicated completion criteria. We believe our proposed text at (c)(1)(ii) clarifies our desired policy. Therefore, we propose that the language at current (c)(1)(i) be eliminated and be replaced by the proposed (c)(1)(ii).

We propose to add paragraph (c)(1)(iii) which moves the health-related requirements currently in paragraph (a). These health-related requirements encompass the goals of the R&I program, that is, the R&I program should include at least one of three health-related requirements as its stated goal: (1) The improvement of health; (2) prevention of injures and illness or (3) promotion of efficient use of health care resources. The target activity must be designed to achieve at least one of the health-related requirements. To illustrate this, we note that (c)(1)(iii)(B), preventing injuries and illness, would allow an MA organizations to reward wearing seat belts. The wearing of the seat belt is considered health related since its purpose is to prevent injury. Paragraph (c)(1)(iii)(C), promoting efficient use of health care resources, would allow MA plans to reward use of online secure web portals that track exercise or weight management.

Next, we propose a new paragraph (c)(2) to list prohibitions connected with target activities. Proposed paragraph (c)(2)(i) specifies that a target activity must not be related to Part D benefits. In other words, Part D benefits may not be targeted for rewards. Our regulations at § 422.134 are only applicable to the MA program, therefore activities that are tied to Part D benefits may not be part of an R&I program under § 422.134. Examples of targeting a Part D benefit or tying a reward to Part D benefits that are prohibited under this proposed regulation text include providing a reward based on filling a prescription, and medication adherence.

We propose new (c)(2)(ii) to prohibit discriminatory use of R&I programs against enrollees. The current regulations prohibit discrimination at (b)(1) and (2) and (c)(2)(ii) but we are concerned that the current regulation text does not adequately address several issues specific to the provision of rewards and incentives. Paragraph (c)(2)(ii) proposes to supplement the general anti-discrimination prohibitions applicable throughout the MA program (currently in § 422.134(b)(1)) by proposing three new anti-discrimination requirements. These three requirements are in response to inquiries CMS has received.

An MA organization may design an R&I program that targets a specific illness or disease state. There are many cases where the target activity of an R&I program is a healthcare service predominately available to or medically necessary for a specific group, such as a reward for enrollees who obtain mammograms at recommended periodic intervals. For example, a high statistical frequency of only women (who are the primary recipients of mammograms) receiving rewards would, in and of itself, raise concerns of possible discrimination. To avoid this possible complication, and to facilitate an environment in which plans may propose R&I programs to address the need for target activities such as mammograms we propose three new requirements designed to assure that R&I programs are not discriminatory.

First, we propose to require R&I programs be uniformly offered to any qualifying individual at new paragraph (c)(2)(ii)(A). We also propose to add to paragraph (a) (''Definitions'') that in the context of a discussion of a plan-covered health benefit or service, the term ''qualifying individual'' means any plan enrollee who would qualify for coverage of the benefit and also satisfies any other plan criteria to participate in the target activity. By this, we mean to be clear that a target activity that is a covered benefit would be medically necessary for the particular enrollee who is seeking to receive the reward and that other conditions on coverage by the MA plan are met. Some illustrations of the use of the term qualifying individual are as follows:

(1) A plan that rewards mammograms can deny, without violating the discrimination prohibition under this proposed regulation, a reward to a man without gynecomastia who obtained a mammogram. The reason for the denial is that mammograms by males without gynecomastia are not plan covered because the mammogram is not medically necessary;

(2) A plan that rewards mammograms can deny, without implicating the anti-discrimination prohibition in this proposed regulation, a reward to a woman not at risk and in good health for obtaining a mammogram one month after previously obtaining a mammogram. The reason for the denial is because the woman is not a qualifying individual for this mammogram since the plan's coverage criteria for Original Medicare benefits must be consistent with Original Medicare and the Original Medicare frequency requirements for coverage of mammograms has not been met; therefore this mammogram taken one month after a previous mammogram does not meet the criteria for a plan-covered benefit.

(3) A plan would reward a man suffering from gynecomastia for obtaining a mammogram since this is a plan-covered service for this individual.

By proposing to require R&I programs be formulated in terms of any qualifying individual, we hope to broaden the rewards and incentives available without permitting discriminatory activity. To avoid misunderstanding we emphasize that this requirement is in addition to all other anti-discrimination prohibitions in this regulation and in the MA program.

The second anti-discrimination requirement we are proposing is related to the requirement currently in (b)(2) that all members may earn rewards. We intended this current regulatory provision to require accommodations for target activities. We continue to believe that providing accommodations to enrollees so that there is fair and equitable ability to earn a reward is important. We are proposing, at paragraph (c)(2)(ii)(B), to require the MA organization to provide accommodations to qualifying individuals who would otherwise be eligible for the reward but are unable to perform the target activity. We intend an accommodation to be something such as permitting the enrollee to engage in a comparable activity in a manner that satisfies the intended goal of the target activity or providing additional access to the target activity for the enrollee. For example, if a target activity encourages individuals with high blood pressure to go to a gym, we propose that accommodations must be made for institutionalized enrollees are not able to access a gym such that they are still engaged in a comparable activity with the same goal, namely engaging in physical activity for purposes of blood pressure management. Similarly, if the MA plan tracks participation in a target activity in a way that involves web access, we propose that accommodations must be made for enrollees without web access, such as by permitting other means to prove participation. We solicit comments from our stakeholders if this requirement of accommodations as formulated is sufficient and ask if some restrictions should be included in the regulatory requirement. To assist in solicitation of comments on the need for accommodations, we note that this proposed requirement for accommodation is intended to be consistent with requirements of HIPAA

wellness programs [93] and at the Appendix to 29 CFR 1630.14(d).

The third anti-discrimination requirement we are proposing addresses the achievement of desirable measurable health statuses. We are proposing to add, at paragraph (c)(2)(ii)(C), a specific requirement that MA plans must not design a R&I program based on the achievement of a specific health status measurement. CMS recognizes that MA organizations designing R&I programs are interested in achieving desirable, measurable health outcomes, such as achieving a desirable blood pressure or target weight. However, if the target activity is formulated this way, it would discriminate against enrollees based on health status. There may be individuals who will never reach a specific blood pressure level or target weight due to circumstances beyond their control (for example, medication side effects). For plans wishing to create such R&I programs, we propose that target activities must be formulated without reference to achieving a specific outcome and focus on a desired behavior instead, such as checking one's blood pressure or exercising regularly. Thus, we propose that the MA organization must not tie or limit the availability of the reward to the achievement of a health status measurement. Under this proposal, an MA organization may reward behaviors such as taking and reporting measurements at particular intervals, undergoing lab tests providing such measurements, or other activities reflecting a motivation to reach desirable measurements of health status or desirable health outcomes.

In summary, we proposed in paragraph (c)(2)(ii) to set out specific anti-discrimination requirements for an R&I program by requiring the program be offered to all qualifying individuals, making accommodations for otherwise qualifying individuals, and be based on enrollee behaviors rather than on desired measurements of health outcomes. As indicated, we believe this approach simultaneously guarantees necessary protections, allows maximum MA organization flexibility, and provides clarity. Finally, we also make explicit that anti-discrimination is a requirement of the entire MA program and these three requirements are in addition to other requirements. This statement is indicated in (c)(2)(ii) by cross-referencing the new proposed (g)(1) which mentions the general requirement of anti-discrimination throughout the MA program.

We believe the new proposed paragraph (c) unifies all current guidance on target activities, clarifies appropriate distinctions, and will facilitate MA organizations in their quest for new innovative designs. We solicit comments whether additional specific prohibitions or requirements for target activities are necessary to meet our described goals for revising the authority for MA organizations to establish and use R&I programs.

We propose a new paragraph (d) address requirements and prohibitions for reward items. Our proposal summarizes and clarifies existing CMS guidance on reward items. We propose to divide new paragraph (d) into three paragraphs: (d)(1) Addressing requirements of reward items, (d)(2) addressing prohibitions associated on reward items, and (d)(3) addressing allowances and flexibilities for reward items.

New paragraph (d)(1)(i) reflects the principles of current paragraph (b)(2); we propose to require that the reward items be offered uniformly to any qualifying individual who performs the target activity. As indicated earlier, the term qualifying individual is defined in new paragraph (a). New paragraph (d)(1)(ii) codifies subregulatory guidance; we propose that the reward item should be a direct tangible benefit to the qualifying individual (as defined in paragraph (a)) who performs the target activity. In a situation where it was suggested that an R&I program provide charitable donations as a reward for enrollees fulfilling a target activity, we denied approval of the R&I program because the charitable donation was not a direct tangible benefit to the enrollee. We believe that the ''charitable donation on behalf of the enrollee'' was somewhat misleading because the charity, not the enrollee, actually benefitted from the reward. In new paragraph (d)(1)(iii), we propose to require rewards be provided, such as through transfer of ownership or delivery, to the enrollee in the contract year in which the activity is completed, regardless of whether the enrollee is likely to use the reward item after the contract year. For example, if an enrollee earns a $25 gift card as a reward in late December, as long as the MA organization transfers that gift card to the enrollee before the contract year is over, the MA organization has fulfilled its obligation under this proposed provision. Consequently, since the enrollee now owns the reward item the plan would not be allowed to erase the card or invalidate the reward in the next contract year because the proposed provision requires transfer of ownership to the enrollee, who would retain the right to use the card whenever he or she wants. We believe that this is an important beneficiary protection to ensure that rewards are timely provided to the enrollee. Provision of the reward item to a third party or caregiver would be prohibited under this regulation.

Proposed new paragraph (d)(2) summarizes prohibitions connected with reward items. Proposed paragraphs (d)(2)(i) prohibits reward items consisting of cash, cash equivalents or monetary rebates (current paragraph (c)(2)(i)). In proposed (d)(2)(i)(A) and (B), we adopt the definition of ''cash equivalent'' formulated by the Office of the Inspector General (OIG) (81 FR 88368, December 7 2016), which defines ''cash equivalent'' to be items convertible to cash (such as a check) or that can be used like cash (such as a general purpose debit card, but not a gift card that can be redeemed only at certain stores, certain store chains, or for a specific category of items like a gasoline gift card).

Current paragraph (c)(1)(iii) says that reward items must ''have a monetary cap as determined by CMS,'' However, over the past five years, CMS has never calculated or published such a cap. We are therefore replacing this requirement with paragraph (d)(2)(ii) which requires that a reward item have a value that does not exceed the value of the target activity itself. This new proposed cap, the value of the target activity, is objectively determined and does not require a CMS determination.

We propose to codify a new paragraph (d)(2)(iii) to prohibit a target activity from involving elements of chance, for example lotteries. We believe this protects enrollees who may be misled by the chance of winning when such chance may be very small.

Plans know that items such as tickets allowing entry to events with a cost or discount coupons for specific items allowing purchases at reduced prices are allowed for rewards under our current guidance. Furthermore, paragraph (d) adequately outlines the requirements for rewards. In new paragraph (d)(3) we propose to present two additional examples of permissible reward items for a target activity. These two examples have arisen from plan inquiries.

In new paragraph (d)(3)(i) we codify current practice to allow reward items to consist of points or tokens which can be redeemed for tangible items. This is unlike a lottery where you only win if you obtain a certain event (like a number coming up) with the winning

[93] *https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/publications/caghipaaandaca.pdf.*

event having a small probability. Here, the value of the point and token is determined and known in advance. More specifically, it is known in advance that with so many points you can redeem them for tangible items listed by the plan. There is no element of chance. The redeemed item, however, must be a tangible and must otherwise comply with all other R&I program requirements.

In new paragraph (d)(3)(ii) we codify the current practice of allowing gift cards for reward items with the added qualification that a gift card is only permissible if it is designated for specific stores, specific store chains, or for specific categories of items or services (such as a gasoline card). There is no requirement that the store, store chain, or category of items or services be health related. Additionally, CMS acknowledges receiving inquiries from plans in states where a gift card must be converted to cash by a retailer if it only has a minimal value. Here, we clarify an MA plan may still offer gift cards as a reward in states with such laws because when the gift card was given to the enrollee it could only be used in certain locations or for certain purposes. We consider this allowable because the gift card is not immediately convertible to cash. The fact that later on it may be worth a nominal amount does not retroactively cancel its non-cash-equivalent status.

We believe the restructured paragraph (d) provides greater clarity, unifies all known guidance, and facilitates MA organizations seeking innovation. We solicit comment on our proposed standards for the reward items that are used in R&I programs authorized by § 422.134. Specifically, we seek comment whether our requirements need to be further clarified or if additional standards or examples are needed as enrollee protections.

As part of our reorganization, we are proposing to move the marketing requirements that are currently addressed at § 422.134(c)(2)(ii) to new provisions in proposed subpart V of 42 CFR part 422, which are discussed in section VI.H. of this proposed rule. We propose to codify, at new paragraph (e) of § 422.134, a requirement that MA organizations, in connection with an R&I program offered under § 422.134, must comply with all communications and marketing requirements as specified in subpart V of part 422.

We are also proposing, at new paragraph (f), that an MA organization must make information available to CMS upon request about the form and manner of any R&I programs the MA organization offers and any evaluations of the effectiveness of such programs. We solicit comment on this proposal and whether specific reporting should be required to support program monitoring and oversight.

Finally, we are proposing to add paragraphs (g)(1) through (3) for miscellaneous provisions from the current regulation. New paragraph (g)(1) proposes to codify the general requirement of anti-discrimination, applicable throughout the MA program (current paragraph (b)(1)). Additionally, the existing requirement that the reward and incentive program comply with all relevant fraud abuse laws including, when applicable the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries is moved to (g)(1).

Proposed new paragraph (g)(2) codifies that violations of R&I regulatory requirements can lead to sanctions (current paragraph (b)(3)). We note that current paragraph (b)(3) discusses sanctions in the context of violations of anti-discrimination. However, sanctions could also be imposed if, for example, an MA organization promised an R&I program (not a benefit) and then reneged on its commitment. This would violate § 422.752(a)(5) and (11) since the plan falsely communicated to enrollees and made misleading marketing about its R&I program. It also might violate (a)(4) since such false communications might be construed as discouraging enrollment. By proposing to codify the sanction provision as a stand-alone provision in proposed new paragraph (g), we clarify our intentions.

We are also proposing to codify, at new paragraph (g)(3), current guidance that an R&I program is not a benefit. We also are proposing, at new paragraph (g)(3)(i), that the MA organization must include all costs associated with the reward and incentive program as an administrative cost and non-benefit expense in the bid for the year in which the reward and incentive program operates. Similarly, we are proposing, at new paragraph (g)(3)(ii), that disputes on rewards and incentives must be treated as a grievance under § 422.564.

We are also proposing, at paragraph (g)(4), to add a prohibition on mid-year changes to an R&I program. This because R&I programs must be included in the plan bid each year as a non-benefit expense. However, we also believe this is an important beneficiary protection and will ensure that beneficiaries are aware when they enroll in a plan what R&I may be available to them.

For the most part, our proposal to revise § 422.134 unifies and codifies existing guidance. We therefore do not believe this provision creates new cost or savings impact for the MA program.

H. Requirements for Medicare Communications and Marketing (§§ 422.2260–422.2274; 423.2260–423.2274)

Sections 1851(h) and (j) of the Act provide a structural framework to define how Medicare Advantage (MA) organizations may market to beneficiaries and direct CMS to adopt additional standards related to review of marketing materials and limitations on marketing activities. Section 1860D–1(b)(1)(B)(vi) of the Act directs that the Secretary use rules similar to and coordinated with the MA rules at section 1851(h) for approval of marketing material and application forms for Part D plan sponsors. Section 1860D–4(l) of the Act applies certain prohibitions under section 1851(h) to Part D sponsors in the same manner as such provisions apply to MA organizations. CMS has adopted regulations related to marketing by MA organizations and Part D sponsors in § 422.111; 42 CFR part 422, subpart V; § 423.128; and 42 CFR part 423, subpart V; these regulations include the specific standards and prohibitions in the statute as well as additional standards and prohibitions promulgated under the statutory authority granted to the agency. Additionally, under the implementation of section 1876(c)(3)(C) of the Act through regulations at § 417.428, the marketing requirements in subpart V of part 422 apply to section 1876 cost plans as well. CMS has long provided sub-regulatory guidance, building upon and intended to provide further interpretation and guidance for these regulations, in the form of a marketing manual titled the Medicare Communications & Marketing Guidelines (MCMG), previously known as the Medicare Marketing Guidelines.

CMS now proposes to codify the additional guidance contained in the MCMG by combining the guidance set forth within the MCMG with the current regulations. In doing so, some reorganization and renumbering of existing regulations is necessary, as the proposed revised regulations are organized according to the topics in the MCMG, rather than fitting into the existing regulation order and flow, as we believe plans are more accustomed to the detailed additional guidance in the MCMG and we intend for the proposed regulations to closely mirror this long-standing sub-regulatory guidance. As part of the reorganization, the proposal in some cases also reorganizes existing regulations, even though CMS does not intend to change

the policy expressed in those regulations. To be clear, the policies we are proposing to codify are not new to the industry; they are already in place in the MCMG and were developed over time in concurrence with industry comments weighing in on the best way to implement marketing requirements in the context of operating the MA, Part D, and cost programs, and plans are accustomed to conforming to these policies. Because this proposal is applicable to MA organizations, Part D plan sponsors and cost plans, we refer to the regulated entity in this proposed rule as a ''plan'' and intend this term to refer to all three of these entities.

The first of the policies that CMS intends to codify, in §§ 422.2260 and 423.2260, is the guidance related to the definitions of ''marketing'' and ''communications,'' as well as additional definitions from the MCMG. CMS has amended and expanded our marketing regulations for both the MA and the Part D programs at 42 CFR parts 422 and 423, subparts V, respectively, several times since their original implementation, and have provided additional sub-regulatory guidance in the MCMG each time, to ensure beneficiaries receive the necessary information to make informed choices. Recently, in the April 2018 final rule, we updated 42 CFR parts 422 and 423, subpart V, including establishing new definitions for communications materials and activities and marketing materials and activities in 42 CFR 422.2260 and 423.2260, which set out the scope of materials and activities subject to our regulations. In the 2019 MCMG, we provided additional guidance that further clarified these definitions based on our interpretation that the regulations used ''intent'' and ''content'' as the deciding factors for when a communication activity or material was marketing.

We now propose to codify the additional guidance we provided in the MCMG and revise the regulation text at §§ 422.2260 and 423.2260 to align more closely with our interpretation. Specifically, we propose, at §§ 422.2260 and 423.2260, that ''marketing'' means communications materials and activities that meet certain standards for intent and content that we enumerate in the regulation text. For the intent standard, we use the same intent language that is in the current regulation with a technical change to separately list out two different intent standards (paragraphs (1)(ii) and (iii) in the proposed definition of marketing) that were previously combined in one paragraph (paragraph (3) in the current definition of marketing materials). As previously practiced, when evaluating the intent or an activity or material, as previously, CMS will consider objective and contextual information (for example, audience, timing, etc.) and is not limited by the plan's statements about its intent.

Under the content standard, we propose in the revised regulations to state affirmatively what must be included for a communications activity or material to be a marketing activity or material, rather than stating what is excluded (as the current regulation does). The first two types of content listed (paragraphs (2)(i) and (ii) under the definition of marketing) are derived from the current regulation (although we specify ''premiums,'' as in the MCMG). The third type of content we enumerate is information on rewards and incentives programs, as we wanted to be clear that while rewards and incentives themselves are not a benefit, they are used as a means of prompting a beneficiary to use a specific benefit, and therefore our policy has been that information on rewards and incentives fall within the definition of marketing. We now propose to explicitly list this as a type of content to avoid any confusion, so that plans continue to be aware that in providing any information on rewards and incentives they should follow the same requirements as for other marketing. We also propose to make some revisions to §§ 422.2260 and 423.2260 to streamline the definitions, such as by removing the list in the current regulation of examples of materials (for example, brochures; posters). We no longer believe this list of examples is necessary, as we have consistently evaluated whether a material is marketing based on intent and content, and not based on its particular form. Additionally, we propose to combine the definitions for ''communications'' and ''communications materials,'' as well as ''marketing'' and ''marketing materials''; this will streamline the definitions section and be consistent with how we have interpreted the current regulations that both activities and materials are subject to the same intent and content standards. We also propose to state explicitly in the definition of ''communications'' that communications activities and use of materials are those ''created or administered by the MA organization or any downstream entity.''

Finally, we propose to codify at §§ 422.2260 and 423.3360 additional definitions that apply to plan marketing. Specifically, we propose to define ''advertisement (ad),'' ''alternate format,'' ''banner,'' ''banner-like advertisements,'' and ''Outdoor Advertising (ODA).'' These definitions are familiar terms that CMS has previously defined and used throughout the MCMG; while we make some technical and clean-up edits primarily to reflect their new form as regulation text, rather than manual guidance, our proposal does not change these definitions in a substantive manner. With the codification of much of the rest of the MCMG, it becomes important to also codify these definitions, which are used throughout the MCMG and are now used throughout the proposed regulations.

We next propose to codify in new §§ 422.2261 and 423.2261 requirements for plans to submit certain materials to CMS for review, the process for CMS review, and the standards by which CMS will perform the review. These requirements are currently found in §§ 422.2262, 422.2264, 423.2622, and 423.2264, as well as in section 90 of the MCMG, which builds upon those sections and includes more detailed operational instructions to plans regarding submission, review, and distribution of marketing materials (including election forms). In particular, we propose at §§ 422.2261(a)(1) and 423.2261(a)(1) that the Health Plan Management System (HPMS) is the primary system of record and the mechanism by which CMS collects and stores submitted plan materials for review and evaluation. Additionally, we propose to codify, at §§ 422.2261(a)(2) and 423.2261(a)(2), our current policy that only plans can submit materials to CMS for review and approval for use. We also propose to specify that this policy prohibits third parties/downstream entities (as they currently are) from submitting materials directly to CMS. Additionally, in new §§ 422.2261(d) and 423.2261(d), we propose to codify that CMS reviews submitted materials for compliance with all applicable requirements in §§ 422.2260 through 422.2267 and §§ 423.2260 through 423.2267, respectively, and that the benefit and cost information is an accurate reflection of what is contained in the MA organization's bid. These standards are consistent with our current policy and how we review marketing materials.

We next propose to codify general standards for plan communications, including requirements related to product endorsements and testimonials and standardization of certain materials (specifically, certain telephone numbers and material IDs) at proposed new §§ 422.2262 and 423.2262. These general standards are currently found in §§ 422.2268(a) and 423.2268(a), which

also include some examples of what plans may not do. While our proposal retains the general standards prohibiting MA plans from misleading, confusing, or providing inaccurate information to current or potential enrollees, we are expanding the lists of examples of what plans may not do (in paragraph (a)(1)), and incorporating examples of what plans are explicitly permitted to do (in paragraph (a)(2)), all consistent with our current guidance in section 30 of the MCMG.

We also propose to codify at §§ 422.2262(b)(2) and 423.2262(b)(2) requirements regarding endorsements and testimonials currently found in section 30.8 of the MCMG. We propose to explicitly note in §§ 422.2262(b)(1) and 423.2262(b)(1) that, consistent with our current policy, product endorsements and testimonials may take different forms. We also propose to codify in §§ 422.2262(c) and 423.2262(c) requirements currently found in section 30 of the MCMG related to including telephone numbers (specifically, customer service numbers and 1–800–MEDICARE) in materials. These additional parameters for how telephone numbers are communicated and included in communications and marketing ensure that beneficiaries get useful and accurate information. And finally, we propose to codify requirements related to standardized material identification, currently found in section 90.1 of the MCMG, in §§ 422.2262(d) and 423.2262(d).

We next propose to codify, at §§ 422.2263 and 423.2263, requirements related to how plans may conduct marketing, which is explicitly specified as a subset of communications and therefore also subject to the requirements proposed in §§ 422.2262 and 423.2262. First, we are proposing to clarify that October 1 is the date plans may begin marketing for the upcoming plan year. This is consistent with the longstanding guidance, but we believe that the current regulation with this date (at §§ 422.2274(b)(4) and 423.2274(b)(3)) lacks specificity on this point. We therefore propose to codify this long-standing policy in §§ 422.2263(a) and 423.2263(a). We also codify, in §§ 422.2263(b) and 423.2263(b), a list of examples of what plans may not do in plan marketing. This list is drawn from existing §§ 422.2268(b), 423.2268(b) and section 40.1 of the MCMG, although we have made some technical clean-up edits. We note that a number of the prohibitions that are currently stated in §§ 422.2268(b) and 423.2268(b) are codified elsewhere in these proposed regulations where they topically fit under the new subpart organization. Finally, at § 422.2263(c), we codify requirements related to marketing of Star ratings that are currently found in section 40.6 of the MCMG.

We next propose to codify, at revised 42 CFR 422.2264 and 423.2264, requirements related to plan contact with Medicare beneficiaries and a beneficiary's caregivers. As used in this proposed regulation, ''beneficiary contact'' includes all outreach activities to a beneficiary or a beneficiary's caregivers by the plan or its agents and brokers. First, in 42 CFR 422.2264(a)(1) and 423.2264(a)(1), we propose to codify the policy for when unsolicited contact is permitted, including direct mail and email which are currently found in the MCMG. Under 42 CFR 422.2264(a)(2) and 423.2264(a)(2), we propose to codify the rules for when unsolicited direct contact with beneficiaries is and is not permitted. Currently, §§ 422.2268(b)(13) and 423.2268(b)(13) explicitly prohibit plans from soliciting door-to-door or engaging in other unsolicited contact and our guidance in section 40.2 of the MCMG addresses this prohibition with additional detail about activities we consider and do not consider to be unsolicited contact. Additionally, under 42 CFR 422.2264(a)(2) and 423.2264(a)(2) we also propose to codify that unsolicited direct messages from social media platforms are also prohibited, which is currently housed in section 30.6 of the MCMG. We also propose to clarify that plans may contact their current members (including those individuals enrolled in commercial plans who are becoming eligible for Medicare) regarding plan business. Finally, in §§ 422.2264(c) and 423.2264(c), we propose to codify requirements regarding events (such as meetings) with beneficiaries, currently found in section 50 of the MCMG; in doing so, we include some additional statements consistent with our current policies of what plans may do. We note that the policy currently housed in §§ 422.2264 and 423.2264, ''Guidelines for CMS Review,'' have been incorporated into the newly proposed §§ 422.2267 and 423.2267. However, whereas the current §§ 422.2264 and 423.2264 provide general guidance on important information that plans must provide to a beneficiary interested in enrolling, §§ 422.2267 and 423.2267 are structured to provide more detailed information on the specific materials or content that a plan is required to produce. Collectively, the required materials and content outlined in §§ 422.2267 and 423.2267 account for the requirements in the current §§ 422.2264 and 423.2264.

We next propose to codify requirements for plan websites at new §§ 422.2265 and 423.2265. The current regulations at §§ 422.111(h)(2) and 423.128(d)(2) establish the requirement for Part C and Part D plans to have an internet website and include requirements regarding content that must be posted on the website. The MCMG has historically provided additional detail on required website content, together with the dates in which the content was required to be posted on a yearly basis. These proposed regulations would redesignate the requirement to have a website at §§ 422.2265 and 423.2265 and supplement that requirement with the additional standards and requirements for websites that are currently in section 70 of the MCMG.

We next propose to codify, in §§ 422.2266 and 423.2266, requirements plans must follow for activities in a healthcare setting, including requirements for provider-initiated activities, plan-initiated provider activities, and plan activities. These requirements are currently articulated in §§ 422.2268(b)(7) and 423.2268(b)(7) and expanded upon in section 60 of the MCMG.

We next propose to codify, at new §§ 422.2267 and 423.2267, instructions for how plans should submit required materials to CMS for review. Specifically, we propose to codify the guidance regarding benchmarks for standardizing and monitoring the production of required documents, including a listing of these required documents, currently found in section 100 and Appendices 2, 3, 4, and 5 of the MCMG. Some of these required materials are discussed in the current regulations (for example, the Annual Notice of Change (ANOC) and the Evidence of Coverage (EOC)). There are some, however, that are only described in the MCMG (for example, the Summary of Benefits (SB)). We propose to codify all of the required materials and content in §§ 422.2267(e) and 423.2267(e); in doing so, we refer to current established regulatory authority when relevant.

Finally, we propose to consolidate, at §§ 422.2274 and 423.2274, requirements related to plan compensation to agents, brokers and other third parties currently found at §§ 422.2272, 422.2274, 423.2272, and 423.2274, and section 110 of the MCMG. For the most part, we do not propose to change the policies currently laid out in these sections but we are proposing significant technical and organizational edits that were

necessary to improve clarity and reduce duplication in the process of consolidation. We refer readers to section V.D. of this proposed rule, where we propose a new policy regarding referral and finder's fees for agents and brokers. Additionally, we are codifying our method for calculating fair market value for agent/broker compensation, as current regulations limit compensation to fair market value but do not further define it or provide the methodology CMS uses for calculating it. CMS first developed the FMV calculation used for purposes of regulating the compensation paid to agents and brokers by plans for contract year 2009 and published these rates in an HPMS memo on December 24, 2008. To develop the FMV, we requested that plans submit the broker fees they paid for 2006 and 2007, as well as the fees planned to be paid in 2009. Plans submitted approximately 19,000 records that we analyzed based on geographic location and organization type. Following this analysis, we developed the FMV for MA plans, 1876 cost plans and Part D plans. The MA FMV rates for enrolling a single beneficiary were established at a national rate of $400, with exceptions for Connecticut, Pennsylvania, and DC ($450), and California and New Jersey ($500), based on higher rates being reported in those geographic areas. The PDP rate was set at $50 for a single enrollment nationally. For years after contract year 2009, we calculated the FMV based on the National Per Capita MA Growth Rate for aged and disabled beneficiaries for Part C and 1876 Cost plans and the Annual Percentage Increase for Part D. The formula is as follows: Current Year FMV + (Current Year FMV * National Per Capita MA Growth Rate for aged and disabled beneficiaries) for MA and 1876 cost plans and Current Year FMV + (Current Year FMV * Annual Percentage Increase for Part D) for PDP plans.

Additionally, section 110.7.1 of the MCMG clarifies when the regulations at §§ 422.2274(b)(2) and 423.2274(b)(2) that require recovery of agent compensation when a newly-enrolled individual disenrolls within the first three months of enrollment (rapid disenrollment) don't apply. We propose to codify those clarifications at §§ 422.2274(g)(2)(ii)(C) and 423.2274(g)(2)(ii)(C).

To reiterate and summarize, the proposed new and revised regulatory sections and their content are as follows:

- Sections 422.2260 and 423.2260 revise and streamline the current definitions of ''communications'' and ''marketing,'' and codify definitions for additional key terms used throughout the proposed regulations from the MCMG.
- Sections 422.2261 and 423.2261 contain requirements for plans to submit certain materials to CMS for review, the process for CMS review and the standards by which CMS will perform the review, taken from current §§ 422.2262, 422.2264, 423.2622, and 423.2264 and section 90 of the MCMG.
- Sections 422.2262 and 423.2262 specify the general standards for plan communications materials and activities, including endorsements and testimonials, and examples of what plans may and may not do. These sections also contain requirements related to standardization of certain key elements of communications materials (specifically, telephone numbers and material IDs). These sections include policies currently articulated in §§ 422.2268 and 423.2268 as well as sections 30 and 90.1 of the MCMG.
- Sections 422.2263 and 423.2263 contain requirements for how plans must conduct marketing. These sections will incorporate requirements currently in §§ 422.2268 and 423.2268 as well as additional guidance from section 40 of the MCMG.
- Sections 422.2264 and 423.2264 address the rules for plan contact with Medicare beneficiaries. These sections include guidance currently in §§ 422.2268 and 423.2268 and further expanded upon in sections 40 and 50 of the MCMG.
- Sections 422.2265 and 423.2265 explain the requirements for plans to have a website as well as what must, can, and must not be on the website. These sections include material currently in section 70 of the MCMG.
- Sections 422.2266 and 423.2266 contain the requirements plans must follow for activities in a healthcare setting. These sections include material from current §§ 422.2268 and 423.2268 and from section 60 of the MCMG.
- Sections 422.2267 and 423.2267 provide instructions on materials and content that CMS requires plans to deliver or make available to beneficiaries, including required disclaimers. These sections include material from section 100 and Appendices 2, 3, 4, and 5 of the MCMG.
- Sections 422.2274 and 423.2274 consolidate requirements from §§ 422.2272, 422.2274, 423.2272, and 423.2274 and section 110 of the MCMG regarding agents, brokers, and compensation to third parties Except as specifically described in the section of the proposed rule, these provisions would codify already-existing guidance and policies and therefore are not expected to have impact.

Finally, we request comment on how CMS should implement prohibitions related to plan marketing during the open enrollment period (OEP). Section 1851(e)(2)(G)(3)(iv) of the Act, as added by section 17005 of the Cures Act, prohibits marketing the opportunity afforded by the open enrollment period (OEP). The current regulations implementing the statutory prohibition on plan marketing during the OEP are at §§ 422.2268(b)(10) and 423.2268(b)(10). The MCMG includes some additional guidance about what activities fall within this prohibition. Specifically, plans are prohibited from sending unsolicited materials that call out the opportunity afforded by the OEP, using mailing lists or other anecdotal information to target individuals who made enrollment requests during the annual coordinated enrollment period (AEP), or leveraging agent/broker activities that target the OEP as a way to make further sales.

I. Past Performance (§§ 422.502 and 423.503)

Since the publication of the first Medicare Advantage (MA) and Part D program regulations in 2005, CMS has established, at §§ 422.502(b) and 423.503(b), that we may deny an application submitted by an organization seeking an MA or Part D sponsor contract if that organization has failed to comply with the requirements of a previous MA or Part D contract. In the April 2011 final rule, we completed rulemaking that placed limits on the period of contract performance CMS would review (that is, 14 months preceding the application deadline) and established that CMS would evaluate contract compliance through a methodology that would be issued periodically through sub-regulatory guidance (75 FR 19684 through 19686). In the April 2018 final rule, we reduced the review period to 12 months (83 FR 16638 through 16639).

In this proposed rule, CMS seeks to add clarity and predictability to our review of MA and Part D applicants' prior MA or Part D contract performance by identifying in the regulation text the criteria we will use to make a determination to deny an application based on prior contract performance. This approach will replace the past performance methodology that CMS developed and issued annually through sub-regulatory guidance.

CMS' overall policy with respect to past performance remains the same. We have an obligation to make certain that MA organizations and Part D sponsors

can fully manage their current contracts and books of business before further expanding. CMS may deny applications based on past contract performance in those instances where the level of previous non-compliance is such that granting additional MA or Part D business opportunities to the responsible organization would pose a high risk to the success and stability of the MA and Part D programs and their enrollees. Accordingly, we propose to adopt three factors, each of which, on its own, represents significant non-compliance with an MA or Part D contract, as bases for denying an MA or Part D application: (A) The imposition of civil money penalties or intermediate sanctions, (B) low Star Ratings scores, and (C) the failure to maintain a fiscally sound operation. We propose that the presence of any one of these factors in an applicant's record during the past performance review period could subject it to the denial of its MA or Part D application. Once finalized, these three bases would be added to our already codified authority and may be used to deny an application based on CMS' termination of an applicant's previous contract under §§ 422.502(b)(3) and 423.503(b)(3). Also, we decline to consider an application from an organization still covered by the 2-year period during which it had agreed, pursuant to §§ 422.508(c) and 423.508(e), not to submit applications for new MA or Part D contracts as part of a mutual termination agreement entered into with CMS pursuant to §§ 422.508(a) and 423.508(a).

In the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2103 and Other Changes Final Rule, CMS established through rulemaking that MA organizations and Part D sponsors are required to achieve Part C or Part D summary ratings scores, respectively, of at least three stars (77 FR 22108 through 22115). In addition, we established that an organization's failure over three consecutive years to achieve Part C or Part D summary ratings of at least three stars is a basis for a CMS-initiated contract termination. In effect, through this rulemaking, CMS established that the failure to achieve at least three stars constitutes a substantial failure to comply with an MA or Part D contract, forming the basis for a CMS-initiated termination. Given the significant impact of low Star Ratings on an organization's ability to continue to hold an MA or Part D contract, we propose to adopt failure to achieve at least a three-star Part C or Part D summary rating in the set of Star Ratings CMS issued during the 12-month review period (CMS currently issues ratings in October of each year) as a basis for denying an application based on past performance. (For example, an application for contract year 2022 would be denied if the organization received less than a three-star rating for contract year 2021, as issued by CMS in October 2020.) In the event that an MA organization requests a review of its eligibility for a Quality Bonus Payment (QBP) under § 422.260, we will use the summary rating that results from the completion of the review process, even if the final decision is not issued until after the expiration of the 12-month review period.

Inherent in a current MA organization or Part D sponsor's submission of a contract qualification application is a representation that it has the financial resources necessary to administer additional lines of Medicare business. A sponsor that CMS has determined does not comply with the financial solvency requirements of § 422.504(b)(14) or § 423.505(b)(23) is not only not in compliance with its current MA or Part D contract, but also would place enrollees of future plans, if it were awarded a new contract, in immediate risk of being unable to gain access to covered benefits should the contracting organization fail to pay legitimately submitted claims. Therefore, CMS believes that an applicant's failure to comply with the solvency requirements also provides a basis, on its own, for the denial of the application based on poor past contract performance.

CMS-imposed intermediate sanctions (for example, suspension of marketing and enrollment activities) and civil money penalties (CMPs) are based on findings of substantial contract compliance failures, consistent with the standards established in sections 1857(g) and 1860D–12 (b)(3)(E) of the Act. For example, the statute (and the corresponding regulations at part 422, subpart O, and part 423, subpart O) provide for the imposition of sanctions or CMPs when a contracting organization substantially fails to provide medically necessary items that are required to be provided to plan enrollees, charges enrollees excess premiums, or contracts with excluded providers. Given the significance of any conduct that would meet these standards, it follows that CMS would consider the imposition of an intermediate sanction or CMP as a failure to comply with an MA or Part D contract warranting the denial of a contract application from that same organization.

In § 422.502(b)(1)(i)(A), we propose to exclude intermediate sanctions imposed on dual eligible special needs plans (D–SNPs) under § 422.752(d) as a basis for denying a MA or Part D application. In the April 2019 final rule, CMS established standards, effective 2021, for the integration of Medicare and Medicaid benefits for D–SNPs pursuant to section 50311(b) of the BBA of 2018, which amends section 1859 of the Act (84 FR 15696 through 15720). We also codified in the April 2019 final rule a requirement at § 422.752(d) that CMS impose an enrollment suspension during plan years 2021 through 2025 when we find that a D–SNP is non-compliant with those integration standards, pursuant to section 50311(b) of the BBA of 2018, which amended section 1859(f) of the Act. As discussed in the April 2019 final rule preamble (84 FR 15719 through 15720), while the new statutory language in section 1859(f)(8)(D)(ii) of the Act permits the Secretary to impose intermediate sanctions for D–SNPs that failed to meet the integration standards, CMS proposed and finalized a requirement that sanctions always be imposed in this case, rather than initiating outright termination. Additionally § 422.752(d) requires that, in cases where CMS imposes such a sanction, the MA organization submit to CMS a corrective action plan.

To achieve compliance with CMS' integration requirements, D–SNPs must work with the states in which they currently operate to negotiate new contractual terms in their state Medicaid agency contracts required under § 422.107. We recognize that states' experience with Medicare and Medicaid integration efforts, and their capacity to facilitate D–SNP compliance with the new integration requirements, varies significantly. While CMS is engaged in capacity building efforts with D–SNPs and states to ensure successful implementation of the D–SNP integration requirements beginning in 2021, the possibility remains that some D–SNPs—despite good faith efforts—may be unsuccessful in meeting their state Medicaid agency contract requirements timely and will therefore be subject to an enrollment sanction under § 422.752(d).

Our proposed policy at § 422.502(b) to deny applications based on past contract performance applies at the MA organization level. However, D–SNP integration requirements apply at the plan level. In most cases, D–SNP PBPs are commingled in contracts that include multiple other non-D–SNP PBPs, such that a sanction imposed on just one D–SNP that is part of an MA

organization with many other plans could result in an inability for the entire MA organization to expand if the proposal were finalized at § 422.502(b)(1)(i)(A), even if that sanctioned D–SNP is working in good faith with a state to meet the relevant integration requirements. Additionally, as noted earlier, § 422.752(d) requires that D–SNPs sanctioned for not meeting the integration criteria submit to CMS a corrective action plan, and CMS retains the ability to terminate a contract or plan for failure to submit such a corrective action plan or to abide by its terms. Therefore, we believe that excluding from the proposed requirement at § 422.502(b)(1)(i)(A) any sanctions CMS imposes on an MA organization with one or more D–SNPs sanctioned specifically under § 422.752(d), during plan years 2021 through 2025, is reasonable given the established mechanism for D–SNPs to be penalized for failure to meet integration requirements established in the April 2019 final rule.

For one of these proposed bases for application denial to be considered, the relevant non-compliance must be documented by CMS (through the issuance of a letter, report, or other publication) during the 12-month review period established at §§ 422.502(b)(1) and 423.503(b)(1). Thus, CMS may include in our analysis conduct that occurred prior to the 12-month past performance review period but either did not come to light, or was not documented, until sometime during the review period.

In evaluating applications submitted by organizations with no recent MA or Part D contracting history, we propose to consider the performance of contracts held by the applicant's parent organization or another organization controlled by the same parent and ascribe that performance to the applicant. Specifically, we propose to identify applying organizations with no recent prior contracting history with CMS (that is, a legal entity brand new to the Medicare program, or one with prior Medicare contract experience that precedes the 12-month review period). We would then determine whether that entity is held by a parent of other MA organizations or Part D sponsors or otherwise shares common control with another contracting organization. In these instances, it is reasonable in the absence of any recent actual contract performance by the applicant due to a lack of recent Part C or Part D participation, to impute to the applicant the performance of its sibling organizations as part of CMS' application evaluation. This approach would prevent parent organizations with subsidiaries that are poor Part C or Part D performers, or the parties that otherwise control poor performing entities, from evading CMS' past performance review authority by creating new legal entities to submit Part C or Part D applications. It would also force organizations responsible for a poor past performance record to direct their attention away from acquiring new Medicare business when their focus should be on bringing their current Medicare contract performance up to an acceptable level. Should one or more of the sibling organizations meet one of the bases for denial stated in (b)(1)(i), the application from the new legal entity would be denied.

We propose to codify the new bases for application denial based on past contract performance as paragraphs (b)(1)(i)(A)—low star ratings, (b)(1)(i)(B)—intermediate sanction or CMP, and (b)(1)(i)(C)—failure to maintain fiscally sound operation under §§ 422.502 and 423.503. The provision governing the consideration of applicant's parent organizations or sibling entities will be stated at §§ 422.502(b)(1)(ii) and 423.503(b)(1)(ii).

J. Prescription Drug Plan Limits (§ 423.265)

Section 1857(e)(1) of the Act, incorporated for Part D by section 1860D–12(b)(3)(D) of the Act, provides CMS with the authority to establish additional contract terms, not inconsistent with Part D, that CMS finds ''necessary and appropriate.'' Section 1860D–11(d)(2)(B) of the Act provides CMS with the authority to negotiate bids and benefits that is ''similar to'' the statutory authority given to the Office of Personnel Management (OPM) in negotiating health benefit plans. We interpreted this authority to mean that we can negotiate a plan's administrative costs, aggregate costs, benefit structure and plan management (70 FR 4296). CMS regulations at §§ 423.272(a) and 423.272(b) require Part D sponsors to submit bids and benefit plans for CMS approval. As stated in § 423.272(b), CMS approves the plan only if the plan's offerings comply with all applicable Part D requirements. Similarly, regulations at § 423.265(b)(2) require that multiple plan offerings by Part D sponsors represent meaningful differences to beneficiaries with respect to beneficiary out-of-pocket costs or formulary structures.

As we have gained experience with the Part D program, we have made consistent efforts to ensure that the number and type of PBPs PDP sponsors may market to beneficiaries are no more numerous than necessary to afford beneficiaries choices from among meaningfully different plan options. CMS has declined to approve more than three stand-alone prescription drug plans offered by a Part D sponsor in a PDP region—one basic plan and (at most) two enhanced plans. A basic plan consists of the following: (1) Standard deductible and cost-sharing amounts (or actuarial equivalents), (2) an initial coverage limit based on a set dollar amount of claims paid on the beneficiary's behalf during the plan year, (3) a coverage gap phase, and (4) a catastrophic coverage phase that applies once a beneficiary's out-of-pocket expenditures for the year have reached a certain threshold. An enhanced plan is an optional plan offering, which provides additional value to beneficiaries in the form of reduced deductibles, reduced cost sharing, additional coverage of some or all drugs while the beneficiary is in the gap phase of the benefit, coverage of drugs that are specifically excluded as Part D drugs under paragraph (2)(ii) of the definition of Part D drug under § 423.100, or some combination of those features. Section 423.104(f)(2) prohibits a Part D sponsor (as defined in § 423.4) from offering enhanced alternative coverage in a service area unless the sponsor also offers a prescription drug plan in that service area that provides basic prescription drug coverage.

Prior to adopting regulations requiring meaningful differences between each plan sponsor's plan offerings in a PDP Region, our guidance allowed sponsors to offer additional basic plans in the same region as long as they were actuarially equivalent to the basic plan structure described in statute. However, under § 423.265(b)(2), PDP sponsors are no longer permitted to offer two basic plans in a PDP Region because Part D sponsors cannot demonstrate a meaningful difference between two basic plans and still satisfy statutory actuarial equivalence requirements. In addition, we believe that allowing more than one basic plan could result in sponsor behaviors that adversely affect the program, such as the creation of plan options designed solely to engage in risk segmentation whereby one basic plan would target enrollment of the LIS beneficiaries and the second basic plan would target a lower risk population. As it stands, healthier beneficiaries are increasingly being incentivized to enroll in low premium enhanced plans, leading to a higher risk pool in the basic plans. Permitting a sponsor to offer two basic plans in a region could ultimately result in increasing bids and premiums

for basic plans, given that LIS auto-enrollment is limited to basic plans. Total government costs would likely increase because CMS pays most of the premium for LIS beneficiaries.

Since the beginning of the Part D program, CMS has consistently tried to ensure that Part D sponsors only market the number and type of PBPs necessary to offer beneficiaries meaningfully different plan options and allow them to carefully examine all of the plan offerings. However, allowing sponsors to offer enhanced prescription drug plan offerings that are not meaningfully different with respect to beneficiary out-of-pocket costs can lead to more innovation and provide sponsors with added flexibility to offer health care options that can be tailored to different beneficiary choices with a portfolio of plan options with different benefits, pharmacy networks, and premiums. As such CMS eliminated the meaningful difference requirement between a plan sponsor's enhanced alternative benefit offerings effective for contract year 2019. As a result of eliminating this requirement, we have seen a greater number of enhanced plan offerings.

CMS has examined Part D plan payment data in cases and markets with different numbers of enhanced plans. When looking at this data, we noted that markets with a greater number of enhanced plans have higher costs than basic plans. This was true even when controlling for other factors, such as population health and age. In these cases, the basic component of enhanced plans' bids was found to trend higher than basic plan bids themselves. Given the upward impact to program costs, CMS proposes to codify our policy of limiting number of allowed enhanced plan offerings by a Part D sponsor in a PDP region.

We believe that limiting a Part D sponsor to three plan offerings per region, (that is, one basic and, at most, two enhanced plans), strikes the right balance between encouraging robust competition and flexibility for plan sponsors to innovate with the need to limit the potential for significant risk segmentation and provide beneficiaries with only clear options that do not create confusion and allow for careful examination of the available choices. Based on our review of current and past plan offerings and our actuarial models, we believe that permitting more than 3 plan options likely would lead to more enhanced plans that offer only the minimum level of supplemental coverage required to meet our meaningful differences tests. These ''low value enhanced plans'' sometimes have lower premiums than basic plans because of the risk profile of the enrollees, as low income subsidy (LIS) enrollees with more serious health issues and higher utilization of prescription drugs generally are not enrolled in these plans because they would be responsible for paying the supplemental premium out of pocket (even though the total premium is less than the basic plan). When many healthy individuals are not included in the basic plans, the cost of the basic plans is increased, and this in turn increases low-income premium subsidies.

We do not believe such risk segmentation is consistent with the design of the Part D program, which has been put in place to save taxpayers' and Medicare beneficiaries' money on prescription drug costs. We do not believe such risk segmentation obtains the best value for the government or the taxpayer. We believe sponsors compete in the Part D market by offering their best bids for basic plans, in order to attract the greatest enrollment through the lowest premiums, and that this competition maintains downward pressure on Part D bids and government subsidies. Our proposal to codify a 3 plan limit would not eliminate the potential for some risk segmentation, but would limit risk segmentation and would prevent any potential growth in plan offerings that could further segment risk.

We are proposing to limit Part D sponsors to offering no more than three prescription drug plans per PDP region by adding a new paragraph at § 423.265(b)(2). Since this proposed change would codify our existing practice, this proposed change would not alter any existing processes or procedures within the Part D bid submission and approval process. Therefore, this provision is not expected to have a budgetary impact.

We seek stakeholder input as to the impact of limiting the number of enhanced plan offerings to two. In addition, we are seeking information on what type of impact expanding the number of enhanced plan alternatives would have and whether there is any real need for more than two standalone enhanced plan options per PDP sponsor per PDP region.

K. Definition of a Parent Organization (§§ 422.2 and 423.4)

Pursuant to our authority under sections 1856(b) and 1860D–12(f)(1) of the Act, we propose to codify our definition of parent organization for purposes of the MA and Part D programs as the legal entity exercising controlling interest in an MA organization or Part D sponsor. We propose adding a definition for the term ''parent organization'' to § 422.2 in part 422, subpart A, and § 423.4 in part 423, subpart A, to reflect this understanding.

This proposal is to ensure that the MA and Part D programs apply a consistent definition of parent organization. CMS uses the identity of an MA organization's or Part D sponsor's parent organization in a variety of operational contexts, including, but not limited to:

—Determining whether an individual can be deemed to have elected an MA dual eligible special needs plan based in part on his enrollment in an affiliated Medicaid managed care plan (§ 422.66(c)(2));

—Accounting for contract consolidations in assigning Star Ratings under the Quality Rating System for health and/or drug services of the same plan type under the same parent organization (§§ 422.162 and 423.182);

—Determining whether a new MA contract constitutes a new MA plan for calculation of star ratings, benchmarks, quality bonus payments, and beneficiary rebates, (§ 422.252).

—Recognizing an individual's appointment as an MA organization's or Part D sponsor's compliance officer based on his or her status as an employee of the organization, its parent organization, or a corporate affiliate (§§ 422.503(b)(4)(vi)(B)(*1*) and 423.504(b)(4)(vi)(B)(*1*));

—Determining whether an applicant for a new PDP contract is eligible to receive a contract in a particular service area (§ 423.503(a)(3)) after evaluating whether the approval of an application would result in a parent organization, directly or through its subsidiaries, holding more than one PDP contract in a PDP region;

—Determining whether to administer an essential operations test to a Part D contract applicant new to the Part D program (§§ 423.503(c)(4) and 423.505(b)(27)), taking into account the exemption for subsidiaries of parent organizations that have existing Part D business from the essential operations test;

—Releasing summary Part D reconciliation payment data at the parent organization level (§ 423.505(o)); and

—Determining whether CMS will recognize the sale or transfer of an organization's PDP line of business, where CMS regulations require the transfer of all PDP contracts held by the selling or transferring sponsor unless the sale or transfer is between wholly owned subsidiaries of the

same parent organization (§ 423.551(g)).

We currently define the term ''parent organization'' for purposes of applying the prohibition against approving an application that would result in a parent organization holding more than one PDP sponsor contract in a region as an entity that exercises a controlling interest in the sponsor. (See § 423.503(a)(3)). Because we are proposing a more detailed definition that would apply throughout the MA and Part D programs, we are proposing to delete that language in § 423.503(a)(3).

Under the proposed definition, a parent organization is the legal entity that holds a controlling interest in the MA organization or Part D sponsor, whether it holds that interest directly or through other subsidiaries. The controlling interest can be represented by share ownership, the power to appoint voting board members, or other means. Control of the appointment of board members is particularly relevant with respect to not-for-profit organizations, where there is often no direct corollary to the ownership of corporate shares in for-profit organizations. We recognize that the many ways that one legal entity may have a controlling interest in another legal entity are varied and could take many forms too numerous for us to create an exhaustive list. Therefore, our proposal includes the ability for us to look at other means of control to be exercised or established. We invite comment on other examples of the form a controlling interest might take.

We further propose to specify that the parent organization cannot itself be a subsidiary of another entity. This ensures that each MA organization or Part D sponsor has a single parent organization for purposes of the MA and Part D programs. For example, if Company A owns 80 percent of Company B, which in turn owns 100 percent of an MA organization, Company A would be the parent organization of the MA organization under the proposed definition.

We believe that the proposed definition will codify current policy and ensure continued consistency throughout the MA and Part D programs. We note that this definition of parent organization would apply in implementing the proposed change to § 422.550 regarding the type of change of ownership that CMS would permit for MA contracts; we discuss that proposal in section VI.D. of this proposed rule.

L. Call Center Requirements (§§ 422.111 and 423.128)

In implementing sections 1851(d) and 1860D–4(a)(3) of the Act, CMS established, at §§ 422.111(h) and 423.128(d), that MA organizations and Part D sponsors are required to have in place a mechanism for providing, on a timely basis, specific information to current and prospective enrollees, and for a Part D plan also to pharmacies in the plan network, upon request. One of these enumerated mechanisms includes operating a toll-free customer service call center. In this proposed rule, CMS seeks to add greater specificity and clarity to our requirements for MA and Part D plans by delineating more explicit performance standards for MA and Part D customer service call centers, as well as ensuring greater protections for beneficiaries. This approach will enhance the current approach, providing plans clear standards under which to operate their customer service call centers and eliminating uncertainty with regard to CMS's expectations. Customer service call centers include call centers operated for current enrollees, prospective enrollees, and for pharmacies in plans' networks that are seeking information on drug coverage for customers enrolled in a particular plan. For the most part, this proposal would codify existing guidance. Under our proposal, CMS's overall policy with respect to operating a toll-free customer service call center would remain largely the same. We have always expected MA organizations and Part D sponsors to operate customer service call centers in a way that ensures beneficiaries and pharmacies have timely and accurate access to information about benefits in a manner that they can understand and use. Providing specific performance standards in regulation text will clearly lay out the performance requirements and our expectations for customer service call centers. Additionally, beneficiaries will benefit from CMS holding plans to clearly defined call center standards. Accordingly, we propose to adopt the following performance requirements for call center functionality. Failure to comply with any of these requirements would represent significant deviation from acceptable call center operational practices and a significant risk to beneficiaries' well-being under our enforcement policies and applicable regulations.

In §§ 422.111(h)(1)(i) and 423.128(d)(1)(i), we propose that customer service call centers must be open from at least 8:00 a.m. to 8:00 p.m., local time, in all service areas and regions served by the MA or Part D plan, and for Part D plans, that any call center serving network pharmacies or pharmacists employed by those pharmacies must be open any time a pharmacy in the plan service area is open. We remind stakeholders that MA–PD plans are Part D plans that must comply with Part 423 requirements. These proposed timeframe standards lend greater specificity to the previous iteration of this regulation which only required a call center to be open during ''normal business hours.'' We believe that 8:00 a.m.–8:00 p.m. constitutes normal business hours for beneficiary access, based both on our knowledge of industry-wide practices and our experience with MA and Part D plans' call center operations in particular. The requirement for call centers serving network pharmacies to be open any time a pharmacy in that network in the plan's service area is open reflects the need to resolve questions about benefits and coverage promptly at the point of sale. The vast majority of current MA and Part D plans meet these standards. By requiring plans to be open from 8:00 a.m. to 8:00 p.m. in all service areas or regions served by that Part C or D plan, CMS is ensuring that in instances in which plans operate in service areas that straddle multiple time zones, all beneficiaries and pharmacists have equal access to call center services.

We are proposing in §§ 422.111(h)(1)(ii) and 423.128(d)(1)(ii) a series of minimum requirements that define specific operational requirements for customer service call centers. In paragraph (h)(1)(ii)(A), CMS proposes to codify the requirement that the average hold time be two minutes or less. We are proposing specific text to explain when the two minute count starts to ensure consistent application of the metric by defining the hold time as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person. In paragraph (h)(1)(ii)(B), CMS proposes to codify the requirements that the call center answer 80 percent of incoming calls within 30 seconds after the Interactive Voice Response (IVR), touch-tone response system, or recorded greeting interaction. In paragraph (h)(1)(ii)(C), CMS proposes to codify the requirement that 5 percent or less of incoming call calls be disconnected or unexpectedly dropped by the plan customer call center. These standards both ensure that beneficiaries can consistently access call centers in a timely manner and set thresholds that plans can reasonably attain. Data

gathered from our call center monitoring studies indicates that 90 percent of MA organizations and Part D sponsors have average hold times of less than two minutes, 87 percent answer 80 percent incoming calls within 30 seconds, and 82 percent have disconnect rates of less than 5 percent. Longstanding CMS policy interpreting the current regulatory requirement for the call center to meet standard business practices requires call centers to answer calls within 30 seconds and plans overwhelmingly comply with this requirement.

CMS also proposes to amend §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii) to further delineate accessibility requirements for non-English speaking and limited English proficient (LEP) individuals. Plans have always been required to provide interpreters as that is consistent with existing civil rights laws. We propose to further require that interpreters be available within 8 minutes of reaching the customer service representative and that the interpreter be available at no cost to the caller. These requirements are consistent with our interpretation of the requirement for call centers to meet standard business practices and performance is measured against this standard in our current monitoring and oversight activities. Data from our call center monitoring indicates that 95% of plans already meet this standard.

CMS proposes to add §§ 422.111(h)(1)(iv) and 423.128(d)(1)(v), explicitly requiring that call centers respond to TTY-to-TTY calls, consistent with standards established under existing law governing access for individuals with disabilities at 47 CFR part 604, subpart F. The Rehabilitation Act and the Americans with Disabilities Act already require the provision of accessibility services for individuals with disabilities, such as deaf or hard-of-hearing individuals. We are also proposing, at §§ 422.111(h)(1)(v) and 423.128(d)(1)(v), that when using automated-attendant systems, MA and Part D plans must provide effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of FCC-approved telecommunications relay systems. See 28 CFR 35.161, 36.303(d). The requirements proposed at §§ 422.111(h)(1)(ii) and 423.128(d)(1)(ii) also apply to TTY-to-TTY calls. CMS will hold plans accountable for complying with the requirements of §§ 422.111(h)(1)(ii) and 423.128(d)(1)(ii) when receiving TTY-to-TTY calls. These standards are consistent with current CMS interpretation and implementation of the requirement that plans have a call center that meets standard business practices. CMS data shows that 91 percent of plans currently respond to TTY-to-TTY calls within 7 minutes. CMS solicits comments on adopting the 7 minute response time as a TTY-to-TTY standard.

We propose to codify our existing interpretations and policies regarding MA and Part D plan call centers as explicit requirements for operating a toll-free customer service call center in §§ 422.111 and 423.128. We are proposing this codification to ensure transparency for plans about the performance standards they must meet. Further, codification of these policies will provide stability for these plans going forward.

M. Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

1. Part C Special Election Periods (§ 422.62)

Section 1851(e)(4) of the Act establishes special election periods (SEPs) during which, if certain circumstances exist, an individual may request enrollment in a Medicare Advantage (MA) plan or discontinue the election of an MA plan and change his or her election to original Medicare or to a different MA plan. We have codified SEPs for the following circumstances specifically addressed in section 1851(e)(4) of the Act:

- When CMS terminates the MA organization's contract for the plan, or the MA organization terminates the plan or discontinues offering the plan in the service or continuation area in which the individual resides, or the MA organization has notified the individual of the impending termination of the plan or the impending discontinuation of the plan in the area in which the individual resides (§ 422.62(b)(1) and section 1851(e)(4)(A) of the Act).
- When the individual is no longer eligible to be enrolled in a certain plan due to a change of residence or other change in circumstances as specified by CMS but not including terminations resulting from a failure to make timely payment of an MA monthly or supplemental beneficiary premium, or from disruptive behavior (§ 422.62(b)(2) and section 1851(e)(4)(B) of the Act).
- When the individual demonstrates to CMS, in accordance with guidelines established by CMS that the MA organization has substantially violated a material provision of its contract or materially misrepresented the plan's provisions in marketing the plan in relation to the individual (§ 422.62(b)(3) and section 1851(e)(4)(C) of the Act).

Section 1851(e)(4)(D) of the Act also grants the Secretary the authority to create SEPs for individuals who meet other exceptional conditions. This authority is codified at § 422.62(b)(4). CMS has historically included in regulation those SEPs that the statute explicitly authorizes and has established the SEPs for exceptional circumstances in our subregulatory guidance rather than through regulation. We are now proposing to codify a number of SEPs that we have adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. Except where noted in this proposed rule, our intent is to codify the current policy, as reflected in section 30.4.4 of Chapter 2 of the Medicare Managed Care Manual. As with all MA enrollments, enrollments into a new MA plan using a SEP require that the individual be otherwise eligible for that MA plan under §§ 422.50 through 422.57. For example, the individual must reside in the service area of the new MA plan. We seek specific comment as to whether we have overlooked any feature of the current policy that should be codified and if there are other exceptional circumstances we have not identified for which we should consider establishing a special election period. Codifying our current policy for these SEPs will provide transparency and stability for stakeholders about the MA program and about the nature and scope of these SEPs by ensuring that the SEPs are changed only through additional rulemaking. Consistent with § 422.68(c), we are also proposing to revise § 422.68(d) to clarify that for SEPs that are described in § 422.62(b), elections are effective as of the first day of the first calendar month following the month in which the election is made, unless otherwise noted. In addition, we note that, consistent with longstanding subregulatory guidance, the organization is not required to contact an applicant to confirm SEP eligibility if the enrollment request includes the applicant's attestation of SEP eligibility.

- *SEP for Employer/Union Group Health Plan (EGHP) Elections.* We are proposing to revise § 422.62(b)(4) to codify a SEP for individuals making MA enrollment requests into or out of employer sponsored MA plans, for individuals to disenroll from an MA plan to take employer sponsored coverage of any kind, and for individuals disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan.

This SEP is available to individuals who have (or are enrolling in) an employer or union sponsored plan for the duration of that enrollment and ends 2 months after the month the employer or union coverage ends. The individual may choose an effective date of up to three months after the month in which the individual completed an enrollment or disenrollment request; however, the effective date may not be earlier than the first of the month following the month in which the request was made.

• *SEP for Individuals Who Disenroll in Connection With a CMS Sanction.* At new § 422.62(b)(5), we are proposing to codify the SEP for individuals enrolled in an MA plan offered by an MA organization that is sanctioned by CMS. Such enrollees would be eligible for a SEP to elect another MA plan, or disenroll to original Medicare and enroll in a PDP, if they believe they are affected by the matter(s) that gave rise to that sanction. We propose that, consistent with § 422.111(g), CMS may require the MA organization to notify the current enrollees that if they believe they are affected by the matter(s) that gave rise to the sanction, they are able to choose another MA plan or enroll in original Medicare and a PDP. The SEP would start with the imposition of the sanction and end when the sanction ends or when the individual makes an election, whichever occurs first.

• *SEP for Individuals Enrolled in Cost Plans That Are Non-Renewing Their Contracts.* At new § 422.62(b)(6), we are proposing to codify the SEP for individuals enrolled in cost plans that are non-renewing their contracts for the area in which the enrollee lives. Such individuals would be eligible for a SEP to elect an MA plan. This SEP would be available only to Medicare beneficiaries who are enrolled with an HMO or CMP under a section 1876 cost plan that will no longer be offered in the area in which the beneficiary lives.

This SEP would begin December 8 of the current contract year, which is the day after the end of the Annual coordinated election period, and end on the last day of February of the following year. Therefore, applying the general rule we propose to codify that elections are effective the first of the month after they are made, enrollment requests received before December 31 would have an effective date of January 1, enrollment requests received between January 1 and January 31 would be effective February 1, and enrollment requests received between February 1 and February 28 (or 29, as the case may be) would be effective March 1.

• *SEP for Individuals in the Program of All-Inclusive Care for the Elderly (PACE).* At new § 422.62(b)(7), we are proposing to codify the SEP allowing an MA plan enrollee to disenroll from an MA plan at any time in order to enroll in PACE. The MA plan enrollee who disenrolls from an MA plan would have a SEP for 2 months after the effective date of MA plan disenrollment to elect a PACE plan. In addition, a PACE enrollee who disenrolls from PACE would have an SEP for 2 months after the effective date of PACE disenrollment to elect an MA plan.

• *SEP for Individuals Who Terminated a Medigap Policy When They Enrolled For the First Time in an MA Plan and Who Are Still in a Trial Period.* For Medicare beneficiaries who terminated a Medigap policy when they enrolled for the first time in an MA plan, section 1882(s)(3)(B)(v) of the Act provides a guaranteed right to purchase another Medigap policy if they disenroll from the MA plan while they are still in a trial period. In most cases, a trial period lasts for 12 months after a person enrolls in an MA plan for the first time. The right to guaranteed issue of a Medigap policy under section 1882(s)(3)(B)(v) of the Act would be meaningless if individuals covered by this provision could not disenroll from the MA plan while they were still in a trial period.

Accordingly, we are proposing, at new § 422.62(b)(8), to codify the SEP for individuals who are eligible for guaranteed issue of a Medigap policy under section 1882(s)(3)(B)(v) of the Act upon disenrollment from the MA plan in which they are enrolled. This SEP would allow a qualified individual to make a one-time election to disenroll from their first MA plan to join original Medicare at any time of the year. The SEP would begin upon enrollment in the MA plan and would end after 12 months of enrollment or when the beneficiary disenrolls, whichever is earlier.

• *SEP for Individuals With ESRD Whose Medicare Entitlement Determination Was Made Retroactively.* If a Medicare entitlement determination based on ESRD is made retroactively, an individual has not been provided the opportunity to elect an MA plan during his or her ICEP. Therefore, we are proposing to codify at new § 422.62(b)(9) that these individuals would have a SEP to prospectively elect an MA plan offered by the MA organization, provided:

++ They were enrolled in a health plan offered by the same MA organization the month before their entitlement to Parts A and B;

++ They developed ESRD while a member of that health plan; and

++ They are still enrolled in that health plan.

This SEP could also be used in cases when there is an administrative delay and the entitlement determination is not made timely. For example, an individual who performs self-dialysis would have his or her entitlement date adjusted to begin at the time of dialysis, rather than the customary 3-month period after dialysis begins.

This SEP would begin the month the individual receives the notice of the Medicare entitlement determination and would continue for 2 months after the month the notice is received. This SEP would be necessary only through the 2020 plan year, as section 17006 of the Cures Act amended section 1851 of the Act to remove the prohibition for beneficiaries with ESRD from enrolling in an MA plan. Although this statutory change is not discussed in current sub-regulatory guidance, we have included this in proposed new § 422.62(b)(9) for clarity.

• *SEP for Individuals Whose Medicare Entitlement Determination Was Made Retroactively.* If a Medicare entitlement determination is made retroactively, an individual has not been provided the opportunity to elect an MA plan during his or her ICEP. Therefore, we are proposing, at new § 422.62(b)(10), to codify the SEP for these individuals to elect an MA plan. This SEP could also be used in cases when there is an administrative delay and the entitlement determination is not made timely by SSA or received by the individual in a timely manner.

The SEP would begin the month the individual receives the notice of the Medicare entitlement determination and would continue for 2 months after the month the notice is received. Consistent with our general rule regarding the effective dates for elections made during an SEP, the election made using this SEP would be effective on the first of the month following the MA organization's receipt of the election but no earlier than the first day of the month in which the notice of entitlement is received. A beneficiary would receive coverage under original Medicare from the date of entitlement until the MA enrollment is effective.

• *SEP for Individuals Who Lose Special Needs Status.* At new § 422.62(b)(11), we are proposing to codify the SEP for individuals enrolled in an MA special needs plan (SNP) who are no longer eligible for the SNP because they no longer meet the applicable special needs status. This SEP would begin the month the individual's special needs status

changes. The SEP would end when the beneficiary makes an enrollment request or the end of the third month after the month of the effective date of involuntary disenrollment from the SNP, whichever is earlier.

• *SEP for Individuals Who Belong to a Qualified SPAP or Who Lose SPAP Eligibility.* At new § 422.62(b)(12), we are proposing to codify a SEP for individuals who belong to a qualified State Pharmaceutical Assistance Program (SPAP) to make one election to enroll in an MA–PD plan each calendar year. SPAP members may use this SEP to enroll in an MA–PD plan outside of existing enrollment opportunities, allowing them, for example, to join an MA–PD plan upon becoming a member of an SPAP. Because SPAP eligibility may influence an individual's choice of MA–PD plan, we have adopted a SEP for MA enrollment to coordinate with the change in SPAP eligibility.

In addition to being available while the individual belongs to the SPAP, the SEP remains available for individuals no longer eligible for SPAP benefits for 2 months. The SEP continues until the month they lose SPAP eligibility or the month they are notified of the loss of SPAP eligibility, whichever is later, and then for an additional 2 months.

• *SEP for Enrollment Into a Chronic Care SNP and for Individuals Found Ineligible for a Chronic Care SNP.* At new § 422.62(b)(13), we are proposing to codify the SEP allowing individuals with severe or disabling chronic conditions to enroll in a Chronic Care SNP (C–SNP) designed to serve individuals with those conditions. This SEP would be available as long as the individual has the qualifying condition and would end once he or she enrolls in a C–SNP. Once the SEP ends, that individual would be able to make enrollment changes only during applicable election periods. In addition, individuals enrolled in a C–SNP who have a severe or disabling chronic condition that is not a focus of their current C–SNP would be eligible for this SEP to change to a C–SNP that does focus on the condition that the individual has. Eligibility for this SEP would end at the time the individual enrolls in the new C–SNP.

Individuals who are found after enrollment not to have the qualifying condition necessary to enroll in a C–SNP would have a SEP to enroll in a different MA plan. This would normally occur when the required post enrollment verification with a provider did not confirm the information provided on the pre-enrollment assessment tool. This SEP would begin when the plan notifies the individual of the lack of eligibility and would extend through the end of that month, plus 2 additional months. The SEP would end when the individual makes an enrollment election or on the last day of the second month following notification.

• *SEP for Disenrollment From Part D To Enroll in or Maintain Other Creditable Coverage.* At new § 422.62(b)(14), we are proposing to codify the SEP that provides an opportunity for individuals to disenroll from an MA–PD plan (only by electing Original Medicare or an MA-only plan) in order to enroll in or maintain other creditable drug coverage (such as TriCare or VA coverage) as defined in § 423.56(b). This SEP may not be used to disenroll from an MA–PD plan by electing another MA–PD plan.

• *SEP to Enroll in an MA Plan With a Star Rating of 5 Stars.* At new § 422.62(b)(15), we are proposing to codify the SEP allowing an eligible individual to enroll in an MA plan with a Star Rating of 5 stars during the plan contract year in which that plan has the 5-star overall rating. A rating of 5 stars is considered ''excellent'' and is the highest performance rating that a plan can achieve. Because these plans have demonstrated exceptional performance, and because there tends to be only a small number of 5 Star plans in a given contract year, we believe a SEP is warranted to allow beneficiaries with access to these plans the opportunity to enroll during the plan year for which the 5 Star rating is applicable. The SEP is available beginning the first day after the Annual Election Period (AEP), December 8, prior to the plan contract year for which the 5 Star Rating is applicable, through November 30 of the plan contract year the 5 Star Rating is applicable. The enrollment effective date would be the first of the month following the month in which the MA organization receives the enrollment request.

An individual using this SEP would be able to enroll in an MA plan with a 5-star overall rating even if coming from original Medicare (with or without concurrent enrollment in a standalone Medicare prescription drug plan). Individuals enrolled in a plan with a 5-star overall rating may also switch to a different plan with a 5-star overall rating. Consistent with our general rules for how enrollment eligibility and elections for Part D and MA work, an individual in a MA-only or MA–PD coordinated care plan who switches to a PDP with a 5-star overall rating would lose MA coverage and will revert to original Medicare for basic medical coverage.

• *SEP for Non-U.S. Citizens Who Become Lawfully Present.* At new § 422.62(b)(16), we are proposing to codify the SEP for non-U.S. citizens who become lawfully present in the United States. The individual would be able to use this SEP to request enrollment in any MA plan for which he or she is eligible. This SEP would begin the month the lawful presence starts and would end when the individual makes an enrollment election or at the end of the second calendar month after the month it begins, whichever occurs first.

• *SEP for Providing Individuals Who Requested Materials in Accessible Formats Equal Time To Make Enrollment Decisions.* As outlined in section 504 of the Rehabilitation Act of 1973, organizations are required to comply with requirements of that Act and provide materials in accessible formats to members. This generally includes formats such as Braille, data, and audio files, or other formats accepted by the member in place of, or in addition to, the original print material.

We are proposing to codify, at new § 422.62(b)(17), the SEP in situations where the MA organization or CMS was unable to provide required notices or information in an accessible format, as requested by an individual, within the same timeframe that it was able to provide the same information to individuals who did not request an accessible format. This limited SEP would ensure that beneficiaries who have requested information in accessible formats are not disadvantaged by any additional time necessary to fulfill their request, including missing an election period deadline.

The SEP would begin at the end of the election period during which the beneficiary was seeking to make an election. The start of the SEP, as well as the enrollment effective date, would be dependent upon the situation, and the length is at least as long as the time it took for the information to be provided to the individual in an accessible format. An individual would be eligible for this SEP when the conditions described in this section are met. MA organizations would be required to maintain adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of the requested materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

• *SEP for Individuals Affected by a FEMA-Declared Weather-Related*

Emergency or Major Disaster. We are proposing to codify, at new § 422.62(b)(18), the SEP for individuals affected by a weather-related emergency or major disaster who were unable to make an election during another valid election period. This would include both enrollment and disenrollment elections. Individuals would be eligible for this SEP if they:

++ Reside, or resided at the start of the incident period, in an area for which Federal Emergency Management Agency (FEMA) has declared an emergency or a major disaster and has designated affected counties as being eligible to apply for individual or public level assistance;

++ Had another valid election period during the incident period; and

++ Did not make an election during that other valid election period due to the emergency or disaster.

In addition, the SEP would be available to those individuals who do not live in the affected areas but rely on help making healthcare decisions from friends or family members who live in the affected areas. The SEP would be available from the start of the incident period and for 4 months after the start of the incident period.

• *SEP for Significant Change in Provider Network.* At new § 422.62(b)(23), we are proposing to codify the SEP that is available when CMS determines that mid-year changes to an MA plan's provider network are significant, based on the effect on, or potential to affect, current plan enrollees' continued access to covered benefits. Mid-year changes are those that are effective other than on January 1. We note that pursuant to § 422.111, an MA plan must furnish information to enrollees before the annual election period about changes in the plan, including changes in the network, that are effective for the next plan year. Because this notice and the annual election period give enrollees the opportunity to change plans for the new year, we have historically limited this SEP to mid-year changes in the network.

CMS considers significant changes to provider networks to be those that go beyond individual or limited provider terminations that occur during the routine course of plan operations and affect, or have the potential to affect, a large number of the MAO's enrollees. CMS will use a variety of criteria for determining whether or not the network terminations are substantial, such as: (1) The number of enrollees affected; (2) the size of the service area affected; (3) the timing of the termination; (4) whether adequate and timely notice is provided to enrollees, (5) and any other information that may be relevant to the particular circumstance(s).

The SEP would be in effect once CMS makes its determination and enrollees have been notified. As with current guidance, we are proposing that the SEP begins the month the individual is notified of the network change and would continue for an additional 2 calendar months after the month in which the enrollee is notified of the SEP. We are proposing for the SEP to begin the month the individual is notified of eligibility for the SEP, as the MA organization may notify members of the network change prior to CMS making its determination, which under current guidance would result in a SEP start date that precedes the existence of the SEP. The SEP would continue for an additional 2 calendar months after the month in which the enrollee is notified of the SEP. Enrollment in the new plan would be effective the first day of the month after the plan receives the enrollment request. This SEP can be used only once per significant change in the provider network.

The scope of individuals eligible for the SEP would be determined by CMS, applying the standards in the regulation, and would include enrollees who have been affected, or who may be affected, by the network change. We propose to define an ''affected enrollee'' as an enrollee who is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated. Individuals eligible for the SEP would be able to disenroll from the MA plan and elect original Medicare or another MA plan, including an MA–PD plan, even if they did not have prescription drug coverage previously. CMS will provide specific instructions directly to the MA organization with the significant network change, including instructions on required beneficiary notifications and information to be provided to affected beneficiaries regarding other enrollment options, if applicable.

• *SEP for Individuals Enrolled in a Plan Placed in Receivership.* We propose to establish a new SEP, at new § 422.62(b)(24), for individuals enrolled in plans offered by MA organizations experiencing financial difficulties to such an extent that a state or territorial regulatory authority has placed the organization in receivership. We believe this SEP constitutes an exceptional circumstance because receiverships have the potential to cause disruption in access to healthcare services and individuals should have the ability to take action to prevent any future disruption to care. The SEP would allow an individual to discontinue the election of an MA plan and change his or her election to a different MA plan or to original Medicare, with or without enrollment in a standalone Medicare prescription drug plan. We propose that the SEP begin the month the receivership is effective and continue until the enrollee makes an election or the receivership is no longer in effect, whichever occurs first.

Also, we propose that when instructed by CMS, the MA plan that has been placed under receivership, or the entity operating the organization in receivership, must notify its enrollees, in the form and manner directed by CMS, of their eligibility for this SEP and how to use the SEP.

• *SEP for Individuals Enrolled in a Plan That Has Been Identified by CMS as a Consistent Poor Performer.* We propose to establish a new SEP, at new § 422.62(b)(25), for individuals who are enrolled in plans identified with the low performing icon (LPI) in accordance with § 422.166(h)(1)(ii). The LPI is assigned to contracts that have summary ratings of less than 3 Stars for three or more years. We believe this SEP constitutes an exceptional circumstance because these contracts have demonstrated performance considered ''below average'' or ''poor'' for a sustained period of time based on critical factors such as beneficiary complaints and access to care. To ensure that beneficiaries are not adversely affected, we believe that beneficiaries enrolled in these contracts should have the ability to enroll in plans rated ''average'' or higher during the year. The SEP would allow an individual to discontinue the election of a consistently poor performing MA plan and change his or her election to an MA plan with an overall Star Rating of 3 or more stars or to original Medicare, with or without enrollment in a standalone Medicare prescription drug plan. We propose that the SEP exist while the individual is enrolled in the consistently poor performing MA plan.

• *SEP for Individuals Affected by a Federal Employee Error.* At new § 422.62(b)(21), we are proposing to codify a SEP for individuals whose enrollment or non-enrollment in an MA–PD plan is erroneous due to an action, inaction or error by a federal employee to permit enrollment in, or disenrollment from, an MA–PD plan. Requests for this SEP would have to be developed and presented to the MA organization's CMS account manager. The CMS account manager will review each case and determine if the enrollment or non-enrollment was caused by the action, inaction or error on the part of a federal employee. This

SEP would begin the month that CMS determines an individual eligible for this SEP and would continue for 2 months.

• *SEP for Other Exceptional Circumstances.* Lastly, we propose to retain the authority currently at § 422.62(b)(4) to create SEPs for individuals who meet other exceptional conditions established by CMS and move it to new § 422.62(b)(26). SEPs established under this authority would be done on a case-by-case basis and in situations which we determine it is in the best interest of the beneficiary to have an enrollment (or disenrollment) opportunity. While our experience with the MA program has informed the SEPs that we have established to date, and are proposing to codify in this regulation, we are mindful that *exceptional circumstances* may arise which may also warrant a SEP, and we note that this list is not meant to be exhaustive.

Also based on the Secretary's authority to create SEPs for individuals who meet exceptional conditions, we propose to codify the following SEPs currently outlined in subregulatory guidance that coordinate with Part D election periods:

• *SEP for Individuals Who Experience an Involuntary Loss of Creditable Prescription Drug Coverage.* At new § 422.62(b)(19), we are proposing to codify the SEP for individuals who experience an involuntary loss of creditable prescription drug coverage, including a reduction in the level of coverage so that it is no longer creditable but not including any such loss or reduction due to a failure to pay premiums, to enroll in an MA–PD plan. The SEP would begin the month in which the individual is advised of the loss of creditable coverage and would end 2 months after either the loss (or reduction) occurs or the individual received notice, whichever is later. The effective date of this SEP may be the first of the month after the request or, at the beneficiary's request, may be up to 3 months prospective.

• *SEP for Individuals Who Are Not Adequately Informed of a Loss of Creditable Prescription Drug Coverage.* At new § 422.62(b)(20), we are proposing to codify a SEP for individuals who are not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage, to permit one enrollment in, or disenrollment from, an MA–PD plan, on a case-by-case basis. CMS will review each case and determine whether an entity offering prescription drug coverage failed to provide accurate and timely disclosure of the loss of creditable prescription drug coverage or whether the prescription drug coverage offered is creditable. This SEP would begin the month that CMS determines an individual eligible for this SEP and would continue for 2 months.

• *SEP for Individuals Eligible for an Additional Part D IEP.* At new § 422.62(b)(22), we are proposing to codify the SEP for an individual who is eligible for an additional Part D Initial Enrollment Period (IEP) to have an MA SEP to coordinate with the additional Part D IEP. One example of a Part D IEP is the one for an individual currently entitled to Medicare due to a disability and who is attaining age 65. The IEP for Part D permits enrollment in a Part D plan, which includes a standalone Part D plan or an MA–PD plan. This proposed coordinating MA SEP may be used to disenroll from an MA plan to original Medicare, or to enroll in a MA plan that does not include Part D benefits, regardless of whether the individual uses the Part D IEP to enroll in a standalone Part D plan. The SEP would begin and end concurrently with the additional Part D IEP.

These previously proposed revisions would codify existing subregulatory guidance for SEPs that MA organizations have previously implemented and are currently following, except the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer. We would also note that we are taking this opportunity to propose minor editorial changes in § 422.62(b) and (c), such as changing ''Original Medicare'' to ''original Medicare.''

2. Part D Special Election Periods (§ 423.38)

Section 1860D–1(b)(3) of the Act establishes special election periods (SEPs) during which, if certain circumstances exist, an individual may enroll in a stand-alone Part D prescription drug plan (PDP) or disenroll from a PDP and enroll in another PDP or in an MA plan that includes Part D benefits (MA–PD plan). We have codified SEPs for the following circumstances, which are explicitly discussed in the Act:

• The individual involuntarily loses creditable prescription drug coverage or such coverage is involuntarily reduced so that it is no longer creditable coverage (§ 423.38(c)(1) and section 1860D–1(b)(3)(A) of the Act).

• The individual was not adequately informed that he or she has lost his or her creditable prescription drug coverage that he or she never had credible prescription drug coverage, or the coverage is involuntarily reduced so that it is no longer creditable prescription drug coverage (§ 423.38(c)(2) and section 1860D–1(b)(3)(A) of the Act).

• The individual's enrollment or non-enrollment in a Part D plan is unintentional, inadvertent, or erroneous because of the error, misrepresentation, or inaction of a federal employee, or any person authorized by the federal government to act on its behalf (§ 423.38(c)(3) and section 1860D–1(b)(3)(B) of the Act).

• The individual is a full subsidy-eligible individual or other subsidy-eligible individual as defined in § 423.772, who is making an allowable one time-per-calendar-quarter election between January through September (§ 423.38(c)(4)) and section 1860D–1(b)(3)(D) of the Act).

• The individual elects to disenroll from a MA–PD plan and elects coverage under Medicare Part A and Part B in accordance with the MA special election period for individuals age 65 (§ 423.38(c)(5) and section 1860D–1(b)(3)(E) of the Act).

Section 1860D–1(b)(1)(B) of the Act directs us to adopt enrollment rules ''similar to (and coordinated with)'' those under Part C. Accordingly, in addition to those SEPs as previously described, we have applied certain SEPs established under the MA program to the Part D program. The SEPs from the MA program that have been codified for Part D include the following:

• The Part D plan sponsor's contract is terminated by the plan sponsor or by CMS or the plan is no longer offered in the area where the individual resides (§ 423.38(c)(6)).

• The individual is no longer eligible for the Part D plan because of a change in his or her place of residence to a location outside of the Part D plan region(s) in which the plan is offered (§ 423.38(c)(7)).

• The individual demonstrates to CMS that the plan sponsor substantially violated a material provision of its contract in relation to the individual (§ 423.38(c)(8)).

Section 1860D–1(b)(3)(C) of the Act also grants the Secretary the authority to create SEPs for individuals who meet other exceptional conditions, which is reflected at § 423.38(c)(8)(ii). Pursuant to this authority, we have previously codified SEPs for the following circumstances:

• The individual is making an election within 3 months after a gain, loss, or change to Medicaid or LIS eligibility, or notification of such a

change, whichever is later (§ 423.38(c)(9)). This would include becoming eligible for additional Medicaid benefits, for example, when an individual newly qualifies as needing nursing home level of care and thus becomes eligible for certain Medicaid long term supports and services, or becomes eligible for full Medicaid benefits after having previously been eligible only for Medicaid coverage of Medicare premiums or cost-sharing.

• The individual is making an election within 3 months after notification of a CMS or state-initiated enrollment action or that enrollment action's effective date, whichever is later (§ 423.38(c)(10)).

CMS now proposes to codify the following SEPs for exceptional circumstances, which are currently outlined in subregulatory guidance. Except as noted in this proposed rule, our intent is to codify the current policy, and we seek specific comment as to whether we have overlooked any feature of the current policy that should be codified and if there are other exceptional circumstances we have not identified for which we should consider establishing a special election period. Codifying our current policy for these SEPs will provide transparency and stability for stakeholders about the Part D program and about the nature and scope of these SEPs by ensuring that the SEPs are changed only through additional rulemaking. We are also proposing to revise § 423.40(c) to clarify that for SEPs that are described in § 423.38(c), elections are effective as of the first day of the first calendar month following the month in which the election is made, unless otherwise noted. In addition, we note that, consistent with longstanding subregulatory guidance, the organization is not required to contact an applicant to confirm SEP eligibility if the enrollment request includes the applicant's attestation of SEP eligibility.

• *SEP for Employer/Union Group Health Plan (EGHP) Elections.* At new § 423.38(c)(11), we are proposing to codify that individuals making enrollment requests into or out of employer sponsored Part D plans (PDPs), for individuals to disenroll from a PDP to take employer sponsored coverage of any kind, and for individuals disenrolling from employer sponsored coverage (including COBRA coverage) would be eligible for a SEP to elect a PDP.

This SEP is available to individuals who have (or are enrolling in) an employer or union plan for the duration of that enrollment and ends 2 months after the month the employer or union coverage ends. The individual may choose the effective date of enrollment or disenrollment, up to 3 months after the month in which the individual completes an enrollment or disenrollment request. However, the effective date may not be earlier than the first of the month following the month in which the request was made.

• *SEP for Individuals Who Disenroll in Connection With a CMS Sanction.* At new § 423.38(c)(12), we are proposing to codify the SEP for individuals enrolled in a PDP offered by a Part D plan sponsor that is sanctioned by CMS. Such enrollees would be eligible for a SEP to elect another PDP if they believe they are affected by the matter(s) that gave rise to that sanction. Once the sanction is imposed, we propose that CMS may require the sponsor to notify the current enrollees that if they believe they are affected by the matter that gave rise to the sanction, they are able to choose another PDP. The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

• *SEP for Individuals Enrolled in Cost Plans That Are Non-Renewing Their Contracts.* At new § 423.38(c)(13), we are proposing to codify the SEP for individuals enrolled in cost plans that are non-renewing their contracts for the area in which the enrollee lives. Such individuals would be eligible for a SEP to elect a PDP. This SEP would be available only to Medicare beneficiaries who are enrolled with an HMO or CMP under a section 1876 cost plan that will no longer be offered in the area in which the beneficiary lives. Beneficiaries electing to enroll in a PDP via this SEP must meet Part D plan eligibility requirements.

This SEP would begin December 8 of the current contract year and end on the last day of February of the following year. Therefore, applying the general rule we propose to codify that elections are effective the first of the month after they are made, enrollment requests received before December 31 would have an effective date of January 1, enrollment requests received between January 1 and January 31 would be effective February 1, and enrollment requests received between February 1 and February 28 (or 29, as the case may be) would be effective March 1.

• *SEP for Individuals in the Program of All-Inclusive Care for the Elderly (PACE).* At new § 423.38(c)(14), we are proposing to codify the SEP allowing individuals to disenroll from a PDP at any time in order to enroll in PACE. The PDP enrollee who disenrolls from a PDP would have a SEP for 2 months after the effective date of PDP disenrollment to elect a PACE plan. In addition, individuals who disenroll from PACE would have a SEP for 2 months after the effective date of PACE disenrollment to elect a PDP.

• *SEP for Institutionalized Individuals.* At new § 423.38(c)(15), we are proposing to codify the SEP allowing individuals who move into, reside in, or move out of an institution, as defined at § 422.2, to enroll in or disenroll from a PDP. Individuals who move out of one of these facilities would have a SEP to enroll in or disenroll from a Part D plan for 2 calendar months after they move out of the facility.

• *SEP for Individuals Who Enroll in Part B During the Part B General Enrollment Period (GEP).* At new § 423.38(c)(16), we are proposing to codify the SEP for individuals who are not entitled to premium free Part A and who enroll in Part B during the GEP for Part B (January–March) for an effective date of July 1st to enroll in a PDP. The SEP would begin April 1st and end June 30th, with an enrollment effective date of July 1st.

• *SEP for Individuals Who Belong to a Qualified SPAP or Who Lose SPAP Eligibility.* At new § 423.38(c)(17), we are proposing to codify a SEP for individuals who belong to a qualified SPAP to make one election to enroll in a Part D plan each calendar year. SPAP members, or the state acting as the authorized representative of members, may use this SEP to enroll in a Part D plan outside of existing enrollment opportunities, allowing them, for example, to join a Part D plan upon becoming a member of an SPAP or to switch to another Part D plan.

In addition to being available while the individual is enrolled in the SPAP, the SEP remains available for individuals no longer eligible for SPAP benefits for 2 months. The SEP continues until the month they lose SPAP eligibility or the month they are notified of the loss of SPAP eligibility, whichever is later, and then for an additional 2 months.

• *SEP for Disenrollment From Part D To Enroll in or Maintain Other Creditable Coverage.* At new § 423.38(c)(18), we are proposing to codify the SEP that provides an opportunity for individuals to disenroll from a Part D plan in order to enroll in or maintain other creditable drug coverage (such as TriCare or VA coverage) as defined in § 423.56(b). This SEP is available to a Part D plan enrollee who is enrolled in, or is enrolling in, other creditable drug coverage.

• *SEP for Individuals Disenrolling From a Cost Plan Who Also Had the Cost Plan Optional Supplemental Part D Benefit.* At new § 423.38(c)(19), we are proposing to codify that individuals who disenroll from a cost plan and the cost plan's optional supplemental Part D benefit would have a SEP to enroll in a PDP. This SEP would begin the month the individual requests disenrollment from the cost plan and end when the individual makes an enrollment election or on the last day of the second month following the month cost plan membership ended, whichever is earlier.

• *SEP To Enroll in a PDP with a Star Rating of 5 Stars.* At new § 423.38(c)(20), we are proposing to codify the SEP allowing an eligible individual to enroll in a PDP with a Star Rating of 5 stars during the plan contract year in which that plan has the 5-star overall rating. A rating of 5 stars is considered ''excellent'' and is the highest performance rating that a PDP can achieve. Because these PDPs have demonstrated exceptional performance, and because there tend to be only a small number of 5 Star PDPs in a given contract year, we believe a SEP is warranted to allow beneficiaries with access to these PDPs the opportunity to enroll during the plan year for which the 5 Star rating is applicable. The SEP is available beginning the first day after the AEP, December 8, prior to the plan contract year for which the 5 Star Rating is applicable, through November 30 of the plan contract year the 5 Star Rating is applicable. The enrollment effective date would be the first of the month following the month in which the plan sponsor receives the enrollment request.

An individual using this SEP would be able to enroll in a PDP with a 5-star overall rating even if coming from original Medicare. Individuals enrolled in a plan with a 5-star overall rating may also switch to a different plan with a 5-star overall rating.

• *SEP for Non-U.S. Citizens Who Become Lawfully Present.* At new § 423.38(c)(21), we are proposing to codify the SEP for non-U.S. citizens who become lawfully present in the United States. The individual may use this SEP to request enrollment in any PDP for which he or she is eligible. This SEP would begin the month the lawful presence starts and ends when the individual makes an enrollment election or at the end of the second calendar month after the month it begins, whichever occurs first.

• *SEP for Providing Individuals Who Requested Materials in Accessible Formats Equal Time To Make Enrollment Decisions.* As outlined in section 504 of the Rehabilitation Act of 1973, plan sponsors are required to comply with requirements of that Act and provide materials in accessible formats to members. This generally includes formats such as Braille, data, and audio files, or other formats accepted by the member in place of, or in addition to, the original print material.

At new § 423.38(c)(22), we are proposing to codify the SEP in situations where the Part D plan sponsor or CMS was unable to provide required notices or information in an accessible format, as requested by an individual, within the same timeframe that it was able to provide the same information to individuals who did not request an accessible format. This limited SEP ensures that beneficiaries who have requested information in accessible formats are not disadvantaged by any additional time necessary to fulfill their request, including missing an election period deadline.

The SEP would begin at the end of the election period during which the beneficiary was seeking to make an election. The start of the SEP, as well as the enrollment effective date, would be dependent upon the situation, and the length is at least as long as the time it took for the information to be provided to the individual in an accessible format. An individual would be eligible for this SEP when the conditions described in this section are met. Part D plan sponsors would be required to maintain adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of the requested materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

• *SEP for Individuals Affected by a FEMA-Declared Weather Related Emergency or Major Disaster.* We are proposing to codify, at new § 423.38(c)(23), the SEP for individuals affected by a weather-related emergency or major disaster who were unable to make an election during another valid election period. This includes both enrollment and disenrollment elections. Individuals would be eligible for this SEP if they:

++ Reside, or resided at the start of the incident period, in an area for which FEMA has declared an emergency or a major disaster and has designated affected counties as being eligible to apply for individual or public level assistance;

++ Had another valid election period during the incident period; and

++ Did not make an election during that other valid election period due to the emergency or disaster.

In addition, the SEP would be available to those individuals who do not live in the affected areas but rely on help making healthcare decisions from friends or family members who live in the affected areas. The SEP would be available from the start of the incident period and for 4 months after the start of the incident period.

• *SEP for Individuals Enrolled in a Plan Placed in Receivership.* We propose to establish a new SEP, at new § 423.38(c)(31), for individuals enrolled in a Part D plans offered by a plan sponsor that is experiencing financial difficulties to such an extent that a state or territorial regulatory authority has placed the sponsor in receivership. We believe this SEP constitutes an exceptional circumstance because receiverships have the potential to cause disruption in access to prescription drug coverage and that individuals should have the ability to take action to prevent any future disruption to drug coverage. The SEP would allow an individual to discontinue the election of a PDP and change his or her election to a different PDP. We propose that the SEP begin the month the receivership is effective and continue until the enrollee makes an election or the receivership is no longer in effect, whichever occurs first.

Also, we propose that when instructed by CMS, the Part D plan sponsor that has been placed under receivership, or the entity operating the organization in receivership, must notify its enrollees, in the form and manner directed by CMS, of their eligibility for this SEP and how to use the SEP.

• *SEP for Individuals Enrolled in a Plan That Has Been Identified by CMS as a Consistent Poor Performer.* We propose to establish a new SEP, at new § 423.38(c)(32), for individuals who are enrolled in plans identified with the low performing icon (LPI) in accordance with § 423.186(h)(1)(ii). The LPI is assigned to contracts that have summary ratings of less than 3 Stars for three or more years. We believe this SEP constitutes an exceptional circumstance because these contracts have demonstrated performance considered ''below average'' or ''poor'' for a sustained period of time based on critical factors such as beneficiary complaints and access to care. To ensure that beneficiaries are not adversely affected, we believe that beneficiaries enrolled in these contracts should have the ability to enroll in plans rated ''average'' or higher during the year. The SEP would allow an

individual to discontinue the election of a consistently poor performing Part D plan and change his or her election to a Part D plan with an overall Star Rating of 3 or more stars. We propose that the SEP exist while the individual is enrolled in the consistently poor performing Part D plan.

• *SEP for Other Exceptional Circumstances.* Lastly, we propose to retain the authority currently at § 423.38(c)(8)(ii) to create SEPs for individuals who meet other exceptional conditions established by CMS and move it to new § 423.38(c)(33). SEPs established under this authority would only be done on a case-by-case basis and in situations which we determine it is in the best interest of the beneficiary to have an enrollment (or disenrollment) opportunity. While our experience with the Part D program has informed the SEPs that we have established to date, and are proposing to codify in this regulation, we are mindful that exceptional circumstances may arise which may also warrant a SEP, and we note that this list is not meant to be exhaustive.

Also based on the Secretary's authority to create SEPs for individuals who meet exceptional conditions, we propose to codify the following SEPs currently outlined in manual instructions that coordinate with Part C election periods:

• *SEP for Individuals Who Terminated a Medigap Policy When They Enrolled For the First Time in an MA Plan, and Who Are Still in a Trial Period.* Individuals who dropped a Medigap policy when they enrolled for the first time in an MA plan are provided a guaranteed right to purchase another Medigap policy if they disenroll from the MA plan while they are still in a ''trial period.'' In most cases, a trial period lasts for 12 months after a person enrolls in an MA plan for the first time. If the individual is using the SEP proposed at § 422.62(b)(8) to disenroll from a MA–PD plan, we are proposing to codify at new § 423.38(c)(24) a coordinating Part D SEP to permit a one-time enrollment into a PDP. This SEP opportunity may only be used in relation to the MA SEP described here and would begin the month he or she disenrolls from the MA plan and continue for 2 additional months.

• *SEP for an Individual Using the MA Open Enrollment Period for Institutionalized Individuals (OEPI) To Disenroll From a MA–PD plan.* Individuals who meet the definition of ''institutionalized'' as defined by CMS are eligible for the MA OEPI election period. At new § 423.38(c)(25), we are proposing to codify that an individual disenrolling from an MA–PD plan has a SEP to request enrollment in a PDP. This SEP would begin the month the individual requests disenrollment from the MA–PD plan and end on the last day of the second month following the month MA enrollment ended.

• *Medicare Advantage Open Enrollment Period (MA OEP).* At new § 423.38(c)(26), we are proposing to codify that MA enrollees using the MA OEP would have a SEP to add or change Part D coverage. Annually, the MA OEP is available from January 1 to March 31. It is also available for the first 3 months an individual has Medicare entitlement. An individual who elects original Medicare during the MA OEP would be able to request enrollment in a PDP during this time.

• *SEP To Request Enrollment Into a PDP After Loss of Special Needs Status or To Disenroll From a PDP in Order To Enroll in an MA SNP.* In new § 423.38(c)(27), we propose to codify the SEP to request enrollment in a PDP for those who are no longer eligible for a SNP because they no longer meet the plan's special needs criteria. In addition, CMS would provide a SEP to allow for disenrollment from a PDP at any time in order to request enrollment in an MA SNP. For example, if state eligibility criteria for a D–SNP is limited to individuals who are enrolled in a Medicaid MCO affiliated with the D–SNP, then disenrollment from the Medicaid MCO would trigger eligibility for this SEP. This SEP would begin the month the individual's special needs status changes and end when he or she makes an election or 3 months after the effective date of the involuntary disenrollment, whichever is earlier.

• *SEP for Enrollment Into a Chronic Care SNP and for Individuals Found Ineligible for a Chronic Care SNP.* At proposed § 423.38(c)(28), we propose to codify the SEP for both Part C and Part D for those individuals with severe or disabling chronic conditions to enroll in a Chronic Care SNP (C–SNP) designed to serve individuals with those conditions. This SEP would apply as long as the individual has the qualifying condition and will end once s/he enrolls in a C–SNP. Once the SEP ends, that individual may make enrollment changes only during applicable election periods. In addition, individuals enrolled in a C–SNP who have a severe or disabling chronic condition that is not a focus of their current C–SNP would be eligible for this SEP to change to a C–SNP that does focus on the condition that the individual has. Eligibility for this SEP would end at the time the individual enrolls in the new C–SNP.

Individuals who are found after enrollment into a Chronic Care SNP not to have the required qualifying condition would have a SEP to enroll in a different MA–PD plan or an MA-only plan with accompanying Part D coverage, if allowed. This SEP would begin when the plan notifies the individual of the lack of eligibility and extends through the end of that month, plus 2 additional months. The SEP would end when the individual makes an enrollment election or on the last day of the second month following notification.

• *SEP for Individuals Using the 5-Star SEP To Enroll in a 5-Star Plan without Part D Coverage.* At new § 423.38(c)(29), we are proposing to codify that individuals who use the 5-star SEP proposed to be codified at § 422.62(b)(15) to enroll in a 5-star MA plan that does not include Part D benefits or a 5-star cost plan would have a SEP to enroll in a PDP or in the cost plan's optional supplemental Part D benefit. The PDP selected using this coordinating SEP does not have to be 5-Star rated. However, individuals may not use this coordinating SEP to disenroll from the plan in which they enrolled using the 5-star SEP.

This SEP would begin the month the individual uses the 5-Star SEP and continue for 2 additional months. Individuals who use the 5-Star SEP to enroll in an MA coordinated care plan would not be eligible for this coordinating Part D SEP and must wait until their next valid election period in order to enroll in a plan with Part D coverage.

• *SEP To Enroll in a PDP for MA Enrollees Using the ''SEP for Significant Change in Provider Network'' To Disenroll From an MA Plan.* We are proposing to codify at new § 423.38(c)(30) that MA enrollees using the ''SEP for Significant Change in Provider Network'' to disenroll from an MA plan (proposed at § 422.62(b)(23)) would be able to request enrollment in a PDP. This coordinating SEP would begin the month the individual is notified of eligibility for the SEP and continue for an additional 2 calendar months. This SEP would permit one enrollment and end when the individual has enrolled in the PDP. An individual may use this SEP to request enrollment in a PDP subsequent to having submitted a disenrollment to the MA plan or may simply request enrollment in the PDP, resulting in automatic disenrollment from the MA plan. Enrollment in the PDP is effective the first day of the month after the plan sponsor receives the enrollment request.

These proposed revisions would codify existing subregulatory guidance for SEPs that Part D sponsors have previously implemented and are currently following, except for the *SEP for Individuals Enrolled in a Plan Placed in Receivership* and the *SEP for Individuals Enrolled in a Plan that has been Identified by CMS as a Consistent Poor Performer.* We would also note that we are taking this opportunity to propose a few minor editorial changes in § 423.38(c), such as changing ''3'' to ''three.''

VII. Proposed Changes to the Programs of All-Inclusive Care for the Elderly (PACE)

The intent of this proposed rule is to revise and update the requirements for the Programs of All-Inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The PACE program is a unique model of managed care service delivery for the frail elderly, most of whom are dually-eligible for Medicare and Medicaid benefits, and all of whom are assessed as being eligible for nursing home placement according to the Medicaid standards established by their respective states. The proposals address reassessments, service delivery requests, appeals, participant rights, required services, excluded services, interdisciplinary team requirements, medical record documentation, access to data and records, safeguarding communications, and service delivery requirements. The proposed changes would reduce unnecessary burden on PACE organizations, provide more detail about CMS expectations and provide more transparent guidance.

A. Service Delivery Request Processes Under PACE (§§ 460.104 and 460.121)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. We issued regulations on grievances at § 460.120, and we issued regulations on appeals at § 460.122. Additionally, CMS created a process under § 460.104(d)(2) to allow participants or their designated representatives to request that the interdisciplinary team (IDT) conduct a reassessment, when the participant or designated representative believes the participant needs to initiate, eliminate or continue a service. The process under § 460.104(d)(2) is commonly referred to by CMS and industry as the service delivery request process. This process serves as an important participant protection, as it allows a participant to advocate for services. As we stated in the Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions; Final Rule (hereinafter referred to as the 2006 PACE final rule), ''[t]he provisions for reassessment at the request of a participant [were] intended to serve as the first stage of the appeals process.'' 71 FR 71292. Section 460.104(d)(2) currently sets out the responsibilities of a PACE organization in processing each request. Currently, a participant or their designated representative initiates a service delivery request when they request to initiate, eliminate, or continue a service. Once the IDT receives the request, the appropriate members of the IDT, as identified by the IDT, must conduct a reassessment. The IDT member(s) may conduct the reassessment via remote technology when the IDT determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or their designated representative agrees to the use of remote technology. However, the appropriate member(s) of the IDT must perform an in-person reassessment when the participant or their designated representative declines the use of remote technology, or before a PACE organization can deny a service request. Following the reassessment, the IDT must notify the participant or designated representative of its decision to approve or deny the request as expeditiously as the participant's condition requires, but generally no later than 72 hours from the date of the request for reassessment. If the request is denied, the PACE organization is responsible for explaining the denial to the participant or the participant's designated representative both orally and in writing. The PACE organization is also responsible for informing the participant of his or her right to appeal the decision, including the right to request an expedited appeal, as specified in § 460.122. If the IDT fails to provide the participant with timely notice of the resolution of the request, or does not furnish the services required by the revised plan of care, the failure constitutes an adverse decision and the participant's request must be automatically processed as an appeal in accordance with § 460.122.

While this section provides an important participant protection, we have heard from stakeholders that the language in § 460.104(d)(2) is overly broad as written, and that even simple requests to initiate a service require a reassessment and a full review of the request by the PACE organization's IDT. Stakeholders have also noted that addressing the service delivery request process in the section of the regulation governing participant assessments undercuts the importance of the requirements for processing these requests. Additionally, through CMS oversight and monitoring, we have identified a need to better define what constitutes a service delivery request and create clearer guidance on how PACE organizations must identify and process these requests.

We are proposing to move the requirements for service delivery requests at § 460.104(d)(2) to a new section of the regulations at § 460.121, titled ''Service Delivery Requests.'' While we are proposing to use the term ''service delivery request'' because that is the term typically used by industry and CMS to describe these actions, we are soliciting comments on whether we should utilize this term or consider something different. For example, the initial decision to cover a drug in Part D is a coverage determination (§ 423.566), and the initial decision to cover an item or service in Part C is an organization determination (§ 422.566). We would appreciate feedback on whether a term other than ''Service Delivery Request,'' such as ''PACE Organization Determination,'' ''Coverage Determination,'' or ''Service Determination,'' would be preferable.

In addition to proposing that the requirements for processing service delivery requests would be moved from § 460.104(d)(2) into a new section, we are also proposing to modify these requirements based on industry feedback and lessons learned through our experience operating the PACE program and monitoring PACE organizations. First, we are proposing to reorganize the requirements for clarity and to better align them with the appeals regulations in subpart M of parts 422 and 423, for Medicare Advantage (MA) and Part D respectively, while also ensuring the requirements address the specific features of the PACE program, which is a unique combination of payer and direct care provider. We believe aligning the layout of the regulation and the notification requirements of the initial determination processes in PACE, MA, and Part D would allow us to minimize confusion for participants, who are often familiar with the initial determination and appeals processes in the Parts C and D programs, and would also increase transparency for PACE organizations regarding CMS' expectations.

While the current regulation at § 460.104(d)(2) begins with the requirements for processing a request for reassessment, we are proposing to add § 460.121(a) to require that a PACE organization must have formal written procedures for identifying and processing service delivery requests in accordance with the requirements of proposed § 460.121. We believe it is important to ensure that PACE organizations develop internal processes and procedures to properly implement this process.

At § 460.121(b), we are proposing to define what constitutes a service delivery request and what does not. We are proposing to define what constitutes a service delivery request at § 460.121(b)(1). Currently, the process in § 460.104(d)(2) is triggered if the participant (or his or her designated representative) believes the participant needs to initiate, eliminate, or continue a particular service. At § 460.121(b)(1), we are proposing to specify that the process for service delivery requests would apply to three distinct types of service delivery requests, specifically, a request to (1) initiate, (2) modify, or (3) continue a service.

We note that the term ''services'' is already defined at 460.6 to include ''items,'' and we are proposing, as discussed in section VII.I. of this proposed rule, to make explicit that this definition is meant to reflect the full scope of the PACE benefit package, and thus also includes ''items'' and ''drugs.'' Therefore, our use of ''service'' or ''services'' throughout newly proposed 460.121 always includes any type of PACE-covered services, items, or drugs, and participants have the right to advocate with respect to all types of PACE-covered services, items, or drugs that they believe may be necessary. The proposed language at § 460.121(b)(1) would retain the existing concepts of '''initiating'' and ''continuing'' services but would replace the term ''eliminate'' with the term ''modify.''

We are proposing at § 460.121(b)(1)(i) that the first type of service delivery request would be a request to initiate a service. This first type of request is based on the existing language at § 460.104(d)(2). We are proposing at § 460.121(b)(1)(ii) that the second type of service delivery request would be a request to modify an existing service. We are proposing to specify that requests to modify an existing service include requests to increase, reduce, eliminate, or otherwise change a particular service. We believe that defining service delivery requests to include requests to modify an existing service is an important protection, as participants may believe that the services they are currently receiving are not sufficient to meet their needs. For example, a participant may request to increase their home care from 3 hours a week to 6 hours a week because they believe that they are becoming less steady in their gait and they are afraid to be alone for long periods.

The third type of service delivery request we are proposing, at § 460.121(b)(1)(iii), is a request to continue a service that the PACE organization is recommending be discontinued or reduced. We are proposing that this type of request would apply to circumstances where the PACE organization is recommending to discontinue or reduce a service that the participant is already receiving, and the participant wishes to continue receiving that service. An example of this type of request would be a participant that is attending the PACE center 5 days a week and the PACE organization decides to reduce attendance to 4 days a week. If the participant requests to continue attending the center 5 days a week, this request must be processed as a service delivery request under our proposal. Another example would be if a participant is receiving a specific drug, and the IDT makes a decision to stop providing that drug. Under this proposal, the participant's request to continue receiving the drug would be processed as a service delivery request. Through our monitoring of PACE organizations, we have identified instances where a participant requests to continue receiving a service that has been reduced or discontinued, and the PACE organization provides the participant appeal rights under § 460.122 instead of conducting a reassessment as required under the current § 460.104(d)(2). We are proposing to include requests to continue coverage of a service in part to ensure that PACE organizations understand that they must process a service delivery request for these situations before processing an appeal under § 460.122. Our proposed revisions to this section, as well as our proposed revisions to the appeals regulation discussed in section VII.B. of this proposed rule, would establish that the service delivery request process is the first level of the appeals process, and requests to continue a service must first be processed under the service delivery request process prior to an appeal being initiated under § 460.122. We discuss the scope of the appeals process in greater depth in our proposals to update the appeals process in section VII.B. of this proposed rule. We are also proposing that participants would be allowed to make this type of service delivery request before a service was actually discontinued, to permit the participant to advocate for a continuation of the service. This requirement is reflected in the language we propose for § 460.121(b)(1)(iii), where we emphasize that this provision relates to a service that the PACE organization is recommending be discontinued or reduced. We believe by wording this requirement in this way, we would make clear that the participant could make a service delivery request as soon as a PACE organization recommends reducing or discontinuing a service. For example, if the IDT was recommending reducing center attendance from three days a week to two days a week, and the participant wanted to continue coming to the center three days a week, the participant could request a service delivery request once the IDT recommended the reduction, even if the reduction in days had not yet been implemented.

We recognize that our proposals define what constitutes a service delivery request broadly. We also understand that there are circumstances that are unique to PACE where a request may not constitute a service delivery request based on the role of a PACE organization as a direct care provider that is responsible for coordinating and delivering care. We are therefore proposing an exception to the definition of a service delivery request. In paragraph (b)(2) we are proposing that certain requests to initiate, modify, or continue a service would not constitute a service delivery request, even if the request would otherwise meet the definition of a service delivery request under (b)(1). Specifically, at § 460.121(b)(2) we are proposing that if a request is made prior to the development of the initial care plan the request would not constitute a service delivery request. This exemption would apply any time before the initial care plan was finalized (and discussions amongst the IDT ceased). We believe this approach would be beneficial to the participant and the PACE organization as the IDT and the participant or caregiver continue to discuss the comprehensive plan of care taking into account all aspects of the participant's condition as well as the participant's wishes. For example, if the PACE organization is developing the initial plan of care and actively considering how many home care hours the participant should receive, and the participant makes a request for a

particular number of home care hours, that request would not be a service delivery request because the IDT was actively considering that question in developing the plan of care. Once the initial plan of care is developed, if a service was not incorporated into the plan of care in a way that satisfies the participant, the participant would always have the right to make a service delivery request at that time.

While drafting this proposal, we considered other ways to potentially limit the application of the service delivery request process to account for situations where it is possible to adequately address a request without undertaking the full service delivery request process. First, we considered excluding requests for services made during the course of a treatment discussion with a member of the IDT from the service delivery request process, so long as the IDT member is able to immediately approve the service. Ultimately we decided these situations should constitute service delivery requests, in order to avoid confusion by requiring PACE organizations to distinguish between requests for services that constitute service delivery requests and those that do not. However, in an effort to reduce burden, we determined that it would be appropriate to process service delivery requests that an IDT member is able to approve in full at the time the request is made in a more streamlined manner than other service delivery requests. We discuss our proposals on this point in more detail in the section relating to proposed § 460.121(e)(2) in this proposed rule.

We also considered whether we could exclude other types of requests from the service delivery request process. For example, we have received questions from PACE organizations about requests that do not relate to health care or to a participant's medical, physical, emotional, and social needs, such as a participant requesting lemons in their water, or a participant requesting a particular condiment at lunch. We considered proposing to exclude requests that are not related to health care or to the participant's medical, physical, emotional, and social needs, and therefore would not constitute a service delivery request. We strongly believe that any time a service may be necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, that request should be processed as a service delivery request. We similarly understand that some requests are completely unrelated to the participant's health care or condition. However, we believe that adding a provision to address this relatively insignificant issue would potentially cause confusion for PACE organizations and participants and therefore we are not proposing such a provision at this time. We are, however, soliciting comments on whether specifying that requests unrelated to a participant's medical, physical, emotional, and social needs need not be processed using the proposed service delivery request process would benefit PACE organizations without restricting participants' ability to advocate for any service they believe may be necessary, regardless of whether that is meals, transportation, drugs, home care, or other services provided as part of the PACE benefit, and if so, how we should word such a provision.

We are also proposing at § 460.121(c) to specify the individuals who can make a service delivery request. Under the current requirements in § 460.104(d)(2), only the participant or the participant's designated representative may request to initiate, eliminate, or continue a particular service. We are proposing to expand the number of individuals who can make a service delivery request on behalf of a PACE participant to include the participant, the participant's designated representative, or the participant's caregivers. We believe that this proposal would be consistent with the current practice of most PACE organizations, in part because caregivers are often also participants' designated representatives; however, we are proposing to affirmatively state in regulation that these individuals may make service delivery requests. We believe this would provide an important safeguard for participants, as caregivers are usually aware of the participant's situation and have valuable insight into what services would be beneficial. For example, if a PACE participant's wife believes that the participant needs more home care to assist with toileting, bathing and dressing, we are proposing that she would be able to make a service delivery request to the PACE organization and advocate for that service delivery request, regardless of whether she is her spouse's designated representative. This proposal also aligns with current care plan regulations which state that the IDT must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver or both. (§ 460.106(e)) Because caregivers are involved in the care planning process and determining what care may be necessary, we believe that it is also appropriate for these individuals to be able to advocate for services as necessary on behalf of a participant, regardless of whether these service delivery requests result in changes to the plan of care. While a designated representative or caregiver such as a family member may initiate the service delivery request process, the PACE organization remains responsible for issuing a decision based on the individual needs of the participant regardless of the party that initiated the request. We are soliciting comments on this proposal to expand the number of individuals who can make a service delivery request on behalf of a PACE participant. In addition we are soliciting comment regarding whether or not there are other individuals that should be allowed to make service delivery requests on behalf of a participant. For example, in MA and Part D, providers or prescribers can initiate a request for coverage (either coverage determination or organization determination) on behalf of a beneficiary, which allows prescribers or other providers to advocate for drugs or services that are unique to their discipline or scope of practice. In PACE, this would mean that if a participant went to a contracted specialist, that specialist would be allowed to advocate or request a service specific to their discipline. We are specifically soliciting comments on whether we should specify that prescribers or providers, outside of the IDT, can make a service delivery request on behalf of a participant in PACE.

We are also proposing at § 460.121(d) to specify how a service delivery request may be made. The current regulation at § 460.104(d)(2) is silent regarding how a participant or his or her designated representative may request to initiate, eliminate, or continue a particular service. We are proposing at § 460.121(d)(1) to permit service delivery requests to be made either orally or in writing. We believe this is consistent with current practice for all PACE organizations. The right to request an initial determination either orally or in writing is provided as an enrollee safeguard in both MA and Part D (see §§ 422.568(a)(1), 422.570(b), 423.568(a)(1), and 423.570(b)), and given the vulnerability of the PACE population, we believe it is important that PACE participants also have the ability to submit service delivery requests in either form. We are proposing at § 460.121(d)(2) that service delivery requests may be made to any individual who provides direct care to a participant on behalf of the PACE organization, whether as an employee or a contractor, as contemplated in

§ 460.71. All employees and contractors that provide direct participant care should be trained to recognize and document these requests when they are made by a participant. Because of the comprehensive nature of the PACE program and the requirement that PACE organizations provide care across all care settings, participants may not know whom they should communicate with when making a service delivery request. For example, certain participants may not attend the PACE center on a routine basis and a home care aide may be the only representative of the PACE organization the participant has contact with frequently. Under our proposal, the participant could make service delivery requests to the home care aide, and those requests would be considered to have been made to the PACE organization. All individuals providing direct care to participants, whether contractors or employees, should be trained to recognize service delivery requests and ensure such requests are documented appropriately and brought to the IDT as part of the training employees and contractors receive under § 460.71(a)(1). While we are proposing to require that all contractors and employees that provide direct care be able to receive service delivery requests from participants, we are soliciting comment on whether this requirement should be limited to a smaller subset of individuals. For example, we seek comment on whether we should instead require only those contractors or employees who provide direct participant care in the participant's residence, the PACE center, or while transporting participants to receive service delivery requests.

CMS is also proposing to establish new requirements at § 460.121(e) specifying how service delivery requests must be processed. We are proposing at § 460.121(e)(1) that all service delivery requests must be brought to the IDT as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the request was made. The existing requirement at § 460.104(d)(2)(iii) specifies that the IDT must generally notify the participant or designated representative of its decision in regard to a request to initiate, eliminate, or continue a particular service no later than 72 hours after the date the IDT receives the request for reassessment. Stakeholders have asked CMS to explain if the current 72-hour timeframe begins when any member of the IDT receives the service delivery request, or when the full IDT receives the request. In order to avoid similar questions about the new service delivery request process we are proposing, we have also proposed to establish two distinct timeframes. Specifically, we are proposing an initial timeframe for the PACE organization to bring a service delivery request to the IDT, and a second timeframe for the IDT to make a decision and provide notice of the decision to the participant. We are proposing to include this second timeframe at § 460.121(i), and discuss this proposal in more detail later in this section. We believe that creating these distinct timeframes would benefit both PACE organizations and participants. We also believe it is necessary to ensure that once a service delivery request is made, it is brought to the IDT for processing as expeditiously as the participant's condition requires but no later than 3 calendar days from when the request was actually made. In monitoring PACE organizations, we have seen organizations take a week or longer after a request was first made to bring the request to the IDT for consideration. By establishing a requirement that service delivery requests must be brought to the IDT as expeditiously as the participant's condition requires but no later than 3 calendar days from the time the request is made, we believe this would ensure participant requests are handled expeditiously while still ensuring the IDT has sufficient time to process the service delivery request and consider all relevant information when making a decision. We are soliciting comments on this proposal to establish a new timeframe for PACE organizations to bring service delivery requests to the IDT.

We are also proposing at § 460.121(e)(2) to specify an exception to the processing requirements for service delivery requests. Specifically, if a member of the IDT receives a service delivery request and is able to approve the request in full at the time the request is made, the PACE organization would not be required to follow certain processing requirements. We understand that PACE organizations, as direct care providers, routinely interact with participants when providing care and services. These interactions often include treatment discussions between an IDT member and a participant about what care may or may not be appropriate for the participant to receive. During these discussions, a participant may request a service that the IDT member receiving the request is able to immediately approve as requested based on their knowledge of the participant and the participant's condition. For example, during a physical therapy session, a participant may request a walker to assist in his or her daily activities. If the physical therapist, who is a member of the IDT, determines that the item is necessary and can approve the walker at the time the participant requests it, then the request would not need to be processed as a normal service delivery request. The exception would not apply if the IDT member cannot approve exactly what is requested. For example, if a participant requested 20 hours per week of home care but the IDT member is only willing to approve 15 hours per week, the exception would not apply because the participant's request would be partially denied. Specifically, we are proposing at § 460.121(e)(2)(i) to require that when a member of the IDT can approve a service delivery request in full at the time the request is made, the PACE organization must fulfill only the requirements in proposed paragraphs (j)(1), (k), and (m). These proposed paragraphs are discussed in more detail later in this section, and generally relate to notice of a decision to approve a service delivery request, effectuation requirements, and record keeping. We are also proposing at § 460.121(e)(2)(ii) that PACE organizations would not be required to process these particular service delivery request in accordance with paragraphs (f) through (i), paragraph (j)(2), or paragraph (l) of this new section, all of which are discussed in more detail in this section of this proposed rule.

We are proposing this exception to how a service delivery request is processed based on feedback from stakeholders that IDT members often have treatment discussions with participants about modifying services and make decisions to accommodate the participants' requests in full at the time the requests are made. Additionally, we have seen situations where a caregiver requests an item or service that an IDT member is able to immediately approve at the time the request is made. In these situations, it is important that the decision to approve the service is communicated to the participant or the requestor at the time the request is made so that the participant/requestor understands the outcome of their request. If a decision to approve a requested service cannot be made in full at the time of the request, the PACE organization must fully process the service delivery request in accordance with all relevant paragraphs of this new section. If an IDT member can quickly approve a service as being necessary for the participant, we do not believe that

it would benefit the participant or the organization to have to fully process a service delivery request, since the participant or requestor has already been successful in advocating for the service. Instead, the participant would be better served by the IDT member quickly communicating the approval, and working to provide the requested service as expeditiously as the participant's condition requires. We want to note that pursuant to our proposal in § 460.121(d)(2), a service delivery request may be made to any contractor or employee who provides direct care to a participant, and that all individuals providing direct care to participants, whether contractors or employees, should be trained to recognize and receive service delivery requests pursuant to § 460.71(a)(1). However, we are proposing to specifically limit the exception in § 460.121(e)(2) to requests made to IDT members, where the receiving member of the IDT is able to approve the service delivery request in full at the time the request is made. This will ensure that the IDT remains responsible for determining the benefits a participant should receive, and that contractors or employees, such as a home care aide, are not authorizing services without the IDT's review.

We also believe this proposed exception at § 460.121(e)(2) would reduce the current burden on PACE organizations in three primary ways. First, PACE organizations would not have to bring requests that can be quickly approved by one IDT member to the full IDT for consideration and discussion, which would allow the IDT to use that time for other purposes, including to focus on requests that require in-depth consideration. Second, because the IDT would not have to conduct a reassessment in each case, we expect that this change would improve the overall speed with which PACE organizations are able to provide necessary services. Third, the IDT would not have to provide separate notification to the participant because the IDT member would inform the participant or requestor that the request was approved in the initial discussion.

Currently the IDT is required to process requests for reassessments from participants and/or designated representatives under § 460.104(d)(2). The IDT is responsible for selecting the appropriate IDT members to conduct the reassessment under § 460.104(d)(2), and for issuing a decision to approve or deny a request under § 460.104(d)(2)(iii). At proposed § 460.121(f), we would require that all service delivery requests, other than those under proposed § 460.121(e)(2), must be brought to the full IDT for review and discussion before the IDT makes a determination to approve, deny or partially deny the request. As required by § 460.102(b), each PACE organization's IDT must, at a minimum, be composed of members qualified to fill the roles of 11 disciplines, each of which offers a unique perspective on the participant's condition. CMS commonly refers to this group as the full IDT. Because service delivery requests not processed under proposed § 460.121(e)(2) are processed only for services that cannot be approved in full at the time the request is received, we believe that it is important that the IDT, as a whole, discuss the service delivery request in order to determine whether the request should be approved or denied. A discussion by the full IDT would allow each discipline to offer their perspective on the participant's condition as it relates to the requested service, and ensure that the IDT is best equipped to determine what services are necessary to improve or maintain the participant's health status. As previously discussed, service delivery requests that are approved in full by a member of the IDT at the time the request is made would not have to be brought to the full IDT for review.

We are also proposing at § 460.121(g) to require that the IDT must consider all relevant information when evaluating a service delivery request. Currently, the regulation is silent on what the IDT must consider when making a decision under § 460.104(d)(2). We are proposing that the IDT must consider, at a minimum, the findings and results of any reassessment(s) conducted in response to a service delivery request, as well as the criteria used to determine required services specified in proposed § 460.92(b), as discussed in section VII.D. of this proposed rule. We have seen through our monitoring efforts that certain IDTs do not always consider the reassessments conducted in response to a service delivery request when making a decision. For example, a physical therapist and occupational therapist may both indicate in their discipline-specific reassessments that a participant would benefit from additional home care hours, but the IDT might deny the request without explaining why the recommendations resulting from those reassessments were not followed. We believe it is important that an IDT is able to demonstrate that it took any reassessments performed in the process of reviewing a service delivery request into consideration when making a decision on that service delivery request. Additionally, we believe that IDT decision making for service delivery requests should be aligned with the IDT's decision making for what constitutes a required service under § 460.92(b). Specifically, we believe that a decision by the IDT to provide or deny services must be based on an evaluation of the participant that takes into account the participant's medical, physical, emotional and social needs. We have encountered situations where the IDT made its decision based on one aspect of the participant's condition, for example, their physical health related to their ability to perform activities of daily living, but disregarded other aspects of the participant's condition, such as their medical, emotional, and social needs. We believe that the IDT must consider all aspects of the participant's condition in order to make an appropriate decision. For example, if the participant is requesting to attend the PACE center on additional days due to feelings of social isolation and depression, it would be inappropriate for the IDT to make a decision based on the participant's physical needs without considering their emotional and social needs. Additionally, under the proposed modifications to § 460.92, we would also expect PACE organizations to utilize current clinical practice guidelines and professional standards of care when rendering decisions, as applicable to a requested service. We discuss this decision making process and use of these guidelines in more detail in section VII.D. of this proposed rule.

Based on feedback from PACE organizations and advocacy groups, we are proposing at § 460.121(h) to require an in-person reassessment only prior to an IDT's decision to deny or partially deny a service delivery request. Currently, the IDT must perform a reassessment as part of its consideration of any request to initiate, eliminate, or continue a service under § 460.104(d)(2), regardless of whether the request is approved or denied. We modified the requirements related to conducting reassessments in response to a participant or designated representative's request to initiate, eliminate, or continue a service in the 2019 PACE Final Rule (84 FR 25644 through 25646). The regulations now permit the IDT to conduct that reassessment via remote technology if certain requirements are met, but the IDT must conduct an in-person reassessment prior to denying a request. However, since that rule was published on June 3, 2019, we have continued to receive feedback from PACE

organizations requesting further action to address the burden of conducting reassessments in response to service delivery requests, specifically when the IDT can approve a request without performing a reassessment. Under our proposal, if a service delivery request is brought to the full IDT and the IDT determines that it can approve the request based on the information available, the IDT would not be required to conduct a reassessment of the participant prior to making a decision to approve the service delivery request. We understand that many IDTs have frequent interactions with PACE participants and may be able to make a decision to approve a request without having to conduct another reassessment based on internal consultation and knowledge of the participant. As we indicated in our discussion for the proposed § 460.121(e)(2), we do not believe that delaying the provision of a requested service the IDT has determined is necessary, in order to conduct a reassessment, benefits the PACE organization or the participant. We believe the IDT, with its knowledge of the participant, is in the best position to determine if a reassessment is necessary prior to approving a service delivery request. Therefore CMS would only require a reassessment prior to the IDT denying or partially denying a request under this proposal.

If, after consideration of all available information, the full IDT expects to make a decision to deny or partially deny a service delivery request, we are proposing that the IDT would be required to perform an unscheduled in-person reassessment pursuant to proposed § 460.121(h)(1), prior to making a final decision. We are proposing to consider a request denied or partially denied whenever the IDT makes a decision that does not fully approve the service delivery request as originally requested. For example, if a participant requested 3 hours of home care a week, and the IDT made a decision that the participant only required 2.5 hours of home care each week, we are proposing that such a decision by the IDT would constitute a partial denial because the request was not fully approved as requested by the participant. In other words, any decision to offer a compromise, an alternative service, or to grant only a portion of the request would constitute a partial denial. We are proposing that this in-person reassessment must be conducted by the appropriate members of the IDT, as identified by the IDT, in order to align with the current requirement under § 460.104(d)(2) that the IDT is responsible for identifying the appropriate members to conduct the reassessment. We believe this change would strike an appropriate balance between protecting participants and ensuring that the process for handling service delivery requests is not overly burdensome for PACE organizations.

We are also proposing in § 460.121(h)(1) to require that any reassessment conducted for a service delivery request must evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs in a manner consistent with § 460.92, as we are proposing to revise those provisions. We have seen through our monitoring efforts that in conducting reassessments as a result of requests to initiate, eliminate or continue particular services, the IDTs are not always evaluating whether the requested service would actually improve or maintain the participant's condition, taking into account all relevant aspects of the participant's condition, including assessing the participant's medical, physical, emotional and/or social needs as applicable. We believe this information is vital, and must be considered by the full IDT in making its decision. For example, if a participant is requesting more days at the PACE center for social reasons, the IDT should ensure that the appropriate members of the IDT conduct the reassessment in order to evaluate the participant's social needs, and whether additional center days are necessary to meet the participant's needs, including improving the participant's social condition. We discuss our proposals for § 460.92 in greater detail in section VII.D. of this proposed rule.

In accordance with our belief that the IDT is in the best position to determine if a reassessment is necessary prior to approving a service delivery request, we are proposing at § 460.121(h)(2) that the IDT may choose to conduct a reassessment (via either remote technology or in-person) before approving a service delivery request, but we do not believe we should require one as part of the process for approving service delivery requests. If the IDT determines a reassessment should be conducted prior to approving the request, the IDT would still be responsible for processing the service delivery request, and notifying the participant, in the timeframe specified at § 460.121(i).

We are proposing at paragraph (i) to establish a time frame in which the IDT must make its determinations regarding service delivery requests and provide notification of its decisions. The current requirement under § 460.104(d)(2)(iii) states that the IDT must notify the participant or designated representative of its decision to approve or deny a service delivery request as expeditiously as the participant's condition requires, but no later than 72 hours after the date the IDT receives the request, unless the IDT extends the timeframe. CMS has interpreted this language as requiring that the IDT must notify the participant or their designated representative within 3 calendar days of receiving a request, based on the wording of the requirement which states ''72 hours from the date'' and thus requires that the timeframe starts on the day received.

We are proposing a similar timeframe at § 460.121(i), to require that the IDT make its determination and notify the participant or their designated representative of the determination as expeditiously as the participant's health condition requires, but no later than 3 calendar days after the date the IDT receives the request. We continue to believe this is a reasonable timeframe for the IDT to discuss the request, conduct reassessments when required, and make a decision. The IDT is currently allowed to extend the timeframe for notifying a participant or their designated representative by no more than 5 additional days under § 460.104(d)(2)(iv). Extensions are currently permitted when the participant or designated representative requests an extension, or when the IDT documents its need for additional information and how the delay is in the interest of the participant. We are proposing in § 460.121(i)(1) to include a similar provision for extensions, which would allow the IDT to extend the timeframe for review by up to 5 calendar days beyond the original deadline in certain circumstances. We are proposing at § 460.121(i)(1)(i) that the IDT may extend the timeline for review and notification if the participant or other requestor listed in § 460.121(c)(2) or (3) requests the extension. We are proposing to change designated representative to requestor to account for the proposed change we made in § 460.121(c) regarding who can make a service delivery request, and including caregivers in situations where that person may not already be a designated representative. We believe that the participant or other requestor should be able to request an extension. For example, the participant may be out of town and the caregiver may request the IDT to take an extension in order for the participant to be in-person for the reassessment related to the request.

We are proposing at § 460.121(i)(1)(ii) that the IDT can extend the timeframe

for review and notification when the extension is in the best interest of the participant due to the IDT's need to obtain additional information from an individual who is not directly employed by the PACE organization, and that information may change the IDT's decision to deny a service. We believe it is important that the IDT does not routinely take extensions when the participant or other requestor has not asked for one. We understand that when the IDT has to obtain information from individuals not employed directly by the organization, it may be difficult to get timely responses. We also understand that obtaining this information is beneficial for the IDT and the participant in order to ensure that the IDT has sufficient information to make a decision on whether or not a service should be approved. For example, if the IDT is considering a request for dentures, information from the participant's dentist would be relevant to the review, and the IDT may need to take an extension if the dentist does not respond within the initial 3 calendar days. However, we believe it is important that PACE organizations develop processes to ensure prompt decisions about service delivery requests, and that IDTs do not routinely or unnecessarily rely on extensions of the notification timeframe, such as when information can be obtained from an employee of the PACE organization. We are also proposing, for extensions based on the need for additional information, to apply the requirements currently in § 460.104(d)(2)(iv)(B) that require the IDT to document the circumstances that led to the extension and to demonstrate why the extension is in the participant's interest. We are proposing to add a new requirement at § 460.121(i)(2) to require the IDT to notify the participant or the designated representative in writing, as expeditiously as the participant's condition requires but no later than 24 hours after the IDT extends the timeframe, and to explain the reason(s) for the delay. We are proposing to require that the notification of the extension must occur within 24 hours from the time the IDT makes the decision to extend the timeframe because we believe it is important that participants or their designated representatives understand that a decision may be delayed and why, especially if the extension was taken by the IDT.

In addition, we are proposing to add requirements at § 460.121(j) related to notifying the participant or the designated representative of the IDT's decision to approve, deny, or partially deny a service delivery request. Currently, IDTs are required to notify the participant or their designated representative of the decision to approve or deny a request under § 460.104(d)(2)(iii). As we previously discussed, in relation to our proposals under § 460.121(c), we are proposing to expand the number of individuals who can make a service delivery request. However, we are not proposing to change the individuals whom the IDT would notify of its decision to approve or deny the service delivery request. We believe that in all circumstances, the participant (or designated representative) should receive the notification of the IDT's decision to approve or deny the service delivery request. In the rare situation where a caregiver, such as a family member, is not the designated representative, notification of the service delivery request would be sent to either the participant or designated representative, and not the family member. As always, under current § 460.102(f), the PACE organization remains responsible for establishing, implementing and maintaining documented internal procedures that govern the exchange of information between participants and their caregivers consistent with the requirements for confidentiality in § 460.200(e). We would expect that PACE organizations, as a part of that documented process, have a method for determining when notification should go to the participant versus a representative (including a caregiver).

We are proposing at paragraph (j)(1) to specify the notification requirements when the IDT approves a service delivery request. Specifically, we are proposing to require the IDT to notify the participant or the designated representative of that decision either orally or in writing. We are proposing that the notification must explain any conditions for the approval in understandable language, including when the participant may expect to receive the approved service. We believe it is important that the IDT explain to the participant or their designated representative any conditions that may apply whenever the IDT approves a service delivery request. For example, if the IDT is approving a service delivery request for home care, the IDT should indicate the days and hours that are being approved and when the home care would start.

For service delivery requests that can be approved in full at the time the request is made under proposed § 460.121(e)(2), the IDT member who approves the request would be responsible for ensuring that the notification satisfies the proposed requirements in new § 460.121(j)(1). Because a request must be able to be approved in full at the time the participant makes the request under this provision, the IDT member who approves the service would be responsible for providing notification, and ensuring that the conditions of the approval (if any) are explained to the participant. While we allow for the IDT to provide approval notification either orally or in writing, because decisions under § 460.121(e)(2) are made in real time, and communicated to the participant at the time the request is made, we do not believe written notification would be necessary in these instances; however, a PACE organization may always choose to send written notification following the oral notification in order to memorialize any conditions of the approval.

We are also proposing at § 460.121(j)(2) provisions similar to those currently set forth in § 460.104(d)(2)(v), to require that PACE organizations must notify participants or the designated representative of a decision to deny or partially deny a service delivery request both orally and in writing. We believe that the requirement to notify the participant or their designated representative both orally and in writing should be maintained to ensure participants or their designated representatives receive and understand the denial. We are also proposing to expand upon the specific requirements for what a denial notice must contain. At § 460.121(j)(2)(i) we are proposing to require that the IDT state the specific reasons for the denial, including an explanation of why the service is not necessary to improve or maintain the participant's overall health status. Under this proposal, the rationale for the denial would have to be specific to the participant, taking the participant's medical, physical, emotional, and social needs into account, and it would include the results of any reassessment(s) conducted by the PACE organization. The rationale would have to be stated in understandable language so that the participant or designated representative can comprehend why the request was denied. We believe that it is important to continue to require that the IDT provide the specific reasons for a denial. However, based on our experiences monitoring PACE organizations, we believe we need to propose more detailed requirements about what the explanation of the specific reason(s) for the denial should include. Providing

this explanation for a denial would allow the participant or their designated representative to more fully understand why the IDT determined a requested service was not necessary. This would also allow a participant or designated representative to better understand what information they may need to provide if they appeal the denial.

At § 460.121(j)(2)(ii) and (iii), we are proposing to retain the requirements currently codified in § 460.104(d)(2)(v)(A) and (B) that the PACE organization inform the participant or designated representative of the right to appeal any denied service delivery request as specified in § 460.122; and that the PACE organization must also describe the process for both standard and expedited appeals, and the conditions for obtaining an expedited appeal. Additionally, with minor modifications, we are proposing to retain a requirement similar to current § 460.104(d)(2)(v)(C): The PACE organization would be required to notify Medicaid participants about their right to, and the conditions for, continuing to receive a disputed service through the duration of the appeal. Medicaid participants include all participants that are enrolled in Medicaid only or both Medicaid and Medicare (dually eligible). Currently, § 460.104(d)(2)(v)(C) cross-references all of § 460.122(e), but we believe that a more tailored reference to § 460.122(e) would be preferable. We are therefore proposing to cross-reference only § 460.122(e)(1) at proposed § 460.121(j)(2)(iv), because the information provided in § 460.122(e)(2) relates to the PACE organization's continued responsibility to continue to furnish to participants all required services other than the disputed service, and is not specifically about continuing to receive the disputed service. We do not believe we need to require that the IDT include information from § 460.122(e)(2) in a service delivery request denial notification because this concept is widely understood and could potentially confuse participants if they received notification of that requirement. However, we solicit comments on whether it would be preferable to retain a cross-reference to all of § 460.122(e).

We are proposing at § 460.121(k) to specify the timeframe in which the PACE organization must provide services approved, in whole or in part, through the service delivery request process. We are proposing to require the PACE organization to provide the requested service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. We are not proposing a specific timeframe due to the many varying types of services that PACE organizations provide. However, we expect PACE organizations to develop processes to help them identify how quickly they need to provide a service based on the participant's condition. For example, we would generally expect that a drug used to treat a participant's diabetes would be provided much more quickly than we would expect a dental cleaning to be provided. That is because a treatment for diabetes may require a more immediate response, whereas a dental cleaning may not be as urgent. We recognize that not all services can be physically provided in a rapid timeframe, however, we do expect that the PACE organization take prompt action to ensure the approved service is provided as expeditiously as needed. Additionally, for services that can be approved under proposed § 460.121(e)(2), while we require that the IDT member be able to approve the request in full at the time the request is made, we do not require that the approved service be physically provided at the time the request is made. Instead, we are proposing that those approved service delivery requests must also be effectuated under the requirements in this proposed section.

The current requirement at § 460.104(d)(2)(vi) states that the PACE organization must automatically process a participant's request as an appeal when the IDT fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care. We are proposing to retain this requirement, unaltered, at § 460.121(l). We continue to believe that this is an important safeguard for participants to ensure they have access to the appeals process, even when a PACE organization does not adhere to the processing requirements under the rules of this part.

We are proposing at paragraph (m) to add requirements that would address record keeping for service delivery requests. While PACE organizations are currently required to document all assessments under § 460.104(f), we believe that it would be important to have a separate section in the new § 460.121 that more specifically addresses the record keeping requirements, to help ensure that PACE organizations accurately document and track all service delivery requests and have a complete and accurate record of each request and how it was resolved. We are proposing at § 460.121(m) that PACE organizations must establish and implement a process to document, track, and maintain records related to all processing requirements for service delivery requests. We are also proposing to specify that PACE organizations must account for, and document, requests received both orally and in writing. PACE participants often call PACE organizations and request a service over the phone, and it is important for the PACE organization to have an established process to accurately document and track those verbal requests, along with requests submitted to the organization in writing. Once a PACE organization receives a service delivery request, the PACE organization would be responsible for documenting, tracking and maintaining all records that relate to the processing of the service delivery request, including but not limited to, the IDT discussion, any reassessments conducted, all notification that was provided to the participant or designated representative, and the provision of the approved service, when applicable. These documentation requirements would apply to all service delivery requests, including service delivery requests that can be approved in full at the time the request is made per proposed § 460.121(e)(2). Additionally, as we mention in our discussion of § 460.200(d) at section VII.C. of this proposed rule, we are proposing to require that documentation be safeguarded against alteration, and that written requests for services must be maintained in their original form. We are also proposing to require that these records must be available to the IDT to ensure that all members remain alert to pertinent participant information.

Because we are proposing to define the requirements for service delivery requests in the new § 460.121, we propose to remove all requirements relating to service delivery requests from the current § 460.104(d)(2). Specifically, we are removing § 460.104(d)(2)(i) through (v) and we are proposing to modify the existing language in § 460.104(d)(2) to reiterate that the PACE organization must conduct an in-person reassessment if it expects to deny or partially deny a service delivery request. Additionally, as we discussed in § 460.121(h)(2), the IDT may conduct a reassessment as determined necessary for services it intends to approve. We are proposing to modify language in 460.104(d)(2) to direct readers to the new § 460.121(h) for the requirements regarding conducting reassessments in response to service delivery requests.

B. Appeals Requirements Under PACE (§§ 460.122 and 460.124)

As discussed previously, sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act require PACE organizations to have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. In the preamble to Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE) Interim Final Rule (hereinafter referred to as the 1999 PACE interim final rule), which was published in the **Federal Register** on November 24, 1999 (64 FR 66234), CMS explained that we considered the appeals requirements under what is now MA when creating the appeals requirements for PACE (see 64 FR 66257–66258). CMS established the requirements for PACE organizations' appeals processes in §§ 460.122 (PACE organization's appeals process) and 460.124 (Additional appeal rights under Medicare or Medicaid). Over time, PACE organizations have asked CMS to explain certain aspects of the appeals processes described in §§ 460.122 and 460.124. We are therefore proposing certain changes to §§ 460.122 and 460.124 that would provide additional detail about the appeals process and help ensure consistency in the administration of the appeals process among PACE organizations. We are also proposing a few other changes to increase beneficiary awareness of and access to the appeals process, and to align with other changes proposed in this rule. The term ''appeal'' is currently defined in § 460.122 as a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services. We are proposing to add a sentence after the definition to require that PACE organizations must process all requests to initiate, modify or continue a service as a service delivery request before processing an appeal under § 460.122. As we discussed in VII.A. of this proposed rule, we have seen through audits that some PACE organizations will process an appeal instead of processing a service delivery request when a participant makes a request to continue receiving a service that the PACE organization is discontinuing or reducing. We are proposing to add a sentence to this introductory paragraph in order to affirmatively require that all requests that satisfy the definition of a service delivery request under § 460.121(b) must first be processed as such before a PACE organization may process an appeal. Section 460.122(b) currently provides that upon enrollment, at least annually thereafter, and whenever the IDT denies a request for services or payment, the PACE organization must give a participant written information on the appeals process. Consistent with the changes that we are proposing to existing § 460.104(d)(2) and new § 460.121, which are discussed in section VII.A. of this proposed rule, we are proposing to modify § 460.122(b) to specify that PACE organizations must provide participants with written information on the appeals process at enrollment, at least annually thereafter, and whenever the IDT denies a service delivery request or other request for services or payment. By proposing this change, CMS is seeking to ensure that participants consistently and timely receive information about their appeal rights, including when PACE organizations deny their service delivery requests.

Section 460.122(c) provides requirements for the minimum written procedures that PACE organizations must establish for their appeals process. We have heard that these requirements have created confusion among PACE organizations, which has led to inconsistent implementation among PACE organizations and a lack of participant awareness of and participation in the appeals process. As a result, we are proposing a number of changes to decrease confusion and increase beneficiary awareness of and access to the appeals process.

We are proposing two modifications at paragraph (c)(2). First, we are proposing to add a participant's designated representative as someone who has the right to appeal on the participant's behalf. We believe that this is an important participant safeguard because it allows for assistance in navigating the appeals process. Additionally, we are proposing that in developing procedures for how a participant or a participant's designated representative files an appeal, PACE organizations would be required to include procedures for receiving oral and written appeal requests. Because of the comprehensive nature of the care PACE organizations provide, participants are likely to have more verbal interactions with staff of the PACE organization and may express their desire to appeal a decision, but may be unsure or confused as to how. We believe that by requiring PACE organizations to accept appeal requests made both orally and in writing, we would create an important safeguard for the participant population enrolled in the PACE program. By allowing both oral and written requests for appeals, this proposal would enhance participant access to the appeals process, and to services covered under the PACE benefit.

Second, in response to questions received from PACE organizations, we are proposing to add language in paragraph (c)(4) to specify the qualifications required of an appropriate third party reviewer or members of a review committee. Specifically, we are proposing changes to require PACE organizations to ensure appeals are reviewed by an appropriate reviewer or committee. This includes separating the requirements that an appropriate third party reviewer and the members of a review committee must be ''independent'' and ''appropriately credentialed'' to emphasize the fact that an appropriate third party reviewer or member of a review committee must be both independent and appropriately credentialed. We discuss the use of a review committee in the preamble to the 2006 PACE final rule (see 71 FR 71302) and PACE organizations currently utilize review committees in their review processes; therefore, we have proposed to incorporate review committees in regulation at this time and require the members of review committees to satisfy the same requirements as appropriate third party reviewers. Employees or contractors may participate in review committees as long as they meet the requirements set forth in proposed § 460.122(c)(4). Consistent with the current requirements at § 460.122(c)(4), we are proposing to specify that in order to be an appropriate third party reviewer or member of a review committee, an individual must be an impartial third party who was not involved in the original action and does not have a stake in the outcome of the appeal. We are also proposing to add language that more clearly defines an appropriately credentialed reviewer. As we discussed in the preamble to the 2006 final rule, the appropriate third party reviewer must be someone with expertise in the appropriate field. Thus it would not be appropriate for a social worker to review an appeal related to a physical therapy denial; nor would it be appropriate for a gynecologist to review a denial of services relating to coronary surgery. 71 FR 71302.

Therefore, we are proposing to modify the language in paragraph (c)(4) to specify that an appropriate third party reviewer is one who is credentialed in a field or discipline related to the appeal. We do not believe that these proposals would affect the way PACE organizations currently choose their third party reviewers since the existing

regulation at § 460.122(c)(4) requires the appointment of an appropriately credentialed and impartial third party that was not involved in the original action and who does not have a stake in the outcome of the appeal to review the participant's appeal. By proposing amendments to expressly state that the same requirements also apply to the members of a review committee, we believe that this proposal would give PACE organizations more clarity and flexibility to utilize resources within the organization as well as contracted employees.

PACE organizations have expressed confusion about the third party review process, and we are aware of inconsistent decisions made by third party reviewers. In order to reduce confusion, create a more consistent application of Medicare and Medicaid coverage requirements under PACE, and increase consistency for participants, we are proposing additional modifications to the requirements under § 460.122(c). Specifically, we are proposing to add a new paragraph (c)(5) that would require PACE organizations to take specific steps to ensure their third party reviewers understand the PACE benefit package and the coverage requirements under the PACE program, and how to review requests in a manner consistent with both. As noted in the preamble to the 2006 PACE final rule at 71 FR 71302, PACE organizations should ensure that credentialed and impartial third party reviewers are trained to make decisions in a manner similar to the determinations under section 1862(a)(1)(A) of the Act. Such determinations would be based on the participant's medical needs and not on other reasons such as the cost of the disputed care, who is paying the third party reviewer's salary or fee, an individual's reputation, or other factors. We are therefore proposing, in new paragraph (c)(5), to require PACE organizations to provide written or electronic materials to an appropriate third party reviewer(s) that, at a minimum, explain that services must be provided in a manner consistent with the requirements in §§ 460.92 and 460.98, the need to make decisions in a manner consistent with determinations made under section 1862(a)(1)(A) of the Act, and the requirements in § 460.90(a) that specify that many of the limitations on the provision of services under Medicare or Medicaid do not apply in PACE.

The requirements for providing appeal notifications are at § 460.122(d) and currently provide that a PACE organization must give all parties involved in the appeal (1) appropriate written notification and (2) a reasonable opportunity to present evidence related to the dispute, in person, as well as in writing. However, PACE organizations have expressed that this section of the regulation is confusing because it discusses both the notification requirements and the participant's opportunity to submit evidence during an appeal. To reduce confusion, we are proposing to separate these requirements. Accordingly, we are proposing to redesignate paragraph (g) as (h) and also change the title of paragraph (h) to ''Actions following a favorable decision.'' This redesignation allows for the addition of the proposed new paragraph (g) that sets forth notification requirements. We also propose to modify paragraph (d) to address the existing requirement that the PACE organization must give all parties involved in the appeal a reasonable opportunity to present evidence related to the dispute in person as well as in writing. At new paragraph (g), we are proposing to revise the notice requirements for appeals to more closely align with the proposed notice requirements for service delivery requests at § 460.121(j) by specifying the content of the notice in order to ensure consistency and minimize confusion for PACE organizations and participants. We are proposing that PACE organizations would be required to give all parties involved in the appeal (for example participants or their designated representatives) appropriate written notice of all appeal decisions. In the case of appeal decisions that are favorable to the participant, the PACE organization would be required to explain any conditions on the approval in understandable language. For partially or fully adverse decisions, the PACE organization would be required to state the specific reason(s) for the denial, explain the reason(s) why the service would not improve or maintain the participant's overall health status, inform the participant of his or her right to appeal the decision, and describe the additional appeal rights under § 460.124. Conditions of approval may include, but are not limited to, the duration of the approval, limitations associated with an approval such as dosage or strength of a drug, or any coverage rules that may apply. We are also proposing to revise and move the current requirements at paragraph (h) into new paragraph (g)(2)(ii). These requirements specify that for determinations that are wholly or partially adverse to a participant, at the same time the decision is made, the PACE organization must notify CMS, the State administering agency, and the participant. Because this paragraph includes additional notification requirements that PACE organizations must follow after a decision is made to deny an appeal, we believe that this belongs in proposed § 460.122(g)(2) for notice of adverse decisions. We are also proposing to revise this requirement to use terminology consistent with our other proposed amendments to § 460.122, specifically, to refer to ''partially or fully adverse'' decisions and to refer to an appeal decision rather than to a determination for consistency with proposed § 460.122(g)(2)(i) and other sections of this regulation.

We are also proposing a few minor changes to align with other changes proposed in this rule. First, we are proposing to change the reference to § 460.104(d)(2)(iv) in § 460.122(c)(1) to reference the service delivery request requirements in § 460.121(i) and (m). The current citation references the extension requirements for unscheduled reassessments; however, we believe that this reference should have been to the general timeframes for processing service delivery requests. We are also proposing to redesignate the current paragraphs (c)(5) and (6) as (c)(6) and (7) in § 460.122 to allow for the addition of a new paragraph (c)(5), as discussed earlier in this section.

Lastly, we are proposing to add language to § 460.124 that delineates the additional appeal rights that PACE participants are entitled to receive under Medicare or Medicaid and add processing requirements for the PACE organization. In response to comments CMS received on the 1999 PACE interim final rule, CMS discussed stakeholder concerns about the PACE appeals process in the preamble to the 2006 PACE final rule and reiterated the intended process in the preamble. See 71 FR 71303–71304. Specifically, CMS stated in the preamble to the 2006 PACE final rule that Medicare beneficiaries have access to the Medicare external appeals route through the IRE that contracts with CMS to resolve MA appeals, while Medicaid eligible participants have access to the State Fair Hearing (SFH) process. See 71 FR 71303. However, despite this clarification, CMS's audits have revealed that PACE organizations continue to misinterpret the requirements under § 460.124 relating to participants' additional appeal rights under Medicare or Medicaid. To address this issue, we are proposing several changes to § 460.124. First, we are proposing to add new paragraphs (a) and (b) at § 460.124. We are proposing at § 460.124(a) to specify that Medicare

participants have the right to a reconsideration by an independent review entity (IRE). We recognize that there are differences in the terminology used in PACE versus MA and therefore have proposed to add similar language at new § 460.124(a)(1), (2), and (3) to establish in regulation the requirements for how an appeal may be made to the independent, outside entity, the timeframe in which the independent outside entity must conduct the review, and who are the parties to the appeal. At proposed § 460.124(a) introductory text and (a)(1) we have intended to parallel the requirements at § 422.592(a) with minor differences. Under MA there is automatic escalation to the independent review entity at this level of appeal if the organization upholds its adverse decision, in whole or in part. However, in PACE, appeals are not automatically escalated because most PACE participants are dually eligible for Medicare and Medicaid benefits and these participants may choose to utilize the Medicaid or Medicare route for independent review. For these dually eligible individuals, it may be more appropriate to pursue an appeal through the Medicaid path rather than the Medicare path. The provisions relating to automatic-escalation in MA ensure that the beneficiary receives a review by an independent reviewer; however, this protection is not necessary in PACE as the PACE participant has already received an independent review on the appeal during the internal appeal processed in accordance with § 460.122. We are therefore proposing at § 460.122(a)(1) to specify that a written request for a reconsideration must be filed with the independent review entity within 60 calendar days of the decision by the third party reviewer. We did not specify who must file the request because we discuss at § 460.124 that the PACE organization must assist the participant in choosing which appeal rights to pursue (that is, Medicaid SFH or Medicare IRE) and as such, we believe that the PACE organization is also responsible for ensuring that the request is filed with the appropriate external entity. However, a participant always maintains the right to file a request without assistance from the PACE organization. At § 460.124(a)(2) we are proposing to add a requirement that the independent review entity must conduct the review as expeditiously as the participant's health condition requires but must not exceed the deadlines specified in the contract. The independent review entity is currently operating under these timeframes, consistent with the requirements at § 422.592(b), and participants are currently utilizing the independent review entity to exercise their external appeal right, consistent with CMS's historical interpretation that these requirements are applicable to the PACE program. We have also proposed the addition of language at § 460.124(a)(3) that would parallel the requirement at § 422.592(c), to specify that when the independent review entity conducts a reconsideration, the parties to the reconsideration are the same parties described in § 460.122(c)(2), with the addition of the PACE organization. We are seeking to enhance transparency and we believe it is important to make PACE organizations aware that they are considered a party to the appeal once it reaches the independent review entity. We are also proposing to add a new paragraph (b) that specifies that Medicaid participants have the right to a SFH as described in part 431, subpart E. Finally, we are proposing a new paragraph (c) to specify that participants who are dually eligible for both Medicare and Medicaid have the right to external review by means of either the IRE or the SFH process. This provision would specify that dually eligible participants may choose to pursue an appeal through either the Medicare or Medicaid process. In accordance with § 460.124, PACE organizations must assist dual eligible participants in choosing which route to pursue if both the IRE and the SFH review processes are applicable. For example, if the appeal is related to an enrollment dispute, the Medicaid SFH process would be the appropriate route for a participant to pursue. Whereas for a dispute related to a Part D medication, the IRE would be the appropriate route for a participant to pursue. By codifying these appeal rights in regulation, we are seeking to enhance transparency for PACE organizations to ensure that participants are able to access additional levels of appeal in order to receive services they believe that they are entitled to under the PACE benefit.

C. Access to Data and Safeguarding Records Under PACE (§ 460.200)

In accordance with sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act, § 460.200 requires PACE organizations to collect data, maintain records, and submit reports, as required by CMS and the State Administering Agency (SAA). The current requirement at § 460.200(b) requires that PACE organizations must allow CMS and the SAA access to data and records, including but not limited to, participant health outcomes data, financial books and records, medical records, and personnel records. Some PACE organizations have asked for clarification on whether access is limited to allowing CMS or the SAA to view requested information. CMS has long interpreted this provision to require that CMS and the SAA must be able to obtain, examine, or retrieve information as needed to administer and evaluate the program and fulfill their oversight obligations. Therefore, we are proposing to codify CMS' interpretation of this requirement. Specifically, we are proposing to redesignate current § 460.200(b)(1) through (4) as § 460.200(b)(1)(i) through (iv), in order to add a new paragraph (b)(2) to state that CMS and the State administering agency (SAA) must be able to obtain, examine, or retrieve the information described under § 460.200(b)(1). This may include CMS or the SAA reviewing information at the PACE site or remotely. It may also include CMS requiring a PACE organization to upload or electronically transmit information, or send hard copies of required information by mail.

PACE organizations are also required to safeguard data and records in accordance with § 460.200(d). This section currently provides that a PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration. Through our monitoring of PACE organizations, CMS has discovered that PACE organizations do not always maintain and safeguard important records such as communications related to a participant's care from family members, caregivers, and the participant's community. In fact, CMS has discovered that organizations may summarize written communications and sometimes destroy or lose original written communications. When CMS has obtained copies of original communications from an outside source (such as the family or caregiver), we have noted that organizations are not accurately summarizing information or retaining the relevant information in the communication. In light of these findings, we believe that any written communication received from a participant or their informal support (for example, a family member, caregiver, designated representative, or other member of the community) that relates to the participant's care, health or safety must be safeguarded and maintained in its original form. Therefore, we are proposing to modify § 460.200(d) to require PACE organizations to maintain all written communications received

from a participant or other parties in their original form when the communication relates to the participant's care, health, or safety. We would expect that this would include most, if not all, communications that an organization receives on these topics. For example, the following types of communications would need to be protected under this provision: Written requests for services that the participant, designated representative or caregiver believes are necessary; grievances or complaints relating to the participant's care or health; and communications from the community that indicate concerns over the well-being of a PACE participant. We are proposing corresponding changes to § 460.210(b)(6), to require PACE organizations to maintain original written communications in the participant's medical record, as discussed at section VII.F. of this proposed rule.

We believe the burden associated with this provision is related to the documentation of these original communications in the medical record. We discuss and account for the burden of documenting these communications in the medical record in the regulatory impact analysis.

We are soliciting comments on these proposals.

D. PACE Services, Excluded PACE Services, and the Interdisciplinary Team (§§ 460.92, 460.96, and 460.102)

1. Required Services

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act state that the PACE program provides comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE protocol.[94] CMS codified these required services in § 460.92 of the regulations, which provides that the PACE benefit package for all participants, regardless of the source of payment, must include all Medicare covered items and services, all Medicaid covered items and services, as specified in the State's approved Medicaid plan, and other services determined necessary by the interdisciplinary team (IDT) to improve and maintain the participant's overall health status.

We are proposing to modify the requirements at § 460.92 to more clearly define required services, and to specify CMS' expectations for making decisions about the services that are required under the PACE benefit package. First, we are proposing to create a new paragraph (a) and include under (a) the current requirements in § 460.92. In order to do that, we propose to renumber existing paragraphs (a), (b), and (c) as (a)(1), (2), and (3). We are proposing to add a new paragraph (b) that provides the standards that the IDT must consider when evaluating whether to provide or deny services described under (a) for a participant.

In addition to redesignating § 460.92(a) as § 460.92(a)(1), we are proposing to modify the language to refer to all Medicare-covered services. In light of our proposed amendments to the definition of ''services'' in § 460.6, and the current definition of that term, PACE organizations should understand that providing necessary drugs, whether they are covered under Medicare Parts A, B, or D, is an important part of the PACE benefit package. See section VII.I. of this proposed rule for a more detailed discussion of the definition of ''services.''

CMS is also proposing to add a new paragraph (b) in order to specify the standards that the IDT must consider when evaluating whether to provide or deny services required under § 460.92(a) for a participant. Under proposed § 460.92(b)(1) we are proposing to require the IDT to take into account all aspects of a participant's condition, including the participant's medical, physical, emotional, and social needs, when determining whether to approve or deny a request for a service. As we discussed in section VII.A. of this proposed rule, the determination for a service should be based on all aspects of the participant's care. For example, additional center days may not be necessary when considering the participant's physical needs, but when taking into account the participant's social needs, the IDT may find that those services become necessary in order to improve the participant's social or emotional condition. We have discovered through audits that PACE organizations sometimes only consider the medical or physical needs of a participant but do not consider their social or emotional needs when those social or emotional needs are relevant to the request.

We are also proposing to add language at § 460.92(b)(2) that would require organizations to utilize current clinical practice guidelines and professional standards of care when making a decision, so long as those guidelines and standards are applicable to the particular service. PACE organizations are currently required to utilize current clinical practice guidelines and professional practice standards when developing the outcome measures for their quality improvement programs at § 460.134(b). When we discussed this requirement in the preamble to the 1999 PACE interim final rule, we stated that we expect that PACE organizations will utilize current clinical standards as a routine part of their daily operations and care management strategies. (See 64 FR 66260). However, we have discovered through our PACE audits that decisions to deny services are sometimes not based on accepted clinical guidelines or standards. We understand that current clinical practice guidelines and professional standards of care may vary based on the type of service that is being considered. For example, when determining if a participant requires a cardiac catheterization, the organization may reference clinical practice guidelines issued by the American Heart Association. On the other hand, when determining the appropriate insulin for a participant the organization may appropriately refer to guidelines published by the American Diabetic Association. We also understand that certain services may not have an applicable clinical practice guideline. For example, determining the frequency of PACE center attendance may not be based on clinical practice guidelines, but may instead be based on the medical, physical, emotional, and social needs of the participant. Therefore, we are proposing to add language to (b)(2) to require the IDT to take into account current clinical practice guidelines and professional standards of care if applicable to a particular service. By adding this requirement, we do not intend to restrict a PACE organization's ability to determine what service is appropriate or necessary for a participant: The IDT would remain responsible for determining the participant's overall health status and needs, and ensuring those needs are met through the provision of necessary services.

We are not scoring this provision in the Regulatory Impact Analysis section because PACE organizations are already required to utilize current clinical

[94] The original PACE protocol was replaced by the PACE program agreement (84 FR 25613).

practice guidelines as a part of their quality improvement program, and they are required to consider the participant's physical, medical, emotional and social needs as a part of care planning discussions. We believe that by modifying this provision we will not be increasing burden on PACE organizations, as they already consider these items on a routine basis.

2. Excluded Services

As we stated earlier in this section, in the discussion regarding Required Services, the PACE benefit package includes all Medicare-covered items and services, all Medicaid-covered items and services, as specified in the state's approved Medicaid plan, and other services determined necessary by the IDT to improve or maintain the participant's overall health status. The regulations at § 460.96 list a number of services that are excluded from coverage under PACE. Currently, paragraph (a) states that any service that is not authorized by the IDT, even if it is a required service, is an excluded service unless it is an emergency service. In addition, paragraph (b) states that in an inpatient facility, private room and private duty nursing services (unless medically necessary), and nonmedical items for personal convenience such as telephone charges and radio or television rental are also excluded from coverage under PACE unless specifically authorized by the IDT as part of the participant's plan of care. We are proposing to remove § 460.96(a) and (b).

These proposals are consistent with our authority to amend the regulations. The exclusions in § 460.96 are not specifically listed in the PACE statute. They were included in the 1999 PACE interim final rule that implemented the PACE program in part because they were included in section A.6 of the PACE Protocol included as Addendum A to the 1999 PACE interim final rule. See 64 FR 66247 and 66301 and subparagraphs 1894(f)(2)(A) and 1934(f)(2)(A) of the Act. Sections 1894(f)(1) and 1934(f)(1) of the Act give the Secretary the authority to issue regulations to carry out the PACE program created under sections 1934 and 1894 of the Act. Sections 1894(f)(2) and 1934(f)(2) of the Act state that, in issuing such regulations the Secretary shall, to the extent consistent with the provisions of sections 1894 and 1934 of the Act, incorporate the requirements applied to PACE demonstration waiver programs under the PACE protocol. As we stated in the 2019 PACE final rule, we believe sections 1894(f) and 1934(f) of the Act primarily apply to issuance of the initial interim and final PACE program regulations because they refer to the PACE Protocol,[95] which has now been replaced by the PACE program agreement.[96] 84 FR 25613. Sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act permit the Secretary to modify or waive provisions of the PACE Protocol as long as any such modification or waiver is not inconsistent with and does not impair any of the essential elements, objectives, and requirements under sections 1894 or 1934 of the Act, but precludes the Secretary from modifying or waiving any of the following provisions:

- The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.
- The delivery of comprehensive integrated acute and long-term care services.
- The IDT approach to care management and service delivery.
- Capitated, integrated financing that allows the PACE organization to pool payments received from public and private programs and individuals.
- The assumption by the PACE organization of full financial risk.

Taking this authority into account, we are proposing to remove 460.96(a) for the following reasons. CMS has gained a significant amount of experience with the PACE program since the 1999 PACE interim final rule, and we now believe that a number of PACE organizations are interpreting the exclusion under § 460.96(a) in a manner that is not consistent with sections 1894 and 1934 of the Act. Many PACE organizations appear to be interpreting § 460.96(a) to allow an IDT to exclude from coverage any service that the IDT does not authorize for a participant, even if it is clearly covered under the Medicare or Medicaid programs and is medically necessary. For example, CMS has identified through audits that some PACE organizations have denied certain types of covered Part D drugs for participants, even when the drug is medically necessary and the participant is qualified to receive the drug under Medicare.

These denials are inconsistent with the statutory requirement under sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act to provide all items and services covered by Medicare and Medicaid, as well as all additional items and services specified in regulations. As we stated in the 2006 PACE final rule, in accordance with sections 1894 and 1934 of the Act, PACE organizations shall provide all medically necessary services including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. 71 FR 71248. PACE organizations are required to provide all Medicare covered services and all Medicaid covered services in accordance with the State's approved Medicaid plan under current § 460.92(a) and (b). In addition, PACE organizations are required to cover other items and services that are determined necessary by the IDT to improve and maintain the participant's overall health status under current § 460.92(c). In order to ensure that IDTs continue to make decisions that are consistent with the statutory requirements, we are proposing to remove paragraph (a) from § 460.96. We believe that removing paragraph (a) is necessary in order to ensure that participants receive the services to which they are entitled under PACE.

By proposing to remove paragraph (a), we do not intend to waive or eliminate the IDT approach to care management and service delivery. The IDT's authority and responsibility are defined throughout the PACE regulations, and under this proposed amendment, the IDT would retain its ability to determine which services are appropriate for a participant, and would remain responsible for coordinating the care of participants 24 hours a day, every day of the year. Additionally, as discussed in our proposed changes to § 460.92, we are proposing that the IDT's decision to provide or deny required services must be based on an evaluation of the participant that takes into account the participant's current medical, physical, emotional and social needs, along with any current clinical practice guidelines and professional standards of care that are applicable to the particular service. We do not believe that the current provision at § 460.96(a) affects an IDT's authority for determining what services are required under § 460.92, or changes the IDT's responsibility for coordinating 24 hour care delivery. However, we are concerned that the current language at § 460.96(a) is confusing and implies that there are some required services that are not covered under the PACE program because they are excluded. The term ''excluded'' implies that a service is outside of the benefit package or never covered. The term ''excluded'' could also suggest that services that are not authorized are not appealable, which runs counter to our historical

[95] *https://www.gpo.gov/fdsys/pkg/FR-1999-11-24/pdf/99-29706.pdf.*

[96] *https://www.cms.gov/Medicare/Health-Plans/pace/downloads/programagreement.pdf.*

interpretation of the PACE statutes and regulations and the policies we have promulgated to safeguard participants' right to appeal adverse decisions by the IDT. While the IDT remains responsible for determining the needs of each participant, and then implementing services that would meet those identified needs, PACE participants should always have the ability to advocate for services, through the service delivery request and appeal process, including any services the IDT determines not to be necessary (or does not authorize).

We are proposing to eliminate paragraph (b) from § 460.96 for the following reasons. Currently, this paragraph generally excludes from PACE coverage private rooms and private duty nursing services, and non-medical items for personal convenience, in an inpatient facility, but notes that a private room or private duty nursing services would be covered if medically necessary, and non-medical items for personal convenience would be covered if specifically authorized by the IDT as part of the participant's plan of care. We continue to believe that services such as a private room, private nursing services, or non-medical personal care items would not be covered under PACE, unless they were medically necessary or authorized by the IDT as part of the participant's plan of care. However, we believe that including this provision under a section of the regulation titled ''Excluded Services'' may give a false impression that the IDT would not have to consider whether those services are medically necessary or necessary to improve and maintain the participant's overall health status. As we previously indicated, the IDT is responsible for comprehensively assessing each individual participant to determine their needs, and then providing services that would meet those needs. If the IDT determines that private nursing services or a telephone are necessary to improve and maintain the participant's health status, those services would be covered for that participant under PACE. Therefore, these are not always or by definition excluded services, and we are proposing to eliminate paragraph (b) from the excluded services provision for that reason.

In addition to proposing to eliminate paragraphs (a) and (b), we are proposing to redesignate paragraphs (c) through (e) as (a) through (c).

We are not scoring this provision in the Regulatory Impact Analysis section because PACE organizations are already required to cover all PACE required services under § 460.92, and by modifying excluded services we are hoping to increase compliance with existing requirements.

3. Responsibilities of the Interdisciplinary Team

A multidisciplinary approach to care management and service delivery is a fundamental aspect of the PACE model of care (see for example, the 1999 PACE interim final rule at 64 FR 66254). The regulations at § 460.102 require in part that the IDT must comprehensively assess and meet the needs of each participant, and that the IDT members must remain alert to pertinent input about participants from team members, participants, and caregivers. While we believe many IDTs appropriately apply the multidisciplinary approach to providing care, we have learned through our monitoring efforts that some IDTs may not consider pertinent input about participants from specialists and other clinical and non-clinical staff, whether employees, or contractors (for example, home health service providers). Because these individuals have direct contact with participants, including in the participant's home, and may have a similar level of expertise as the members of the IDT listed in § 460.102(b) or expertise in another medical field, they are likely to be in the best position to provide input that may contribute to a participant's treatment plan. An IDT could not comprehensively assess a participant and provide a multidisciplinary approach to care management if it did not consider pertinent input about a participant from any individual with direct knowledge of or contact with the participant, including caregivers, employees, or contractors of the PACE organization, or a specialist. For example, if a home care aide informed the organization that a participant seems more confused than normal, the IDT might not be able to fully meet the participant's needs if it did not take this information into consideration. While the IDT is responsible for many aspects of care provided to their participants, it might not interact with their participants on a regular basis. It is important that the IDT consider input from other individuals that have more regular or direct contact with the participant population, in order to inform its ability to appropriately meet participants' needs. Therefore, we are proposing to revise § 460.102(d)(2)(ii) by adding employees, contractors, and specialists to the individuals from whom the IDT must remain alert to pertinent input. We are proposing to include specialists because there may be circumstances in which a participant is receiving care or seeking treatment options from a provider that specializes in a particular area and we believe that input from these medical professionals is vital in order for a PACE organization to provide comprehensive care to its participants. We are also proposing to add these individuals as unique sub-paragraphs under § 460.102(d)(2)(ii) in order to emphasize that these are unique groups of individuals, each of whom may provide information that is pertinent to the IDT. As part of the requirement that the IDT members remain alert to pertinent input from these individuals, we expect that the IDT members would consider all recommendations for care or services made by other team members, participants, caregivers, employees, contractors, or specialists for a participant when making treatment decisions.

We are proposing a minor change to redesignate the provisions at § 460.102(d)(1) under a new (d)(1)(i), where we are proposing to retain the current requirement that the IDT is responsible for the initial assessment, periodic reassessment, plan of care, and coordination of 24 hour care delivery. We are also proposing to add a new § 460.102(d)(1)(ii) to require the IDT to document all recommendations for care and services and, if the service is not approved, the reasons for not approving or providing that care or service in accordance with the requirements in § 460.210(b). By requiring the IDT to document all recommendations for care or services and, if not approved or provided, the rationale supporting the IDT's decisions, we believe our proposals under § 460.102(d) would better position the PACE organization and the IDT to remain alert to pertinent information and to share that information with participants, caregivers, and appeal entities when applicable.

We believe the burden associated with this provision is related to the documentation of the recommendations in the medical record. We discuss and account for the burden of documenting these recommendations in the medical record in the regulatory impact analysis.

E. Documenting and Tracking the Provision of Services Under PACE (§ 460.98)

As discussed at section VII.D. of this proposed rule, under sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act, PACE organizations provide comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b)(1)(A) and 1934(b)(1)(A)

of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE protocol.[97] Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities. Additionally, sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act require that a PACE organization must provide participants access to all necessary covered items and services 24 hours per day, every day of the year. These statutory provisions ensure that a PACE participant can receive all PACE covered services, as needed, 24 hours a day, every day of the year. This includes the full range of services required under the PACE statute and regulations. We have implemented these requirements in several sections of the PACE regulations. For example, we require in § 460.70 that PACE organizations must have written contracts that meet specific regulatory requirements with any outside entity furnishing administrative or care-related services not furnished directly by the PACE organization, except for emergency services as described in § 460.100. We also require PACE organizations to establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year at § 460.98(a). Through oversight and monitoring, we recognized that some PACE organizations are not appropriately implementing these requirements. CMS routinely sees PACE organizations deny or restrict necessary services. PACE organizations have also documented in participants' medical records that they do not provide access to care and services 24 hours a day, regardless of participant need. CMS has also learned through monitoring of PACE organizations that some organizations are not providing all care and services through employees or contractors of the organization. Instead, these organizations purport to rely on caregivers such as family members to provide necessary care and services to participants.

We are proposing to make several modifications to § 460.98 ''Service Delivery'' in response to failure by certain PACE organizations to fulfill their responsibilities to provide all necessary care and services, through the use of employees or contractors, as expeditiously as the participant's health condition requires, and ensure access to those services 24 hours a day, every day of the year. Currently, § 460.98(a) requires that PACE organizations establish and implement a written plan to furnish the care that meets the needs of each participant in all care settings 24 hours a day, every day of the year. We are concerned that the current version of this paragraph places more emphasis on the requirement to establish a written plan than it does on the requirement that the PACE organization actually implement such a plan by furnishing services. Therefore, we are proposing to modify paragraph (a) to more clearly emphasize that PACE organizations must not only have a plan to furnish care as described in existing § 460.98(a), but must also carry it out. We propose to change the title of § 460.98(a) from ''Plan'' to ''Access to services'' in order to emphasize that the requirement is that PACE organizations provide access to services and not just have a plan. We also propose to revise the language of § 460.98(a) to emphasize that PACE organizations are responsible for providing care that meets the needs of each participant, across all care settings, 24 hours a day, every day of the year, as well as establishing a written plan to ensure that care is appropriately furnished. We believe the proposed amendments would align with the statutory requirement that PACE organizations provide access to necessary care and services at all times. We are also proposing to retain the requirement that PACE organizations must establish and implement a written plan to furnish care, with one modification to specify that the plan must ensure that care is appropriately furnished. Additionally, we want to emphasize that, both under the current regulation and the proposed amendments, the PACE organization is (and would remain, if our proposed amendments are finalized) responsible for providing this care regardless of the care setting. In other words, regardless of whether the participant receives care in the home, at the PACE center, or in an inpatient facility, the PACE organization is (and would remain) responsible for furnishing care in all care settings, 24 hours a day, every day of the year.

Currently, § 460.98(b) specifies in part that the PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long term care to each participant, and must furnish these services in at least the PACE center, the home, and inpatient facilities. We are proposing to make three changes to § 460.98(b) by modifying paragraph (b)(1) and adding new paragraphs (b)(4) and (5). Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act, and the PACE regulations at § 460.70(a), require PACE organizations to furnish administrative and care-related services by employees or contractors of the organization. Through monitoring and oversight we have identified instances where PACE organizations have relied on individuals other than employees or contractors to provide necessary care and services to participants. To address these concerns we are proposing to add a reference to § 460.70(a) at § 460.98(b)(1) to reiterate the requirement that PACE organizations furnish all services through employees or contractors, regardless of whether the services relate to medical, health, or social services, including both acute and long term care.

We are also proposing to add a new paragraph at § 460.98(b)(4), to require that all services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's overall medical, physical, emotional and social needs. While there is a similar requirement in § 460.104(e)(4), that services that result in a change to the care plan must be provided as expeditiously as the participant's health condition requires, we have identified through monitoring and oversight that participants routinely receive care that is determined necessary but is not formally incorporated into the care plan, and is instead handled through discipline-specific progress notes or treatment plans. For example, the primary care provider may order pain medication for a participant, but not incorporate that order into the participant's plan of care. Regardless of whether the service is in the plan of care, we believe that the PACE organization retains the responsibility of ensuring that participants receive all recommended or ordered treatment or care as expeditiously as the participant requires. We are proposing to specify at § 460.98(b)(4) that services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs. We do not believe that we could implement a specific timeframe given the vast array of services that PACE organizations provide. Additionally, determining how quickly a service must

[97] The original PACE protocol was replaced by the PACE program agreement (84 FR 25613).

be provided would depend on more than just the physical health of the participant, and PACE organizations should consider all aspects of the participant's condition, including their social, emotional, and medical needs, when determining the provision of services. For example, if the participant has a high risk of falling, the provision of a service that mitigates that risk may be necessary within a very short window of time. However, if the necessary service is a preventative trip to the dentist for routine care, the provision of that service may not be as urgent. These decisions must be made on a case by case basis and the PACE organization will be expected to demonstrate that services were provided as expeditiously as the participant's medical, physical, emotional, and social needs require through monitoring efforts by CMS.

Lastly, we are proposing adding a new paragraph (b)(5) to § 460.98 to require PACE organizations to document, track, and monitor the provision of services across all care settings, regardless of whether services are formally incorporated into the participant's plan of care. We are proposing that PACE organizations would be required to document, track and monitor necessary services in order to ensure that they are actually provided in accordance with § 460.98(b)(4). CMS' audits have revealed that in practice, certain PACE organizations do not routinely track the services provided and often lack documentation that services have been rendered. In order for the IDT to remain alert to pertinent information and coordinate care appropriately, we believe the PACE organization must be capable of ensuring that all approved services are tracked and documented, regardless of whether they are formally incorporated into the participant's plan of care. This means that not only should a PACE organization document that a service has been ordered, but that the PACE organization should also document when and how the approved service was provided. We believe that monitoring the provision of services is vital for a PACE organization in order to ensure their participants are receiving appropriate services, and that those services are achieving the desired effect. In addition, CMS regulations at § 460.134 require that PACE organizations use objective measures to demonstrate improvement across a range of areas, such as the utilization of PACE services and the effectiveness and safety of staff-provided and contracted services, including the promptness of service delivery, among other requirements. We believe that this proposal will ensure that PACE organizations are able to more effectively meet the minimum requirements established at § 460.134.

F. Documentation in Medical Records Under PACE (§ 460.210)

In accordance with § 460.210(a), a PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards, that is accurately documented and available to all staff, among other requirements. We have previously discussed the importance of maintaining a complete record for each participant. In the preamble to the 2006 PACE final rule, we stated that, because care for the PACE population will be provided by a variety of sources (for example, PACE center employees, contracted personnel, hospital staff, nursing home staff, etc.), it is critical that all information on the participant be documented in the medical record to ensure quality and continuity of care. 71 FR 71326. CMS currently specifies at § 460.210(b) the minimum required contents of a medical record. Based on audit and oversight experience, we have identified additional requirements that we believe should be added under § 460.210(b) to ensure that participant medical records are fully comprehensive.

We are proposing to redesignate § 460.210(b)(4) through (12) as (7) through (15), and to add three new paragraphs under § 460.210(b) to address how recommendations for care and treatment, decisions regarding those recommendations, and communications relating to a participant's care, health or safety should be documented in the medical record. Specifically, we are proposing to add a new paragraph (b)(4) that would require the PACE organization to document all recommendations for services made by employees and contractors of the PACE organization, including by all specialists such as dentists, neurologists, cardiologists, and others, in the participant's medical record. We believe that all recommendations for services from these sources must be documented in order for the IDT to remain alert to all pertinent information, even if the IDT decides not to pursue the recommendations, for example based on a determination that the service is not necessary. Recommendations are made based on the employee or contractor's determination that a participant might benefit from a particular service given the participant's health status or condition. Even if the IDT ultimately decides that the recommended service would not be necessary to improve and maintain the participant's health status, the IDT should document that recommendation in order to remain alert to why a particular contractor or employee believed that service was necessary as required by § 460.102(d)(2)(ii).

Additionally, we are proposing to add a new paragraph (b)(5) that would require the IDT to document in the medical record the reason(s) for not approving or providing a service recommended by one of these sources. When an employee, contractor, or specialist recommends a service within the scope of their authority to practice, we believe that it is necessary for the IDT to consider this information and document any decision against providing the recommended service in the medical record. For example, if a gastroenterologist recommends that a participant receive drug therapy for Hepatitis C, and after reviewing the recommendation the IDT determines that treatment is not medically necessary or is contraindicated, we are proposing to require the IDT to document in the participant's medical record the rationale for not providing the recommended drug therapy, including the clinical criteria used as the basis for that determination. This would not only ensure that the IDT can review the information used to make the decision, but also that the participant has access to information about the basis of the decision not to provide a recommended service. This proposal would also align with the requirement we finalized in the 2019 PACE final rule that requires the IDT to document the rationale for determining certain services are not necessary in the participant's plan of care following the initial comprehensive assessment. 84 FR 25643. While the 2019 PACE final rule required the IDT to follow this process during the development of the initial care plan, we are expanding the requirement to account for situations that arise after the initial plan of care is developed. For example, a participant may be diagnosed with diabetes after the development of the initial care plan, and should the PACE organization determine that treatment is not necessary, we would expect that it document that decision and the reasons for that decision in the participant's medical record.

We are also proposing to require PACE organizations to maintain certain written communications received by the PACE organization in the participant's medical record. The PACE program presents unique challenges in terms of providing care to participants. PACE

participants require a nursing facility level of care and often have complex medical needs. When a Medicare or Medicaid beneficiary is in a nursing home, they have daily interactions with staff, and their needs, including changes in condition, are noted by the staff and acted upon. PACE participants, on the other hand, largely remain in their own homes and might not be seen on a daily basis by PACE organization staff. PACE participants do, however, often have regular interactions with caregivers, family members, neighbors, and other members of their communities, as well as with social service organizations like a local Area Agency on Aging (AAA) or Adult Protective Services (APS) agency. We believe that maintaining a comprehensive, complete, and accurate medical record allows a PACE organization to remain alert to all information that is relevant to a participant's care, health, or safety and to provide appropriate and timely care to the participant. We also believe information about a participant's care, health, or safety provided to a PACE organization by any of the sources previously noted could be a critical part of providing comprehensive care to the participant. We are therefore proposing to add a new paragraph (b)(6) to § 460.210, to require PACE organizations to maintain in a participant's medical record original documentation of any written communication relating to the care, health, or safety of a participant that the PACE organization receives from certain sources in any format (for example, emails, faxes, letters, etc.). At a minimum, PACE organizations would be required to maintain communications from the participant, his or her designated representative, family members, caregivers, or any other individual who provides information pertinent to a participant's care, health or safety, as well as communications from advocacy or governmental agencies like an AAA or APS. As we indicated in the discussion regarding § 460.200 at section VII.C. of this proposed rule, we are also requiring that the PACE organization maintain this information in its original written form rather than summarizing the information in the participant's record.

G. PACE Participant Rights: Contact Information and Access Requirements (§ 460.112)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify in part that PACE organizations must have in effect written safeguards of the rights of enrolled participants including a patient bill of rights. Previously, we established in § 460.112 certain rights to which a participant is entitled. This includes the participant's right to receive accurate, easily understood information and to receive assistance in making informed health care decisions under § 460.112(b); and the participant's right to a choice of health care providers, within the PACE organizations network, that is sufficient to ensure access to appropriate high-quality health care under § 460.112(c). CMS is proposing to add three new participant rights in § 460.112 to increase beneficiary protections: The right to contact 1–800–MEDICARE for information or to make a complaint; the right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines; and the right to receive necessary care across all care settings, up to and including placement in a long term care facility when the PACE organization can no longer maintain the participant safely in the community through the support of PACE services.

Section 1804(b) of the Act requires CMS to provide information on Medicare programs through 1–800–MEDICARE, as a means by which individuals may seek information and assistance for Medicare programs. This number may be utilized by Medicare beneficiaries to address coverage questions, find plan information, or make complaints related to the Medicare program. While PACE organizations are responsible for providing to all participants all services covered under Medicare and Medicaid, including prescription drugs, and other services determined necessary by the IDT to improve and maintain the participant's overall health status, PACE organizations are not required to provide this toll-free number to participants in any current communication. In the MA program, MA organizations must provide this information to beneficiaries in their Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) under § 422.111 as well as longstanding guidance under the Medicare Communications and Marketing Guidelines.[98] We have discovered through oversight and monitoring efforts that PACE participants and/or their caregivers are often not aware that, in addition to the internal grievance process under § 460.120, participants also have the right to contact 1–800–MEDICARE; for example, to file quality of care complaints, including filing a complaint regarding the delivery of a necessary service. For example, if the IDT approved treatment for a specific condition, but the participant never received that treatment, the participant or caregiver could call 1–800–Medicare to lodge a complaint. Given the frailty of the PACE population, we believe it is important that these participants be explicitly notified of their right to have their complaints heard and resolved by calling 1–800–MEDICARE. When a participant files a complaint with 1–800–MEDICARE, the complaint gets logged and routed to a CMS account manager or case worker in order to ensure it is appropriately responded to and resolved. To ensure PACE participants are notified about 1–800–MEDICARE, we are proposing to amend § 460.112 by adding a new paragraph (b)(4) which would specify that participants have the right to contact 1–800–MEDICARE for information and assistance, including to make a complaint related to quality of care or delivery of a service. PACE organizations are required under § 460.116(c)(2) to display the PACE participant rights in a prominent location in the PACE center, and to include the participant bill of rights in the enrollment agreement under § 460.154(m). Thus, we believe adding (b)(4) would ensure each PACE organization makes the 1–800–MEDICARE number available to participants by posting it in an accessible location at the PACE center and including it in the enrollment agreement.

We also propose to include a participant's right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines at new § 460.112(c)(3). PACE organizations are responsible for ensuring participants receive all necessary care from specialists, which is coordinated through the primary care provider and IDT in accordance with § 460.102(c)(2)(ii) and (d)(1). In addition, as noted in the preamble to the 1999 PACE interim final rule that implemented the PACE program (see 64 FR 66260) and the preamble to the 2006 PACE final rule that implemented § 460.92 of the regulations (see 71 FR 71305), PACE organizations must utilize clinical practice guidelines to ensure the quality of care for PACE participants. CMS has also historically required the use of clinical practice guidelines and professional standards in determining outcome measures applicable to the care

[98] *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial.html.*

of PACE participants as part of the PACE organizations quality improvement program (see § 460.134(b)). The 1999 PACE interim final rule also established the expectation that PACE organizations will utilize current clinical standards as a routine part of their daily operations. 64 FR 66260. Because part of the purpose of the quality improvement program is to identify areas to improve or maintain the delivery of services and patient care, CMS believes that these same guidelines and standards should be used as part of care planning and in making determinations about services as discussed in section VII.D. of this proposed rule. However, CMS' audits of PACE organizations have shown that some PACE participants have not received timely access to appropriate specialists as necessary to improve and maintain the participant's overall health status and in accordance with current clinical practice guidelines. Instead, the IDTs at some PACE organizations seem to be making their decisions based on factors not related to the participant's health condition. In some instances, participants have experienced negative outcomes because they have not received access to a specialist. Therefore, we propose to redesignate paragraph (c)(3) as (c)(5) and add a new paragraph (c)(3), which expressly states each participant has the right to reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines.

Lastly, we are proposing to add a new paragraph at § 460.112(c)(4) to address a participant's right to receive care across all care settings. A PACE organization is expected to provide for the care that is necessary for each participant and determine the appropriate setting in which to provide that care, up to and including placement in a long term care facility when a participant's condition requires it (see § 460.98(a) and (b)). However, CMS' monitoring and audit activity show that some PACE organizations are not providing long-term care services, even when their IDTs determine a participant can no longer live safely in their home and requires a higher level of care. We have learned that in some cases, affected participants disenroll from PACE in order to receive the long-term care that is needed. One of the purposes of the PACE program is to enable frail, older adults to live in the community as long as medically and socially feasible (see § 460.4(b)(3)). PACE organizations are also responsible for furnishing comprehensive medical, health, and social services that integrate acute and long-term care, and providing services that are accessible and adequate to meet the needs of its participants. (See § 460.98(b) and (d)(2) respectively). Lastly, enrollment in the PACE program continues until the participant's death, regardless of changes in health status, unless the participant voluntarily disenrolls, or is involuntarily disenrolled. (See § 460.160(a)). A PACE organization cannot deny placement in a long-term care facility if the IDT determines the participant requires 24 hour care but the PACE organization does not have a method for providing that care in the home through either its employees or contractors. See the relevant discussion under section VII.E. of this proposed rule regarding providing participants access to services 24 hours a day, every day of the year, across all care settings. In order to provide more specific detail about what this fundamental program requirement entails, we are proposing to add § 460.112(c)(4) which would state that a participant has the right to receive necessary care in all care settings up to and including placement in a long term care facility when the PACE organization can no longer provide the services necessary to maintain the participant safely in the community.

H. Enforcement Action Appeal Rights Under PACE (§ 460.56)

Sections 1894(e)(7) and 1934(e)(7) of the Act specify that, under regulations, the provisions at section 1857(h) of the Act, governing the procedures for termination of a contract with an MA organization, apply to the termination and sanctions of a PACE program agreement and PACE organization in the same manner as they apply to an MA organization under Medicare Advantage. The current enforcement provisions at 42 CFR part 460, subpart D, do not specify a process for appeals related to civil money penalties or intermediate sanctions. However, at § 460.54, the regulations include appeal rights for termination procedures. In the preamble to the 1999 PACE interim final rule, we discuss the requirement in the BBA of 1997 that we take into account some of the requirements established for MA as we develop regulations for PACE organizations in certain areas common to both programs, such as beneficiary protections, payment rates, and sanctions. 64 FR 66236. CMS has interpreted this legal framework as granting the agency the authority to utilize the appeals processes that apply to MA organizations under § 422.756 when imposing a suspension of enrollment or payment, or imposing civil money penalties on PACE organizations. Although it has not been codified in regulation, CMS currently provides PACE organizations with these appeal rights when imposing enforcement actions under §§ 460.42, 460.46, and 460.48(b).

Therefore, in an effort to enhance transparency and ensure that PACE organizations are aware of their right to appeal an enforcement action, we are proposing to add a new § 460.56 in subpart D of the PACE regulations to affirmatively state that a PACE organization may request a hearing according to the procedures at § 422.756 when CMS imposes a sanction or civil money penalty under § 460.42, § 460.46, or § 460.48(b) on PACE organizations.

For suspensions of enrollment or payment listed under §§ 460.42 and 460.48(b), CMS will follow the hearing procedures for imposing intermediate sanctions at § 422.756(b), which includes the right to a hearing before a CMS designated hearing officer under subpart N of part 422. Under the process specified at § 422.756(b), CMS provides organizations with a notice of intent to impose sanctions and their right to a hearing before a CMS hearing officer. Organizations are given 15 days from the date of the notice to request a hearing.

For civil money penalties listed under § 460.46, CMS will follow the procedures for imposition of civil money penalties at § 422.756(e)(2)(v), which includes the right to a hearing before an Administrative Law Judge (ALJ) under subpart T of part 422. In addition, CMS must send a written notice of the agency's decision to impose a civil money penalty, the amount of the penalty, the date the penalty is due, information about the organization's right to a hearing and where to file the request for hearing.

We believe this proposal will ensure PACE organizations understand the process CMS utilizes for imposing these enforcement actions, as well as the PACE organization's right to appeal those actions.

We have not included § 460.48(a) or (c) in the proposed regulation because those provisions refer to the termination of a PACE program agreement, for which procedures are already set forth at § 460.54. However, § 460.48(b) authorizes CMS to withhold payment under the PACE program agreement, which is similar to the suspension of payment provided at § 460.42(b)(1). Therefore, the procedures at § 422.756 would apply, as we are proposing to specify at § 460.56(a).

I. PACE Definitions (§ 460.6)

As discussed briefly at section VII.A. of this proposed rule, we are proposing to modify our existing definition of ''services.'' Currently, the term ''services'' is defined as including items and services. We are proposing a change to use the term ''service'' in § 460.6 to be consistent with the use of the singular in the terms defined under § 460.6. The definition of the singular ''service'' would also apply to the plural ''services.'' In addition, we are proposing to modify our definition of ''service'' to better reflect the full scope of the PACE benefit package by stating that the term ''service'', as used in part 460, means all services that could be required under § 460.92, including items and drugs. In the 1999 PACE interim final rule, we stated that required services included all current Medicare services, all Medicaid-covered services as specified by the state's approved Medicaid plan, and specifically included ''drugs and biologicals'' as a part of a list of minimum benefits PACE organizations were required to provide. (64 FR 66246 and 66301). In the 2006 PACE final rule, we removed the specific listing of all required services because we determined that it was not possible to provide a complete list of all services that must be furnished to participants if ordered by the IDT. (71 FR 71281). Instead, we adopted the language that is currently used in § 460.92 to identify the services required as a part of the PACE benefit package. Since that time, through CMS' monitoring and oversight, we have found that some PACE organizations do not realize that they are responsible for providing the full Medicare benefit, including the provision of Part D drugs. Therefore, we are proposing to make changes by adding ''drugs'' to the definition of services for PACE purposes which is consistent with how we have historically defined the types of services that are required in PACE. We believe this change is necessary to remove potential ambiguity about the meaning of the terms ''service'' or ''services'' when used in the PACE regulations.

VIII. Technical Changes

A. Exclusion of Services Furnished Under a Private Contract (§ 422.220)

CMS proposes to update regulations that pertain to private contracts in order to provide greater clarity as to how such provisions should apply. Currently, section 1802(b)(6)(B) of the Act defines ''physician,'' in respect to private contracts, as a term that is defined by paragraphs (1), (2), (3), and (4) of section 1861(r) of the Act; however, § 422.220 currently defines ''physician,'' in respect to private contracts, using only paragraph (1) of section 1861(r) of the Act—narrowing the regulatory definition to exclude physicians who are not doctors of medicine or osteopathy. To avoid confusion about what kinds of providers the opt-out and private contracting rules apply to, we propose to extend the regulatory definition of ''physician'' to match the statutory definition when the term is used in regard to private contracts. CMS proposes to achieve this by adding references to paragraphs (2), (3) and (4) of section 1861(r) of the Act to the definition of ''physician'' at § 422.220 to make the regulatory provision consistent with the statute.

In addition, CMS proposes to clarify the prohibition at § 422.220 in regard to the types of items and services an opt-out provider may and may not receive payment for from an MA organization. Section 4507 of the BBA of 1997 amended section 1802 of the Act to allow private contracts for Part B services when, among other things, a physician or practitioner (as those terms are defined in section 1802(b)(6)) of the Act signs an affidavit that states the physician or practitioner will not submit any claim for a Medicare-covered item or service except in specified cases of emergency or urgent care, and a copy of the affidavit is filed with the Secretary. When a physician or practitioner chooses to file a signed affidavit as described in section 1802(b) of the Act and enters into a private contract with a Medicare beneficiary for services covered under Part B, the physician or practitioner is considered by CMS to be ''opted out.'' Section 1802 of the Act permits private contracts for Part B services under specific conditions when a physician or practitioner agrees to forego Medicare payment for benefits under Title XVIII, among other requirements (for example, related to information provided to the beneficiary) that are not specifically relevant here. As relevant to the MA program, section 1802(b)(1)(B)(ii) states that an opt-out physician or practitioner must receive ''no amount for such item or service from an organization which receives reimbursement for such item or service under this title directly or on a capitated basis.'' The Medicare statute, specifically sections 1853 and 1854 of the Act, provide for *capitation payments* to MA organizations for items and services that are covered under Parts A and B (excluding hospice; beginning January 1, 2021, kidney acquisition costs for kidney transplants; and when there is a national coverage determination or legislative change in Medicare benefits). We believe that payments for supplemental benefits are outside the scope of the statutory restriction on payments to opt-out providers. This is also consistent with how § 405.455 limits the consequences of the opt-out to ''Medicare covered services,'' which means items, services and drugs covered by Part A, Part B or Part D. Section 40.19, Chapter 15 of the Medicare Benefit Policy Manual reiterates that the rules for private contracts do not pertain to items and services ''categorically not covered'' under Medicare. Further, in the final rule published June 29, 2000 (65 FR 40170) that adopted § 422.220, we explained that a Medigap policy may cover—and pay—for items and services furnished by an opted-out provider when the benefits are not covered by Medicare regardless of the opt-out. (65 FR 40262). By amending § 422.220 to exclude supplemental benefits—which may only be benefits that are not otherwise covered by Medicare—from the prohibition on payment to opted-out providers, we would be bringing the MA regulation into alignment with the policy in the FFS program.

Thus, CMS proposes amending § 422.220 to clarify that the restrictions on payments to opt-out providers apply only to payments for basic benefits (that is, items and services covered under Parts A and B). As the term ''basic benefits'' is defined in § 422.100(c) and used throughout Part 422 regulations governing the MA program to refer to these Medicare benefits, we use that term here and in our proposed amendments to § 422.220. We also propose to specify in these amendments that MA organizations may make payments to opt-out providers for supplemental benefits.

To ensure that the regulation is clear, we are also proposing some restructuring of the regulation so that paragraph (a) states the prohibition on payment while paragraphs (b) and (c) direct when an MA organization must or may nonetheless pay an opt-out provider. As proposed, paragraph (a) largely parrots the existing regulation text but limits the prohibition on payment to basic benefits and has new text to explain how paragraphs (b) and (c) are the exceptions to the prohibition. We propose to designate the last sentence of the current regulation, which requires an MA organization to pay for emergency or urgently needed services furnished by an opted-out physician or practitioner who has not signed a private contract with the beneficiary, as paragraph (b); our

proposal includes some minor technical revisions to the sentence. We also propose a new paragraph (c) to state that an MA organization may make payment to an opted-out physician or practitioner that are not basic benefits, but are provided to a beneficiary as a supplemental benefit. We use the terms ''basic benefits'' and ''supplemental benefits'' in our proposal consistent with how those terms are used in §§ 422.100(c) and 422.102 and with our proposals in sections II.A. and VI.F. of this proposed rule.

B. Disclosure Requirements (§ 422.111)

On April 15, 2011, CMS amended § 422.111(b)(12) to state that CMS may require an MA organization to furnish directly to enrollees, in a manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under Part 422. While the text of paragraph (b)(12) accurately reflects the intent of the proposal, its placement is inconsistent with the type of information paragraph (b) requires for disclosure; paragraph (b) pertains to generalized information about a plan, and generally specifies what information must be included in a plan description that is provided on an annual basis. The claims information that must be disclosed under paragraph (b)(12) is specific and unique to an individual enrollee and does not describe the plan's design and benefits. Therefore, we do not believe it is appropriate to list this notice as part of § 422.111(b) and are proposing to redesignate this requirement to paragraph (k) with changes to codify existing guidance on the scope and content of the EOB. Under our proposal, the substance of current paragraph (b)(12) is moved to paragraph (k), with a minor change to delete the phrase ''CMS may require'' and to add the word ''must'' after ''MA organization'' to clarify that the notices are required.

Currently, MA organizations are required to disclose claims data such as the amount a provider billed a plan and the corresponding billing code(s) used, the total cost approved by the plan, the plan's share of the total cost, and the enrollee's share of total cost. MA organizations are required to disclose specific claims data to their enrollees on a monthly or quarterly cycle, in an EOB. The MA organization must include all Part C claims processed during the reporting period, including all claims for Part A and Part B covered items and services, mandatory supplemental benefits, and optional supplemental benefits. CMS proposes to codify these existing requirements at § 422.111(k)(1), including that the disclosed data include the following for each claim: Descriptor, billing code and amount billed; total cost approved for reimbursement; share of the total cost paid by the plan; and the share of the total cost for which the enrollee is liable.

In addition, the current guidance provides that the claims data elements must include year-to-date information. For each reporting period, EOBs must contain cumulative, year-to-date totals for the amount providers have billed the plan, the total costs that have been approved by the plan, the plan's share of the total costs, and the enrollee's share of the total costs. We are proposing to codify this guidance in paragraph (k)(2) by requiring the EOB to include specific year-to-date totals as follows: (i) The cumulative amount billed by all providers; (ii) The cumulative total costs approved by the plan; (iii) The cumulative share of total cost paid for by the plan; (iv) The cumulative share of total cost for which the enrollee is liable; (v) The amount an enrollee has incurred toward the MOOP limit, as applicable; and (vi) The amount an enrollee has incurred toward the deductible, as applicable.

In addition to EOB claims data elements, we are also proposing to codify existing requirements concerning additional information at § 422.111(k)(3). Currently, an MA organization must also include in the EOB (i) clear contact information for enrollee customer service; (ii) instructions on how to report fraud; and (iii) for any EOB that includes 1 or more denied claims, the EOB must include, in the same correspondence, a clear identification of the claim(s) denied as well as information about the denial and the enrollee's appeal rights. We note that the requirement to inform an enrollee of a claims denial at the time the EOB is issued is not a substitute for the denial notices required under the appeal regulations in subpart M.

CMS also proposes to codify the existing issuance cycles for which an MA organization must send EOBs. Currently, MA organizations choose to either send EOBs on a monthly basis or quarterly basis with per-claim notification. MA organizations that send EOBs monthly must send them before the end of each month that follows the month a claim was filed. For example, an MA organization must send a monthly EOB for a claim filed on June 1, 2019 no later than July 31, 2019. A per-claim notice must be sent on the same cycle as a monthly EOB, which is before the end of each month that follows the month a claim was filed; MA organizations that choose to send per-claim notices must also send quarterly summary EOBs. MA organizations that choose to send EOBs on a quarterly basis must send an EOB no later than the end of each month following the quarter a claim was filed. A per-claim notice is not a substitute for the quarterly EOB. CMS proposes to codify these existing requirements at paragraph (k)(4).

C. Special Requirements During a Disaster or Emergency (§ 422.100)

Section 422.100(m)(5)(iii) currently states, ''Provide the information described in paragraphs (m)(1), (2), (3), and (4)(i) of this section on its website.'' However, § 422.100(m) does not have a paragraph (m)(4)(i). In the Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs proposed rule (79 FR 1918) and the Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs final rule (80 FR 7912), we explained that this requirement was to post the disaster and emergency policies in order to facilitate enrollee access to needed services while normal care delivery is unavailable, which would enable enrollees and providers to know the payment policies for out-of-network services provided during disasters. Paragraph (m)(5)(i) describes the terms and conditions of payment during the public health emergency or disaster for non-contracted providers furnishing benefits to plan enrollees residing in the state-of-disaster area, and is clearly the information we intended to be posted by the MA organization. Therefore, we are proposing to amend § 422.100(m)(5)(iii) to correct the cross-reference from paragraph (m)(4)(i) to paragraph (m)(5)(i). In addition, the regulation text uses the term ''website'' but the non-hyphenated non-capitalized term ''website'' is now commonly used and more consistent with other regulations in part 422. We are proposing to update the regulation text to use ''website'' as well.

D. Effective Date for Exclusion of Coverage for Kidney Acquisitions From Basic Benefits (§ 422.100)

Section 1852(a)(1)(B)(i) of the Act defines the term ''benefits under the original Medicare Fee-for-Service program option'' for purposes of the requirement in subparagraph (a)(1)(A) that each MA organization provide enrollees such benefits. Section 17006(c)(1) of the Cures Act amended

section 1852(a)(1)(B)(i) of the Act by inserting ''or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)'' after ''hospice care.'' Per section 17006(c)(3) of the Cures Act, this amendment applies with respect to plan years beginning on or after January 1, 2021. Thus, effective January 1, 2021, MA plans will no longer cover organ acquisitions for kidney transplants.

In the April 2019 final rule, we amended the definition of ''basic benefits'' at § 422.100(c)(1) to include ''additional telehealth benefits,'' and in doing so, we also amended § 422.100(c)(1) to note the new exclusion of coverage for organ acquisitions for kidney transplants (in addition to the existing exclusion for hospice care). However, we inadvertently omitted the identification of the 2021 effective date for this change set forth in the Cures Act.

We are proposing a technical correction that would add the 2021 effective date to § 422.100(c)(1) for the exclusion of original Medicare coverage for organ acquisitions for kidney transplants. Specifically, we propose to correct the phrase ''(other than hospice care or coverage for organ acquisitions for kidney transplants)'' to read: ''(other than hospice care or, beginning in 2021, coverage for organ acquisitions for kidney transplants).'' This provision is technical and is therefore not expected to have economic impact beyond current operating expenses.

E. Add Back Cost Plan Related Sections From Previous Final Regulation (§ 422.503)

In the Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Final Rule (hereinafter referred to as the May 2014 final rule), we finalized regulations affecting the cost plan non-renewal-related requirements (79 FR 29959). The final regulation inadvertently identified the non-renewal section as § 422.503(b)(4)(vi)(G)(*5*)(*i*) and (*ii*) when instead the revisions should have been specified as revising § 422.503(b)(5)(i) and (ii). Although the regulatory text for the provision was published in the May 2014 final rule, it was not correctly codified in the CFR. In this rule, we propose to designate the provision in the correct paragraph of § 422.503. For additional discussion of this provision, including public comments on the proposal, see the May 2014 final rule.

This section provides that an entity seeking to offer an MA organization may not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan. We are proposing to codify a policy adopted in the May 2014 final rule (79 FR 29850 through 29851 and 29959). In new § 422.503(b)(5)(i), we specify that an entity seeking to contract as an MA organization must not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan. In new § 422.503(b)(5)(ii), we specify that an entity seeking to offer an MA organization must not accept, or be either the parent organization owning a controlling interest of or subsidiary of, an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan. We are also proposing minor technical corrections to the regulation text described in the May 2014 final rule to improve the flow of the regulation text.

F. Definition of ''Institutionalized'' for Institutional Special Needs Plans (I–SNPs) (§ 422.2)

Section 1859(b)(6)(B)(i) of the Act permits the Secretary to define the term ''institutionalized'' for the purposes of establishing eligibility criteria for Medicare Advantage (MA) special needs plans for individuals who are institutionalized (I–SNPs). In addition, section 1851(e)(2)(D) of the Act permits the Secretary to define the term for purposes of eligibility for a continuous open enrollment person to enroll or change enrollment in an MA plan, except for MA MSA plans. As currently defined in § 422.2, ''institutionalized'' means an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in a long-term care (LTC) facility which is a skilled nursing facility (SNF) nursing facility (NF); SNF/NF; an intermediate care facility for individuals with intellectual disabilities (ICF/IID); or an inpatient psychiatric facility. CMS codified this definition of institutionalized at § 422.2 in the January 2005 final rule) (70 FR 4588). In combination with the definition of ''special needs individual'' (also in § 422.2) and the eligibility requirements in § 422.52, this definition restricts enrollment by MA eligible individuals into I–SNPs, which are one of three specific coordinated care plans (CCPs) for special needs individuals authorized by section 1859 of the Act. CMS also uses this definition to establish a special election period (SEP) for institutionalized individuals. Under § 422.62(a)(4), an individual who is eligible to elect an MA plan and who is institutionalized, as defined in § 422.2, is not limited, except as provided in § 422.62(d) for MA MSA plans, in the number of enrollment elections or changes the individual may make.

As currently defined under § 422.2, the definition of institutionalized is limited in scope, given the array of institution types that exist today. We are proposing to revise the current regulatory definition of the term for purposes of defining a special needs individual and eligibility for the continuous open enrollment period to take into account current guidance and to provide additional flexibility to account for changes in the types of institutions that could potentially be used for I–SNPs that are not covered by the current definition of institutionalized. The current sub-regulatory definition for an institutionalized individual is broader than the regulatory definition and includes three additional institution types, which has led to some confusion among MA organizations seeking to offer I–SNPs. We are proposing to expand the definition of ''institutionalized'' in § 422.2 to reflect the evolution of institutions over time and the current landscape of institutional health care today. We are proposing to amend the definition of institutionalized, as defined in § 422.2, to incorporate additional types of long-stay institutions. Our proposed change would align the regulatory text with existing operational practice and current guidance, clarify our policy for MA organizations, and promote the expansion of I–SNP offerings under the MA program.

The current definition of institutionalized in § 422.2 is based on a list of five institutional settings. While chapter 16b of the Medicare Managed Care Manual (MMCM) also lists the same five types of institutions, it also refers to the MA Enrollment and Disenrollment Guidance, which lists seven institutional categories. The list in the MA Enrollment and Disenrollment Guidance is based on institutions that are identified in some way in Titles XVIII or XIX of the Act in connection with the Medicare and Medicaid programs. As defined in the MA Enrollment and Disenrollment Guidance, an institutionalized individual is an individual who resides in an institution of the following settings:

- SNF as defined in section 1819(a) of the Act;
- NF as defined in section 1919(a) of the Act;

• Intermediate care facility for the mentally retarded (ICF/MR) as defined in section 1905(d) of the Act (now generally referred to as an intermediate care facility for the intellectually and developmentally disabled);
• Psychiatric hospital as defined in section 1861(f) of the Act;
• Rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act;
• LTC hospital as defined in section 1886(d)(1)(B) of the Act; or
• Hospital which has an agreement under section 1883 of the Act (a swing-bed hospital). We propose to codify this list of seven institutions in the definition of institutionalized such that an individual who continuously resides in or is expected to continuously reside in one of these institutions for 90 days or longer meets the definition.

We are also proposing to create criteria that would accommodate changes in forms of institutional care within American healthcare without sacrificing regulatory and statutory provisions surrounding I–SNPs. Specifically, we are proposing that the definition of institutionalized include, subject to CMS approval, an additional facility that is not listed previously but (i) furnishes similar long-term, healthcare services that are covered under Medicare Part A or Part B or Medicaid and (ii) whose residents have similar needs and healthcare status as residents of one or more facilities previously listed. Therefore, under this proposal, CMS could permit an MA organization to offer an I–SNP to serve beneficiaries that continuously reside in facilities that meet this new standard but are not listed in the definition, provided the plan meets the remaining criteria for I–SNPs.

We are proposing to amend the definition of institutionalized at § 422.2 to incorporate the list of institutions from the MA Enrollment and Disenrollment Guidance and to adopt a standard for the identification of additional institutions. We believe these proposed changes will provide greater clarity in terms of institutional status and beneficiary eligibility to enroll in an I–SNP. The current regulatory definition of institutionalized lacks critical statutory criteria establishing I–SNP enrollment qualifications and institutional status. In addition, our proposal broadens the definition of institutionalized to include rehabilitation hospitals, LTC hospitals, and swing-bed hospitals. The extension of the definition to these other institution types will increase enrollee choice regarding MA plan options that deliver specialized services to residents of qualifying institutions. Further, making the special enrollment period described in § 422.62(a)(4) available to residents of these facilities reduces confusion among stakeholders and eligible beneficiaries by aligning the SEP and I–SNP eligibility policies.

We seek comment on our proposed amendment to the definition of institutionalized at § 422.2 and specifically on the expansion of the definition to include rehabilitation hospitals, LTC hospitals, swing-bed hospitals, and for other institutions meeting the proposed standard. We also solicit comment on whether our proposed standard should use additional criteria. We acknowledge that this proposed definition does not align with § 423.772, which defines ''institutionalized individual'' as a full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act. When we published the January 2005 final rule, we noted that provision was an income and resource-based definition for the purpose of determining Part D premiums and cost sharing subsidies for low-income individuals. The term ''institutionalized'' as defined in § 422.4 is used for purposes of identifying a vulnerable population of individuals who reside in certain institutions and might benefit from enrollment into an I–SNP. In proposing a redefinition of ''institutionalized'' at § 422.2, we continue our position that § 423.772 serves a different purpose, unrelated to defining an institutionalized special needs individual who is eligible for I–SNP enrollment or for the special enrollment period for such individuals. We believe that the most immediate impact of this definitional change will be on I–SNP options, and that this change will help provide further clarity for stakeholders regarding the applicability of the definition as part of the criteria for establishing I–SNP beneficiary eligibility as it pertains to the authority under section 1859(b)(6)(B)(i) of the Act.

In addition to institution-based enrollment, I–SNPs may also enroll MA eligible individuals living in the community, but requiring an institutional level of care. These types of I–SNPs are known as Institutional Equivalent SNPs. When an I–SNP opts to enroll individuals prior to having at least 90 days of institutional level care, a CMS-approved needs assessment must be conducted. Results of the assessment must demonstrate that the individual's condition makes it likely that either the length of stay or the need for an institutional level of care will be at least 90 days. We are not proposing to amend the definition of ''institutionalized-equivalent'' in § 422.2 because it is not impacted the by our proposed amendment to the definition of ''institutionalized'' under § 422.2.

We are not scoring this provision in the Regulatory Impact Analysis section because it codifies and reconciles existing guidance and practice for the uses of the term ''institutionalized'' in part 422. We believe that there is no impact on stakeholders following the current guidance. We are also not scoring this provision in the Collection of Information section since we believe all information impacts of this provision have already been accounted for under OMB control number 0938–1296 (CMS–10565), but seek comment on this assumption.

We seek comment on the proposed amendment to the definition of institutionalized under § 422.2 and the potential impact the proposal would have on MA organizations offering I–SNPs, enrollees, and providers.

G. Medicare Electronic Complaint Form (§§ 422.504 and 423.505)

On April 15, 2011, CMS amended §§ 422.504 and 423.505 to add a new §§ 422.504(a)(15) and 423.505(b)(22) requiring MA and Part D plans to address and resolve complaints received through CMS' complaint tracking system and to provide a direct link on their main web page to the *Medicare.gov* electronic complaint form. We are proposing to modify §§ 422.504(a)(15) and 423.505(b)(22) by moving §§ 422.504(a)(15)(ii) and 423.505(b)(22)(ii) to subpart V, Communication requirements. Sections 422.111(h)(2) and 423.128(d)(2) require MA and Part D plans to maintain a website. In section VI.H. of this proposed rule, we are proposing to add a new §§ 422.2265 and 423.2265, which provides requirements for MA and Part D plan websites. Specifically, in §§ 422.2265(b) and 423.2265(b), we are proposing to identify the required content for websites, including a link to the *Medicare.gov* electronic complaint form. We believe the requirement for a direct link is more appropriate in CMS' website requirements rather than in §§ 422.504(a)(15) and 423.505(b)(22).

We are not proposing any substantive changes to §§ 422.504(a)(15) and 423.505(b)(22) other than minor changes in the text to make it clear that plans must use the CMS complaint tracking system to address and resolve complaints received by CMS against the plan. In connection with removing

§§ 422.504(a)(15)(ii) and 423.505(b)(22)(ii), we propose to redesignate the substance §§ 422.504(a)(15)(i) and 423.505(b)(22)(i) as §§ 422.504(a)(15) and 423.505(b)(22).

H. Advance Notice and Announcement of Part D Risk Adjustment Factors (§ 423.329)

The MMA, enacted on December 8, 2003, added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 42 of the Act) establishing the Medicare Prescription Drug Benefit Program. The final provisions implementing the MMA for the MA and Part D programs appeared in the January 2005 final rule (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively). The MMA directed that important aspects of the Part D program be similar to, and coordinated with law for, the MA program.

As is done in Part C, CMS uses risk adjustment factors to adjust a Part D plan's standardized bid amount. Risk adjustment accounts for the variation in plan liability for prescription drug costs that result from the demographics and health status of a plan's enrollees. In so doing, payments to plans reflect the beneficiaries they serve. The Part D statute, and the regulations implementing the statute, specify that CMS must publish the Part D risk adjustment factors at the time of publication of the Part C risk adjustment factors (section 1860D–15(c)(1)(D) of the Act and § 423.329(b)(4)). Part C risk adjustment factors are published through the Advance Notice and Rate Announcement process. By statute, the Part C factors are to be announced no later than the first Monday in April before the calendar year they will be in use (section 1853(b)(1)(B) of the Act and § 422.312(a)(1)(ii)). In addition, the statute requires CMS to give MA organizations advanced notice of proposed changes in methodology no later than 60 days prior to publishing the Rate Announcement, with a 30-day comment period.

In the vein of the MMA, which directed that important aspects of the Part D program be similar to, and coordinated with law for, the MA program, CMS interpreted section 1860D–15(c)(1)(D) of the Act to mean that Part D risk adjustment factors should be published as part of the Advance Notice and Rate Announcement process used for Part C. Since the inception of the Part D program in 2006, CMS has consistently proposed and finalized the Part D risk adjustment factors via the Advance Notice and Rate Announcement, respectively. The existing regulation codifying section 1860D–15(c)(1)(D) of the Act mirrors the statutory language of publishing Part D risk adjustment at the time of Part C risk adjustment factor publication but does not specify the means by which CMS will do so. The proposed amendment revises the regulation text to clarify our interpretation of the statute under which we will continue to publish Part D risk adjustment factors through the Advance Notice and Rate Announcement process. Specifically, we propose to amend the requirements at § 423.329(b)(4) by revising the paragraph to stipulate our intention to publish Part D risk adjustment factors using the process through which CMS proposes, adopts, and announces the capitation rates and risk adjustment methodology for the MA program. This provision codifies the current interpretation of the statutory requirement and will not change how we propose and finalize the Part D risk adjustment model. Therefore, it is not expected to have economic impact beyond current operating expenses. We are not scoring this provision in the Regulatory Impact Analysis section since it codifies statutory provisions that are followed in practice by the agency.

I. Advance Notice and Announcement of Part C Annual Capitation Rate, Benchmarks, and Methodology Changes (§ 422.312)

When enacted by the BBA of 1997, section 1853(b) of the Act mandated that the Secretary annually determine and announce capitation rates and the risk and other factors to be used in adjusting such rates for payment to Medicare Advantage (MA) organizations (then referred to as Medicare+Choice organizations). Section 1853(b) of the Act specifies the process through which CMS proposes, adopts, and announces changes in risk adjustment methodology and capitation rates for the MA program. Paragraph (b)(2) requires that CMS provide notice and an opportunity to submit comment on proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement. Paragraph (b)(1) provides for a final notice in which the rates and the risk and other factors used in adjusting payment will be published.

When first written, section 1853(b)(2) of the Act called for a 45 day advance notice period for the annual capitation rate and factors (for example, risk) used to adjust those rates and did not explicitly address a minimum comment period. However, beginning in 2017, amendments to section 1853(b) of the Act by the Securing Fairness in Regulatory Timing Act of 2015 (SFRTA) require a 60-day advance notice period and a 30-day comment period. The regulation implementing the advance notice and comment period, as currently written, mirrors the statute's original timeframe for issuance of the advance notice and requires only a 15-day comment period, which we adopted in the June 26, 1998, Medicare Program; Establishment of the Medicare+Choice Program Interim Final Rule with comment period (63 FR 34968, 35093) to adopt the initial implementing regulations for the MA program. While we adjusted our operational practice to comply with current statutory requirements, we did not update the CFR provision. The proposed revision will align the timeframes identified in § 422.312(b)(1) and (2) with the current statutory text. Specifically, we propose to revise the advance notice of changes in methodology requirements at § 422.312(b)(1) and (2) by revising paragraph (b)(1) to say 60 days and paragraph (b)(2) to say 30 days. We are not scoring this provision in the Regulatory Impact Analysis section since it codifies statutory provisions that are followed in practice by the agency.

J. General Requirements for Applicable Integrated Plans and Continuation of Benefits (§§ 422.629 and 422.632)

We propose to make technical changes to § 422.629(k)(4)(ii) to correct four technical errors from the April 2019 final rule. This paragraph references Medicare coverage criteria, however Medicaid coverage criteria are also applicable during the unified appeals process described in this section. Therefore, we are proposing to add the phrase ''and Medicaid'' following ''knowledge of Medicare'' in § 422.629(k)(4)(ii).

Also in paragraph (k)(4)(ii) of this section, there is an incorrect reference to the MA organization. We are proposing to replace ''MA organization'' with the correct term, ''applicable integrated plan''. We also propose adding the word ''integrated'' before ''organization determination decision'' to conform to the terminology used elsewhere in § 422.629(k). Lastly, we are also proposing to remove the comma between the words ''expertise'' and ''in'' in the regulation text to clarify that the required expertise is in the topics identified in the text.

In § 422.632(b)(1), we propose to change the citation from § 422.633(e) to (d). Section 422.632(b)(1) reflects the requirement that the enrollee file a

request for an integrated appeal in a timely manner, with a cross reference to the regulation that sets the timeframe for such appeals. Paragraph (d) of § 422.633 sets that timeframe while paragraph (e) addresses the requirements for expedited integrated reconsiderations. We are therefore proposing to amend § 422.632(b)(1) to use the correct cross-reference.

K. Representatives in Part D Appeals (§§ 423.560, 423.566, 423.578, 423.2014, and 423.2036)

The regulations for Medicare fee-for-service (Part A and Part B) claims and entitlement appeals at part 405, subpart I, reference two types of representatives—authorized and appointed. Section 405.902 defines an authorized representative as an individual authorized under state or other applicable law to act on behalf of a beneficiary or other party involved in an appeal, and separately defines an appointed representative as an individual appointed by a party to represent the party in a Medicare claim or claim appeal. The term ''representative'' is used throughout part 405, subpart I, to refer to either an authorized or appointed representative, except in some instances the regulations deal exclusively with appointed representatives. See, for example, §§ 405.910 and 405.1112(c).

Similarly, for appeals of Medicare Part C organization determinations, § 422.561 defines ''representative'' as an individual appointed by an enrollee or other party, or authorized under state or other applicable law, to act on behalf of an enrollee or other party involved in the grievance or appeal. The term ''representative'' is then used throughout part 422, subpart M, to refer to either an authorized or appointed representative.

For appeals of Medicare Part D coverage determinations, however, § 423.560 defines ''appointed representative'' as meaning either an individual appointed by an enrollee or authorized under state or other applicable law to act on behalf of the enrollee. The term ''appointed representative'' is then used throughout part 423, subparts M and U, to refer to either an appointed representative or an authorized representative. We believe that including authorized representatives in the definition of appointed representatives for Part D appeals is confusing since the terms represent two distinct types of representation and are treated separately in part 405, subpart I, and part 422, subpart M.

Accordingly, we are proposing to replace the definition of ''appointed representative'' in § 423.560 with a definition of ''representative.'' Although the term being defined would change, we are proposing no other changes to the definition. To be consistent with this proposed change, we are also proposing to replace references to appointed representatives in §§ 423.566(c)(2), 423.578(b)(4), 423.2014(a)(1)(ii), and 423.2036(c) and (d) with references to representatives. These proposed changes establish consistency in use of the term ''representative'' across Medicare programs. These provisions codify existing guidance and therefore are not expected to have economic impact beyond current operating expenses. We welcome comments on these proposed changes.

L. Copayments and Coinsurance in Amount in Controversy Calculations (§§ 422.600 and 423.2006)

Section 1869(b)(1)(E) of the Act, as amended by section 521 of BIPA, established the amount in controversy (AIC) threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review at $100 and $1,000, respectively, for Medicare Part A and Part B appeals. Section 940 of the MMA amended section 1869(b)(1)(E) of the Act to require the AIC threshold amounts for ALJ hearings and judicial review to be adjusted annually. Section 940(b)(2) of the MMA provided conforming amendments to apply the AIC adjustment requirement to the amount in controversy thresholds applicable to appeals for Medicare Part C/Medicare Advantage (MA) plans and health maintenance organization and competitive health plans offered pursuant to section 1876 of the Act. Under § 405.840, health care prepayment plans offered pursuant to section 1833 of the Act are also subject to MA appeals rules, including the AIC adjustment requirement. Section 101 of the MMA provides for the application of the AIC adjustment requirement to Medicare Part D appeals.

The regulations at part 405, subpart I, specifically § 405.1006(d), provide the methodology for calculating the AIC in Medicare fee-for-service (Part A and Part B) claims and entitlement appeals. In general, and subject to the exceptions listed in §§ 405.1006(d)(2) through (6), § 405.1006(d)(1) provides that the AIC is computed as the amount that the provider or supplier bills (''the actual amount charged the individual'') for the items and services in the disputed claim, reduced by any Medicare payments already made or awarded for the items or services, and further reduced by ''any deductible and/or coinsurance amounts that may be collected for the items or services.''

For Medicare Part C appeals under part 422, subpart M, § 422.600(b) provides that the AIC is computed in accordance with the part 405 rules (concerning appeals of initial determinations under original (fee-for-service) Medicare). However, while original Medicare uses deductibles and coinsurance (where the beneficiary pays a percentage of the cost for an item or service) as forms of cost sharing, MA plans may also use copayments (where the enrollee pays a flat fee for an item or service) as a form of cost sharing. Because § 405.1006(d)(1) provides that the AIC excludes ''any deductibles and/or coinsurance amounts that may be collected for the items or services,'' questions have arisen regarding whether it is also appropriate to exclude any copayment amounts that may be collected for the items or services when applying the part 405 rules to appeals of Part C organization determinations made under part 422, subpart M. To resolve the ambiguity and help ensure that the AIC in Part C appeals is reflective of the actual amount at issue for the enrollee, we are proposing to revise § 422.600(b) to clarify that the AIC, which can include any combination of Part A and Part B services, is computed in accordance with part 405, and that any references to coinsurance in the part 405 regulations for computing the AIC should be read to include both coinsurance and copayment amounts.

We are also proposing a revision to the regulations for appeals of Part D plan sponsor coverage determination and at-risk determinations made under part 423, subpart M. The AIC for these appeals is addressed in § 423.2006, which does not reference cost-sharing amounts. Instead, current sub-regulatory guidance states that applicable deductible or coinsurance amounts are excluded from the AIC calculation in Part C and D appeals. *See* Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (Parts C and D Appeals Guidance), section 70.2 (*https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf*). To clarify the AIC calculation for Part D appeals and help ensure that the AIC in Part D appeals is reflective of the actual amount at issue for the enrollee, we are proposing to revise § 423.2006 to reflect the AIC calculation provisions currently

set forth in the Parts C and D Appeals Guidance, further revised to exclude all cost-sharing amounts, including copayments. Specifically, we are proposing to redesignate paragraphs § 423.2006(c)(1) and (2) to (2) and (3), and amend (c)(1) to provide general AIC calculation provisions for Part D appeals, modeled after those in § 405.1006. This section will also provide that the AIC calculation is reduced by any cost-sharing amounts, including deductible, coinsurance, or copayment amounts, that may be collected from the enrollee for the Part D drug(s). This provision codifies existing guidance and is therefore not expected to have economic impact beyond current operating expenses.

M. Stipulated Decisions in Part C (§ 422.562)

The regulations for Medicare fee-for-service (FFS) (Part A and Part B) claims and entitlement appeals at part 405, subpart I provide for stipulated decisions at § 405.1038(c). This provision permits Office of Medicare Hearings and Appeals (OMHA) adjudicators to issue abbreviated, stipulated decisions if CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or payment may be made.[99] In this situation, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on the basis of the written or oral statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

The MA appeal regulations at § 422.562(d) provides-that the FFS appeals procedures in part 405, subpart I apply to appeals of Part C organization determinations to the extent they are appropriate and identifies specific part 405 regulations that are not appropriate to apply to MA appeals. Because MA organizations are not generally included within the definition of ''contractors'' in § 405.902, we are concerned it is not clear that § 405.1038(c) extends to stipulations made by MA organizations in Part C cases. The parallel Part D regulations for stipulated decisions at § 423.2038(c) specifically apply to stipulations made by Part D plan sponsors.

For consistency with the Part D regulations (which allow stipulations to be made by Part D plan sponsors under § 423.2038(c)), and to afford OMHA adjudicators the same flexibilities in Part C cases where the MA organization that issued the organization determination and plan reconsideration no longer disputes that an item or service should be covered or that payment should be made, we are proposing to revise § 422.562 by adding new paragraph (d)(3) to clarify that, for the sole purpose of applying the regulations at § 405.1038(c) to Part C appeals under part 422, subpart M, an MA organization is included in the § 405.902 definition of ''contractors'' as that definition relates to stipulated decisions issued by ALJs and attorney adjudicators. We believe this proposed clarification would permit OMHA adjudicators to more efficiently issue decisions where there is no longer any material issue in dispute, which would ultimately benefit MA enrollees because these decisions could potentially be issued, and effectuated by the MA organization, sooner. We solicit comment whether our proposed revision to add § 422.562(d)(3) this way raises unintended consequences for how the part 405 appeal rules apply to reviews at the ALJ of Part C appeals.

N. Beneficiaries With Sickle Cell Disease (SCD) (§ 423.100)

Section 1860D–4(c)(5)(C)(ii) of the Act contains exemptions from DMPs for certain beneficiaries. These exemptions are for an individual who receives hospice care, or is a resident of a long-term care facility for which FADs are dispensed for residents through a contract with a single pharmacy. We codified these exemptions contained in the definition of ''exempted individual'' in § 423.100. In addition, section 1860D–4(c)(5)(C)(ii)(III) of the Act provides the Secretary with the authority to elect to treat other beneficiaries as an exempted individual. Consistent with this authority and current clinical literature, CMS is proposing to add to the categories of exempted beneficiaries in § 423.100 those beneficiaries with SCD.

A recent analysis[100] by the Centers for Medicare & Medicaid Services Office of Minority Health identified 11,790 Medicare FFS beneficiaries in 2016 with SCD. The prevalence rate of SCD in the United States among the Medicare FFS population is 0.20 per 1,000 beneficiaries, of whom 72.6 percent were dually eligible for both Medicare and Medicaid. In April 2019, the CDC released guidance[101] that advised against the misapplication of the Guideline for Prescribing Opioids for Chronic Pain. Cited examples of misapplication included applying the Guideline to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain. Based on these clinical guidelines and information, CMS recognizes the unique clinical nature of SCD, and as such believes that beneficiaries with this diagnosis should be exempted from DMPs given the: (1) Clinical nature of the disease; (2) unique presentation of SCD crises; (3) limited evidence to guide opioid administration in SCD; (4) limited knowledge of SCD among providers;[102] and (5) lack of other available therapies or modalities for treatment.

O. Drug Management Programs (DMPs): Additional Requirements (§ 423.153)

In an attempt to improve the clarity of the DMP regulations, CMS proposes the following wording and reference changes:

In the current DMP regulations, § 423.153(f)(3) states the types of coverage limitations on FADs that a Part D sponsor may implement and § 423.153(f)(3)(ii) specifically pertains to limitations to selected prescribers and pharmacies. Section 423.153(f)(9) through (13) pertain to the prescriber and pharmacy selection process. However, § 423.153(f)(3)(ii) references only paragraphs (f)(10) and (11). For completeness, we propose making a change to § 423.153(f)(3)(ii) so that it additionally references paragraphs (f)(9), (12), and (13). This provision is technical and is therefore not expected to have economic impact beyond current operating expenses.

In the current DMP regulations at § 423.153(f)(4), the regulation contains two inaccurate cross references. At § 423.153(f)(4)(ii)(A), a prescriber limitation is listed as existing in paragraph (f)(2)(ii)(B) of this section. This paragraph does not exist. Therefore, we are proposing to correct this reference to the intended paragraph: (f)(3)(ii)(A). In the same § 423.153(f)(4)(ii)(A), a reference to the section on eliciting information from

[99] For appeals in which the amount of payment is an issue before the ALJ or attorney adjudicator, § 405.1038(c) further provides that the written or oral statement must agree to the amount of payment the parties believe should be made.

[100] Wilson-Frederick SM, Hulihan M, Blaz J, et al. Prevalence of Sickle Cell Disease among Medicare Fee-for-Service Beneficiaries. CMS Office of Minority Health Data Highlight, No. 15. Baltimore, MD. 2019. Available from: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-15-Sickle-Cell-Disease.pdf.*

[101] Dowell D, Haegerich T, Chou R. N Engl J Med. 2019 Jun 13;380(24):2285–2287. doi: 10.1056/NEJMp1904190. Epub 2019 Apr 24. No abstract available. PMID:31018066. Available from: *https://www.nejm.org/doi/full/10.1056/NEJMp1904190.*

[102] *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Opioid-Prescription-in-Medicare-Beneficiaries-Report.pdf.*

prescriber lists paragraph (f)(4)(i)(B). CMS proposes correcting this reference to the intended paragraph, (f)(2)(i)(B). This provision is technical and is therefore not expected to have economic impact beyond current operating expenses.

Section 423.153(f)(8) addresses the timing and exceptions relevant to the beneficiary notice requirements. It provides that the second notice or alternate second notice must be provided on a date that is not less than 30 days, but does not clearly specify that this date is to be measured from the date of the initial notice. We propose to add this clarifying language to the paragraph. This provision is technical and is therefore not expected to have economic impact beyond current operating expenses.

In addition, § 423.153(f)(8) provides that the second notice or alternate second notice must be provided on a date that is not more than the earlier of two dates: (1) The date the sponsor makes the determination; or (2) 60 days after the date of the initial notice. No regulatory text is missing; however, we propose to structure the text to make it more readable and understandable.

The current DMP regulations on data disclosure at § 423.153(f)(15) are the basis for Part D sponsors' reports to OMS and MARx. Section 423.153(f)(15)(ii)(C) requires Part D sponsors to provide information to CMS about any potential at-risk beneficiary that meets paragraph (2) of the definition in § 423.100 that a sponsor identifies within 30 days from the date of the most recent CMS report identifying PARBs. A PARB meeting this definition refers to a beneficiary about whom a new plan sponsor receives notice upon the beneficiary's enrollment through the MARx system that the beneficiary was identified as potentially at-risk by the immediately prior plan sponsor under its DMP, but a coverage limitation on FADs had not yet been implemented by the prior plan before the beneficiary disenrolled.

As we explained in the applicable proposed and final rules,[103] in line with statutory requirements and previous opioid policy, we intended to also apply this requirement to at-risk beneficiaries (ARBs) who change plans. This intent is also reflected in our current policy and technical guidance,[104] as well as in current practice. CMS needs this information to properly oversee Part D drug management programs. Therefore, we propose to insert ''or at-risk beneficiary'' to this section. This means that Part D sponsors would be required to provide information to CMS about any ARB that is reported to the sponsor through MARx 30 days from the date of the most recent OMS report, as sponsors currently do in practice. This provision is technical and is therefore not expected to have economic impact beyond current operating expenses.

We would also like to take this opportunity to note mistakes in the Data Disclosure section of the Part D Drug Management Program Policy Guidance (November 20, 2018) on pages 30–31. In subsection I.2, we state that CMS has established the following procedures under which sponsors must share information about PARB 2s and ARB 2s. However, we clearly meant about PARBs and ARBs generally, as subsection I.2. details various data disclosures that Part D sponsors with DMPs must make about PARB 1s and ARB 1s also. In addition, in subsection I.2.b. on page 31, we state that a sponsor must provide coverage limitation information to CMS about PARB 2s and ARB 2s by entering information into MARx. Again, we meant PARBs and ARBs generally, as the subsection details information sponsors must enter into MARx about PARBs and ARBs and it is not limited to PARB 2s and ARB 2s. CMS needs this information in order to properly oversee Part D drug management programs, and this guidance is in line with existing § 423.153(f)(15)(ii)(D) which states that sponsors must provide information about initial notices (all PARBs) and second notices (all ARBs). We have not had an issue with Part D sponsors providing this information—only a question whether there were mistakes.

IX. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information,'' as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement (ICR) should be approved by OMB, section 3506(c)(2)(A) of the PRA 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 estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule we are soliciting public comment on each of these issues for the following sections that contain proposed collection of information requirements. The provisions that are not discussed under this section of the preamble do not propose any new or revised collection of information requirements and/or burden and, therefore, are not subject to the requirements of the PRA. Please see section IX.C. of this proposed rule for the total burden implications.

A. Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2018 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 9 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

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[103] See pages 56359–60 of CMS–4182–P (November 28, 2017) and pages 16479–80 of the April 2018 final rule.

[104] See page 31 of the Part D Drug Management Program Policy Guidance (November 20, 2018). *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2019-Part-D-Drug-Management-Program-Policy-Guidance-Memo-November-20-2018-.pdf.*

TABLE 9: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Actuaries	15-2011	55.89	55.89	111.78
All Occupations [used for impact on enrollees filling out forms]	00-0000	24.98	n/a	n/a
Business Operations Specialist, all others	13-1199	37.00	37.00	74.00
Compliance Officer	13-1041	34.86	34.86	69.72
Computer Programmers	15-1131	43.07	43.07	86.14
Computer System Analysts	15-1121	45.01	45.01	90.02
Dietician	29-1031	29.43	29.43	58.86
Driver	53-3022	16.05	16.05	32.10
General Operations Manager	11-1021	59.56	59.56	119.12
Health Care Social Workers	21-1022	28.11	28.11	56.22
Home Care Coordinator (often a RN)	29-1141	36.30	36.30	72.60
Management Analyst	13-1111	45.38	45.38	90.76
Masters of Social Work	21-1022	28.11	28.11	56.22
Occupational Therapist	29-1122	41.04	41.04	82.08
Office Support and Administrative Support	43-9199	18.02	18.02	36.04
Medical and Health Services Managers (PACE Center Manager)	11-9111	54.68	54.68	109.36
Home Health Aides (Personal Care Attendant)	31-1011	12.18	12.18	24.36
Pharmacist	29-1051	59.45	59.45	118.90
Physical Therapist	29-1123	42.73	42.73	85.46
Primary Care Provider	29-1069	98.02	98.02	196.04
Recreational Therapist	29-1125	24.34	24.34	48.68
Registered Nurse	29-1141	36.30	36.30	72.60
Technicians, all other	19-4099	25.45	25.45	50.90

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As indicated, we are adjusting 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. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Wages for Individuals: For beneficiaries, we believe that the burden will be addressed under All Occupations (at $24.98/hr) since the group of individual respondents varies widely from working and nonworking

individuals and by respondent age, location, years of employment, and educational attainment, etc. Unlike our private sector adjustment to the respondent hourly wage, we did not adjust this figure for fringe benefits and overhead since the individuals' activities will occur outside the scope of their employment.

B. Proposed Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble (see sections II through VIII) of this proposed rule.

1. ICRs Regarding Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)

The following proposed changes will be submitted to OMB for approval under control number 0938–1296 (CMS–10565). Subject to renewal, the control number is currently set to expire on June 30, 2022. It was last approved on June 30, 2019 and remains active.

This provision proposes to amend § 422.101(f) to implement the new requirements legislated by the BBA of 2018 to section 1859(f) of the Act for C–SNPs and to extend them to all SNP types. Specifically, we propose to add the following new regulations to account for new requirements governing SNP enrollee care management and SNP MOC submissions. The proposed regulations impacting MA SNP MOCs are as follows:

- We propose an amendment to § 422.101(f)(1)(i) following the end of the current text that would add the following language to the current regulation: ''and ensure that results from the initial and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan as required under paragraph (f)(1)(ii) of this section.'' In order to comply with this rule, MA SNPs would have to provide the necessary guidance to and develop related internal processes for employees of the SNP that are responsible for incorporating this requirement into their MOC.
- We propose a new regulation at § 422.101(f)(3)(ii)(A)–(C) to implement the requirement that: As part of the evaluation and approval of the SNP model of care, NCQA must evaluate whether goals were fulfilled from the previous model of care; plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals; plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval; and if the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC. Under this proposed regulation, each plan's MOC must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals. Note, all SNPs are currently required to identify and clearly define measureable goals and health outcomes as part of their MOC under MOC 4, Element B: Measureable Goals and Health Outcomes for the MOC.
- Lastly, we propose a new regulation at § 422.101(f)(3)(iii) to implement the requirements that each SNP MOC submitted to CMS will be evaluated by NCQA based on a minimum benchmark (of 50 percent) for each of the existing four elements.

At the time SNP applications are due, MA organizations wishing to offer a new SNP will submit a MOC with their SNP application in the Application module in HPMS for NCQA review and approval. MA organizations wishing to renew their current SNP will submit a MOC in the MOC module in HPMS for NCQA review and approval. Based on their MOC scores, I–SNPs and D–SNPs receive an approval for a period of 1, 2, or 3 years. C–SNPs must renew their MOCs annually per section 1859(b)(6)(B)(iii) of the Act. For calendar year 2020, CMS received 273 SNP MOCs during the annual submission process and received 11 off-cycle submissions during the following time period. We believe these figures are representative of future SNP MOC submission totals going forward.

The burden related to the new requirements for SNP MOCs reflects the time and effort needed to collect the information as previously described, as well as all other MOC data, and report this information to CMS. To derive average costs, we selected the position of registered nurse because the SNP nurse usually develops and submits the MOC to CMS and typically interacts with the health plan quality registered nurse in matters related to the MOC after it is submitted to CMS.

The SNP will access HPMS and follow the appropriate instructions. The MA organization/SNP will click on the Application or MOC module in HPMS and download the SNP MOC Matrix document. The SNP will complete the document, and then upload its MOC matrix document with the MOC narrative. The SNP MOC Matrix upload document outlines the CMS SNP MOC standards and elements that must be addressed in the MOC narrative. The document also serves as a table of contents for the MOC narrative. Training to use the MOC module will be minimal at three hours annually, and training materials and non-mandatory webinar sessions are provided by CMS at no cost to the SNPs except for the time (and cost) to participate.

Using HPMS contract year 2020 submission data, for off-cycle submissions we estimate that 273 SNPs will submit MOCs annually. Note, this calculation is based on estimates that include annual MOC submissions for C–SNPs and semi-annual submissions for I–SNPs and D–SNPs. I–SNPs and D–SNPs submitting a MOC can receive MOC approval for one, two, or three year terms. For each SNP, we assume an additional 6 hours at $72.60/hr for a registered nurse. In aggregate, we estimate an ongoing annual burden of 1,638 hours (273 SNPs * 6 hr) at a cost of $118,919 (1,638 hr * $72.60/hr).

For plans seeking to revise their MOC based on qualifying events during the off-cycle season, we estimate that approximately 11 SNPs (D–SNPs/I–SNPs) will submit off-cycle MOC changes. For each SNP submitting off-cycle MOC changes, we assume an additional 4 hours at $72.60/hr for a registered nurse. In aggregate, we estimate an ongoing annual burden of 44 hours (11 SNPs * 4 hr) at a cost of $3,194 (44 hr * $72.60/hr).

Since the proposed § 422.101(f)(3)(iii) sets a minimum benchmark for each MOC element, we anticipate that there will be some impact to the number of MOC submissions that will not pass NCQA's initial MOC review. Looking at data for contract year 2020, our proposed element benchmark of 50 percent would have impacted 20 of the 273 MOCs submitted, or 7.3 percent. For contract year 2020, seven plans required submitting their MOCs for revision based on the current scoring system and an additional seven plans decided to withdraw their MOCs before the revision process for a total of 14 MOCs. The 14 SNPs must resubmit, taking 3 hours, or half the full 6 hour estimate. In aggregate, we estimate an added ongoing annual burden of 42 hours (14 SNPs * 3 hr) at a cost of $3,049 (42 hr * $72.60/hr).

For the aforementioned MOC requirements, we estimate an added annual burden of 1,724 hours (1,638 hr for MOC submissions + 44 hr for MOC revisions + 42 hr for MOC resubmissions) at a cost of $125,162 ($118,919 + $3,194 + $3,049, respectively).

Separate from the proposed changes to the MOC process, we propose a new regulation at § 422.101(f)(1)(iv) to implement a new requirement that plans provide face-to-face encounters with consenting individuals enrolled in the plan not less frequently than on an annual basis. The new regulation would require an annual face-to-face visit, that is, in-person or by remote technology such as telehealth, to occur starting within the first 12 months of enrollment within the plan. CMS would consider a visit to or by employed and/or contracted staff that perform clinical functions, such as direct enrollee care, as a qualifying encounter. Such activities may include, but are not limited to, annual wellness visits and/or physicals, HRA completion, meeting with the interdisciplinary team (IDT), care plan review, health-related education, and care coordination activities. It is also the expectation that any concerns related to physical, mental/behavioral health, and overall health status, including functional status, are addressed and any appropriate referrals, follow-up, and care coordination activities are provided or scheduled as necessary.

We believe that most, if not all, SNP enrollees will have a qualifying face-to-face encounter as proposed under § 422.101(f)(1)(iv) through an initial or annual HRA, a qualifying encounter with an IDT member, or an annual wellness visit. We estimate that approximately 734 SNPs that have at least 11 members will need to track face-to-face encounters for their enrollees annually. For each SNP tracking face-to-face encounters, we assume 4 hours of work by SNP personnel, typically a registered nurse. In aggregate, we estimate 2,936 hours (734 SNPs * 4 hr) at a cost of $213,154 (2,936 hr * $72.60/hr).

In addition, we propose to require in new § 422.101(f)(1)(iii) that MA organizations offering a SNP must provide each enrollee with an IDT in the management of care that includes a team of providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the plan. We propose that plans develop and implement this requirement into their MOC components to assure an effective management structure. We believe this requirement is consistent with currently approved information tracking practices for all existing SNPs, and thus, does not impose any new or revised ICRs and/or burden beyond what is currently approved by OMB under the aforementioned control number.

For the remaining proposed regulations under § 422.101(f)(2) and (3), SNP MOC submission requirements and burden are currently approved by OMB under said control number. The proposed changes would codify current guidance governing SNP MOC submission practices, which is captured under the active information collection request.

2. ICRs Regarding Contracting Standards for Dual Eligible Special Needs Plan (D–SNP) Look-Alikes (§ 422.514)

The following proposed changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). Subject to renewal, the control number is currently set to expire on December 31, 2021. It was last approved on December 3, 2018 and remains active. The proposed requirements are associated with burden on MA plans identified as D–SNP look-alikes under § 422.514(d) (see section IX.B.2.a. of this proposed rule) and burden on the enrollees in these MA plans (see section IX.B.2.b. of this proposed rule).

As described in section II.E. of this proposed rule, we propose new contract requirements that we believe are necessary to fully implement D–SNP requirements, especially those related to Medicare-Medicaid integration codified at §§ 422.2, 422.107, and 422.629 through 422.634 pursuant to the BBA of 2018. We are proposing a prohibition on CMS entering into or renewing a contract for any non-SNP MA plan that an MA organization offers, or proposes to offer that:

- Projects in its bid submitted under § 422.254 that 80 percent or more of the plan's total enrollment are enrollees entitled to medical assistance under a state plan under Title XIX of the Act, or
- Has actual enrollment, as determined by CMS in January of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under Title XIX of the Act, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

Our proposed dually eligible enrollment threshold at § 422.514(d) would apply to any plan that is not a SNP as defined in § 422.2. We propose applying this requirement only to non-SNP plans to allow for the disproportionate dually eligible enrollment that characterizes D–SNPs, I–SNPs, and some C–SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. The proposed requirement would also be limited to states where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals, such as MMPs. We propose this limitation because it is only in such states that the implementation of D–SNP requirements necessitates our proposed new contracting requirements. That is, in a state with no D–SNP or comparable managed care plan, the D–SNP requirements have not had any relevance historically, and therefore the operation of a D–SNP look-alike would not have any material impact on the full implementation of federal D–SNP requirements.

The proposed contract requirement based on the projected enrollment in the plan bid at § 422.514(d)(1) would prevent MA organizations from designing new D–SNP look-alikes. Under our proposal at § 422.514(d)(2), we would make the determination whether an MA organization has a non-SNP MA plan with actual enrollment exceeding the established threshold using the enrollment in January of the current year. Using data from the contract year 2020 bid submission process, we estimate that there are 67 MA plans that have enrollment of dually eligible individuals that is 80 percent or more of total enrollment. Of these 67 MA plans, 62 plans are in states where there are D–SNPs or comparable managed care plans and would be subject to § 422.514(d). These 62 plans project a total enrollment of 180,758 for contract year 2020.

MA organizations would likely terminate at the end of the plan year those plans that exceed our proposed criteria in § 422.514(d)(1) and (2). The MA organization would have the opportunity to make an informed business decision to transition enrollees into another MA plan by: (1) Identifying, or applying and contracting for, a qualified existing MA plan, including a D–SNP, in the same service area; or (2) creating a new D–SNP through the annual bid submission process. Alternatively, the terminating plan may choose to not transition enrollees.

The changes required of MA organizations based on this proposed rule would trigger collection of information by D–SNP look-alikes (see section IX.B.2.a. of this proposed rule) and their enrollees (see section IX.B.2.b. of this proposed rule). While we cannot predict the action of each affected MA organization, we base our proposed burden estimates on the current landscape of D–SNP look-alikes, the availability of D–SNPs or MA plans under the same parent organization in

the same service area, and the size and resources of the MA organization.

a. Burden on MA Plans

At § 422.514(e), we propose a process for transitioning individuals who are enrolled in a D–SNP look-alike to another MA–PD plan offered by the MA organization, or by another MA organization with the same parent organization as the MA organization, to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. Under our proposal, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in proposed paragraph (d) could transition enrollees into another MA plan offered by the same MA organization (or by another MA organization with the same parent organization as the MA organization), as long as that MA plan meets certain proposed criteria. This process would allow an MA enrollee to be transitioned from one MA plan offered by an MA organization to another MA plan without having to complete an election form. Under this process, as described in § 422.514(e)(2), the MA organization would be required to describe changes to MA–PD benefits and provide information about the MA–PD plan into which the individual is enrolled in the Annual Notice of Change that the MA organization must send, consistent with § 422.111(a), (d), and (e) and proposed § 422.2267(e)(3).

Under § 422.514(e)(1), we propose to allow a terminating D–SNP look-alike to transition enrollment to another MA plan (or plans) only if the resulting total enrollment in each of the non-SNP MA plans receiving enrollment consists of less than 80 percent dually eligible individuals. This criterion would ensure that the enrollment transitions under this regulation do not result in another non-SNP MA plan being treated as a D–SNP look-alike under proposed § 422.514(d). Proposed § 422.514(e)(1)(ii) would require that any plan receiving transitioned enrollment be an MA–PD plan as defined in § 422.2. Proposed paragraph (e)(1)(iii) would require that any MA plan receiving transitioned enrollment from a D–SNP look-alike have a combined Part C and D premium of $0 after application of the premium subsidy for full subsidy eligible individuals described at § 423.780(a).

The proposed process at § 422.514(e) would allow, but not require, the MA organization to transition dually eligible enrollees from D–SNP look-alikes into D–SNPs and allow such enrollees to retain coverage under the MA organization and benefit from the care coordination and Medicaid benefit integration offered by a D–SNP. Proposed paragraph (e)(1) specifies that the MA organization could only transition individuals in a D–SNP look-alike into another MA plan (including a D–SNP) if they are eligible to enroll in the receiving plan. This proposed transition process is conceptually similar with ''crosswalk exception'' procedures proposed in section VI.C. of this proposed rule and in § 422.530(a) and (b); however, our proposal would allow the transition process to apply across contracts or legal entities and plan types (for example, non-SNP to SNP).

While the proposed prohibition on D–SNP look-alikes would only apply to plans starting in the 2022 plan year, we intend for the transition process to take effect in time for D–SNP look-alikes operating in 2020 to utilize the transition process for enrollments to be effective January 1, 2021. Based on the current landscape for D–SNP look-alikes, we believe the vast majority of these plans would be able to move current enrollees into another MA plan using the proposed transition process. By 2022, we expect that all 62 D–SNP look-alikes would choose to transition current enrollees to another MA plan for the forthcoming contract year. We estimate the burden for transitioning current enrollees to another MA plan at an average of 2 hours at $74.00/hr for a business operations specialist to submit enrollment changes to CMS. D–SNP look-alikes that transition enrollees into another MA plan would take less time than D–SNP look-alikes that transition eligible beneficiaries into a D–SNP. The 2-hour time estimate accounts for any additional work to confirm an enrollee's Medicaid eligibility for D–SNP look-alikes transitioning eligible enrollees to a D–SNP. For the estimated 62 D–SNP look-alikes, the one-time burden for transitioning enrollees to another MA plan by the 2022 plan year would be 124 hours (62 D–SNP look-alikes * 2 hr/response) at a cost of $9,176 (124 hr * $74.00/hr).

The vast majority of MA organizations with existing D–SNP look-alikes also have an MA plan with a premium of $0 or a D–SNP in the same service area as the D–SNP look-alike. Therefore, we do not believe MA organizations would choose to create a new D–SNP as a result of this proposed rule. The prevalence of existing MA plans and D–SNPs also make it unlikely that an MA organization would need to expand a service area for an existing MA plan or D–SNP. Since we estimate fewer than 10 respondents would apply as a new D–SNP or expand an existing MA plan service area, the information collection requirements are exempt under 5 CFR 1320.3(c) from the requirements of the PRA.

Additionally, we do not expect any plans would be required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2) and described at proposed § 422.514(e)(4), as we anticipate all MA organizations with D–SNP look-alikes would be able to transition their enrollees into another MA plan (or plans). However, we propose the requirement to ensure protection of enrollees if the situation did occur.

In subsequent years, we estimate that at most five plans per year would be identified as D–SNP look-alikes under § 422.514(d) due to meeting the enrollment threshold for dually eligible individuals or operating in a state that will begin contracting with D–SNPs or other integrated plans. We believe that these plans would terminate and transition their membership into another MA plan or a D–SNP. Therefore the annual burden after the 2022 plan year is estimated at 10 hours (5 plans * 2 hr/plan) at a cost of $740 (10 hr * $74.00/hr) for a business operations specialist to transition enrollees into a new MA plan. The impacts are summarized in Table 10.

b. Burden on MA Plan Enrollees

Proposed § 422.514(e)(2) would allow any individual transitioned from a D–SNP look-alike to another MA plan to stay in the MA plan receiving the enrollment or make a different election. The enrollees may choose new forms of coverage for the following plan year, including a new MA plan or services through the original Medicare fee-for-service program option and a Prescription Drug Plan (PDP). Because the proposed enrollment transition process would be effective on January 1 and notices would be provided during the annual election period, affected individuals would have opportunities to make different plan selections through the annual coordinated election period (prior to January 1) or the open enrollment period (after January 1). Additionally, dually eligible individuals qualify for a special election period at § 423.38(c).

We estimate that one percent of the 180,758 transitioning D–SNP look-alike enrollees would select a new plan or the original Medicare fee-for-service program and PDP option accepting the transition into a different MA plan or D–SNP under the same MA organization as the D–SNP look-alike they are currently enrolled in. Based on our experience

with passive enrollment of dually eligible beneficiaries into a new plan under the same parent organization for MMPs in the Financial Alignment Initiative, we estimate that 1,808 enrollees (180,758 transitioning D–SNP look-alike enrollees * 0.01), would opt out of their new plan for contract year 2021. Consistent with our currently approved burden estimates under the aforementioned control number, the enrollment process would require 0.5 hours. For this proposed rule, the total added burden for enrollees would be 904 hours (1,808 enrollees * 0.5 hr/response) at a cost of $22,582 (904 hr * $24.98/hr).

As stated previously, we believe that in subsequent years, at most five plans would be identified as D–SNP look-alikes and therefore this proposed regulation would have a much smaller impact on MA enrollees. Since the current 62 D–SNP look-alike plans have 182,758 enrollees in 62 plans, we estimate 14,577 enrollees (180,758 * 5/62) in five plans. Therefore, the maximum number of enrollees affected per year is estimated as 146 enrollees (14,577 total enrollees estimated in five plans * 0.01 who would select another plan). This would amount to a maximum annual burden of 73 hours (146 enrollees * 0.5 hr) at a cost of $1,824 (73 hr * $24.98/hr).

c. Summary

The burden for the proposed provisions are summarized in Table 10.

TABLE 10: SUMMARY OF BURDEN ESTIMATES FOR PROPOSED CONTRACT REQUIREMENTS AT § 422.514

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time Per Response (hr)	Total Hours (hr)	Labor Cost ($/hr)	Total Cost in 1st Year ($)	Total Cost in Subsequent Years ($)
§ 422.514(e)	Transition enrollees, 1st year	62	62	2	124.0	74.00	9,176	0
§ 422.514(e)	Transition enrollees, after 1st year	5	5	2	10.0	74.00	0	740
§ 422.514(e)	Filling out enrollment form 1st year	1,808	1,808	0.5	904.0	24.98	22,582	0
§ 422.514(e)	Filling out enrollment form after 1st year	146	146	0.5	73.0	24.98	0	1,824
TOTAL		2,021	2,021	*Varies*	1,111	*Varies*	31,758	2,564

3. ICRs Regarding Mandatory Drug Management Programs (DMPs) (§ 423.153)

The following proposed changes will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Subject to renewal, the control number is currently set to expire on November 30, 2021.

As discussed in section III.A. of this proposed rule, we propose to codify the statutory requirement that Part D plan sponsors establish DMPs by 2022. We also propose that, beginning in 2021, DMPs evaluate enrollees with a history of opioid-related overdose as potential at-risk beneficiaries (PARBs) that CMS reports to sponsors through the Overutilization Monitoring System (OMS).

As brief background on DMPs for context for this section, in general, the DMP requirements are codified at § 423.153(f). These provisions require Part D sponsors to conduct case management of PARBs identified by OMS through contact with their prescribers to determine if a beneficiary is at-risk for abuse or misuse of opioids and benzodiazepines.[105] After case management is completed, if a plan sponsor intends to limit a beneficiary's access to coverage of opioids and benzodiazepines, the sponsor must provide an initial written notice to the beneficiary and their prescribers. After the beneficiary has a 30-day time period to respond, the plan sponsor sends a second notice to the beneficiary, if the sponsor determines the beneficiary is an at-risk beneficiary (ARB), that the sponsor is implementing a coverage limitation on opioids and/or benzodiazepines, or an alternative second notice if the plan sponsor determines that the beneficiary is not an

[105] CMS currently designates both opioids and benzodiazepines as ''Frequently Abused Drugs'' for purposes of DMPs. See ''Part D Drug Management Program Policy Guidance'', November 20, 2018, p. 6; *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2019-Part-D-Drug-Management-Program-Policy-Guidance-Memo-November-20-2018-.pdf.*

ARB. Thus, every beneficiary who receives an initial notice receives a second or alternate second notice.

In 2019, a CMS analysis found that a majority of Part D contracts (669 of 779), or 85.9 percent) voluntarily included a DMP. Our proposal to codify the requirement that sponsors adopt DMPs would only affect the remaining minority of sponsors currently not offering such programs. There are 111 contracts (plan sponsors) run by 79 parent organizations that would be involved. Furthermore, we estimate that only 158 additional PARBs will be identified by these 111 contracts due to meeting the minimum OMS criteria. We estimate burden at the parent organization level because we believe that is a closer reflection of the number of systems that will need to be updated versus the contract level.

The estimated reporting burden to these sponsors has four aspects. Under § 423.153(f), sponsors must: (1) Design a DMP; (2) conduct case management, which includes sending written information about PARBs to prescribers; (3) program and issue written notices to PARBs and ARBs; and (4) disclose data to CMS about the outcome of case management via OMS and about any coverage limitation information into MARx.

For one-time initial development, we estimate it will take each parent organization without a DMP 80 hours for a team of clinical and non-clinical staff to design its DMP. Thus, we estimate 6,320 hours (79 parent organizations * 80 hr) program-wide for all remaining parent organizations to develop DMPs consistent with the requirements of § 423.153(f). We solicit comment as to the accuracy of these estimates.

We estimate that development will likely require two pharmacists (working at $118.90/hr) and two general operation managers (working at $119.12/hr) per organization. Thus, the hourly wage for the organization's development team is $476.04 [2 pharmacists * $118.90/hr] + [2 managers * $119.12/hr]. The labor rates for the development team is summarized in Table 11.

TABLE 11—LABOR RATES FOR THE DEVELOPMENT TEAM

Occupation	Adjusted hourly wage ($/hr)	Number of staff	Total wages ($/hr)
General operations manager	119.12	2	238.24
Pharmacist	118.90	2	237.80
Total	238.02	4	476.04

Therefore, each of the 79 parent organizations affected by this proposal will spend 80 hours at a cost of $38,083 (80 hr * $476.04/hr) for the team of four professionals to develop the DMP. The aggregate burden will therefore be 6,320 hours (79 parent organizations * 80 hr) at a cost of $3,008,573 (6,320 hr * $476.04/hr).

Once a DMP is developed and in place, the primary operations for impacted sponsors will involve case management by the sponsor to assess those enrollees reported as PARBs by CMS's OMS. The 111 contracts run by 79 parent organizations that did not voluntarily establish a DMP are generally smaller plans that in some cases offered alternative means of managing comprehensive beneficiary care, such as through PACE. They enroll only 410,000 Part D beneficiaries (less than 1 percent of total Part D enrollment in 2019). Accordingly, based on analysis of the first 3 quarters (January, April, and July 2019) of the OMS report data, we found that only 127 beneficiaries (about 0.7 percent) who met the minimum OMS criteria were not reported thus far in 2019 by CMS to the sponsors, because the sponsors did not have a DMP. Using this estimate, we can project that annually that about 158 beneficiaries would not be reported to their plan sponsors due to not having a DMP until DMPs become mandatory no later than January 1, 2022.

Once required DMP policies are developed and operational, sponsors would have to case-manage their PARBs (as outlined in § 423.153(f)(2)). The case management requirement includes a requirement that sponsors send written information to prescribers about PARBs. We estimated it would take an average of 5 hours for a sponsor to case-manage a PARB. We assume certain components of case management can be completed by staff of differing specialization and credentialing. We assume that 2 of the 5 hours on average would be conducted by a pharmacist (such as initial review of medication profiles, utilization, etc.) at $118.90/hr, 2 hours would be conducted by a health technician (''Technician, All other'') at $50.90/hr, and 1 hour would be conducted by a physician at $202.86/hr to work directly with providers on discussing available options and determining the best course of action. In aggregate, we estimate an annual burden for an estimated 158 enrollees annually newly subject to case management under this proposal to cost $85,708.68 per year (158 enrollees * ([2 hr * $118.90/hr for Pharmacists] + [2 hr * $50.90/hr for Technicians, All other] + [1 hr * $202.86/hr for Physician]).

The 79 Part D parent organizations affected by this proposal also would have to upload beneficiary notices into their internal claims systems before they could issue them. We estimate that it will take each, on average, 5 hours at $86.14/hr for a computer programmer to upload all of the notices into their claims systems (note, this is an estimate to upload all of the documents in total, not per document). In aggregate, we estimate a one-time burden of 395 hours (5 hr * 79 sponsors) at a cost of $34,025 (395 hr * $86.14/hr).

Since currently 5 percent of PARBs receive an initial and second notice (or alternate second notice), we estimate that 8 beneficiaries (158 beneficiaries * 0.05) would receive an initial notice and 8 would receive a second notice (or alternate second notice). Since fewer than 10 beneficiaries are affected by this, the burden of sending these notices is exempt from PRA.

As to disclosure of DMP case management outcomes data to CMS pursuant to § 423.153(f)(15), as stated earlier, the plan sponsors newly impacted by a mandatory DMP policy would be required to report to CMS the outcome of case management via OMS and any associated coverage limitation information into MARx. We estimate that it would take sponsors on average 1 minute (0.0167 hr) to report this information to OMS and MARx. In aggregate, we estimate an annual burden of 2.6386 hours (158 newly identified PARBs annually * 0.0167 hr) at a cost of $134 (2.6386 hr * $50.90/hr).

4. ICRs Regarding Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

The following proposed changes will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Subject to renewal, the control number is currently set to expire on November 30, 2021.

Our proposal under § 423.100 to identify and report beneficiaries with a history of opioid-related overdose through OMS to Part D plan sponsors would mean that additional beneficiaries would be reported by OMS as PARBs. Based on July 2017 through June 2018 opioid-related overdose data, CMS's internal analysis estimates that about 18,268 enrollees meet the proposed criteria of an opioid-related overdose and would be PARBs. We project using this one-year estimate that in 2021 about 18,268 additional PARBs with an opioid-related overdose would be identified and reported by OMS. The estimated reporting burden associated with these new PARBs has three of the four aspects of the burden we estimated for mandatory DMPs, as previously described. Under § 423.153(f), sponsors must: (1) Conduct case management, which includes sending written information about PARBs to prescribers; (2) issue written notices to PARBs and ARBs; and (3) disclose data to CMS about the outcome of case management via OMS and about any coverage limitation information into MARx.

The assumptions surrounding case management by plan sponsors in the previous section were applied to the estimated population of 18,268 PARBs projected to be identified annually under this proposal. In aggregate, we estimate an annual burden for a projected 18,268 enrollees annually newly subject to case management, including sending the required written information to the prescribers of PARBs, under this proposal to cost $9,909,659.28 per year (18,268 enrollees * ([2 hr * $118.90/hr for Pharmacists] + [2 hr * $50.90/hr for Technicians, All other] + [1 hr * $202.86/hr for Physician]).

In order to estimate the impact of providing beneficiary notices, we compare two populations: (1) Part D beneficiaries projected to be potentially at-risk, by meeting the OMS criteria (which CMS estimates as 22,516 PARBs, based on internal data); and (2) beneficiaries with a history of opioid-related overdose (which CMS estimates as 18,268 PARBs, based on internal data).

We believe the population of beneficiaries with a history of opioid-related overdose would have a much higher rate of coverage limitations imposed by sponsors, due to the history of overdose being the risk factor most predictive for another overdose or suicide-related event.[106] We estimate that about 47.5 percent or 8,677 beneficiaries (18,268 beneficiaries * 0.475) of this population will receive an initial notice from the plan sponsor, informing the beneficiary of the sponsor's intention to limit their access to coverage of opioids and/or benzodiazepines. Thus, the beneficiary will also receive a second or alternate second notice informing them whether the limitation was in fact implemented.

This is in contrast to the PARBs meeting minimum and supplemental OMS criteria, where Part D program experience demonstrates a significantly lower incidence of coverage limitations (that is, only about 1,126 or 5 percent of the 22,516 beneficiaries receive notices).[107]

Following these assumptions, of the 40,784 (22,516 PARBs + 18,268 PARBs) Part D beneficiaries projected to be potentially at-risk, either by meeting the OMS criteria (22,516 PARBs) or the history of opioid-related overdose as defined (18,268 PARBs), those receiving a first notice from their plan sponsor informing them of the sponsor's intention to apply a coverage limitation are projected to total 9,803 enrollees (8,677 with history of opioid-related overdose + 1,126 meeting OMS minimum and supplemental criteria), or 24 percent of PARBs (40,784 * 0.24).

We estimate it would take 10 minutes (0.1667 hr) at $50.90/hr for a health technician to send two notices (each notice would require 5 minutes). In aggregate, we estimate an annual burden of 1,446 hours (8,677 enrollees * 0.1667 hr) at a cost of $73,601 (1,446 hr * $50.90/hr).

Evaluation of the use of POS claim edits under OMS since 2013 does not demonstrate a steady increase or decrease in edits. The OMS and POS edit reporting systems commenced in 2013 and 2014, and then between 2015 and 2018 the number of beneficiaries with opioid POS claim edits only ranged from 1,152 to 1,351 annually. As such, given that the vast majority of Part D enrollees are in a plan already offering a DMP, including the majority of Part D enrollees with a history of opioid-related overdose, we do not anticipate major shifts in the baseline average number of annual POS edits (and related initial notices). This stability in the annual number of ARBs and related notices to date appears largely unaffected by the baseline population of identified PARBs. However, we recognize that this proposed change is projected to approximately double the number of beneficiaries CMS identifies to sponsors as PARBs and accordingly solicit comment as to whether including beneficiaries with a history of opioid-related overdose and the projected doubling in identified PARBs is expected to require significant modifications by sponsors to respond to this increase in case management volume.

Model beneficiary notices[108] provided by CMS, as well as the required written information sent by sponsors to prescribers of PARBs as part of the case management process, would need to be revised to incorporate language specific to a PARB having a history of opioid-related overdose. For the model beneficiary notices, this includes updates to the sections defining DMPs and possible justifications for applying a coverage limitation. Proposed changes to the model beneficiary notices will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Additionally, sponsors may need to update their DMP prescriber written communications to include history of opioid-related overdose as a possible reason for a beneficiary meeting the OMS criteria. The changes needed to align the model beneficiary notices and the written communication are expected to be minimal.

We estimate it would take no more than 1 hour at $50.90/hr for a health technician to draft and implement such changes. In aggregate, we estimate a one-time burden of 288 hours (288 parent organizations * 1 hr/response) at a cost of $14,659 (288 hr * $50.90/hr). With respect to the burden of disclosure of DMP data to CMS associated with the increase in PARBs, we estimate that it will take sponsors on average 1 minute (0.0167 hr) at $50.90/hr for a health technician to document OMS and/or MARx the outcome of case management and any applicable coverage limitations.

[106] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul; 11/2(7):1193–1201. doi: 10.1111/add.13774.

[107] CMS' internal analysis estimates that about 22,516 PARBs would meet the current OMS criteria based on 2018 data. An additional 18,268 PARBs are projected annually to meet the proposed criteria of opioid-related overdose.

[108] Notice documents available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Drug-Management-Program-Notices-.zip.*

In aggregate, we estimate an annual burden of 305 hours (18,268 PARBs * 0.0167 hr) at a cost of $15,525 (305 hr * $50.90/hr).

Table 12 summarizes the DMP provisions for which impact is discussed in sections IX.B.3. and IX.B.4. of this proposed rule.

TABLE 12: SUMMARY FOR MANDATORY DMPs AND IDENTIFICATION OF ADDITIONAL PARBs

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st Year ($)	Total Cost in Subsequent Years ($)
§ 423.153	Creating DMP (those without DMPs)	79	79	80.00	6,320.0	476.04	3,008,573	0
§ 423.153	Upload Model Notices	79	79	5.00	395.0	86.14	34,025	0
§ 423.153	Conduct Case Management	79	158	1	158	542.46	85,709	85,709
§ 423.153	Disclosure to CMS	79	158	0.0167	2.6386	50.90	134	134
§ 423.100	Revise Model Notices	288	288	1.00	288.0	50.90	14,659	0
§ 423.100	Send Model Notices	288	8,677	0.1667	1446	50.90	73,601	73,601
§ 423.100	Conduct Case Management	288	18,268	1	18,268	542.46	9,909,659	9,909,659
§ 423.100	Disclosure to CMS (newly identified PARBs)	288	18,268	0.0167	305	50.90	15,525	15,525
TOTAL		288	1864	*Varies*	27,183	*Varies*	13,056,176	10,084,628

5. ICRs Regarding Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153) and Information on the Safe Disposal of Prescription Drugs

The following proposed changes to the MTM Standardized Format will be submitted to OMB for approval under control number 0938–1154 (CMS–10396). Subject to renewal, the control number is currently set to expire on August 31, 2020. The complete information collection request, which includes the proposed changes along with the unchanged provisions, will be posted for public review and comment (see section IX.D. of this proposed rule for further information).

Since the inception of the Medicare Part D benefit, the Act has required that all Part D plans offer a MTM program to eligible beneficiaries. The Act also established criteria for targeting beneficiaries for MTM program enrollment and a minimum set of services that must be included in MTM.

Under the current regulation at § 423.153(c), all MTM enrollees must be offered a Comprehensive Medication Review (CMR) at least annually and Targeted Medication Reviews (TMRs) no less than quarterly. A CMR is an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider that includes a review of the individual's medications and may result in the creation of a recommended medication action plan. An individualized, written summary in CMS's Standardized Format must be provided following each CMR. The SUPPORT Act expanded the population of beneficiaries that must be targeted for Part D MTM starting in 2021 and also added an additional requirement that information on the safe disposal of prescription drugs that are controlled substances be furnished to all MTM program enrollees; we are now proposing to modify our Part D regulations to conform with the changes to the MTM requirements enacted in the SUPPORT Act. These provisions of the

SUPPORT Act will affect the number of beneficiaries enrolled in MTM programs and potentially some of the content for the Standardized Format for the CMR and, therefore, the burden estimates for this document. We are estimating:

(A) The burden of the expanded population of beneficiaries that must be targeted for enrollment in MTM programs,

(B) the burden of mailing safe disposal information as part of the CMR summary, and

(C) the burden of mailing safe disposal information once a year as part of a TMR or another follow up service.

(A) The burden of the expanded population of beneficiaries that must be targeted for enrollment in MTM programs:

TABLE 13: ESTIMATED BURDEN OF TARGETING ARBs FOR MTM

Line ID	Item	Data	Source	Percentage of Part D Enrollees
(1)	Estimated number of Part D enrollees in 2021	48,338,879	Internal CMS data	N/A
(2)	Enrollees in the Enhanced MTM model tested by CMMI	1,550,300	Internal CMS data	3.2071%
(3)	Part D enrollees not in an Enhanced MTM program under the Enhanced MTM model	46,788,579	(1) * (2)	96.7929%
(4)	Number of Part D enrollees who are estimated to meet ARB criteria	10,000	Internal CMS data	N/A
(5)	Estimated number of ARBs in Enhanced MTM	321	Percentage in (2)*(4)	N/A
(6)	Number of ARBs who will be targeted for MTM	9,679	Percentage in (3)*(4)	N/A
(7)	Percent of targeted beneficiaries estimated to accept CMR offer under current MTMP	87%	Internal CMS data	N/A
(8)	Number of ARBs estimated to accept CMR offer under new provision	8,421	(6)*(7)	N/A
(9)	40 minutes is the industry standard for preparing a CMR	0.6667	Industry data	N/A
(10)	Number of hours needed to fulfill the preparation of CMRs including stuffing and mailing	5,614	(9)*(8)	N/A
(11)	Wage for a pharmacist to conduct a CMR	$118.90/hr	BLS Wage data	N/A
(12)	Cost to conduct CMRs for ARBs under the new provision	$667,505	(10)*(11)	N/A
(13)	Non-labor costs of cost of mailing: 6 pages * ($2.50/500 cost per page + $50/10000 cost of toner)+ 0.08 stuffing + 0.08 envelope + $0.70 for postage	$0.92	See narrative	N/A
(14)	Non-labor cost of mailing CMRs to ARBs	$7,747	(12)*(13)	N/A
(15)	Total cost for preparing and mailing CMRs to ARBs	$675,252	(12)+(14)	N/A

We estimate that in 2021 there will be 48,338,879 beneficiaries enrolled in Part D plans with MTM programs (line 1). Out of these, 1,550,300 (or 3.2071% = 1,550,300/48,338,879) are estimated to be enrolled in an Enhanced MTM program under the Enhanced MTM Model, which is a model tested by the Center for Medicare and Medicaid Innovation (the Innovation Center) under section 1115A(b) of the Act and is not subject to the current or proposed MTM requirements, and therefore these beneficiaries are excluded from the total number of Part D enrollees (line 2). This leaves 46,788,579 Part D enrollees (96.7929% = 46,788,579/48,338,879) who may be eligible for MTM if they meet the targeting criteria (line 3).

According to internal data, we estimate that the SUPPORT Act requires targeting 10,000 ARBs for MTM in 2021 (line 4), of which 9,679 (10,000 * 96.7929 percent of enrollees who are not in an enhanced MTM program) will be

targeted for a CMR (line 6) since those ARBs in the Enhanced MTM model plans (line 5) may not be targeted. Based on our previous experience with the MTM program, we estimate that 87 percent of beneficiaries targeted for MTM under the current requirements will accept the offer of a CMR (line 7). We assume this percentage will also apply to beneficiaries who will be enrolled in MTM programs under the new criteria; therefore, 8,421 ARBs (line 8) (9,679 targeted ARBs not in an enhanced MTM program * 87 percent who are expected to accept a CMR) are expected to accept a CMR based on the proposed provision.

To estimate the burden on Part D plans of furnishing CMRs to the 8,421 ARBs who would be expected to accept the offer of a CMR under the proposed policy, we separately calculate the non-labor cost of mailing and the labor cost of preparing the CMR and packaging it.

To estimate the cost of mailing, we note that paper costs $2.50 per ream (500 sheets) of paper (at $0.005 per sheet) and toner costs $50.00 and lasts for 10,000 sheets. Since CMR summaries contain private health information, they must be mailed first class for which postage costs $0.70 per mailing. Based on industry standards, we assume envelopes cost $0.08, and folding and stuffing costs about $0.08 per document. We therefore estimate the non-labor cost to print and mail a CMR summary in CMS's Standardized Format will be $0.92 per mailing (line 13). This results in a cost of $7,747 (line 14) ($0.92 cost per mailing * 8,421 ARBs).

To estimate the labor cost of preparing the CMS, we note that the CMR is a clinical consultation service and therefore must be administered by a pharmacist, physician, nurse practitioner, or other clinician. Currently, 100% percent of MTMPs employ pharmacists to conduct CMRs, which is the basis of the hourly rate estimate. Industry standards indicate that an average CMR requires 40 minutes or 0.6667 hours (line 9) at $118.90/hr (line 11) for a pharmacist to complete and would result in a CMR summary that averages 6 pages in length based on proposed revisions which would streamline the Standardized Format. This is a decrease in length from the currently approved Standardized Format which averages 10 pages. This results in an annual labor burden of 5,614 hours (line 10) (8,421 ARBs * 0.6667 hours) at a cost of $667,505 (line 12) (5,614 hours * $118.90/hr).

Therefore, the estimated total annual cost of providing CMRs to 8,421 ARBs would be $675,252 (line 15) ($667,505 labor costs + $7,747 non-labor mailing costs). These calculations are summarized in Table 13.

(B) The burden of mailing safe disposal information as part of the CMR summary:

TABLE 14: ESTIMATED BURDEN FOR MAILING SAFE DISPOSAL INFORMATION AS PART OF THE CMR

Line ID	Item	Data	Source
(16)	Part D enrollees not in an Enhanced MTM program under the Enhanced MTM model	46,788,579	(3)
(17)	ARBs not in an Enhanced MTM program under the Enhanced MTM model	9,679	(6)
(18)	Part D enrollees that are neither in Enhanced MTM nor meet ARB criteria	46,778,900	(16)-(17)
(19)	Percentage of Part D enrollees who meet the current criteria for MTM	5.34%	Internal CMS data
(20)	Estimated number of Part D enrollees not in an Enhanced MTM program under the Enhanced MTM model and not meeting ARB criteria who are targeted for MTM under the current criteria	2,497,993	(18)*(19)
(21)	Percent of enrollees targeted for a CMR under the current criteria who accept the offer	87%	Internal CMS data
(22)	Estimated Part D enrollees under the current criteria who will receive a CMR	2,173,254	(20)*(21)
(23)	Estimated Part D enrollees under the proposed provisions meeting ARB criteria who will receive a CMR	8,421	(8)
(24)	Total Part D enrollees (under the current and proposed rule) who will receive a CMR	2,181,675	(22)+(23)
(25)	Non-labor costs of one extra page (2.50/500) and toner for one page ($50/10,000)	$0.01	See narrative
(26)	Estimated cost of mailing safe disposal items to those receiving a CMR (under assumption that the plan will bundle the safe disposal and CMR)	$21,817	(24)*(25)

Under our proposed regulatory change to § 423.153(d)(1), Part D plans would be required to provide all MTM enrollees with information about safe disposal of prescription medications that are controlled substances. The proposed provision would allow plans to mail the newly required safe disposal information either as part of the CMR summary or as part of a TMR or other follow-up service. We estimate the safe disposal information will take one page, has no personal information, and can for example be mailed out as a standalone flier if not included in the annual CMR.

However, for those enrollees receiving a CMR, we believe it most economical to include the 1 page with the already existing CMR summary. We solicit industry input on the accuracy of this assumption. Therefore, the cost of mailing one extra page per enrollee is $0.01 (line 25) (1 page * $2.50/ream of 500 sheets + 1 page * $50 toner/10,000 sheets). We note that the envelope to mail the CMR is already being paid for under current regulations (although folding and stuffing of 7 pages versus 6 pages might require some extra effort, we do not believe this will raise the $0.08 current cost but solicit stakeholder comment on this assumption); the $0.70 first class postage for 2 ounces is sufficient for 7 pages (there would be no increase in postage).

To estimate total mailing cost, we must add the estimates of i) total number of Part D enrollees not in an Enhanced MTM program under the Enhanced MTM model and who are not ARBs who will receive a CMR under the current criteria and ii) total number of ARBs who will receive a CMR under the proposed criteria.

(i) As shown in Table 13, lines (3) and (6), we estimate that in 2021, there will be 46,788,579 Part D enrollees not in an Enhanced MTM program under the Enhanced MTM program (line 16) and as previously determined, 9,679 of those will meet the new MTM targeting criteria as ARBs (line 17). This leaves 46,778,900 Part D enrollees (46,788,579 not in an Enhanced MTM program minus 9,679 enrollees meeting the ARB criteria) that must be targeted for MTM if they meet the current criteria (line 18). Our internal data shows that 5.34 percent (line 19) of the Part D enrollees will be targeted for MTM programs under the current criteria. Hence, this leaves 2,497,993 Part D enrollees (5.34 percent * 46,778,900) who will be targeted for MTM under the current criteria (line 20). Of these 2,497,993 targeted enrollees, as stated previously, based on internal CMS data, we estimate 87 percent will accept the annual CMR offer (line 21). Therefore 2,173,254 beneficiaries (2,497,993 * 0.87) will receive a CMR under the current criteria (line 22).

(ii) As shown in Table 13, line (8), 8,421 ARBs are estimated to receive a CMR under the proposed criteria.

Hence, in 2021 a total of 2,181,675 enrollees will receive a CMR under the current and proposed criteria (8,421 ARBs under the proposed criteria + 2,497,993 under the current criteria) (line 24), at a total non-labor mailing cost of $21,817 (2,181,675 enrollees * $0.01 mailing cost per enrollee) to add an additional page containing safe disposal information to all CMRs (line 25).

These calculations are summarized in Table 15.

(C) The burden of mailing safe disposal information once a year as part of a TMR or other follow-up service:

TABLE 15: BURDEN OF MAILING SAFE DISPOSAL INFORMATION TO ENROLLEES NOT RECEIVING A CMR

Line ID	Item	Data	Source
(27)	Number of Part D enrollees who meet the current criteria for MTM	2,497,993	(20)
(28)	Number of Part D enrollees who meet the criteria for ARB under the proposed rule	9,679	(6)
(29)	Number of Part D enrollees meeting current or proposed criteria for MTM	2,507,672	(27)+(28)
(30)	Percentage of enrollees estimated to refuse the offer of a CMR	13%	100% - (21)
(31)	Number of enrollees to whom safe disposal information must be mailed even though they don't receive a CMR	325,997	(29)*(30)
(32)	Non-labor cost of mailing a one page flier (at 2.50/500 cost per page + $50/10000 cost of toner for one page + $0.19/200 cost of mailing a flier)	$0.01095	See narrative
(33)	Cost of mailing safe disposal information to those who do not receive a CMR	$3,570	(31)*(32)
(34)	Cost of mailing safe disposal information to those who do receive a CMR	$21,817	(26)
(35)	Total cost of mailing safe disposal information	$25,387	(33)*(34)

All targeted beneficiaries who have not opted out of the MTM program must receive TMRs at least quarterly, and we are allowing Part D sponsors the flexibility of choosing whether to include safe disposal information in the CMR, through a TMR, or another follow-up service at least once annually. Since we assume that 87 percent of targeted enrollees accept an offer of a CMR (Table 13, line (7)), it follows that 13 percent (100 percent − 87 percent) (line 30) of Part enrollees who are targeted for enrollment in an MTM program refuse the CMR offer but do not opt out of the MTM program completely. As discussed previously, 9,679 ARBs (Table 13, line (6)) under the proposed criteria and 2,497,993 enrollees (Table 14, line 20) under the current criteria, or a total of 2,507,672 enrollees (2,497,003 + 9,679) (line (29)) will be targeted to receive a CMR. Therefore 325,997 enrollees (2,507,672 total enrollees * 13 percent who refuse a CMR) would need to be mailed the safe disposal information as part of a TMR or other follow-up service (line 31). The cost to mail 1 page of safe disposal information is $0.01095 per enrollee if the letter does not contain private health information and thus bulk mailing is used (line 32) (1 page * $2.50 per ream of paper/500 sheets + 1 page * $50 per toner/10,000 pages + $0.19/200 items). Therefore, the estimated cost of mailing safe disposal information to those MTM enrollees who do not receive a CMR is $3,570 (line 33) (325,997 enrollees * $0.01095 mailing cost per page).

The total cost of mailing safe disposal information to all Part D beneficiaries enrolled in MTM programs is then estimated to be $25,387 (line 35) ($3,570 for those enrollees who refuse a CMR + $21,817 for those enrollees who accept a CMR). These calculations are summarized in Table 15.

The total additional annual cost for 288 parent organizations to provide CMRs to ARBs and to send safe disposal information of prescription medications that are controlled substances to all MTM program enrollees is $700,369.

Table 16 provides a compact summary of the bottom lines of impact by activity.

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TABLE 16: SUMMARY FOR ELIGIBILITY FOR MTMPs (§ 423.153) AND INFORMATION ON THE SAFE DISPOSAL OF PRESCRIPTION DRUGS

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
§ 423.153	Mailing ARBs CMR	288	8,421	N/A	N/A	0.92	7,747
§ 423.153	Targeting ARBs for CMR	288	8,421	0.6667	5,614	118.90	667,505
§ 423.153	Safe Disposal Page in CMR	288	2,181,675	N/A	N/A	0.010	21,817
§ 423.153	Safe Disposal Page as part of TMR or other follow-up service	288	325,997	N/A	N/A	0.01095	3,570
TOTAL		288	2,507,672	5,614	*Varies*	*Varies*	700,639

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6. ICRs Regarding Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

In this rule, we are proposing under § 423.128 to require Part D sponsors to disclose, beginning 2021, information about the risks of prolonged opioid use to enrollees. In addition to this information, Part D sponsors of MA–PDs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Part C. Part D sponsors of PDPs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B.

Before Part D sponsors can send this information, they would have to create and upload materials into their internal systems. Based on 2019 CMS data, there are 608 Part D legal entities (sponsors) with which CMS contracts, associated with 288 parent organizations that these contracts identified in their initial applications, which is confirmed annually. Based on our knowledge of the way parent organizations and their Part D legal entities are structured, we believe it is appropriate to estimate burden at the parent organization level, as it is a closer reflection of the number of systems that will need to be updated versus at the contract level.

We estimate that 288 Part D sponsors would be subject to this proposal, based on 2019 data. We estimate that it will take on average 2 hours at $86.14/hr for a computer programmer to upload the

information into the systems. This would result in a one-time burden of 576 hours (2 hr * 288 parent organizations) at a cost of $49,617 (576 hours * $86.14/hr). Once the information is uploaded into the parent organization's database, we anticipate no further cost associated with this task, as the process will be automated after the initial upload with the same information on subsequent materials that are sent. The automation would include the sending of information to those enrollees who wish to receive an electronic copy. The automation would also cover updates in future years as the plan enrollment changes.

We also estimate a one-time burden of 2 hours at $118.90/hr for a pharmacist to develop the materials(s) to be sent to the beneficiaries. In aggregate, we estimate a one-time burden of 576 hours (288 parent organizations * 2 hr) at a cost of $ 68,486 (576 hr * $118.90/hr). Although there might be the need for updates in future years (if opioid risk and/or coverage information changes), we believe the burden to making such updates to existing materials will be negligible as the changes will be minor and may only occur in some future years. Hence, the more accurate approach adopted here is to estimate this as a one-time update.

We propose that Part D sponsors may disclose the opioid and coverage information in electronic form. Some enrollees prefer electronic notification and some prefer paper mailing. We have no way of estimating the proportions for each preference, but our experience suggests that most enrollees expect a paper mailing. Therefore, we assume 75 percent (the average of 50 percent and 100 percent) would prefer a paper mailing, while the remaining 25 percent would prefer electronic notification.

There are several Part D enrollee groups presented in section III.D. of this proposed rule that we suggest could be sent the required information and thus, several approaches to estimate the burden. These enrollee group estimates range from sending the information to 46,759,911 enrollees to 2,698,064 enrollees, Therefore, for plans convenience and planning, Table 17 presents an alternative cost analysis of the wide range of alternatives discussed in section III.D. of this proposed rule.

We also include calculations under assumption that only 50 percent want paper and calculations under assumption that 75 percent want paper. As can be seen, the range of costs are $0.1 to $0.5 million (for sending notices by paper to all Part D enrollees. Thus, cost need not be a factor in plan choice.

Since the range of costs are $0.1 million to $0.5 million, for purposes of the Summary Table, we are listing the $0.1 million or $118,103 first year cost ($68,486 for creation of materials + $49,617 for system updates) but leaving out mailing costs until we receive feedback from our stakeholders. We however, solicit stakeholder feedback on which alternatives they believe are most likely and unlikely, as well as stakeholder feedback on our estimation of printing and delivery costs.

In making estimates on the burden of sending out notices, we assume that the IT systems of the plan would generate and mail the documents once a template is produced. Thus, the only costs per enrollee are paper, toner, and postage. We also assume one page per notice. We therefore estimate:

- *Cost of paper:* Typical wholesale costs of paper are approximately $2.50 for a ream of 500 sheets. Thus cost for one page is 2.50/500 = $0.005.
- *Cost of toner:* Toner costs can range from $50 to $200 and each toner can last 4,000 to 10,000 sheets. CMS assumes a cost of $50.00 for 10,000 pages. Thus cost per page is $50/10,000 = $0.005.
- *Cost of postage:* For 2019, the bulk postage rates are $0.19 per 200 pages. Thus the cost per page is 0.19/200 = 0.000950.

Thus, the aggregate cost per page is 0.01095 (0.005 + 0.005 + 0.000950). This per page amount is multiplied by the number of enrollees receiving the notification. Note that mailing costs are annual while the programming updates and the development of materials are first-year costs with minimal or no costs in future years. The product of the cost per page times the number of enrollees plus the first year costs are the costs listed for each possibility in Table 17.

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TABLE 17: IMPACTS OF SEVERAL ALTERNATIVES FOR PROVIDING INFORMATION TO OPIOID USERS

(A) Issue	(B) Number of Opioid Users in this Category	(C) Number of Part D Sponsors	(D) Percentage of Enrollees Wanting Paper Delivery	(E) Cost per Plan or Enrollee for Paper Copies	(F) Aggregate Cost (B)*(D)*(E)	(G) Total Cost for this Scenario	Total Cost Rounded (millions)
2 hours of programming	N/A	288	N/A	172.28	49,617	N/A	N/A
2 hours for a pharmacist to develop the materials	N/A	288	N/A	237.8	68,486	N/A	N/A
Total first year programming and development cost	N/A	N/A	N/A	N/A	118,103	N/A	N/A
75% want paper; 90-day usage with 7 day (or less) gap	2,698,064	N/A	75%	0.01095	22,158	140,261	0.1
50% want paper; 90-day usage with 7 day (or less) gap	2,698,064	N/A	50%	0.01095	14,772	132,875	0.1
75% want paper; 30-day usage with 7 day (or less) gap	3,816,731	N/A	75%	0.01095	31,345	149,448	0.1
50% want paper; 30-day usage with 7 day (or less) gap	3,816,731	N/A	50%	0.01095	20,897	139,000	0.1
75% want paper; 7-day usage	7,163,615	N/A	75%	0.01095	58,831	176,934	0.2
50% want paper; 7-day usage	7,163,615	N/A	50%	0.01095	39,221	157,324	0.2
75% want paper; All opioid users (1 year)	11,027,271	N/A	75%	0.01095	90,561	208,665	0.2
50% want paper; All opioid users (1 year)	11,027,271	N/A	50%	0.01095	60,374	178,477	0.2
75% want paper; any opioid use in last 2 years excluding cancer and hospice patients	16,134,063	N/A	75%	0.01095	132,501	250,604	0.3
50% want paper; any opioid use in last 2 years excluding cancer and hospice patients	16,134,063	N/A	50%	0.01095	88,334	206,437	0.2
75% want paper; All Part D enrollees	46,759,911	N/A	75%	0.01095	384,016	502,119	0.5
50% want paper; All Part D enrollees	46,759,911	N/A	50%	0.01095	256,011	374,114	0.4

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The burden associated with developing and uploading these materials into sponsors' internal systems will be submitted to OMB under PRA package number CMS–10141 (OMB 0938–0964). Subject to renewal, it is currently set to expire on November 30th, 2021. It was last approved on November 28, 2018, and remains active.

7. ICRs Regarding Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

The following proposed changes will be submitted to OMB for approval under control number 0938–TBD (CMS–10724) for Medicare Advantage Plans and 0938–1262 (CMS–10517) for Part D Plans.

Proposed §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) would require the MA organization or Part D plan sponsor, respectively, to have procedures to identify and report to CMS or designee: (1) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy; which must be implemented in the same manner as the Secretary does under 1862(o)(1) of the Act; and (2) any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan.

CMS initiated a reporting pilot program in December 2016 with six plan sponsors to test the effectiveness of mandatory reporting of fraud, waste and abuse. The pilot collected all external or internal Medicare complaints and referrals submitted to the plan's Special Investigations Unit (SIU). The data collected as part of the pilot program was time limited, but broader than the scope of reporting required by sections 2008 and 6063 of the SUPPORT Act. The scope of that pilot tested the reporting of all types of health care fraud, waste, and abuse that the plan sponsors could encounter in their operations and, therefore, could be utilized as a reasonable estimate of burden involved with the quarterly plan reporting to CMS that CMS will use to implement sections 2008 and 6063 of the SUPPORT Act. The pilot program analyzed information that was reported from five of six plan participants on time spent collecting three quarterly data submissions. Based on the results of the pilot study, if every plan reported, we estimate it would take 605 MA plans and 63 Part D plans 164,996 hours (668 plans * 247 hr/plan) at a cost of $14,975,037 (164,996 hr * $90.76/hr) to fulfill the proposed reporting and procedure preparation in the first year. The first-year costs consist of the time and effort needed to prepare the procedures and report the inappropriate prescribing information. Subsequent effort consists solely of the ongoing time and cost to report the inappropriate prescribing information to CMS. We cannot anticipate how many plans will need to report any payment suspension to pharmacies in the plans' network or information on inappropriate opioid prescribing to CMS.

In subsequent years, we estimate an annual burden of 104,208 hours (668 plans *156 hr/plan) at a cost of $9,457,918 (104,208 hr * $90.76/hr).

The following Tables 18 and 19 show—

- MA Organization and Part D Plan Sponsor Time Estimate (HOURS) (Table 18); and
- MA Organization and Part D Plan Sponsor Cost Estimate ($) (Table 19).

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TABLE 18: MA ORGANIZATION AND PART D PLAN SPONSOR TIME ESTIMATE (HOURS)

OMB Control Number (CMS ID No.)	Requirements	Number of Respondents	Total Burden Hours (Initial Year)[2]	Total Burden Hours (Subsequent Years)[2]
0938-TBD (CMS-10724)	MA Organizations: § 422.503(b)(4)(vi)(G)(*4*)	605	149,435	94,380
0938-1262 (CMS 10517)	Part D Plans: § 423.504(b)(4)(vi)(G)(*4*)	63[1]	15,561	9,828
TOTAL		668	164,996	104,208
FIRST YEAR BURDEN:			**164,996 (668 plans * 247 hr/plan)**	
SUBSEQUENT YEARS ANNUAL BURDEN:			**104,208 (668 plans* 156 hr/plan)**	

[1] Total number of PDPs in 2020 determined through a review of HPMS; the total number excludes PACE plans who are not required to report via HPMS.

[2] Burden Hours: Utilizing the pilot as a basis for the burden calculation, it should be noted that a higher level of effort (plan burden) was required for the first data submission as plan sponsors became familiar with the data fields and mapped their data. However, the following data submissions required a significantly reduced level of effort. The first year as previously shown reflects that higher level of effort, 247 hours per plan. For each future year, the estimate is shown at 156 hours per plan.

Note: (1) The estimates are based on the reporting structure, as outlined in our proposals; (2) the reporting will occur at the contract level; (3) the number of plans does not include PACE plans.

TABLE 19: MA ORGANIZATION AND PART D PLANS COST ESTIMATE ($)

OMB Control Number (CMS ID No.)	Requirements	Number of Respondents	Time Burden (Initial Year)[1]	Hourly Rate ($/hr)[2]	Total Annual Burden ($)
0938-TBD (CMS-10724)	MA Organizations: § 422.503(b)(4)(vi)(G)(*4*)	605	149,435	90.76	13,562,721
0938-1262 (CMS 10517)	Part D Plans: § 423.504(b)(4)(vi)(G)(*4*)	63	15,561	90.76	1,412,316
	FIRST YEAR BURDEN		164,996	90.76	**14,975,037**
	BURDEN IN EACH SUBSEQUENT YEAR	668 Total Plans	104,208	90.76	**9,457,918**

[1] Burden Hours (Initial Year): Utilizing the pilot as a basis for the burden calculation, it should be noted that a higher level of effort (plan burden) was required for the first data submission as plan sponsors became familiar with the data fields and mapped their data. However, the subsequent data submissions required a significantly reduced level of effort.

[2] Using wages of Management Analyst (Occupational title 13-1111).

Note: (1) The estimates are based on the reporting structure, as outlined in our proposals; (2) the reporting will occur at the contract level; (3) the number of plans does not include PACE plans.

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8. ICRs Regarding Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

As discussed in section IV.A. of this proposed rule, we propose to revise §§ 422.50(a)(2), 422.52(c), and 422.110(b) to allow ESRD beneficiaries, without exception, to enroll in an MA plan. In estimating the impact of this provision, we separately estimate impact on beneficiaries and plans. Enrollment processing and notification requirements are codified at § 422.60 and are not being revised as part of this rulemaking, and no new or additional ICRs are being imposed. The additional paperwork burden for this provision to account for ESRD beneficiaries to enroll in a MA plan, as outlined in the next section, will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). Subject to renewal, the control number is currently set to expire on December 31, 2021.

a. Beneficiary Burden

The burden associated with this requirement would be related to the effort it takes for a beneficiary to complete an enrollment request. Because there will be an increase in the number of beneficiaries eligible to elect an MA plan starting in plan year 2021, the universal burden for beneficiaries would increase (that is, the number of beneficiaries who are expected to initiate an enrollment action would increase). However, the currently approved response time estimate (0.5 hr) would not change.

To elect an MA plan, an individual must complete and sign an election form, complete another CMS-approved election method offered by the MA plan, or call the 1–800–MEDICARE Call Center, and provide information required for enrollment. The burden associated with this requirement is the time it takes a new enrollee to complete an enrollment form or other CMS-approved election method offered by the MA plan. The enrollment form and other election methods vary for each organization, but similar identifying information is collected.

As detailed in section X.C.4. of this proposed rule, OACT expects an average increase of 59,000 ESRD beneficiaries to enroll in MA plans per year in 2021 through 2023. Therefore, we expect a burden of 29,500 hours (59,000 new ESRD enrollees * 0.5 hr) to complete an enrollment form at a cost of $736,910 (29,500 hr * $24.98/hr).

CMS is proposing changes to the current, standard (''long'') model form used for MA and PDP enrollment in order to reduce data collection and simplify the enrollment process. CMS is not revising the current, ''long'' model form under CMS–R–267. The ''shortened'' enrollment form, three pages in length, (compared to the current model form which is seven pages), would limit data collection to what is lawfully required to process the enrollment, and, other limited information that the sponsor is, required or chooses to, provide to the beneficiary. A new ''stand-alone'' PRA notice (CMS–10718, OMB 0938–TBD) that is specific to the shortened enrollment form published in the **Federal Register** on November 18 (84 FR 63655) with a 60-day comment period and November 21, 2019 (84 FR 64319) with a burden correction. The shortened form has been made available for public review/comment outside of the rulemaking process since it is not tied to any of the provisions proposed in this rule, and it would not be subject to the effective date of the subsequent, final rule.

b. Plan Burden

Although not effective until January 1, 2021, section 17006 of the Cures Act amends the Act by allowing ESRD beneficiaries, without exception, to enroll in an MA plan. Consequently, OACT has incorporated an increase in ESRD enrollment in the Medicare Trust Fund baseline due to the legislation. The increases cover the plans' required revenue or submitted bid amounts, both medical (benefit) and administrative (non-benefit). The non-benefit expense portion of the bids include direct administrative expenses, indirect administrative expenses, gain and loss margins, marketing, and other items such as the net cost of private re-insurance as well as insurer fees. These non-benefit expenses generally make up a sizeable portion of the bid (about 16 percent for the 2020 bids).

Consequently, the expected increase to the plan for administering additional enrollments, due to additional ESRD beneficiaries enrolling in MA plans, has already been included in the currently approved burden estimates; therefore, this provision, which simply codifies the existing requirement, is not expected to have further impact beyond what is currently approved by OMB.

9. ICRs Regarding Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

The following proposed changes will be submitted to OMB for approval under control number 0938–0763 (CMS–R–262). Subject to renewal, the control number is currently set to expire on April 30, 2022.

As described in section V.G. of this proposed rule, the proposed new paragraphs at § 423.128(d)(4) and (5) would require each Part D plan to implement a beneficiary RTBT no later than January 1, 2022. This tool would allow enrollees to view a plan-defined subset of the information included in the prescriber RTBT system which includes complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information (including cost, formulary alternatives, and utilization management requirements). Plans would be able to use existing secure patient portals to fulfill this requirement, to develop a new portal, or to use a computer application.

As discussed in section V.G. of this proposed rule, we understand that most Part D plans have already created beneficiary portals that satisfy existing privacy and security requirements. Based on our conversations with the industry, we believe that the few plans that have yet to create a portal or web application will have one in place by January 1, 2022.

We estimate it would take 104 hours at $86.14/hr for a computer programmer to program this information into the beneficiary portal and an additional 52 hours to put this information into a user interface that is easily understood by enrollees. The time estimates are based on consultation with the healthcare industry and their IT staff to determine the time that it takes for minor changes in programming. Thus the cost of implementing RTBT is 44,928 hours (288 organizations * 56 hr) at a cost of 3,870,098 (44,928 hr * $86.14/hr).

We next estimate the cost of implementing the rewards and incentives program for use of RTBT. We will estimate three items: (A) Development of policies for the new program, (B) updating of systems, and (C) maintaining the program. We solicit stakeholder feedback on all our assumptions. We informally asked stakeholders who thought that only 10 percent of parent part D sponsors would create such a program. Since there are 288 Part D sponsors we expect 29 (288 * 0.10 or 10 percent) organizations to develop and use a reward and incentive program.

(A) Development of policy: We estimate that for each parent organization an operations manager and compliance officer working together at a combined hourly wage of $188.84/hr ($119.12/hr + $69.72/hr) would take a week of work, 40 hours, Therefore the aggregate impact is 1,160 hours (40 hr * 29 parent organizations) at a cost of $219,054 (1,160 hr * $188.84/hr).

(B) Since systems already exist to collect enrollee data, they will only have to be updated to collect data on use of RTBT and most of this work will be done when creating the RTBT. We therefore estimate, per parent organization, an extra week of work, 40 hours. Therefore, the aggregate impact is 1,160 hours (40 hr * 29 organizations) at a cost of $99,922 (1,160 hr * $86.14/hr).

(C) Since computer systems are doing most of the work we estimate that 2 administrative support workers each working at $36.04/hr will take 15 hours every month to maintain the program. Thus each parent organization will spend 360 hours per year (15 hr/month * 12 months * 2 workers). The aggregate impact is 10,440 hours (360 hr/organization * 29 organizations) at a cost of $376,258 (10,400 hr * $36.04/hr).

The aggregate impact for implementing the rewards and incentives for RTBT among those Part D sponsors who wish to do so is s 13,920 hours (1,160 hr + 1,160 hr + 10,440) at a cost of $695,234 ($219,054 + $99,922 + $376,258).

Since plans are in the best position to estimate their implementation costs, we seek comment on the accuracy of this burden estimate and on any measures that CMS can take to decrease the impact of this provision, while maintaining its utility for enrollees. In addition, because plans are in the best position to estimate any information collection implications, since they will be the stakeholders implementing this provision, we solicit comment on any other potential information collection implications.

While we are proposing to allow plans to offer rewards and incentives to enrollees who use the tool, we are not estimating burden for including rewards and incentives, since we are not requiring that plans provide rewards and incentives, and CMS does not have a means of calculating the costs and benefits of rewards and incentives at this time.

10. ICRs Regarding Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

The following proposed changes will be submitted to OMB for approval under control number 0938–0992 (CMS–10185). Subject to renewal, the control number is currently set to expire on December 31, 2021. It was last approved on December 7, 2018, and remains active.

We propose to amend § 423.514(a) by requiring that Part D sponsors report to CMS the pharmacy performance measures they use to evaluate pharmacy performance, as established in their network pharmacy agreement. Given the growing practice of Part D sponsors measuring the performance of pharmacies that service Part D beneficiaries to determine the final cost of a drug under Part D, this reporting requirement will enable CMS to monitor the impact of these recoupment practices. This new Part D reporting requirements section would require plans to report their pharmacy performance measures' data. We estimate a collection of less than 15 data elements. As noted in the preamble, the Part D reporting requirements data elements, consistent with our proposed standard, would be specified through the standard non-rule PRA process after publication of the final rule, if this proposal is finalized. The standard non-rule process includes the publication of 60- and 30-day **Federal Register** notices.

Although the data elements will be made available for public review through the standard PRA process, we are providing the interested parties with

an initial projection of the potential burden estimates. In this regard there are currently 627 contracts that would be required to report their pharmacy performance measures' data. Part D sponsors currently report 6 sections of data to CMS in accordance with the Part D reporting requirements. Therefore, CMS does not expect compliance to these reporting requirements would result in additional start-up costs. Anticipated staff time spent performing these data collection would be 30 minutes for data analysts and/or IT analysts at a rate of $90.02/hr. We would require this information to be reported at the plan level once annually. Reporting at the plan level would generate 5,234 responses since there are currently 5,234 plans. In aggregate, we estimate an annual plan sponsor burden of 2,617 hours (5,234 plans * 1 report/year * 0.5 hr/report) at a cost of $235,582 (2,617 hr * $90.02/hr). We are soliciting input from stakeholders on the accuracy of these estimates and on any measures that CMS can take to decrease the burden of this provision.

11. ICRs Regarding Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2430)

MSA Enrollment

The proposed changes affecting MSA enrollment will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). Subject to renewal, the control number is currently set to expire on December 31, 2021.

As discussed in section V.I.4. of this proposed rule, CMS is proposing to amend § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA MSA contracts that receive a credibility adjustment. The proposed deductible factor would serve as a multiplier on the credibility factor. The application of the proposed deductible factor would increase the MLRs of MSA contracts that receive this adjustment.

We believe that the proposed change to the MLR calculation for MSAs could potentially cause the number of enrollees in MSA plans to increase relative to enrollment projections under the current regulations. For this impact estimate, we make the following assumptions. If the proposed changes take effect, we assume:

- Enrollment in MSAs will double over the first 3 years that the proposed change is in effect. We believe 3 years is a reasonable time frame for the enrollment changes resulting from this policy to be phased in. We project that enrollment will double in order to avoid potentially understating the cost for the proposal. Our estimate is based on the largest potential change in enrollment that we could reasonably anticipate. We acknowledge that the proposed change could have no impact on enrollment.
- Relative to projections in the baseline, MSA enrollment will be 33.33 percent higher in contract year (CY) 2021 (increasing from 7,435 to 9,913), 66.67 percent higher in 2022 (increasing from 7,812 to 13,020), and 100 percent higher in CY 2023 (increasing from 8,179 to 16,358) to CY 2030 (increasing from 10,354 to 20,708).
- Half of the new enrollees in MA MSA plans would otherwise have been enrolled in other types of MA plans, and half would otherwise have been enrolled in FFS Medicare. We did not have a basis for assuming that migration to MSAs would predominantly be from FFS Medicare or from non-MSA MA plans.

The process for enrolling in an MA plan is the same regardless of whether that plan is an MSA or a non-MSA. Therefore, we assume that the burden to enroll in an MSA plan and a non-MSA plan is the same. Therefore, the increased burden related to changes in MSA enrollment is attributable only to the portion of potential new MSA enrollees who would be expected to enroll in FFS Medicare if the proposal is not finalized. The cost burden of this proposal is summarized in Table 20.

a. Beneficiary Burden

For beneficiaries, the burden associated with the expected increase in MSA enrollment as a consequence of our proposal would be related to the effort it takes for a beneficiary to complete an enrollment request. It takes 0.5 hours at $24.98/hr for a beneficiary to complete an enrollment form. We assume no burden increase for the estimated fifty percent of additional MSA enrollees who would otherwise be enrolled in a non-MSA MA plan. For 2021, the burden for all beneficiaries is estimated at approximately 620 hours (2,478/2 beneficiaries * 0.5 hr) at a cost of $15,488 (620 hr * $24.98/hr). For 2022, the burden for all beneficiaries is estimated at approximately 1,302 hours (5,208/2 beneficiaries * 0.5 hr) at a cost of $32,524 (1,302 hr * $24.98/hr). For 2023, the burden for all beneficiaries is estimated at approximately 2,045 hours (8,179/2 beneficiaries * 0.5 hr) at a cost of $51,084 (2,045 hr * $24.98/hr).

The average burden per year is 1,322 hours ([620 + 1,302 + 2,045]/3) at an average cost of $33,032 ([$15,488 + $32,254 + $51,084]/3).

b. MA Organization Estimate

There are currently four MA organizations offering MSA plans in 2020. We project that this number will double in 2021 as a result of the proposed change. We therefore estimate that the proposed change would result in approximately 2,478 total additional enrollments in MSAs in 2021, or 310 additional enrollments per organization (2,478 individuals/8 organizations); in 2022, 5,308 total additional enrollments in MSAs, or 664 additional enrollments per organization (5,308 individuals/8 organizations); and in 2023, and 8,531 total additional enrollments, or 1,066 additional enrollments per organization (8,531 individuals/8 organizations).

The MA organization must give the beneficiary prompt written notice of acceptance or denial of the enrollment request in a format specified by CMS that meets the requirements set forth in this section. The burden associated with each organization providing the beneficiary prompt written notice, performed by an automated system, is estimated at 1 minute per application processed. We estimate that it will take 1 minute at $74.00/hr for a business operations specialist to electronically generate and submit a notice to convey the enrollment or disenrollment decision for each beneficiary. As noted previously, we anticipate that half of the new enrollees in MSAs will already be enrolled in other MA plans, meaning the current burden estimate for their enrollment is already accounted for in the currently approved collection. For 2021, the burden to complete the notices for the other half of new MSA enrollees (that is, the new enrollees who would otherwise enroll in FFS Medicare) is approximately 21 hours (2,478/2 notices * 1 min/60) at a cost of $1,554 (21 hr * $74.00/hr) or $1.25 per notice ($1,554/1,239 notices) or $194.25 per organization ($1,554/8 MA organizations). For 2022, the burden to complete the notices for the half of new MSA enrollees who would otherwise enroll in FFS Medicare is approximately 43 hours (5,208/2 notices * 1 min/60) at a cost of $3,182 (43 hr * $74.00/hr) or $1.22 per notice ($3,182/2,604 notices) or $397.75 per organization ($3,182/8 MA organizations). For 2023, the burden is approximately 68 hours (8,179/2 notices * 1 min/60) at a cost of $5,032 (68 hr * $74.00/hr) or $1.23 per notice ($5,032/4,090 notices) or $629.00 per organization ($5,032/8 MA organizations).

The average burden per year is 44 hours ([21 hr + 43 hr + 68 hr]/3) at an average cost of $3,256 ([$1,554 + $3,182 + $5,032]/3).

The burden associated with electronic submission of enrollment information to CMS is estimated at 1 minute at $74.00/hr for a business operations specialist to submit the enrollment information to CMS during the open enrollment period. The total burden for 2021 is approximately 21 hours (2,478/2 submissions × 1 min/60) at a cost of $1,554 (21 hr * $74.00/hr) or $1.25 per submission ($1,554/1,239 submissions) or $194.25 per organization ($1,554/8 MA organizations). For 2022, the total burden is approximately 43 hours (5,208/2 submissions × 1 min/60) at a cost of $3,182 (43 hr * $74.00/hr) or $1.22 per submission ($3,182/2,604 submission) or $397.75 per organization ($3,182/8 MA organizations). For 2023, the total burden is approximately 68 hours (8,179/2 submissions * 1 min/60) at a cost of $5,032 (68 hr * $74.00/hr) or $1.23 per submission ($5,032/4,090 submissions) or $629.00 per organization ($5,032/8 MA organizations).

The average burden per year is 44 hours ([21 hr + 43 hr + 68 hr]/3) at an average cost of $3,256 ([$1,554 + $3,182 + $5,032]/3).

Additionally, MA organizations will have to retain a copy of the notice in the beneficiary's records. The burden associated with this task is estimated at 5 minutes at $36.04/hr for an office and administrative support worker to perform record retention for the additional MA MSA enrollees. In aggregate, we estimate an annual burden for 2021 of 103 hours (2,478/2 beneficiaries * 5 min/60) at a cost of approximately $3,712 (103 hr * $36.04/hr) or $473 per organization ($3,784/8 MA organizations). For 2022, we estimate an aggregated annual burden of 217 hours (5,208/2 beneficiaries * 5 min/60) at a cost of approximately $7,821 (217 hr * $36.04/hr) or $978 per organization ($7,821/8 MA organizations). For 2023, we estimate an aggregated annual burden of 341 hours (8,179/2 beneficiaries * 5 min/60) at a cost of approximately $12,290 (341 hr * $36.04/hr) or $1,536.25 per organization ($12,290/8 MA organizations).

The average burden per year is 220 hours ([103 hr + 217 hr + 341 hr]/3) at an average cost of $7,941 ([$3,712 + $7,821 + $12,290]/3).

MLR Calculation

The proposed changes affecting the MLR calculation will be submitted to OMB for approval under control number 0938–1232 (CMS–10476). Subject to renewal, the control number is currently set to expire on December 31, 2021.

MA organizations will need to spend additional time calculating the MLRs for MSA contracts in order to apply the proposed deductible factor. We estimate that for each of the 8 MA organizations that we anticipate will offer MSA contracts in 2021 and in each year through 2030, it will take an actuary approximately 5 minutes at a wage of $111.78/hr to calculate the deductible factor for the contract. In aggregate, we estimate an annual burden of 0.6667 hours (5 min/60 * 8 MA organizations) at a cost of approximately $75 (0.6667 hr × $111.78/hr) or approximately $9 per organization ($111.78/hr * 0.0833 hr).

The average (in fact, actual) burden per year is 0.6667 hr at a cost of $75. For 2021, we estimate a total burden for all MA organizations resulting from this proposed provision to be 145.6667 hours (21 hr + 21 hr + 103 hr + 0.6667 hr) at a cost of $6,895 ($1,554 + $1,554 + $3,712 + $75). Per organization, we estimate an annual burden of approximately 18.2 hours (145.6667 hr/8 MA organizations) at a cost of $861.88 ($6,895/8 organizations). For beneficiaries we estimate a total annual burden of 620 hours at a cost of $15,488 and a per beneficiary burden of 30 minutes at $12.50.

For 2022, we estimate a total burden for all MA organizations resulting from this proposed provision to be 303.6667 hours (43 hr + 43 hr + 217 hr + 0.6667 hr) at a cost of $14,260 ($3,182 + $3,182 + $7,821 + $75). Per organization, we estimate an annual burden of approximately 38 hours (303.6667 hr/8 MA organizations) at a cost of $1,782.50 ($14,260/8 organizations). For beneficiaries we estimate a total annual burden of 620 hours at a cost of $15,488 and a per beneficiary burden of 30 minutes at $12.50.

For 2023, we estimate a total burden for all MA organizations resulting from this proposed provision to be 477.6667 hours (68 hr + 68 hr + 341 hr + 0.6667 hr) at a cost of $22,429 ($5,032 + $5,032 + $12,290 + $75). Per organization, we estimate an annual burden of approximately 60 hours (477 hr/8 MA organizations) at a cost of $2,803.63 ($22,429/8 organizations). For beneficiaries we estimate a total annual burden of 620 hours at a cost of $15,488 and a per beneficiary burden of 30 minutes at $12.50.

Summary

TABLE 20: IMPACT OF MSA/MLR BY SUBJECT

Respondents	Subject	2021	2022	2023	3-year average
Beneficiaries	Enrollment request	$15,488 (620 hours)	$32,524 (1,302 hours)	$51,084 (2,045 hours)	$33,032 (1,322 hours)
MA organizations	Notice to beneficiaries	$1,554 (21 hours)	$3,182 (43 hours)	$5,032 (68 hours)	$3,256 (44 hours)
MA organizations	Submission to CMS	$1,554 (21 hours)	$3,182 (43 hours)	$5,032 (68 hours)	$3,256 (44 hours)
MA organizations	Record retention	$3,712 (103 hours)	$7,821 (217 hours)	$12,290 (341 hours)	$7,941 (220 hours)
MA organizations	Calculation of deductible factor	$75 (0.6667 hours)	$75 (0.6667 hours)	$75 (0.6667 hours)	$75 (0.6667 hours)
MA ORGANIZATIONS TOTAL		$6,895 (145.6667 hours)	$14,260 (303.6667 hours)	$22,429 (477.6667 hours)	$14,528 (309 hours)

12. ICRs Regarding Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

The following proposed changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D.

We are proposing to codify certain Part C (at § 422.62(b)(4) through (25)) and Part D (at § 423.38(c)(11) through (32)) SEPs for exceptional circumstances currently set out in sub-regulatory guidance that MA organizations and Part D plan sponsors have implemented and are currently following. We are also proposing to establish two new additional SEPs for exceptional circumstances: The SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.

We do not believe the proposed changes will adversely impact individuals requesting enrollment in Medicare health or drug plans, the plans themselves, or their current enrollees. Similarly, we do not believe the proposed changes would have any impact on the Medicare Trust Fund.

Our proposal represents the codification of existing policy on SEPs for exceptional circumstances that has been specified in sub-regulatory guidance for quite some time, as well as the addition of the two aforementioned new SEPs for exceptional circumstances. MA organizations and Part D plan sponsors are currently assessing applicants' eligibility for election periods as part of existing enrollment processes; therefore, no additional burden is anticipated from this proposal. However, because a burden estimate for determining an applicant's eligibility for an election period has not previously been submitted to OMB, due to inadvertent oversight, we are seeking their approval under the aforementioned OMB control numbers.

We estimate it would take approximately 5 minutes (0.0833 hr) at $74.00/hr for a business operations specialist to determine an applicant's eligibility for an election period.

The burden for all MA organizations is estimated at 142,497 hours (1,710,650 beneficiary SEP elections * 0.0833 hr) at a cost of $10,544,778 (142,497.1450 hr * $74.00/hr) or 58,258 per parent organization ($10,544,778/181 MA parent organizations).

The burden for all Part D parent organizations is estimated at 155,564 hours (1,867,519 beneficiary SEP elections * 0.0833 hr) at a cost of $11,511,736 (155,564 hr * $74.00/hr) or $217,203 per Part D parent organization ($11,511,736/53 Part D parent organization).

13. ICRs Regarding Service Delivery Request Processes Under PACE (§§ 460.104 and 460.121)

The following proposed changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on June 30, 2020.

Under new § 460.121(i)(2) discussed in section VII.A. of this proposed rule, we are proposing to require that PACE organizations provide written notification to participants whenever they extend the processing timeframe for service delivery requests. Based on our experience with PACE audits during 2017 and 2018, during which time we reviewed all PACE organizations in operation in that period, we found a total of 34,146 service delivery requests. The average PACE total enrollment during that period was 40,040. Thus the average number of service delivery requests per 1,000 enrollees was 852.8 (34,146/40.040). Based on the same audit experience and data collected, we further estimate that:

- Approximately 12 percent of all service delivery requests currently received are extended,
- Of those 852.8 service delivery requests currently received, 80 percent are approved, while 20 percent are denied.

Based on our proposed amendments to this section, we believe that half of the requests that are approved (that is, 50 percent of the 80 percent of requests not denied) could be approved in full by an IDT member at the time the request is made. Because those approval decisions could be made immediately (and therefore would not need to be fully processed as service delivery requests), the extension notification would not apply to those service delivery requests.

The proposed requirement of written notification for requests that are extended would apply to:

- The 2.4 percent of service delivery requests which are extended and subsequently denied (20 percent of service delivery requests are denied * 12 percent of service delivery requests are extended), and
- The 4.8 percent of service delivery requests that are approved and not routine (that is, a member of the IDT cannot approve the service delivery request in full at the time the request is made) and are extended (80 percent not denied * 50 percent not routine * 12 percent extended).

Thus the proposal would apply to 7.2 percent (2.4 percent denied and extended and 4.8 percent approved, not routine, and extended) of all service delivery requests. Based on OACT estimates, the average projected PACE enrollment for 2021–2023 is 47,680.

We also estimate, based on our audit experience, that to prepare and issue notification of the extension to a participant or the designated representative would take the IDT approximately 1 hour.

Consequently, the total annual burden of this request is 2,928 hours (852.8 requests per 1,000 * 47,680 projected enrollment for 2021–2023 * 7.2 percent of requests that require extensions * 1 hour to process each service delivery request extension) at a cost of $164,612 (2,928 hr * $56.22/hr for a Master's-level Social Worker (MSW) to process them).

Section 460.104(d)(2) currently states the requirements for processing service delivery requests (that is, requests from participants or their designated representatives to initiate, eliminate, or continue a service). We are proposing to move these requirements to new § 460.121 and modify the requirements to reduce burden on PACE organizations while ensuring appropriate participant protections are in place. We are proposing to require PACE organizations to notify participants or their designated representatives when they take an extension when processing a service delivery request. We expect most PACE organizations would develop a template letter to notify the appropriate parties in these situations. We are also clarifying requirements regarding the content of denial notifications following the determination of a service delivery request, which would require PACE organizations to update their denial notification letter templates.

For the development and revision of the extension notification and denial notification, we estimate a burden of 2 hours at $69.72/hr for a compliance officer to create and revise the materials. We estimate a one-time burden of 262 hours (131 PACE organizations * 2 hr) at a cost of $18,267 (262 hr * $69.72/hr).

14. ICRs Regarding Appeals Requirements Under PACE (§§ 460.122 and 460.124)

The following proposed changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on June 30, 2020.

Section 460.122 currently states the requirements for implementing an appeals process in PACE. We are proposing to modify the appeals section to increase clarity for organizations and ensure appropriate participant protections are in place. We are proposing to require PACE organizations to develop and distribute written materials that would explain the PACE requirements to the third party reviewers that are responsible for making appeal determinations. Additionally, we are proposing to increase requirements around what appeal decision notifications must include, which we expect would require PACE organizations to revise their current appeal notification materials.

For the development and distribution of materials to the third party reviewer, we estimate it would take 4 hours at $69.72/hr for a quality officer at each PACE organization to create and distribute these materials (3 hr to create and 1 hr to distribute). For the revision of the written appeal notices, we estimate it would take 1 hour at $69.72/hr for a quality officer at each PACE organization to revise the current notices.

In aggregate, we estimate a one-time burden of 655 hours [131 PACE organizations * (4 hr + 1 hr)] at a cost of $45,667 (655 hr * $69.72/hr).

15. ICRs Regarding Documenting and Tracking the Provision of Services Under PACE (§ 460.98)

The following proposed changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on June 30, 2020.

As discussed in section VII.E. of this proposed rule, we are proposing to amend § 460.98 in part to require PACE organizations to document, track and monitor the provision of services across all care settings, regardless of whether services are formally incorporated into a participant's plan of care. The burden associated with this requirement would consist of the time and effort required for PACE organizations to develop and implement procedures and to perform the required documentation, tracking and monitoring.

We estimate a one-time burden of 50 hours at $50.90/hr for technical staff at each PACE organization to develop the necessary procedures and written materials. We estimate a one-time burden of 6,550 hours (131 PACE organizations * 50 hr) at a cost of $333,395 (6,550 hr * $50.90/hr) for the first year. Since PACE organizations are already required to document all services furnished in the medical record in accordance with § 460.210(b)(2), we believe that by adding the requirement to track and monitor the provision of those services, the one-time burden of 50 hours would be a reasonable estimate on how long it would take to ensure procedures were developed.

We also estimate this provision would result in increased ongoing costs to PACE organizations. To estimate the increased burden, we use the following assumptions about the documentation, tracking, and monitoring of services, based on our experience monitoring and auditing PACE organizations.

As organizations are already required to document services furnished in the participant's medical record, PACE organizations would need to devote time to tracking and monitoring the provision of services in order to ensure services are being provided. We therefore estimate a burden of 50 hours at $50.90/hr for technical staff to complete these activities, including, when warranted, revision of the aforementioned program procedures and monitoring measures. We estimate a total aggregate annual cost at $333,395 (131 PACE organizations * 50 hr * $50.90/hr). This annual cost combined with the one-time cost of $333,395 for developing written procedures and materials would total $666,790 for the first year of implementation.

16. ICRs Regarding Documentation in Medical Records Under PACE (§ 460.210)

The following proposed changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on June 30, 2020.

Section 460.210 currently includes the requirements relating to medical records for PACE participants. This includes the minimum content of participant medical records. As discussed in section VII.F. of this proposed rule, we are proposing to require PACE organizations to maintain additional documentation in the medical record, including documentation of all recommendations for services made by employees or contractors of the PACE organization, the reasons for not approving or providing any service recommended by an employee or contractor of the PACE organization, and original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant. While PACE organizations would not have to develop new systems for maintaining this documentation, we expect that they would have to revise their policies and procedures and re-train staff on the new requirements. We believe that a compliance officer or quality officer would be responsible for ensuring the necessary materials are updated and that staff are trained. For revising materials and training staff, we estimate a one-time burden of 10 hours at $69.72/hr for technical staff to revise materials and lead training. Therefore, the one-time burden to implement this provision is 1,310 hours (131 PACE organizations * 10 hr) at a cost of $91,333 (1,310 hr * $69.72/hr).

We also estimate this provision would result in increased ongoing costs to PACE organizations. To estimate the increased burden, we use the following assumptions about medical record documentation. These assumptions are based on our experience monitoring and auditing PACE organizations' compliance with clinical processing requirements and medical record documentation.

As discussed previously, we proposed requiring three additional types of documentation to be included within a participant's medical record. Specifically, the documentation of recommendations made by employees and/or contractors, the reasons for not approving or providing a recommended service, and the original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant. Of these new requirements, we estimate that the requirement to maintain original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format, would not create a large burden, as organizations would only be required to save the already created documentation within a medical record. Therefore, we estimate that the total burden for part of the provision would be 5 hours per PACE organization or 655 total hours (5 hr/organization * 131 organizations).

We also proposed to require a PACE organization to document recommendations for services from employees or contractors of the PACE organization, including specialists. Furthermore, we are proposing to require PACE organizations to document the reasons a service recommended by an employee or contractor of the PACE organization is not approved or provided. We considered several factors when determining the estimated burden associated with these provisions. First, PACE organizations are already required under § 460.104(b)(1) to document the

rationale for not providing services following initial comprehensive assessments in the development of the care plan; therefore this provision would only apply to services recommended following the initial care plan development. Second, PACE organizations would only have to document the rationale under proposed § 460.210(b)(5) when the PACE organization does not approve or provide a recommended service, so there would be no additional burden in situations where the PACE organization approves or provides a recommended service. Considering these two factors, we determined that each PACE organization would have to spend approximately 51 hours (approximately 1 hr per week) to implement this part of the regulation. Therefore, we estimate a total of 56 hours per organization (51 hr + 5 hr), or a total of 7,336 hours (56 hr * 131 organizations).

Additionally, any IDT occupation may be involved in the documentation of this rationale depending on the type of service being recommended. Therefore, to determine the cost associated with this provision, we took the cost of one hour of wages for the full IDT ($838.36) and divided it by the 11 occupations included in the IDT (see Table 21) to determine an average wage of $76.21 ($838.36/11). We believe this is the most accurate estimate as it would be unlikely all occupations were working at the same time, and we are unable to estimate how much any one occupation would work over a different occupation.

TABLE 21—WAGES FOR IDT STAFF MEMBERS *

Occupation title	Occupation code	Mean hourly wage with fringe benefits and overhead ($/hr)
Primary Care Provider	29–1069	196.04
Registered Nurse	29–1141	72.60
Home Care Coordinator (often a RN)	29–1141	72.60
Physical Therapist	29–1123	85.46
Occupational Therapist	29–1122	82.08
Masters of Social Work	21–1022	56.22
Recreational Therapist	29–1125	48.68
Dietician	29–1031	58.86
Driver	53–3022	32.10
Personal Care Attendant	31–1011	24.36
PACE Center Manager	11–9111	109.36
Total		838.36
Average IDT Cost Per Hour		76.21

*See section IX.A. of this proposed rule.

We estimate the total cost of this provision to be $559,077 (7,336 hr * $76.21/hr).

17. ICRs Regarding PACE Participant Rights: Contact Information and Access Requirements (§ 460.112)

The following proposed changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244). Subject to renewal, the control number is currently set to expire on June 30, 2020.

Section 460.112 currently includes the specific rights to which PACE participants are entitled. As discussed in section VII.G. of this proposed rule, we are proposing to modify the participant rights to include three new distinct rights, specifically, the participant's right to have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines, the right to call 1–800–MEDICARE with questions or concerns regarding the program, and the right to receive necessary care in all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer maintain the participant safely in the community. The PACE organization is currently required to provide a copy of this set of participant rights to participants at the time of enrollment, and they are required to post a copy of the rights in the center. Under these proposals, the PACE organization would be required to revise the current participant rights to account for the three new requirements.

We estimate it would take 2 hours at $69.72/hr for technical staff to update the participant rights information included in the enrollment information and post the new participant rights in the center. In aggregate, we estimate a one-time burden of 262 hr (131 PACE organizations * 2 hr) at a cost of $18,267 (262 hr * $69.72/hr).

18. ICRs Regarding Stipulated Decisions in Part C (§ 422.562)

In order to permit OMHA adjudicators to more efficiently issue decisions where there is no longer any material issue in dispute, we are proposing to include MA organizations in the definition of ''contractors'' as that definition relates to stipulated decisions issued by ALJs and attorney adjudicators under § 405.1038. We are scoring this impact as negligible for several reasons. The total number of favorable decisions in MA for contract year 2018, the most recent year for which we have complete appeals data, was 578. The number of these overturned denials that were stipulated decisions is not currently quantifiable as it is not data that existing appeals systems are equipped to track, and ALJs do not track this data on their own.

We consulted with OMHA for its opinion on stipulated decisions, and OMHA estimated that the number of contractors submitting oral or written statements in an ALJ hearing or attorney adjudicator review was in the single digits because plans prefer an alternate, informal approach that removes the claim from the appeals process altogether: Requesting that the beneficiary withdraw their appeal and resubmit their claim for payment. The

reason for this preference is currently speculative at best.

CMS estimates that while this proposal would positively impact beneficiaries both in receipt of their items or services, and afford beneficiaries due process protections in a formalized stipulated decisions process, the number of beneficiaries that would be affected is minimal. Despite this estimation of negligible impact, CMS is proposing inclusion of this provision to promote regulatory uniformity in their approach to stipulate decisions as far as Medicare contractors are concerned. The submission of a written or oral statement seeking a stipulated decision is an ICR that is associated with an administrative action pertaining to specific individuals or entities (5 CFR 1320.4(a)(2) and (c)). Consequently, the burden for preparing and filing the oral or written statement for use in the appeal is exempt from the requirements and collection burden estimates of the PRA.

C. Summary of Proposed Information Collection Requirements and Associated Estimates

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TABLE 22: ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS[1, 2, 3]

Provision	Regulatory Citation	OMB Control Number	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
SNPs	§ 422.101	0938-1296	MOC submission	273	273	6	1,638	73	118,919	118,919
SNPs	§ 422.101	0938-1296	MOC revision	11	11	4	44	73	3,194	3,194
SNPs	§ 422.101	0938-1296	MOC resubmission	14	14	3	42	73	3,049	3,049
SNPs	§ 422.101(f)(1)(iv)	0938-1296	Face-to-face	734	734	4	2,936	73	213,154	213,154
D-SNP Look-Alikes	§ 422.514 (e)	0938-0753	Transition enrollees, 1st year	62	62	2	124	74	9,176	
D-SNP Look-Alikes	§ 422.514 (e)	0938-0753	Transition enrollees, subsequent years	5	5	2	10	74		740
D-SNP Look-Alikes	§ 422.514 (e)	0938-0753	Filling out enrollment form	1,808	1,808	1	904	25	22,582	
D-SNP Look-Alikes	§ 422.514 (e)	0938-0753	Filling out enrollment form	146	146	1	73	25		1,824
DMP	§ 423.153	0938-0964	Upload model notices	79	79	5	395	86	34,025	
DMP	§ 423.153	0938-0964	Disclosure to CMS	79	158	0	3	51	134	134
DMP	§ 423.153	0938-0964	Creating DMP (those without DMPs)	79	79	80	6,320	476	3,008,573	
DMP	§ 423.100	0938-0964	Send model notices	288	8,677	0	1,446	51	73,601	73,601
DMP	§ 423.100	0938-0964	Revise model notices	288	288	1	288	51	14,659	

Provision	Regulatory Citation	OMB Control Number	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
DMP	§ 423.100	0938-0964	Disclosure to CMS (newly identified PARBs)	288	18,268	0	305	51	15,525	15,525
DMP	§ 423.100	0938-0964	Case management	288	18,268	1	18,268	542	9,909,659	9,909,659
DMP	§ 423.100	0938-0964	Case management	288	158	1	158	542		85,636
MTMP	§ 423.153	0938-1154	Mailing ARBs CMR	288	8,421			1	7,747	7,747
MTMP	§ 423.153	0938-1154	Targeting ARBs for MTM	288	8,421	1	5,614	119	667,505	667,505
MTMP	§ 423.153	0938-1154	Safe disposal page in CMR	288	2,181,675			0	21,817	21,817
MTMP	§ 423.153	0938-1154	Safe disposal page in TMR	288	325,997			0	3,570	3,570
Education on Addiction	§ 423.128	0938-0964	Update systems	288	288	2	576	86	49,617	
Education on Addiction	§ 423.128	0938-0964	Create materials	288	288	2	576	119	68,486	
Fraud & Abuse Pt C & D	§§422.503(b)(4)(vi)(G)(3) and 422.504(b)(4)(vi)(G)(3)	0938-TBD and 0938-1262	Report fraud and abuse	668	668	247	164,996	91	14,975,037	
Fraud & Abuse Pt C & D	§§422.503(b)(4)(vi)(G)(3) and 422.504(b)(4)(vi)(G)(3)	0938-TBD and 0938-1262	Report fraud and abuse	668	668	156	104,208	91		9,457,918
ESRD	§§422.50 and 422.52	0938-0753	Enrollment	59,000	59,000	1	29,500	25	736,910	736,910
RTBT	§ 423.128	0938-0763	Policy development	29	29	40	1,160	189	219,054	

Provision	Regulatory Citation	OMB Control Number	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
RTBT	§ 423.128	0938-0763	Updating systems	29	29	40	1,160	86	99,922	
RTBT	§ 423.128	0938-0763	Program maintenance	29	29	360	10,440	36	376,258	376,258
RTBT	§ 423.128	0938-0763	Implementing RTBT	288	288	156	44,928	86	3,870,098	
Pharmacy performance	§ 423.514	0938-0992	Pharmacy performance	5,234	5,234	1	2,617	90	235,582	235,582
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-1252	Calculation of the deductible factor	3	3		1	112	75	75
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-0753	Filling out enrollment forms	3	3		1,322		33,032	33,032
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-0753	Notify enrollees	3	3		44		3,256	3,256
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-0753	Submit to CMS	3	3		44		3,256	3,256
MSA MLR	§§ 422.2420, 422.2440, and 422.2430	0938-0753	Archive	3	3		220		7,941	7,941
SEP Part C	§ 422.62	0938-0753	Filling out enrollment forms	181	1,710,650	0	142,497	74	10,544,778	10,544,778
SEP Part D	§ 422.38	0938-0964	Filling out enrollment forms	53	1,867,519	0	155,564	74	11,511,736	11,511,736
PACE	§§ 460.104 and 460.121	0938-0790	Extension notification	131	2,928	1	2,928	56	164,612	164,612

Provision	Regulatory Citation	OMB Control Number	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st year ($)	Total Cost in Subsequent Years ($)
PACE	§ 460.104(d)(2)	0938-0790	Update for extension notification	131	131	2	262	70	18,267	-
PACE	§ 460.104(d)(2)	0938-0790	Update appeal notices	131	131	5	655	70	45,667	
PACE	§460.104(d)(2)	0938-0790	Develop written materials for tracking	131	131	50	6,550	51	333,395	
PACE	§460.104(d)(2)	0938-0790	Tracking services	131	131	50	6,550	51	333,395	333,395
PACE	§§ 460.104 and 460.121	0938-0790	Medical record documentation training	131	131	10	1,310	70	91,333	
PACE	460.104(d)(2)	0938-0790	Medical record documentation	131	131	56	7,336	76	559,077	559,077
PACE	§ 460.104(d)(2)	0938-0790	Update for patients' rights	131	131	2	262	70	18,267	
TOTAL	*Varies*	*Varies*	*Varies*	6,190	6,180,284		724,273	*Varies*	58,425,940	45,093,900
Subtotal Enrollees							328,538		22,816,006	22,795,248
Subtotal Plans							395,735		35,609,934	22,298,652

NOTES:

[1] The hours and dollars for MSA MLR are averages over three years. Consequently hours * wages/hr does not exactly equal total cost. Since the number of respondents varied per year, "*Varies*" was placed in that cell.

[2] N/A refers to non-labor mailing cost.

[3] Total row contains "*Varies*" because, for example, respondents could be plans, cohorts of plan, enrollees, cohorts of enrollees, or parent organizations.

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D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. These 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/RegulationsandGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html,* or call the Reports Clearance Office at (410) 786–1326.

We invite public comments on these proposed information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–4190–P) and where applicable the ICR's CFR citation, CMS ID number, and OMB control number.

See the **DATES** and **ADDRESSES** sections of this proposed rule for further information.

X. Regulatory Impact Analysis

A. Statement of Need

This rule proposes several mandatory regulatory changes stemming from federal laws related to the Part C and D programs—including the BBA of 2018, the SUPPORT Act, and the Cures Act. The statutory need for these policies is clear. However, this rule contains various other proposals that are discretionary policies, including enhancements to the Programs of All-Inclusive Care for the Elderly (PACE) requirements, hence we provide economic justification for some of these noteworthy provisions in the following paragraphs.

We estimate that the proposed Star Ratings provisions would result in an overall net savings for the Medicare Trust Fund. There are two proposed changes that may impact a contract's Star Rating: (1) We propose to increase measure weights for patient experience/complaints and access measures from two to four to further emphasize the patient voice, and (2) we propose the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers, to increase the stability and predictability of the non-CAHPS measure cut points. The proposed increased weight reflects CMS's commitment to put patients first and to empower patients to work with their doctors to make health care decisions that are best for them. Since more outliers tend to be at the low end of the distribution (worse performers), directly removing outliers causes some shifting downward in overall Star Ratings. The increased measure weights for patient experience/complaints and access revision is assumed to be a cost to the Medicare Trust Fund given the ratings for these measures tend to be higher relative to other measures, and the Tukey outlier deletion is assumed to be a saver to the Medicare Trust Fund since directly removing outliers results in a shift downward in ratings. The aggregate savings to the Medicare Trust Fund over 2024–2030 is $4.9 billion.

Based on industry feedback over the course of several years, and our experiences auditing PACE organizations, we are proposing to modify certain PACE requirements to enhance stakeholders' understanding of our requirements and reduce administrative burden. Stakeholders have suggested that the existing processes for addressing service delivery requests is burdensome for PACE organizations, and can delay participants' access to services. We are proposing several changes to the PACE regulations to streamline these processes while ensuring that important participant protections remain intact. We believe these changes will save PACE organizations approximately $20 million a year.

B. Overall Impact

We examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (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).

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This proposed rule affects MA and PACE organizations and Part D sponsors (North American Industry Classification System (NAICS) category 524114) with a minimum threshold for small business size of $41.5 million (*http://www.sba.gov/content/small-business-size-standards*). This proposed rule additionally affects hospitals (NAICS subsector 622), a variety of provider categories, including physicians and specialists (NAICS subsector 621), pharmacy related businesses (NAICS code 3254), and information technology (IT) services (54141).

To clarify the flow of payments between these entities and the federal government, note that MA organizations and Part D sponsors submit bids (that is, proposed plan designs and projections of the revenue needed to provide those benefits, divided into three categories—basic benefits, supplemental benefits, and Part D drug benefits) in June 2020 for operation in contract year 2021. These bids project utilization of services from and payments to hospitals, providers, and staff as well as the cost of plan administration and profits. These bids in turn determine the payments from the Medicare Trust Fund to the MA organizations and Part D Sponsors that pay providers and other stakeholders for their provision of covered benefits to enrollees. Consequently, our analysis will focus on those plan types that submit bids (primarily MA organizations and Part D Sponsors) for which we have complete data. We will supplement this data with internal CMS financial data, which we have for all plan types.

There are various types of Medicare health plans, including MA organizations and their plans, Part D sponsors and Part D plans (PDPs), demonstration plans, section 1876 cost plans, PDPs, and PACE organizations. We use the term ''Medicare health plan'' as a general term referring to any of these plan types just listed. By examining records from the most recent year for which we have complete data, 2019, we determined, that to the nearest 10 percent, approximately 40 percent of all Medicare health plan organizations are not-for-profit. Note that the 40 percent applies to all Medicare health plans. Some important subcategories have different proportions. For example, coordinated care plans are 30 percent not-for-profit, PACE plans are 90 percent not-for-profit, and PDPs are about 50 percent not-for-profit. The attribute ''small business'' only applies to for-profit entities and, for insurers such as MA plans and Part D sponsors, refers to for-profit entities whose receipts are under $41.5 million. While we have financial information on MA plans and Part D sponsors, we do not

have total receipts. We have used proposed bids and payments as a proxy for receipts.

Executive Order 13272 requires that HHS thoroughly review rules to assess and take appropriate account of their potential impact on small business, small governmental jurisdictions, and small organizations (as mandated by the RFA).

If a proposed rule may have a significant economic impact on a substantial number of small entities, then the proposed rule must discuss steps taken, including alternatives, to minimize burden on small entities. The RFA does not define the terms ''significant economic impact'' or ''substantial number.'' The Small Business Administration (SBA) [109] advises that this absence of statutory specificity allows what is ''significant'' or ''substantial'' to vary, depending on the problem that is to be addressed in the rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. To ensure that a broad range of impacts are fully considered in the analysis, we consider ''substantial number'' to mean 3–5 percent or more of the affected small entities within an identified industry.

The 1984 HHS Handbook, On Developing Low Burden and Low Cost Regulatory Proposals, set forth the following definitional narrative for the term ''significant economic impact'' and is still applicable: A rule has a significant economic impact on the small entities it affects, if it significantly affects their total costs or revenues. If the economic impact is expected to be similar for all affected small entities and those entities have similar costs and revenues, then an average impact can be calculated. If the average annual impact on small entities is 3 to 5 percent or more, then we consider the rule has a significant economic impact on small entities.

While a significant number (more than 30 percent) of the organizations affected by this proposed rule are not-for-profit organizations, the impact is not significant. As shown in Table 41, the net impact of this rule is an annualized savings of $5.8 million a year resulting from a $28.8 million savings versus a $23 million cost. This annualized cost is significantly below 3–5 percent of the net receipts of all plans.

While this rule has significant impact on the Medicare Trust Fund and United States Treasury as detailed in this Regulatory Impact Analysis, neither of these entities are ''small businesses.'' Consequently, this impact is not discussed in this section.

We next discuss the impact on hospitals, physician and other provider practices, pharmacy related businesses, and IT services.

As discussed in sections IX and X of this proposed rule, many of the provisions require system updates necessitating programming and other IT services. More specifically, the following provisions have PRA impacts involving IT services: Beneficiary RTBT, Fraud and Abuse, PACE, ESRD, SEP Part C/D, DMP, and Education on Addiction. Based on estimates in section IX, the combined cost of IT services is approximately $50 million, which is significantly below the 3–5 percent threshold that would trigger further discussion. Furthermore, this $50 million represents payments for services rendered not a burden per se.

The provisions of this rule primarily affect the responsibility of MA organizations and Part D sponsors to furnish services. This means that services that were formerly paid for out-of-pocket or by other insurances are now paid for by the Part C and D programs. Therefore, the provisions of this proposed rule do not impose specific burdens on hospitals or providers.

For example, the various provisions affecting enrollment (ESRD, SEP Part C/D, MSA) require that the Medicare Trust Fund pay for services provided to those who enroll. In some cases, this change is limited to who pays. In other cases, surgeries and other procedures that would not have been purchased are not being furnished to enrollees. However, these services are being paid for; they are not independent burdens.

Unlike the previous mentioned stakeholders (where there was no impact), we do expect pharmacy-related businesses to be impacted by this rule. For example, the DMP provisions will likely reduce prescription utilization for the targeted population. As a result, the Medicare Trust Fund will have lower expenditures. Similarly, pharmacies and drug manufacturers will have lower sales volumes. The provisions for mandatory DMPs and the provisions to include beneficiaries with a history of opioid overdose as PARBs will involve prescribers in case management. We believe network providers are typically contractually obligated to participate in utilization review activities by plan sponsors, and non-network providers are not. If any pharmacy limitations are implemented as a result, this will involve network pharmacies, which we believe are also contractually obligated to participate in drug utilization review activities. Additionally, we estimate approximately 40,000 beneficiaries will be identified as PARBs, which constitutes approximately 0.08 percent of Part D enrollees.

As detailed in this Regulatory Impact Analysis, the DMP provisions will reduce spending by about $7.7 million a year and, as just indicated, likely reduce revenue to pharmacies and manufacturers. The MTMP provisions will bring in an extra $0.7 million per year due to increased requirements. The preferred specialty tier for Part D could have the effect that brand manufacturers may have to lower their prices and/or offer better rebates for placement on the preferred specialty tier relative to other brands or the potential for more generic drug or biosimilar/interchangeable biological product alternatives. Similarly, this provision may encourage generic manufacturers to develop more generic drug or biosimilar/interchangeable biological product alternatives at competitive prices (that is, relative to pricing changes by brand manufacturers). The Office of the Actuary (OACT) could not estimate this effect of the preferred specialty tier for Part D. The combined total impacts to pharmacies is estimated at under $25 million a year (the big drivers being the reduced drug utilization due to DMP, the DMP case management, and the MTMP requirements). This is significantly less than the 3–5 percent of total revenue of pharmacies required to trigger further discussion.

Consequently, the Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities, and we have met the requirements of Executive Order 13271 and the RFA. In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any rule under title XVIII, title XIX, or part B of title XI of the Act that may have significant impact on the operations of a substantial number of small rural hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This proposed rule is not

[109] The Regulatory Flexibility Act An Implementation Guide for Federal Agencies, pages 17–19. Issued by SBA's Office of Advocacy, and accessible at *www.sba.gov/advo.*

anticipated to have an unfunded effect on state, local, or tribal governments, in the aggregate, or on the private sector of $154 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on state or local governments, preempt state law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this proposed rule, then we should estimate the cost associated with regulatory review. There are currently 795 contracts (which includes MA, MA–PD, and PDP contracts), 55 state Medicaid Agencies, and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, major Pharmacy Benefit Managers). Each organization will designate one person to review the rule. A reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this proposed rule is $109.36 per hour, including fringe benefits and overhead costs (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 100 hours for each person to review this proposed rule. For each entity that reviews the rule, the estimated cost is therefore $10,936 (100 hours * $109.36). Therefore, we estimate that the maximum total cost of reviewing this proposed rule is $21 million ($10,936 * 2,000 reviewers). We expect that many reviewers will not review the entire rule but just the sections that are relevant to them. If each person on average reviews 10 percent of the rule, then the cost would be $2 million.

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we believe it is likely that review will be performed by contract. The argument for this is that a parent organization might have local reviewers assessing potential region-specific effects from this proposed rule.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by OMB.

C. Anticipated Effects

Many of the provisions of this proposed rule have no impact either because they are technical provisions or are provisions that codify existing guidance. Other provisions have an impact although it cannot be quantified or whose estimated impact is zero. Throughout the preamble, we have noted when provisions have no impact. Additionally, this Regulatory Impact Analysis discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions are estimated in section IX of this proposed rule and in this Regulatory Impact Analysis. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this Regulatory Impact Analysis cross-references impacts from section IX of this proposed rule in order to arrive at total impact. Additionally, this Regulatory Impact Analysis provides pre-statutory impact of several provisions whose additional current impact is zero because their impact has already been included in the appropriate baselines. For further discussion of what is estimated in this Regulatory Impact Analysis, see Table 10 and the discussion afterwards.

1. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

This provision would require that CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose (as defined by the Secretary) and include such individuals as PARBs for prescription drug abuse under the Part D sponsor's drug management program. We projected a list of approximately 18,000 beneficiaries that met the criteria for this provision between July 2017 and June 2018, but did not meet other criteria for classification as a potential at-risk beneficiary. Under this proposal, this population is projected to (1) increase the population of enrollees requiring case management by plan sponsors (see section IX.B.3. of this proposed rule), and (2) reduce Part D drug cost.

We evaluated their Prescription Drug Event (PDE) data for the same July 2017 and June 2018 period to determine the effects of this provision. After examining the PDE data, we found that these beneficiaries had an average gross drug cost per beneficiary per year of $9,675. Because this amount is high relative to the typical Part D spending and because they do not meet other at-risk criteria, it is likely that many of these beneficiaries have conditions that require expensive specialty medications. These drugs have complex clinical criteria that are difficult to alter through utilization management. Accordingly, we have assumed that 5 percent of their Part D drug cost would be reduced through additional plan management. Our estimated fiscal year federal savings rounded to the nearest million are shown in Table 23. Since these drugs would not be purchased as a result of efficient case management, they represent reduction in goods consumed and are true savings to the Medicare Trust Fund.

TABLE 23—ESTIMATED BENEFITS TO THE MEDICARE TRUST FUND OF THE INCLUSION OF ADDITIONAL AT-RISK BENEFICIARIES

Fiscal Year	Fiscal year ($ in millions)										Total 2021–2030 Impact ($ in millions)
	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2021–2030
Estimated Impact	$6	$8	$8	$8	$8	$8	$8	$8	$8	$8	$75

Table 24 summarizes the aggregate impact of the changes to DMPs. It reflects all the estimates related to DMPs in section IX of this proposed rule (which incur costs) and the savings due to reduction in drug costs discussed in this Regulatory Impact Analysis.

TABLE 24—SUMMARY OF DMP IMPACTS BY PROVISION

[Millions $]

	1st yr savings	1st year cost	Annual savings 2nd–10th year	Annual cost 2nd–10th year	Total 10-year savings	Total 10-year cost
Mandatory DMP Case Management (COI)				0.1		0.8
DMP Paperwork (COI)		3.1		0.1		3.9
DMP Overdose Case Management (COI)		9.9		10.0		99.9
DMP Drug savings	5.8		7.7		75.4	
Total					75.4	104.6
Net Impact (Cost) over 10 years						29.2

2. Automatic Escalation to External Review Under a Medicare Part D Drug Management Program (DMP) for At-Risk Beneficiaries (§§ 423.153, 423.590, and 423.600)

As stated in the preamble, starting in 2022, the SUPPORT Act requires automatic escalation of drug management program appeals to the independent outside entity contracted with the Secretary for review and resolution. We are proposing rules to codify that provision.

To estimate the impact of this proposal, we first determined how many Part D sponsors had implemented drug management plans. As of July 9, 2019, we found that 60 Part D sponsors had implemented drug management plans. Next, we estimated of the number of CARA-appeals per 1,000 enrollees and the percentage of plan denials related to CARA. To do this, we contacted nine Part D sponsors and asked how many CARA related appeals they had received from January 1, 2019 through July 31, 2019.

Of those nine, eight plans responded they had have not received any CARA appeals. One Part D sponsor responded to say they had received CARA related appeals. That plan reported a rate of 0.014 CARA related appeals per 1000 enrollees. This accounted for 0.08 percent of plan denials. Since there are about 28,600 appeals per year, therefore there are only about 23 cases (0.08 percent * 28,600) affected by this provision. Since most IRE cases are judged by a physician at a wage of $202.46 and typically an IRE will take at most 1 hour to review most cases, the total burden is about $4,656.58 (23 cases * $202.46 * 1 hour) or $0.0 million.

3. Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)

We are unable to determine the overall impact of implementing sections 2008 and 6063 of the SUPPORT Act because we do not have adequate data to support an estimate of the potential costs and savings. While we do have access to estimates of overall Medicare Part D opioid spending, sections 2008 and 6063 of the SUPPORT ACT are not expected to impact all Part D opioid prescriptions, nor do we expect that they would impact all pharmacies that dispense those medications. For example, section 2008 of the SUPPORT Act requires Part D plan sponsors to report to CMS any payment suspension pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o) of the Act. In addition, section 6063 of the SUPPORT Act requires MA organizations and Part D plan sponsors to report information on the investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier related to fraud, and other actions taken by the plan related to inappropriate prescribing of opioids. In both cases, these provisions would directly impact a percentage of all opioid prescriptions written by doctors and dispensed by pharmacies. While we believe there may be savings generated through actions taken by Part D plan sponsors that will conduct their own due diligence from the reporting and sharing of administrative actions between CMS, MA organizations and Medicare Part D plan sponsors (including MA organizations offering MA–PD plans), as well as additional law enforcement actions, we cannot estimate the impact at this time. We welcome comment and suggestions for data that could be relied upon for this purpose.

4. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

CMS is proposing to codify requirements under section 17006 of the Cures Act that, effective for the plan year beginning January 1, 2021, would remove the prohibition for beneficiaries with ESRD from enrolling in an MA plan. Since CMS is proposing to codify existing statute, there would be no impact to program expenditures. In order to estimate the impact of requirements under section 17006 of the Cures Act, a pre-statute baseline was used to estimate the impacts.

There are two primary assumptions that contribute to the regulatory impact analysis for this provision: (1) The increased number of beneficiaries with ESRD who choose to enroll in an MA health plan; and (2) The cost differential between MA and FFS for those enrollees with ESRD.

We are expecting that there will be an influx of beneficiaries switching from FFS to MA beginning on January 1, 2021 due to the provision. In 2019, there were 532,000 enrollees in ESRD status with Medicare Part A benefits as shown in the Medicare Enrollment Projections tables of the 2020 Medicare Advantage Rate Announcement. Of these, 401,000 enrollees were in the FFS program, which results in 131,000 in Private Health Plans. This equates to a private health penetration rate of about 25 percent. Absent the ESRD enrollment provision of the Cures Act, we project that ESRD enrollment in Private Health plans will grow to 144,000 in 2021, representing about 26 percent of the projected 2021 total ESRD population of 559,000. Based on an analysis by OACT, ESRD enrollment in MA plans is expected to increase by 83,000 due to the Cures Act provision. This increase is assumed to be phased in over 6 years,

with half of the beneficiaries (41,500) enrolling during 2021.

Next, we determine the cost differential of the projected ESRD enrollees that are new to MA in 2021 due to the Cures Act. The cost differential between MA and FFS ESRD enrollees is attributed to the adjustment to MA risk scores for differences in diagnosis coding between MA and FFS beneficiaries. The Coding Intensity (Annual) was derived by examining historical risk score data and computing the differences between MA and FFS risk scores. Demographic differences (age, gender factors) for enrollees have been separated and removed from risk score comparisons so that the final differences are considered health status differences.

Table 25 shows the cost for codifying section 17006 of the Cures Act, removing the prohibition for ESRD beneficiaries to enroll in MA plans. The United States Per Capita Cost (USPCC) amounts for Part A and Part B can be found in the 2020 Medicare Advantage Rate Announcement. The Gross Costs (before backing out the Part B premium portion) is calculated by multiplying the Additional MA ESRD Enrollment by the ESRD–USPCC rates, which are on a per member per month basis, multiplied by 12 (the number of months in a year) multiplied by the Composite Coding Intensity. The Net Cost is calculated by multiplying the Gross Costs by the Net of Part B Premium amount which averages between 85.6% and 84.9% from 2021–2030. The Net Costs range from $23 million in Calendar Year 2021 to $440 million in CY 2030.

TABLE 25: ESTIMATED COST PER YEAR (MILLIONS) TO THE MEDICARE TRUST FUND FOR REMOVING THE PROHIBITION FOR ESRD BENEFICIARIES TO ENROLL IN MA PLANS

Contract Year	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Additional MA ESRD Enrollment:	41,500	62,250	73,317	78,850	81,617	83,000	83,000	83,000	83,000	83,000
USPCC Pt A FFS ($):	3,206	3,328	3,447	3,562	3,681	3,801	3,924	4,052	4,184	4,320
USPCC Pt B FFS ($):	4,900	5,109	5,329	5,573	6,383	6,662	6,953	7,257	7,574	7,905
USPCC FFS ($):	8,106	8,437	8,776	9,136	10,063	10,462	10,877	11,309	11,758	12,225
Coding Intensity (Annual):	0.65%	0.80%	0.79%	0.63%	0.46%	0.30%	0.14%	0.14%	0.13%	0.13%
Coding Intensity (Composite):	0.65%	1.46%	2.26%	2.90%	3.38%	3.69%	3.84%	3.98%	4.12%	4.25%
Gross Cost ($ millions):	26	92	174	251	333	384	416	448	482	518
Net of Part B Premium:	85.60%	85.60%	85.50%	85.40%	85.30%	85.20%	85.00%	84.90%	84.90%	84.90%
Net Cost ($ millions):	23	79	149	214	284	327	353	381	410	440

Because these increases are already included in the baseline, they are not included in Table 41, nor do they contribute to the monetized table calculations (Table 40). However, notes to Table 41 and observations in the conclusion do mention this impact.

5. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322) and Exclusion of Kidney Acquisition Costs From Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Section 17006(b) of the Cures Act amended section 1853(k) and (n) of the Act to exclude standardized costs for kidney acquisitions from MA benchmarks starting in 2021. As such, CMS is proposing to codify these requirements so that, effective for the contract year beginning January 1, 2021, MA organizations will no longer be responsible for costs for organ acquisitions for kidney transplants for

their beneficiaries. Removing these costs from the MA benchmarks will decrease the amounts paid to the plans from the Medicare trust funds. Instead, as required by statute, CMS proposes to require that Medicare FFS cover the kidney acquisition costs for MA beneficiaries, effective 2021.

Since the budget baseline has reflected this change from the publication of the Cures Act, there is no additional impact of the proposed codification of this change to the computation of rates. To estimate the impact of the statute when published we used a pre-statute baseline. This impact of the statute will therefore not be included in Table 41 or Table 40, which deal with impacts of current provision.

Our analysis in the next section shows that: (1) FFS coverage of kidney acquisition costs for MA beneficiaries results in net costs to the Medicare Trust Funds ranging from $212 million in 2021 to $981 million in 2030; (2) Excluding kidney acquisition costs from MA benchmarks results in net savings estimated to range from $594 million in 2021 to $1,346 million in 2030. In addition, we anticipate no change in plan, provider, or beneficiary burden for these provisions. Plan burden would not be impacted by the change in their payment rate. Provider burden will not be impacted because they continue to bill for kidney acquisition regardless of whether they receive payment from FFS Medicare or MA organizations. Finally, beneficiaries would not be impacted by the change in the source of payment for the acquisition of the organ.

Next, we describe the steps used to calculate the savings associated with excluding kidney acquisition costs from MA benchmarks as well as the costs associated with requiring FFS coverage of kidney acquisition costs for MA beneficiaries.

First, we examined the FFS cost of kidney acquisition coverage. We calculate the expected costs to the FFS program for covering kidney acquisitions from the MA population starting in 2021. The costs for these services are expected to be lower than the amount that is expected to be excluded from the MA benchmarks for two reasons.

1. The MA penetration rate for ESRD enrollees is lower than for the non-ESRD enrollees. This means that a higher percentage of beneficiaries with ESRD are in FFS than in MA, so there will likely be fewer kidney transplants in MA versus FFS. However, this enrollment difference will likely lessen as ESRD enrollees are permitted to enroll in MA plans beginning in 2021.

2. The kidney transplant incidence rate for MA ESRD enrollees has historically been much lower than the kidney transplant incidence rate for FFS ESRD enrollees. We suspect that this is due to MA ESRD enrollees being in dialysis status for a shorter duration than FFS enrollees. Again, we believe that this difference (between MA and FFS) in the kidney transplant incidence rate will decrease over time as more ESRD beneficiaries enroll in MA plans.

The kidney transplant incidence rate is computed by dividing the number of kidney transplants by the ESRD enrollment separately for the MA and FFS programs. As shown in table 26, the FFS kidney transplant incidence rate has historically often been more than three times the MA rate.

TABLE 26: MEDICARE FFS AND MA KIDNEY TRANSPLANTS (2013-2017)

	2013	2014	2015	2016	2017
Number of Kidney Transplants FFS:	13,964	13,866	14,400	15,191	15,346
ESRD Enrollment FFS (000's):	385	390	394	401	402
Transplant Incidence FFS:	3.6%	3.6%	3.7%	3.8%	3.8%
Number of Kidney Transplants MA:	929	1,015	957	1,137	1,382
ESRD Enrollment MA (000's):	69	78	89	96	108
Transplant Incidence MA:	1.3%	1.3%	1.1%	1.2%	1.3%

As mentioned, we expect that as a greater portion of enrollees with ESRD will join MA plans, starting in 2021, the difference in the kidney transplant incidence rate between MA and FFS will begin to lessen, as shown in table 27. The total number of MA and FFS kidney transplants are expected to grow by 3 percent per year which is based on the 2013–2017 historical growth rate. That rate is higher than the average increase in MA and FFS ESRD enrollment of 2 percent for 2013–2017. Since the kidney transplant growth is projected to be higher than the ESRD enrollment growth, we expect the kidney transplant incidence rate to increase over time.

TABLE 27: MEDICARE FFS AND MA KIDNEY TRANSPLANTS (2018-2030)

	2018	2019	2020	2021	2022	2023	2024
Number of Kidney Transplants MA & FFS:	17,230	17,747	18,279	18,828	19,392	19,974	20,573
Kidney Transplant Incidence FFS:	3.9%	4.0%	4.0%	4.2%	4.3%	4.4%	4.3%
Kidney Transplant Incidence MA:	1.4%	1.4%	1.4%	1.6%	1.8%	2.0%	2.2%
ESRD Enrollment FFS (000's):	401	401	408	373	358	353	352
ESRD Enrollment MA (000's):	120	131	137	186	213	231	242
	2025	2026	2027	2028	2029	2030	
Number of Kidney Transplants MA & FFS:	21,191	21,826	22,481	23,155	23,850	24,566	
Kidney Transplant Incidence FFS:	4.3%	4.2%	4.2%	4.1%	4.1%	4.0%	
Kidney Transplant Incidence MA:	2.4%	2.6%	2.8%	3.0%	3.2%	3.4%	
ESRD Enrollment FFS (000's):	354	358	364	369	374	379	
ESRD Enrollment MA (000's):	250	256	261	266	270	274	

We then calculate the average kidney acquisition costs using FFS claims data from CMS data systems. The average kidney acquisition costs ranged from $69,000 in 2013 to $83,000 in 2017, which equates to an annual growth rate of 4.7 percent. This percentage was used to estimate average kidney acquisition costs during the projection period of 2018 to 2030.

The gross costs to the FFS program for covering MA kidney acquisition costs are computed by multiplying the MA transplant incidence rate by the number of MA ESRD enrollees multiplied by the average kidney acquisition cost. This computation was completed for the years 2021–2030. The gross costs, as found in the Table 28, range from $298 million in 2021 to $1,384 million in 2030. Again, we apply the government share of the gross savings factors as well as the Part B premium factors to compute the net costs to the Medicare Trust Funds. These factors are the same as those used to calculate the savings for excluding kidney acquisition costs from the MA benchmarks. The net costs to the Medicare Trust Funds after applying these factors are expected range from $212 million in 2021 to $981 million in 2030.

TABLE 28: COSTS TO THE FFS PROGRAM FOR COVERING MA KIDNEY ACQUISITION COSTS

	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Kidney Transplant Incidence MA:	1.6%	1.8%	2.0%	2.2%	2.4%	2.6%	2.8%	3.0%	3.2%	3.4%
ESRD Enrollment MA (000's):	186	213	231	242	250	256	261	266	270	274
Avg Kidney Acq Costs ($'s):	99,146	103,804	108,680	113,786	119,131	124,728	130,587	136,722	143,145	149,870
Gross Costs ($Millions):	297.9	401.3	503.0	605.7	713.5	828.7	950.2	1,082.5	1,226.1	1,383.7
Avg Gov't Share of Gross Savings:	83.0%	83.0%	83.0%	83.1%	83.2%	83.2%	83.2%	83.4%	83.4%	83.4%
Net of Part B Premium:	85.6%	85.6%	85.5%	85.4%	85.3%	85.2%	85.0%	84.9%	84.9%	84.9%
Net Costs ($Millions):	211.7	284.9	357.0	429.5	506.0	587.1	672.3	766.5	869.1	980.8

Next, we examined the MA cost of kidney acquisition coverage. We used data based on the kidney acquisition costs for the FFS beneficiaries to compute the portion of the MA benchmark that has been attributed to kidney acquisition costs. In order to compute the amount that the MA health plans have been reimbursed for these costs in the past, we tabulated Medicare's share of kidney acquisition costs and the number of Medicare discharges from the Medicare Cost Reports (Form CMS–2552–10) for certified kidney transplant centers. The kidney acquisition costs were computed for the years 2013–2017 (the latest data that was available at the time of this study) using information from the Medicare Cost Reports for FFS beneficiaries at the county-level. The county level per member per month (PMPM) costs are derived by summing the kidney acquisition costs for each county and dividing these amounts by the county specific Medicare FFS enrollment. These annual costs per member are then divided by 12 in order to compute the PMPM's.

Next, we examine the historical kidney acquisition cost PMPM trend for the years 2013–2017 to project these costs for the years 2018–2030. In aggregate, the kidney acquisition PMPM costs grew at an average rate of 6.4 percent during 2013–2017. This trend is used to estimate these costs for the 2018–2030 period.

To calculate the gross savings to the Medicare Trust Funds, we multiply the projected MA enrollment by the annual per member kidney acquisition costs. We then apply two additional factors to the gross savings in order to compute the net savings to the Medicare Trust Funds:

1. Average government share of gross savings. Government expenditures are the sum of bids and rebates. Rebates are the portion of the difference between the MA benchmarks and MA bids that the health plans use to pay for additional supplemental benefits or reductions in enrollee cost sharing. The government retains the remaining difference between MA benchmarks and MA bids. We estimate that bids will be reduced by 50 percent of the total reduction in benchmarks.

2. Net of Part B premium. Medicare enrollees, not the Trust Funds, are responsible for approximately 25 percent of their Part B costs.

The government share of gross savings factors are expected to be between 83.0 percent and 83.4 percent during the period 2021–2030. The net of Part B premium factors are expected to be 85.6 percent and 84.9 percent during that same period. The results can be found in table 29. The net savings due to excluding kidney acquisition costs from MA benchmarks is estimated to range from $594 million in 2021 to $1,346 million in 2030.

TABLE 29: MEDICARE FFS KIDNEY ACQUISITION COST DATA

	2013	2014	2015	2016	2017	2018	2019	2020		
Kidney Acq Costs (PMPM):	1.72	1.82	1.95	2.08	2.20	2.34	2.49	2.65		
	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Kidney Acq Costs (PMPM):	2.82	3.00	3.20	3.40	3.62	3.85	4.10	4.36	4.64	4.94
Medicare Advantage Enrollment Projection (000's):	24,690	25,624	26,508	27,380	28,237	29,070	29,861	30,607	31,313	32,035
Gross Savings ($Millions):	836.2	923.5	1,016.6	1,117.4	1,226.3	1,343.4	1,468.4	1,601.7	1,743.7	1,898.4
Average government share of Gross Savings:	83.0%	83.0%	83.0%	83.1%	83.2%	83.2%	83.2%	83.4%	83.4%	83.4%
Net of Part B Premium:	85.6%	85.6%	85.5%	85.4%	85.3%	85.2%	85.0%	84.9%	84.9%	84.9%
Net Savings ($Millions):	594.1	655.7	721.5	792.3	869.5	951.7	1,038.9	1,134.1	1,235.9	1,345.6

6. Reinsurance Exceptions (§ 422.3)

It is difficult to determine whether there would be a cost or savings impact to this proposal. The use of reinsurance or other arrangements permitted by the proposal is a choice for MA organizations, which they can exercise if they believe it is in their business interests to purchase. While purchasing reinsurance coverage has a cost associated with it, the use of reinsurance provides financial protection that may generate offsetting savings to the MA organization, or reduce their risk. We therefore are unable to quantitatively estimate the impacts of this provision. We solicit stakeholder comment on (i) how this provision may be used, (ii) likely costs and savings, and (iii) other related impacts.

7. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

We are proposing some measure updates and technical clarifications as well as the methodology changes (concerning outliers and the weight of patient experience/complaints and access measures). These measure updates and technical clarifications are routine and do not have an impact on the highest ratings of contracts (that is,

overall rating for MA–PDs, Part C summary rating for MA-only contracts, and Part D summary rating for PDPs). These type of routine changes have historically had very little or no impact on the highest ratings. Hence, there will be no, or negligible, impact on the Medicare Trust Fund from the routine changes.

We are also proposing to clarify some of the current rules around assigning Quality Bonus Payment (QBP) ratings and to codify the rules around assigning QBP ratings for new contracts under existing parent organizations. We are not proposing any changes to our current QBP policies, so there will be no impact on the Medicare Trust Fund from these proposals.

The cost impacts due to the Star Ratings updates are calculated by quantifying the difference in the MA organization's final Star Rating with the proposed rule and without the proposed rule. There are two ways that our proposed rule could cause a contract's Star Rating to change: (1) We propose in this rule to increase measure weights for patient experience/complaints and access measures from two to four, and (2) we propose the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers. There are assumed to be Medicare Trust Fund impacts due to the Star Ratings changes associated with these two revisions to the methodology. The increased measure weights for patient experience/complaints and access revision is assumed to be a cost to the Medicare Trust Fund, as there are more contracts that would see their Star Ratings increase than decrease. The Tukey outlier deletion is assumed to be a saver to the Medicare Trust Fund, as more contracts would see their Star Ratings decrease rather than increase.

All impacts are considered transfers since no goods or services are increased or decreased.

The impact analysis for the Star Ratings updates takes into consideration the final quality ratings for those contracts that would have Star Ratings changes under this proposed rule. There are two ways that Star Ratings changes will impact the Medicare Trust Fund:

1. A Star Rating of 4.0 or higher will result in a QBP for the MA organization, which, in turn, leads to a higher benchmark. MA organizations that achieve an overall Star Rating of at least 4.0 qualify for a QBP that is capped at 5 percent (or 10 percent for certain counties).

2. The rebate share of the savings will be higher for those MA organizations that achieve a higher Star Rating. The rebate share of savings amounts to 50 percent for plans with a rating of 3.0 or fewer stars, 65 percent for plans with a rating of 3.5 or 4.0 stars, and 70 percent for plans with a rating of 4.5 or 5.0 stars.

In order to estimate the impact of the Star Ratings updates, the MA baseline assumptions are updated with the assumed Star Ratings changes described in this proposed rule. The MA baseline is completed using a complicated, internal CMS model. The main inputs into the MA baseline model include enrollment and expenditure projections. Enrollment projections are based on three cohorts of beneficiaries: (i) Dual-eligible beneficiaries, (ii) beneficiaries with employer-sponsored coverage, and (iii) all others, including individual-market enrollees. MA enrollment for all markets is projected by trending the growth in the penetration rates for the 2011 through 2018 base data. The key inputs for the expenditure projections include:

- United States Per Capita Cost (USPCC) growth rates.
- Adjustment to MA risk scores for differences in diagnosis coding between MA and fee-for-service beneficiaries.
- Quality bonus (county-specific).
- Phase-out of Indirect Medical Education (county-specific).

Projections are performed separately for payments from the Part A and Part B trust funds. Aggregate projected payments are calculated as the projected per capita cost times the projected enrollment. The Medicare Trust Fund impacts are calculated by taking the difference of the MA baseline with the Star Ratings changes and the original MA baseline.

The results are presented in Table 30. The last column of Table 29 presents net savings to the Medicare Trust Fund; in 2024 the savings is $368.1 million; this will grow over time reaching $999.4 million by 2030. The aggregate savings over 2024–2030 is $4.9 billion. Ordinary inflation is carved out of these estimates. The source for ordinary inflation is Table II.D1 of the 2019 Medicare Trustees report. It should be noted that there are inflationary factors that are used in the projected Star Ratings and are used in these estimates. The Star Ratings are assumed to inflate at a higher rate for the lower rated contracts than for the higher rated contracts. MA organizations with low Star Ratings have a better chance of improving their quality ratings than MA organizations that have already achieved a high Star Rating. For instance, a contract with a Star Rating of 4.5 has less room to increase its Star Rating than a contract with a Star Rating of 3.0.

There is a large projected reduction in the costs associated with the proposed increase in the weight of measures classified as patient experience/complaints and access measures in 2029. This is due to several contracts that are projected to achieve the required 4.0 Star Rating in 2029 and are eligible for the QBP at that time, even after this proposed rule is applied. This narrows the difference in costs between the proposed rule and the original baseline.

TABLE 30: CALCULATIONS OF NET SAVINGS PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES

Calendar Year	Cost of Increased Weight in Patient Experience/ Complaints and Access Measures ($ Millions)	Net Savings from Tukey Outlier Deletion ($ Millions)	Net Savings	Ordinary Inflation	Net Savings with Ordinary Inflation Carved Out ($ Millions)
2024	391.4	808.9	417.5	3.20%	368.1
2025	305.4	935.0	629.6	3.20%	537.9
2026	296.1	1,029.0	732.9	3.20%	606.7
2027	343.4	1,110.5	767.1	3.20%	615.3
2028	301.1	1,296.5	995.4	3.20%	773.7
2029	93.9	1,356.9	1,263.0	2.60%	956.8
2030	95.7	1,449.2	1,353.5	2.60%	999.4
Total 2024-2030					4857.9

8. Permitting a Second, ''Preferred'', Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

The proposed option for Part D sponsors to offer a second, ''preferred'' specialty tier has the potential to impact Part D drug costs in two ways. First, a Part D sponsor may have additional negotiating power with brand drug manufacturers by offering a preferential tier position relative to the current single specialty tier. Second, Part D sponsors may promote lower-cost biosimilar biological products on a preferred specialty tier. We consider each of these possibilities in the following discussion.

For a Part D sponsor to be able to negotiate better formulary position and lower beneficiary cost sharing for a particular specialty drug, there must be a substantial difference between the cost sharing on the preferred specialty tier and the higher cost sharing specialty tier. As the proposed regulation limits the maximum allowable cost sharing to the range of 25 to 33 percent, Part D sponsors must achieve this difference by lowering the cost sharing on the preferred specialty tier. Because of the high cost for specialty drugs and the structure of the Part D benefit, Part D enrollees and prescribers might not significantly alter their behavior in response to a five percent change in coinsurance, for example. A substantial reduction in the cost sharing for this tier would necessitate a substantial increase in cost sharing for other tiers to maintain an actuarially equivalent benefit, which may unfavorably change the competitive position of the Part D sponsor's plan offering. In particular, a plan that offers lower cost sharing on high-cost specialty drugs and higher cost sharing on conventional drugs would risk adverse selection from Part D enrollees.

In addition, allowing tiering exceptions between the preferred specialty tier and the higher cost sharing specialty tier creates a risk for the Part D sponsor that may exceed the benefit of being better able to negotiate with respect to brand drugs. A portion of the higher cost-sharing specialty drugs may be granted exceptions as the clinical criteria for such Part D drugs is complex and can lead to different prescriptions for beneficiaries with similar conditions. These Part D drugs are often more complicated chemically and apply to complex conditions, such as Rheumatoid Arthritis or Multiple Sclerosis. This added complexity requires greater specialized knowledge than a traditional small molecule drug would for denying an exception. This will be known to manufacturers, who will be less inclined to provide additional incentives for the preferred placement given that a significant amount of non-preferred use will limit any market share gains from their enhanced formulary position. Part D sponsors would also face additional liability from the difference in cost sharing between the preferred and the higher cost sharing specialty tier on prescriptions that are granted exceptions. This dynamic is what prevents Part D sponsors from placing specialty drugs on a non-preferred drug tier under current regulation.

Regarding savings from biosimilar biological products that could be promoted through a preferred specialty tier, some of the same previously discussed issues still apply. For example, Part D sponsors may expect a portion of a non-preferred reference biological product to be given an exception to the preferred tier for a biosimilar biological product if such biosimilar biological product is not licensed for all of the same indications as the reference biological product. Furthermore, the selection of these drugs is often largely determined by the behavior of the prescriber rather than the formulary status of the Part D sponsor. If the prescriber prefers the reference biological product, they are more likely to prescribe it rather than the biosimilar biological product, regardless of the formulary position. This is particularly true for specialty drugs, where the differences in total drug cost and in the cost-sharing provisions of the plan are not as extreme as the differences between conventional brand and generic drugs. Finally, it is worth noting that several large Part D sponsors do not currently promote biosimilar biological products. For example, Zarxio®, the biosimilar biological product to Neupogen®, is not included on the formulary for several large Part D plans.

Our conclusion is that the provisions of the proposed rule to allow Part D sponsors to structure their benefits with

a second, ''preferred'' specialty tier are unlikely to have a material impact on Part D costs. While it is possible that a small savings to the Part D program could result from the enhanced flexibility, particularly for MA–PD plans with greater prescriber integration, broad adoption of a second specialty tier is unlikely. Nevertheless, we believe there are reasons to propose a second specialty tier. As discussed in more detail in section V.F. of this proposed rule, stakeholders requesting this change have posited that it might lead to better rebates on certain Part D drugs and reduced costs for Part D enrollees and CMS. Most importantly, we are currently not aware of any major adverse effects that could result to Part D enrollees by allowing Part D sponsors to structure their benefits with a second, ''preferred'' specialty tier as proposed. For example, concern for undue financial burden on some Part D enrollees has prompted us to propose to retain the current maximum allowable cost sharing (that is, 25/33 percent, as discussed in more detail in section V.F. of this proposed rule). Additionally, we solicit comment regarding whether negative consequences to Part D enrollees could result from this proposal. If there were no foreseeable notable harms to Part D enrollees, it would seem reasonable to provide the requested flexibility to Part D sponsors and see if additional benefits do result, while monitoring implementation for adverse effects and responding as necessary.

As discussed in section V.F. of this proposed rule, improving Part D enrollee access to needed drugs, including lowering drug costs, are central goals for CMS. While this regulatory impact analysis assesses the potential impact this proposal will have on Part D drug costs, we also believe this proposal has the potential to impact patient access and lower drug costs more broadly by providing further incentives for manufacturers to develop generic drugs and biosimilar and interchangeable biological products. Even if notable savings for the Part D program were not to materialize, individual Part D enrollees might save a great deal on rebated Part D drugs. Or, the policy might result in the benefit of (1) more formulary choices, or (2) more choices at a lower cost than might have otherwise been the case. These, in turn, might lead to positive health outcomes with associated indirect savings to Part D enrollees or the government. We solicit comment on any other unforeseen benefits that might result. And, again, if we were to finalize this proposal, we would closely monitor for any adverse effects and take any necessary action including proposing warranted changes for future rulemaking.

9. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

Regulatory Changes to Incurred Claims (§ 422.2420)

CMS is proposing to amend the regulation at § 422.2420(b)(2)(i) so that the incurred claims portion of the MLR numerator for an MA contract would include all amounts that an MA organization pays (including under capitation contracts) for covered services for all enrollees under the contract. Currently, § 422.2420(b)(2)(i) specifies that incurred claims include direct claims that an MA organization pays to providers (including under capitation contracts with physicians) for covered services provided to all enrollees under the contract.

CMS is proposing this amendment so that incurred claims in the MLR numerator will include expenditures for certain supplemental benefits that MA organizations are newly authorized to include in their PBPs as a result of recent policy and legislative changes. As explained in greater detail in sections II.A. and VI.F. of this proposed rule, recent subregulatory guidance and statutory changes have expanded the types of supplemental benefits that MA organizations may include in their PBPs. Beginning in 2020, pursuant to section 1852(a)(3)(D) of the Act, as amended by the BBA of 2018, MA organizations may provide SSBCI. SSBCI can include benefits that are not primarily health related, as long as the item or service has the reasonable expectation to improve or maintain the chronically ill enrollee's health or overall function. In addition, effective January 1, 2019, CMS's interpretation of ''primarily health related benefits,'' which is used as a criteria for supplemental benefits, has been changed to include services or items used to diagnose, compensate for physical impairments, ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. To be considered ''primarily health related,'' a supplemental benefit must focus directly on an enrollee's health care needs and should be recommended by a licensed medical professional as part of a health care plan, but it need not be directly provided by one.

This impact analysis assumes that the proposed amendments to the MLR regulations would not impact MA enrollee benefits. In other words, the analysis assumes the proposed amendments would change the types of expenditures that could be included in the MLR numerator as incurred claims, but there would be no impact on the level or number of permissible enrollee benefits that MA plans elect to offer. We request comment on this assumption.

The requirements pertaining to the calculation and reporting of MA contracts' MLRs are presented in subpart X of 42 CFR part 422. MA organizations' contracts that do not meet the 85 percent minimum MLR requirement for a contract year are required to remit funds to CMS (§ 422.2410(b)). CMS collects remittances by deducting the amounts owed from MA organizations' monthly payments (§ 422.2470(c)). In the absence of statutory language directing CMS to return remitted funds to the Medicare Trust Fund, CMS transfers remittances to the Treasury. For purposes of this impact analysis, we assume contracts that have an MLR of less than 85 percent for one contract year do not continue to fail to meet the MLR requirement for an additional two consecutive contract years, which would result in imposition of enrollment sanctions, or for an additional four consecutive contract years, which would result in contract termination. This is consistent with our experience; although the MLR requirement has only been in effect for five contract years, to date, very few contracts have been subject to MLR-related enrollment sanctions, and only one contract has failed to meet the MLR requirement for more than three consecutive contract years. No contract has been terminated for failure to satisfy the MLR requirement for five consecutive contract years.

Total remittances for individual contract years can be substantial. Based on internal CMS data, the simple average of total remittances across all contracts for contract years 2014–2017 is $131 million. If we adjusted these payments to a 2017 level by trending for enrollment and per capita growth but carving out ordinary inflation, the average would be $139 million.

We anticipate that, if finalized, the proposed amendments to § 422.2420(b)(2)(i) would increase the numerator of the MLR because the incurred claims category would include certain expenditures that would not qualify for inclusion in the numerator under the current regulations. Specifically, under the proposed amendments to § 422.2420(b)(2)(i), incurred claims would include amounts

that an MA organization pays (including under capitation contracts) for covered services, regardless of whether payment is made to an individual or entity that is a provider as defined at § 422.2. We expect that this will cause some MA contracts which formerly did not satisfy the minimum MLR requirement of 85 percent to now meet or exceed it. For contracts that still fail to meet the 85 percent threshold, we anticipate that the amount of remittances would decrease. In other words, the proposed regulation would, if finalized, effectively result in a transfer of funds from the Treasury to the MA organizations through the Medicare Trust Fund. Amounts that MA organizations would remit and which the Treasury would receive under the current regulations would instead remain with the MA organizations, implying that MA organizations enjoy cost savings while the Treasury has a cost impact. The net impact on the Medicare Trust Fund would be zero, since there are no additional transfers from or to the Medicare Trust Fund; the only issue being whether the MA organizations retain additional funds or the Treasury receives fewer funds.

To estimate the amount of payments made for services that would be included in incurred claims under the proposed amendments to § 422.2420(b)(2)(i), we used data in the 2019 submitted bids to estimate the increase in the supplemental benefits category for the primarily health related benefits that MA organizations could include in their PBPs starting in 2019. This estimate is complicated by the fact that, in the absence of the proposed amendments to § 422.2420(b)(2)(i), some types of supplemental benefits that MA organizations could offer starting in 2019 could potentially meet the requirements at § 422.2430 to be quality improvement activities (QIAs) for MLR purposes, meaning expenditures for those benefits could be included in the MLR numerator. Based on the 2019 submitted bid information, a consideration of the types of benefits that MA organizations could offer under CMS's reinterpretation of the ''primarily health related'' definition, and the likelihood that some of these benefits would meet the requirements at § 422.2430(a) to be QIAs, we estimated a 52 percent increase in projected expenditures for the categories of ''primarily health related'' supplemental benefits that would not qualify for inclusion in the MLR numerator as ''incurred claims'' under current § 422.2420(b)(i) or as QIA under § 422.2430(a). The first year that the expanded interpretation of ''primarily health related benefits'' was implemented was 2019, and so the increase seen in these categories for 2019 is attributed to this reinterpretation. To date, MA organizations have only been able to include non-primarily health related SSBCI in their plan offerings for one year (that is, 2020). While early indications show that utilization for these benefits have been low, we expect the use of these benefits to grow over time as MA organizations become more familiar with them and have time to include them in future plan offerings. Due to the absence of credible data for SSBCI, the impact on future MLR remittances is currently unquantifiable. We will continue to track SSBCI information and adjust the forecasts as more information becomes available.

We then reevaluated the MLRs for those contracts that failed to meet the 85 percent MLR requirement for contract years 2014–2017 by revising the numerator calculation to incorporate the 52 percent increase in the previously listed benefits. The change in the numerator calculation resulted in several of the contracts passing the MLR requirement instead of failing. For contracts that would not have met the MLR requirement even with the revised numerator calculation, the amount of remittances decreased. The average decrease in remittance payments over the four year period (that is, 2014–2017) is estimated to be $25.8 million (in 2017 dollars).

In order to project the decrease in remittances for the years 2021–2030, the $25.8 million was increased using estimated enrollment and per capita increases based on Tables IV.C1 and IV.C3 of the 2019 Medicare Trustees Report, with ordinary inflation (Table II.D1 of the 2019 Medicare Trustees Report) carved out of the estimates.

The results are presented in Table 31, which shows that in the first year of the proposed provision, 2021, there would effectively be a transfer from the Treasury through the Medicare Trust Fund of $35.3 million to MA organizations. For computational transparency, the amounts in 2017–2020 are also shown representing amounts paid to the Treasury in those years. This transfer would take the form of a reduction in the remittance amounts withheld from MA capitated payments. This amount (that is, the amount of remittances *not* withheld from MA capitated payments if the proposal were finalized) is projected to grow over 10 years, resulting in a $56.4 million transfer from the Treasury through the Medicare Trust Fund to MA organizations in 2030. The total transfer from the Treasury to MA organizations over 10 years is $455 million. There is $0 impact on the Medicare Trust Fund.

TABLE 31: TRANSFER OF REMITTANCES FROM THE TREASURY TO MA ORGANIZATIONS

Year	Medicare Advantage Enrollment Increases	Average Annual Per Capita Increases	Ordinary Inflation	Net costs ($ millions)
2017				25.8
2018	7.7%	5.5%	3.2%	28.4
2019	6.7%	5.5%	3.2%	31.0
2020	5.0%	5.5%	3.2%	33.3
2021	3.6%	5.5%	3.2%	35.3
2022	3.8%	5.5%	3.2%	37.5
2023	3.5%	5.5%	3.2%	39.7
2024	3.3%	5.5%	3.2%	41.9
2025	3.1%	5.5%	3.2%	44.2
2026	3.0%	5.5%	3.2%	46.5
2027	2.7%	5.5%	3.2%	48.8
2028	2.5%	5.5%	3.2%	51.1
2029	2.3%	5.5%	2.6%	53.8
2030	2.0%	5.5%	2.6%	56.4
Total 2021-2030				455.2

Deductible Factor for MA Medical Savings Account (MSA) Contracts (§ 422.2440)

CMS is proposing to amend the regulation at § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA MSA contracts that receive a credibility adjustment. The proposed deductible factor would serve as a multiplier on the credibility factor. CMS is proposing to adopt and codify in new paragraph (g) of § 422.2440 the same deductible factors that appear in the commercial MLR regulations at 45 CFR 158.232(c)(2). For partially credible MA MSA contracts, the deductible factor would range from 1.0 for MA MSA contracts that have a weighted average deductible of less than $2,500 to 1.736 for MA MSA contracts have a weighted average deductible of $10,000 or more.

As discussed in section V.I.4. of this proposed rule, CMS is proposing to add a deductible factor to the MLR calculation for MSAs so that organizations currently offering MSA plans, or those that are considering entering the market, are not deterred from offering MSAs due to concern that they will be unable to meet the MLR requirement as a result of random variations in claims experience. Although we believe that the proposed deductible factors would, if finalized, adequately address any such concerns by making it less likely that an MSA contract will fail to meet the MLR requirement due to random variations in claims experience, we are unable to predict with confidence whether or how the proposed change to the MLR calculation for MA MSA contracts will impact the availability of MA MSAs or the number of beneficiaries enrolled in MA MSAs. Due to this uncertainty, we estimate that the cost impact of the proposed change to the MLR calculation for MA MSAs will be as low as $0 or as high as $43.2 million over 10 years (2021–2030).

We do not anticipate that applying a deductible factor to the MLR calculation for MA MSA contracts, as proposed, would have an impact on remittances to the federal government. For CYs 2014–2017 (the most recent contract year for which MA MSAs have submitted MLR data), no MA MSA contract has failed to meet the 85 percent minimum MLR requirement. If the proposed deductible factors had applied to the MLR calculation for MA MSAs for CYs 2014–2017, although the MLRs for partially credible MA MSAs would have been higher, total remittances by MA MSAs would have remained at $0. We do not anticipate that MSA contracts that currently meet the MLR requirement will have more difficulty doing so if the proposed changes are finalized. We anticipate that new MA MSA contracts that MA organizations may choose to offer as a result of the proposed change will also succeed in meeting the MLR requirement, in light of the experience of current MSAs and in consideration of the more generous credibility adjustment that potential new MSAs would be expected to receive as a result of the application of the proposed deductible factor.

We believe that the cost impact of this proposed change, if any, will be attributable to an increase in MA MSA enrollment as these plans become more widely available as a result of MA organizations choosing to offer MA MSAs in response to the proposed change to the MLR calculation. To develop the upper limit of the cost estimate for this proposal ($43.2 million over 10 years), we assumed that the proposed change to the MLR calculation for MSAs would cause MA MSA enrollment to double over the first 3 years that the proposed change is in effect. We estimated that, relative to enrollment projections under the current regulations, if the proposed changes took effect, MSA enrollment will be 33.33 percent higher in 2021, 66.67 percent higher in 2022, and 100 percent higher in 2023 to 2030. We assumed that half of the new enrollees in MA MSA plans would otherwise have been enrolled in other types of MA plans, and half would otherwise have been enrolled in FFS Medicare.

We then determined the difference between the amount that CMS pays for each MA MSA plan enrollee and the amount CMS pays for each enrollee in a non-MSA MA plan or FFS Medicare. CMS generally incurs greater costs for MA MSA enrollees relative to enrollees in other MA plans because 100 percent of the difference between the MA MSA's projection of the cost of A/B services (referred to as the MSA premium) and the benchmark is deposited in the enrollee's account. By contrast, for MA plans that bid under the benchmark,

CMS retains between 30 percent and 50 percent of the difference between the bid and the benchmark. FFS spending per enrollee is approximately 100 percent of the amount CMS pays to MA plans for each enrollee. Therefore, the cost to the Medicare program for each additional MA MSA enrollee is approximately the same regardless of whether the enrollee would otherwise have been enrolled in a non-MSA MA plan or in FFS Medicare.

The estimated annual cost to the Medicare Trust fund by contract year is presented in Table 32. This estimate takes into account the projected growth in MSA enrollment in the Part C baseline projection supporting the Mid-Session Review of the FY 2020 President's Budget. The estimated annual cost reflects the additional cost to the Medicare program for each beneficiary who enrolls in an MA MSA plan in lieu of a non-MSA MA plan or FFS Medicare, multiplied by the projected increase in the number of enrollees in MA MSA plans.

TABLE 32—ESTIMATED COST PER YEAR TO THE MEDICARE TRUST FUND FOR PROPOSED CHANGES TO MLR CALCULATION FOR MA MSA CONTRACTS

Contract year	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	Contract year 2021–2030
Annual cost (millions)	$1.0	$2.2	$3.6	$4.0	$4.4	$4.8	$5.2	$5.6	$6.0	$6.4	$43.2
Proposed Annual Increase in MA MSA Enrollment	2,478	5,208	8,179	8,531	8,876	9,213	9,531	9,833	10,118	10,354	

10. Maximum Out-of-Pocket (MOOP) Limits for Medicare Parts A and B Services (§§ 422.100 and 422.101) and Service Category Cost Sharing Limits for Medicare Parts A and B Services and Per Member Per Month Actuarial Equivalence Cost Sharing (§§ 422.100 and 422.113)

MOOP and cost sharing limits are an important beneficiary protection and integral to ensuring that MA enrollees who need extensive or expensive health care because of their health status are not targeted or discriminated against. Requiring MOOP and cost sharing limits in MA plan design is necessary in order not to discourage enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory in violation of section 1852(b)(1) of the Act). CMS expects adopting transparent rules to govern MOOP and cost sharing limits for local and regional plans, including rules for incorporating out-of-pocket costs incurred by beneficiaries with diagnoses of ESRD, will provide stability for MA organizations and plan enrollees. We expect that our proposed approach to including ESRD costs would increase all in-network and combined MOOP limits for local and regional MA plan types; however, based on our program experience, we believe this is an important and necessary step to ensure that plan designs are not discriminatory and beneficiaries are protected from high and unreasonable financial costs regardless of which MA plan they enroll in. We have coordinated the MOOP and cost sharing proposals in sections VI.A. and VI.B. of this proposed rule in an effort to prevent substantial increases in MOOP limits, cost sharing limits, and premiums to protect beneficiaries, while also proposing reasonable updates and flexibilities for MA organizations to offer sustainable MA plans with stable benefit designs.

CMS expects the proposals in sections VI.A. and VI.B. of this proposed rule, related to transitioning ESRD costs into the data used to set MOOP and cost sharing limits, may result in a combination of savings and costs for MA organizations. Depending upon an individual's health status and health care coverage selections some enrollees may experience increased costs while others may experience decreased costs. CMS is not able to quantify these potential impacts accurately. CMS has not historically estimated potential cost impacts due to changes in cost sharing standards, MOOP limits, and other benefits such as additional telehealth benefits becoming a basic benefit.[110] Accordingly, we provide background and a qualitative discussion to share our rationale. The cost to the MA organization of having a MOOP limit and cost sharing are captured as a supplemental benefit in the bid pricing tool. With a higher MOOP limit or cost sharing, the cost of the MOOP limit and benefits are lower to the MA organization which allows additional rebate dollars to be spent elsewhere (for example, for cost sharing reductions or additional benefits). From an actuarial perspective, on average, the MA enrollee is receiving the same level of benefits in total (of course, individual impacts will vary). As a result, we believe the MOOP and Cost Sharing provisions will have minimal impact.

Before the amendments made by the Cures Act are effective, individuals medically determined to have ESRD cannot enroll in a MA plan, subject to limited exceptions. Generally, those exceptions include the following circumstances: An individual that develops ESRD while enrolled in a MA plan can remain in that plan, or, can enroll in a MA plan in the same organization; if enrolled in a health plan within an organization, an ESRD individual can enroll in a MA plan within that same organization; an ESRD individual enrolled in a plan which is terminated or discontinued has a one-time opportunity to join another plan; or, an individual may enroll in a special needs plan that has obtained a waiver to be open for enrollment to individuals with ESRD. Further information on enrollment exceptions for ESRD individuals is located in Chapter 2 of the Medicare Managed Care Manual. CMS establishes separate rates of payment to address the higher costs MA plans may experience when managing care for these enrollees with ESRD, and will continue to do so after Medicare beneficiaries with diagnoses of ESRD are allowed to enroll in MA plans in greater numbers than they can under the current limitations. For additional information on enrollment impacts from the Cures Act, CMS directs readers to sections IV.A., IX.B.8., and X.C.4. of this proposed rule.

MA organizations have been aware of the program change to allow Medicare beneficiaries with diagnoses of ESRD to enroll in MA since the Cures Act was enacted in December 2016. Following the Cures Act, the OACT has included projections of the number of individuals with diagnoses of ESRD that may enroll in MA within the President's Budget.[111] The OACT will update these projections for the FY 2021 President's Budget. As such, CMS expects MA organizations

[110] April 2019 Final Rule; Past draft and final Call Letters may be accessed at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

[111] The Fiscal Year President's Budgets may be accessed at *https://www.govinfo.gov/app/collection/BUDGET/.*

have planned and prepared for this upcoming program change as they have conducted business activities, such as defining plan benefits, provider contracting with network providers, developing case management programs, and making reinsurance arrangements.

CMS recognizes MA organizations are in a competitive market and design their plan bids to manage risk, encourage enrollment, and satisfy Medicare coverage requirements. CMS does not require MA organizations to report these unique approaches and as such cannot quantitatively report an accurate projection of what savings or costs MA organizations may incur from the changes in MOOP and cost sharing limits that will result from implementation of this proposal. CMS's goal in this proposed rule is to provide predictable and transparent MOOP limits and cost sharing standards and to set limits at a level that should not result in significant new costs for MA organizations or enrollees. By taking the program changes from the Cures Act into account within our existing process to set and update MOOP limits and cost sharing standards, we are looking to protect MA enrollees against high out of pocket costs and sudden changes in those costs.

CMS recognizes the MOOP limit in the MA program provides a unique protection to MA enrollees from high out-of-pocket costs. CMS notes beneficiaries with diagnoses of ESRD previously enrolled in Medicare FFS with or without Medigap coverage may experience different cost sharing and out-of-pocket costs if they switch to a MA plan. For example, a Medicare beneficiary with a diagnosis of ESRD enrolled in Medicare FFS (without Medigap or employer coverage) may experience higher out-of-pocket costs annually if their annual health care treatment out-of-pocket costs go above a MOOP limit available in MA. In addition, current and new MA enrollees without diagnoses of ESRD may also experience, or have already experienced, plan changes as MA organizations prepare for increased MA enrollment by beneficiaries with diagnoses of ESRD beyond those already enrolled in the program.

CMS cannot accurately project the cost impacts of these MOOP limit and cost sharing proposals for beneficiaries and MA organizations because potential savings and costs are largely influenced by: (1) The rate of transition for Medicare beneficiaries with diagnoses of ESRD into the MA program, (2) the mechanisms MA organizations choose to address this programmatic change (such as provider contracting, case management, plan benefits designs, and benefit flexibilities including Special Supplemental Benefits for the Chronically Ill, MA uniformity flexibility, as well as MOOP limits and cost sharing flexibilities proposed in this rule). In addition, there are multiple factors that CMS cannot currently disaggregate in order to attribute MOOP limit or cost sharing changes or a portion of cost sharing or MOOP limit changes to the changes in ESRD enrollment policy. These factors include:

- CMS does not collect enrollee level cost sharing information from MA organizations about the individuals reaching the MOOP limit each year;
- The MA enrollee population constantly changes based on individuals who are aging-in to the Medicare program on a monthly basis, existing enrollees dying, and enrollees switching plans;
- MA enrollees who may reach the MOOP limit one year may not meet the MOOP limit the following year; and
- MA organizations prepare plan bids that address many business factors at once, such as capitated payments, quality bonus payments and rebates, provider contracting, reinsurance arrangements, health insurance providers' fee, margins, along with policy changes such as beneficiaries with ESRD diagnoses being able to enroll in the MA program.

By implementing more than two levels of MOOP limits and by providing increased flexibility in setting cost sharing amounts for MA organizations with lower MOOP limits, we expect to encourage plan offerings with more favorable benefit designs for Medicare beneficiaries to choose from. We note that beneficiaries consider the MOOP limit and cost sharing structure when choosing an MA plan, however we do not expect them to face more complex plan options due to these proposals. From a beneficiary perspective, they will see and review the same volume of information about MOOP limits and cost sharing structures as they do currently. We also do not expect these proposals to drive MA plans to offer more plan options than they currently do as they can already create different MOOP limit and cost sharing structures. CMS will continue evaluations and enforcement of the current authority prohibiting plans from misleading beneficiaries in their communication materials and continue efforts to improve plan offerings and plan comparison tools and resources (for example, Medicare & You and 1–800–MEDICARE). In addition, we will disapprove a plan bid if its proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals.

11. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

Our proposal codifies the standards and methodology, with some modifications, used currently to evaluate network adequacy for MA plans and section 1876 cost plans; the proposal includes the list of provider and facility specialty types subject to network adequacy reviews, county type designations and ratios, maximum time and distance standards and minimum number requirements. The proposal also formalizes the CMS exceptions process and requires the annual publishing of the Health Services Delivery (HSD) reference file, which will provide updated numbers and maximums for these standards in subsequent years, and the Provider Supply File, which lists available providers and facilities, including their corresponding office locations and specialty types. CMS will continue to use the current PRA-approved collection of information in conjunction with the HPMS Network Management Module as a means for MA organizations to submit network information when required. As this has been the process for conducting network adequacy reviews since 2016, we do not expect any additional burden on MA plans as it relates to the network adequacy review process.

Our proposal is solely related to the sufficiency of contracted networks that MA organizations must maintain and has no impact on the provision of Medicare benefits that must be provided in either in-network and out-of-network settings. As a result, we do not expect any impact on the Medicare Trust Fund.

However, we propose three modifications to current network adequacy policy that may have qualitative impacts on MA organizations. We propose to reduce the required percentage of beneficiaries residing within maximum time and distance standards in Micro, Rural, and CEAC from 90 percent to 85 percent. We propose to allow for a 10 percentage point credit towards this percentage when MA organizations contract with one or more telehealth providers in the specialties of dermatology, psychiatry, neurology, otolaryngology and cardiology. Similarly, we propose that MA organizations may receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON

laws, or other state imposed anti-competitive restrictions, that limit the number of providers or facilities in a county or state.

With respect to the reduction in percentage of beneficiaries residing within maximum time and distance standards in rural counties, we expect that MA organizations will have a greater likelihood of complying with our reduced percentage in the initial network submission and will not need to request an exception for CMS's consideration. It is not possible to fully quantify the level of effort or hours required for an MA organization to submit an exception request, as they are submitted for multiple reasons. However, generally, we expect that this change will decrease the administrative burden on MA organizations when going through the network review process. Conceivably, the administrative costs included in an MA organization's bid could decrease. However, the decrease in administrative burden could be offset by the increase in administrative burden of contracting with telehealth providers. Additionally, more MA organizations may consider providing contracted services in areas that have traditionally been difficult to establish a sufficient network. The ability to meet compliance standards in new markets is a reasonable factor that may drive MA organization behavior, but we cannot quantify the likelihood of this, as many other factors are considered when entering new markets. In theory, the reduction in the rural percentage could conceivably increase MA enrollment, however our enrollment projections currently do not consider health plans' network adequacy information, and any changes to enrollment projections would be very minor.

By crediting MA organizations 10-percentage points towards the percentage of beneficiaries residing within time and distance standards for contracting with telehealth providers for certain specialties, we anticipate that this will be one of many factors that will help encourage MA organizations to contract with providers that offer telehealth services. However, we do not expect this policy change to significantly alter MA organization contracting patterns related to telehealth providers.

For the 10-percentage point credit for affected providers and facilities in states with CON laws, we expect that MA organizations will have a greater likelihood of complying with network adequacy standards in the initial network submission and will not need to request an exception for CMS's consideration. As we discussed earlier, it is not possible to fully quantify the level of effort or hours required for an MA organization to submit an exception request, but it is possible the administrative costs included in an MA organization's bid could decrease. However, we believe time associated with completing exception requests is nominal will not have a significant impact on the overall administrative costs submitted in a plan's bid.

In summary, we believe this proposal will have a non-quantifiable, negligible economic impact.

12. Service Delivery Request Processes Under PACE (§§ 460.104 and 460.121)

We estimate that our proposed amendments to these provisions, as discussed in section VII.A. of this proposed rule, would result in savings to PACE organizations. To estimate the savings from our proposed revisions to the service delivery request provisions we rely upon the assumptions described in the next section. These assumptions are based on our experience monitoring PACE organizations' compliance with current service delivery request requirements, and on data collected during those monitoring efforts.

We estimate that under the current regulation, the aggregate total annual cost to all PACE organizations for processing service delivery requests is approximately $37.1 million.

We estimated that cost by using the following assumptions. First, we estimate the wages for each of the 11 Interdisciplinary team (IDT) members in order to better estimate a total cost. The eleven disciplines shown are those disciplines required for the IDT composition under § 460.102(b). The Job codes and wages to be used come from the BLS's website allowing 100 for overhead and fringe benefits. Table 33 allows us to estimate the mean hourly wage of the IDT as a whole.

TABLE 33—WAGES FOR IDT STAFF MEMBERS

Occupation title	Occupation code	Mean hourly wage with fringe benefits and overhead ($/hr)
Primary Care Provider	29–1069	196.04
Registered Nurse	29–1141	72.60
Home Care Coordinator (often a RN)	29–1141	72.60
Physical Therapist	29–1123	85.46
Occupational Therapist	29–1122	82.08
Masters of Social Work	21–1022	56.22
Recreational Therapist	29–1125	48.68
Dietician	29–1031	58.86
Driver	53–3022	32.10
Personal Care Attendant	31–1011	24.36
PACE Center Manager	11–9111	109.36
TOTAL		838.36

Currently, when processing a service delivery request, the IDT must determine the appropriate discipline(s) to conduct a reassessment under § 460.104(d)(2) and is responsible for notifying the participant or designated representative of its decision to approve or deny a request under § 460.104(d)(2)(iii). Based on our experiences monitoring PACE organizations, we estimate that the IDT takes approximately 1 hour to handle these responsibilities for each service delivery request (1 * $838.36 = $838.36).

Reassessments performed in response to service delivery requests are varied and may be done by multiple disciplines. For purposes of this

estimate, we assume a registered nurse (RN) and Master's-level Social Worker (MSW) conducts reassessments, and that the total hours for reassessments equals 1.5 hours per discipline. Therefore, we estimate that reassessments would cost (1.5 * $72.60 = $108.90) and (1.5 * $56.22 = $84.33). This is summarized in Table 34.

TABLE 34—COST PER SERVICE DELIVERY REQUEST FOR A PACE ORGANIZATION ASSESSMENT

Professional	Occupational code	Hourly wage ($/hr)	Time (hr)	Total cost ($)
Registered Nurse	29–1141	72.60	1.5	108.90
Masters-level of Social Work	21–1022	56.22	1.5	84.33
Total Cost				193.23

Additionally, once a decision has been rendered, one discipline (usually the MSW) notifies the participant and/or designated representative which we believe takes about 1 hour (1 * $56.22 = $56.22). This is summarized in Table 35.

TABLE 35—COST PER SERVICE DELIVERY REQUEST FOR A PACE ORGANIZATION NOTIFICATION

Professional	Occupational code	Hourly wage ($/hr)	Time (hr)	Total Cost ($)
Masters-level of Social Work	21–1022	56.22	1	56.22

Therefore, the processing of a service delivery request under current regulations is approximately $1,087.81 (838.36 + 108.90 + 84.33 + 56.22) per request.

Additionally, based on combined audit data collected from all PACE organizations in 2017 and 2018, we estimate there are 852.8 service delivery requests per 1000 enrollees (34,146 total service delivery requests for 2017 and 2018 divided by 40,040 the average enrollment for that time period). Consequently, the total cost of processing service delivery requests for 2017–2018 under the current regulations was approximately $37.1 million (852.8 service delivery requests/1000 enrollees * 40,040 thousand enrollees * $1,087.81 per hour of work by the IDT) per year.

We anticipate our proposed regulation would reduce burden on PACE organizations in the following ways. First, the proposal would establish a streamlined approval process for service delivery requests that an IDT member can approve in full at the time the request is made under new § 460.121(e)(2). These approved requests would not need to be brought to the full IDT for review and would not require the IDT to conduct a separate assessment. We also do not anticipate notification of the approval adding an additional burden because the IDT member would approve the request immediately and therefore satisfy the notification requirement at the time the request is made. As discussed in section IX.B.13. of this proposed rule, we estimate:

(i) 20 percent of all service delivery requests are denied, while 80 percent are approved

(ii) Of the 80 percent of service delivery requests that are approved, 50 percent of those are routine (that is, can be approved in full by an IDT member), while 50 percent are not routine.

Consequently,

(a) 341 service delivery requests/1000 enrollees are routine and approved (50 percent routine * 80 percent approved * 852.8 service delivery requests/1000 total)

(b) 171 service delivery requests/1000 enrollees are denied (20 percent * 852.8 service delivery requests/1000 enrollees)

(c) 341 service delivery requests/1000 enrollees are approved but not routine (80 percent approved * 50 percent not routine * 852.8 service delivery requests/1000)

These estimates are summarized in Table 36.

TABLE 36: BREAKOUT OF SERVICE DELIVERY REQUESTS BY TYPE

Line ID	Formula	Item	Number or percentage
(1)		Average enrollment PACE, 2017,2018	40,040
(2)		Total service delivery requests 2017/2018	34,146
(3)	(2 / [(1)/1000]	Service delivery requests per 1000 enrollees	852.8
(4)		Percentage of approved service delivery requests	80%
(5)	100%-80%	Percentage of denied service delivery requests	20%
(6)		Percentage of approved service delivery requests, routine	50%
(7)	(3) * (4)	Total approved service delivery requests	682
(8)	(3) * (5)	Total denied service delivery requests	171
(9)	(7) * (6)	Total easily approved (routine) service delivery requests	341
(10)	(7)-(9)	Total not-easily approved (not routine) service delivery requests	341
(11)	(8)+(9)+(10)	Aggregate service delivery requests per year	853

We are proposing that:

(i) Service delivery requests that can be approved in full at the time the request is made would not require full IDT review, assessment, or a separate notification; Although work is involved in this approval, we are estimating the cost as $0 since (i) no separate assessment is needed, (ii) no separate notification is needed, (iii) the full IDT is not needed and (iv) the estimated time for an IDT member to approve in full an easily approved service delivery request is small and hence the total cost is negligible and can be done as a part of the PACE organization's routine day to day activities.

(ii) Denied service delivery requests require (as is the case under current provisions) IDT review, an in-person assessment and notification.

(iii) Service delivery requests that are approved, but cannot be approved in full at the time the request is made would require IDT review and notification but no assessment.

In section IX.B. of this proposed rule, we indicated five proposals anticipated to create increased burden for PACE organizations: The proposals, their projected first year costs, and their projected annual costs after the first year are summarized in Table 37.

TABLE 37: PAPERWORK COSTS ASSOCIATED WITH THIS PROPOSED RULE

Item	1st Year Cost	Annual Cost All Years	Only 1st Year Cost
Medical record documentation Training (§ 460.210(b))	91,333	-	91,333
Medical record documentation (§ 460.210(b))	559,110	559,110	
Develop written material for tracking services (§ 460.98)	333,395		
Tracking services (§ 460.98)	333,395	333,395	
Extension notification (§ 460.121)	164,612	164,612	
Update for extension notification (§ 460.121)	18,267	-	18,267
Update for patients' rights (§ 460.112)	18,267	-	18,267
Update Appeal Notices (§ 460.122)	45,667		45,667
Totals (in Millions $)	1.6	1.1	0.5

To estimate the total savings over 10 years we proceed as follows:

- We estimate the total savings without additional paperwork for 2017–2018 by subtracting the projected cost under the proposed provisions from the actual cost under the current provisions. Table 37 presents these calculations, showing a $17.5 million savings, without considering paperwork, for 2017–2018.
- For any year between 2021 and 2030, we divide the projected enrollment for that year by the actual enrollment for 2017/2018. Since costs are per 1000 enrollees, this quotient when multiplied by 17.5 million will give the savings for that year without considering paperwork requests.
- Finally, since, paperwork requests are an additional burden, we subtract paperwork costs from the savings to ascertain the projected savings for that year. In subtracting paperwork costs, we must subtract an annual cost in all years and a special one-time first year cost in 2021. Table 38 presents this 10 year projection.

We illustrate these calculations by deriving the $17.5 million savings estimated based upon the data for 2018, and presented in Table 40. That is, if the proposed provisions of this rule had been adopted in 2018, there would have been a savings of $17.5 million. This can be shown as follows:

- Actual Cost (without paperwork) for 2018: 37.1 million
- Cost (without paperwork) if these provisions were adopted: 19.6 million
- Total savings (Difference of the last two rows) 17.5 million

As we explained previously, in order to arrive at the 37.1 million and the 19.6 million for 2018, we considered the following:

- $37.1 = 40,040 (enrollees) * 852.8 service delivery requests/1000 enrollees * $1087.81 (IDT + assessment + notification)
- $19.6 = $12.2 + $7.4 + $0
  - $12.2 = 40,040 enrollees * 341 service delivery requests/1000 enrollee * ($1087.81 − 193.23)
  - $7.4 = 40,040 enrollees * 171 service delivery requests/1000 enrollee * ($1087.81)
  - $0 = $40,040 enrollees * 341 service delivery requests/1000 enrollee * $0

As can be seen, the savings comes from the fact that whereas current regulations require that all 852.8 service delivery requests/1000 enrollees be processed by the IDT (at a cost of $1087.81), the proposed regulations only require that 512 service delivery requests (171 service delivery requests/1000 enrollees that are denied and 341 service delivery requests/1000 enrollees that are approved but not routine) would go to the full IDT for processing, but another 341 service delivery requests would be approved and routine and therefore would not impose any cost on the PACE organization. Additionally, the 341 approved but not routine requests that would go to the IDT would be a reduced cost of $1087.81 − $193.23 since assessments would not be done for those approvals. We believe our proposal will reduce administrative burden on the PACE organization, and allow IDT members to focus more time on providing participant care.

TABLE 38: ITEMIZED AND TOTAL COST PER YEAR FOR CURRENT OPERATIONS AND PROPOSED

	Current	Proposed	Proposed	Proposed	Proposed
	Aggregate Service Delivery Requests	Total Service Delivery Requests Approved - Routine	Total Service Delivery Requests Approved - Not Routine	Total Service Delivery Requests Denied	Total Cost (Millions $) Proposed
Aggregate service delivery requests per 1000 per year	852.8	341	341	171	
Full IDT review	$838.36		$838.36	$838.36	
Assessment	$193.23			$193.23	
Notification	$56.22		$56.22	$56.22	
Total cost/service delivery requests without Paperwork	$1,087.81		$894.58	$1,087.81	
Average Enrollment 2017/2018	40,040		40,040	40,040	
Total Cost (millions) (2017/18)	$37.1		$12.2	$7.4	$19.6
Total Savings 2018 without paperwork					$17.50

TABLE 39: 10-YEAR AGGREGATE PROJECTED SAVINGS FROM PROPOSED PACE PROVISIONS

Year	Enrollment	Base Year Enrollment	Annual Savings 2018/2017 Without Paperwork	Annual Paperwork Cost	Special 1st Year Paperwork Cost	Adjusted Savings Current Year
(1)	(2)	(3)	(4)	(5)	(6)	(2)/(3)*(4)-((5)+(6))
2021	46,311	40,040	$ 17.5	1.1	0.5	18.7
2022	47,697	40,040	$ 17.5	1.1	0	19.8
2023	49,032	40,040	$ 17.5	1.1	0	20.4
2024	50,322	40,040	$ 17.5	1.1	0	20.9
2025	51,594	40,040	$ 17.5	1.1	0	21.5
2026	52,827	40,040	$ 17.5	1.1	0	22.0
2027	54,001	40,040	$ 17.5	1.1	0	22.5
2028	55,120	40,040	$ 17.5	1.1	0	23.0
2029	56,170	40,040	$ 17.5	1.1	0	23.5
2030	57,159	40,040	$ 17.5	1.1	0	23.9

To clarify Table 39, consider the following:

- As noted previously, the actual non-paper savings for the base year, had this provision been implemented in 2018, would have been $17.5 million for the 40,040 enrollees.
- The OACT projects 46,311 PACE enrollees for 2021.
- Since enrollment is projected to increase by a factor of 1.1566 (46,311/40,040), and we are estimating service delivery requests per 1000 enrollees, we project the non-paper savings for 2021 to be 1.1566 * $17.5 = $20.2 million. In other words the 2018 costs under the current regulation and proposed regulation would involve a product of 2018 enrollment (about 40,040) times the number of service requests per 1000. The 2021 costs use the same formula, however the 40,040 is replaced by 46,311. It follows that multiplying 2018 numbers by 46,311/40,040 gives us the correct 2021 number. Since the difference between current and proposed is savings, it follows that multiplying this difference by the ratio of 46,311/40,040 gives the updated savings.)
- However, these are savings without paperwork costs. Table 38 shows that total annual paperwork costs is $1.1 million and additionally there is a special $0.5 million cost for the first year.
- Therefore, the total savings for 2021 would be approximately $20.2 − (1.1 + 0.5) = $18.7 million.
- The other rows are calculated similarly.

Accordingly, our proposals to streamline the processes for addressing service delivery requests in PACE are projected to save PACE organizations $18.7 million in 2021 with a gradual increase in savings to $23.9 million by 2030. These savings are to industry (PACE organizations) because administrative burden is being reduced. Additionally, each blank cell in Table 37 corresponds to a proposal to eliminate an unnecessary burden.

13. Beneficiaries With Sickle Cell Disease (§ 423.100)

Based on analysis of 2018 data, we found that about 683 beneficiaries (1.3 percent) who met the minimum OMS criteria or who had a history of an opioid-related overdose had sickle cell disease and would be affected by the proposed exemption. Since we estimate that less than 10 percent of these 683 beneficiaries would have been targeted for case management, the resulting savings is $0.0 million (10 percent * 683 enrollees * $542.46 for each case management).

D. Alternatives Considered

1. Beneficiaries With History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

As the Medicare Part D program is a prescription drug benefit and opioid-related overdoses can be due to both prescription opioids, which may be covered under Part D, and illicit opioids, this raises a question of how CMS should define history of opioid-related overdose. CMS considered two options for defining history of an opioid-related overdose plus two alternatives.

Opioid overdose codes (ICD–10) [112] were identified using Medicare FFS Claims data and Part C Encounter data. When considering overdose, we noted that prescription opioids can also be obtained through illegal or illicit means. The available overdose diagnosis codes describe the type of drug involved in the poisoning but do not specify how the drugs were obtained. There is also an unspecified opioid overdose code. Therefore, assumptions were made to classify an overdose code as prescription or illicit. For example, code 40.4 (other synthetic opioids) was classified as illicit opioid overdose but in some cases fentanyl may have been obtained by prescription. Conversely, code 40.2 (other opioids) may include poisoning due to oxycodone which was classified as prescription opioid overdose but may have been obtained illegally.

Option #1. Include beneficiaries with either prescription or illicit opioid-related overdoses. This option would allow CMS to proactively identify the most potential at-risk beneficiaries with a history of opioid-related overdoses, regardless whether the opioid is prescription or illicit, so that they can be reported to the Part D sponsor and reviewed through a DMP. This option represents the largest program size of all of the options. Based on data between July 2017 and June 2018, CMS estimates that there were about 28,891 beneficiaries with prescription or illicit opioid-related overdoses who would have been identified and reported as potential at-risk beneficiaries through the OMS.

Option #1 (Alternative): The program size for this option decreases by 37 percent to 18,268 if we were to identify only those beneficiaries reported to have at least one opioid prescription drug claim during the 6-month OMS measurement period (approximately 63 percent had opioid Part D claim(s)), which means that they have at least one relatively current opioid prescriber.

Option #2: Identify beneficiaries with only prescription opioid-related overdoses. This approach would utilize a 12-month lookback period to identify beneficiaries with a history of prescription opioid overdoses. Based on data between July 2017 and June 2018, CMS estimates that there were about 21,037 beneficiaries with prescription opioid-related overdoses who would be identified and reported by OMS.

Option #2 (Alternative): Since about 72 percent of beneficiaries had at least one Part D opioid claim in the 6-month OMS measurement period, this option decreases the program size to 15,217 beneficiaries if we were to require beneficiaries reported to have at least one opioid prescription drug claim, which means that they have at least one relatively current opioid prescriber.

As noted, the primary impact will result from needing to case manage the additional beneficiaries identified as meeting the proposed definition. At the proposed hour and skill levels defined, this introduces a projected cost of $542.46 per additional beneficiary undergoing case management. The various economic impacts for the alternatives considered are summarized in Table 40.

TABLE 40—ECONOMIC IMPACT OF ALTERNATIVES CONSIDERED

Alternative (criteria)	Number of enrollees affected	Total cost ($)
Option 1	28,891	15,672,211.86
Option 1 (alternative)	18,268	9,909,659.28
Option 2	21,037	11,411,731.02
Option 2 (alternative)	15,217	8,254,613.82

As noted in the preamble, CMS proposed to define history of opioid-related overdose as defined in Option 1 (Alternative). This option incorporates the risk factor most predictive for another overdose or suicide-related event [113] and is commensurate with the Administration's commitment to vigorously address the opioid epidemic. However, this approach keeps a clear tie between opioid-related overdoses and the Part D program by requiring a recent prescription opioid prescriber, which simultaneously increases the likelihood for successful provider outreach through

[112] World Health Organization. (2015). International statistical classification of diseases and related health problems, 10th revision, Fifth edition, 2016. World Health Organization.

[113] Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul;112(7):1193–1201. doi: 10.1111/add.13774. Epub 2017 Mar 16. PubMed PMID: 28301070.

case management by the sponsor. We note that should an option be finalized that does not include a requirement for a recent PDE, related changes to other provisions of the DMP regulations may need to be considered. For example, the current regulation language on case management could be revised to include outreach to relevant providers generally, not just prescribers of FADs as there may not be an active current prescriber for purposes of sponsor-led case management.

2. Eligibility for Medication Therapy Management (MTMPs) (§ 423.153)

We initially contemplated requiring that each plan as part of the MTM service develop educational materials regarding the safe disposal of prescription drugs that are controlled substances for its beneficiaries. Though each plan would have had a greater cost to develop such materials, the information might have included more local resources specific to individual plans. However, for the sake of consistency and to reduce burden on MTM programs we are proposing that Part D plans would be required to furnish materials in their MTM programs that meet criteria specified in § 422.111(j) as part of a CMR, TMR, or other follow-up. We also considered whether we should extend MTM eligibility to potential at-risk beneficiaries (PARBs) instead of to just those determined to be at risk. We believe that providing MTM to PARBs might have been beneficial for this population. However, the SUPPORT Act is clear that the extended MTM should apply only to at risk beneficiaries.

3. Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

The provision regarding educating MA and Part D beneficiaries on opioid risks and alternative treatments has been fully discussed in section III.D. of this proposed rule, including various suggested enrollee groups to receive the information. The impact of this provision was estimated in section IX.B.6. of this proposed rule, which includes discussion of paper versus electronic delivery options.

We emphasize that the SUPPORT Act does not require CMS to set a standard as to which enrollees receive the required information. As indicated in section III.D. of this proposed rule, the SUPPORT Act gives plans flexibility to choose which enrollees to send the information. To facilitate plan choice, we have provided a wide range of alternatives in Table 17 in section IX.B.6. of this proposed rule, including an alternative of sending notices to all Part D enrollees. As can be seen, costs vary between $0.1 and $0.5 million. We refer the reader to the narrative in that section.

4. Permitting a Second, ''Preferred'', Specialty Tier in Part D (§§ 423.104, 423.560, and 423.578)

In proposing to allow Part D sponsors to have two specialty tiers, under the existing policy at § 423.578(c)(3)(ii), Part D sponsors would be required to permit tiering exceptions between the two specialty tiers. CMS is also considering permitting Part D sponsors to exempt tiering exceptions between the two specialty tiers, but CMS is concerned that removing the Part D enrollee protection requiring exceptions between the two specialty tiers could negate benefits that might otherwise have accrued to Part D enrollees under a two specialty tier policy when there is a therapeutic alternative on the preferred specialty tier that a Part D enrollee is unable to take.

Additionally, although CMS is proposing to codify at § 423.104(d)(2)(iv)(E) the maximum allowable cost sharing under current policy, because CMS notes that the deductible applies to all tiers and it is unclear that we should continue to differentiate the specialty tier from other tiers on the basis of the deductible, CMS is also considering decreasing the maximum permissible cost sharing to the 25 percent Defined Standard coinsurance for Part D plans with decreased or no deductibles. As a result, we would anticipate that Part D sponsors would need to raise cost sharing on non-specialty drugs to maintain actuarial equivalence. If this applies to all plans, then there should be no budget impact, as they must still return to a basic benefit design that is actuarially equivalent to the Defined Standard benefit, and there will be no adverse selection. Additionally, we do not expect impacts from this proposal to the private sector, as additional specialty tiers already exist in that market. Plans with a high proportion of dual-eligible enrollees are less likely to offer a second specialty tier, because the lower cost sharing would be less impactful for those beneficiaries. As a result, we don't expect material impacts to Medicaid costs.

Finally, although CMS is proposing at § 423.104(d)(2)(iv)(B) to increase the specialty-tier cost threshold for all plan years in which CMS determines that no less than a ten percent increase in the specialty-tier cost threshold, before rounding ''to'' the nearest $10 increment, in order to reestablish the one percent outlier threshold, CMS is also considering a change in this methodology such that CMS would always round ''up'' to the nearest $10 increment. This rounding up methodology would: (a) Ensure that the new specialty-tier cost threshold actually meets the one percent outlier threshold, and (b) provide more stability to the specialty-tier cost threshold. Although the $780 30-day equivalent ingredient cost we determined to be the specialty-tier cost threshold for this proposed rule did not require rounding, had we arrived at a 30-day equivalent ingredient cost of, for example, $772, rounding up to $780 30-day equivalent ingredient cost would have an insignificant impact on the number of drugs meeting the specialty-tier cost threshold.

5. Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)

We propose to require that each Part D plan adopt a beneficiary RTBT by January 1, 2022. We had considered requiring that this regulatory action occur by January 1, 2021 to coincide with the requirement of a prescriber RTBT and the other regulatory actions in this rule. However, we wanted to ensure that plans had adequate time to focus on implementing the prescriber RTBT by the currently mandated January 1, 2021 deadline.

We also considered requiring that plans display this information via a third party website or web application. However, since we discovered that plans already have patient portals that provide some of the mandated information, we believe it would be less confusing for beneficiaries to keep this information on the plan portal. In addition, it would be less of a burden on plans for them put the information on the portals, rather than supply the information to a third party.

E. Accounting Statement and Table

The following table summarizes savings, costs, and transfers by provision. As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Table 41, we have prepared an accounting statement showing the savings, costs, and transfers associated with the provisions of this proposed rule for calendar years 2021 through 2030. Table 41 is based on Tables 42A, 42B, and 42C which lists savings, costs, and transfers by provision. Table 41 is expressed in millions of dollars with both costs and savings listed as positive numbers. The sign of the transfers follow the convention of Table 41 with positive

numbers reflecting costs (as transfers) to government entities (the Medicare Trust Fund and the Treasury) and negative numbers reflecting savings to government entities. As can be seen, the net annualized savings of this rule is about $6 million per year. The raw savings over 10 years is $292 million. Due to transfers, there is net annualized reduced spending by government agencies (the Medicare Trust Fund and Treasury) of $370–$405 million. A breakdown of these savings from various perspectives may be found in Table 41.

TABLE 41—ACCOUNTING TABLE

[Millions $]*

Item	Annualized at 7%	Annualized at 3%	Period	Who is impacted
Net Annualized Monetized Savings.	5.8	6.3	Contract Years 2021–2030.	Federal government, MA organizations and Part D Sponsors.
Annualized Monetized Savings.	28.8	29.0	Contract Years 2021–2030.	Federal government, MA organizations and Part D Sponsors.
Annualized Monetized Cost.	23.0	22.7	Contract Years 2021–2030.	Federal government, MA organizations and Part D Sponsors.
Transfers	(369.0)	(406.5)	Contract Years 2021–2030.	Transfers between the Dept of Treasury and CMS (Medicare Trust Fund, Plans, and Sponsors).

* The ESRD enrollment and Kidney acquisition cost provisions which affected the pre-statutory baseline but did not further impact the codifications of this rule would have added $128.3 and $113.1 million respectively in annualized transfer savings, resulting in total annualized transfer savings of $497.3 and $519.7 savings at 7 percent and 3 percent respectively.

The following Table 42 summarizes savings, costs, and transfers by provision and forms a basis for the accounting table. For reasons of space, Table 42 is broken into Table 42A (2021 through 2024), Table 42B (2025 through 2028), and Table 42C (2029–2030), as well as raw totals. In these tables, all numbers are positive; positive numbers in the savings columns indicate actual dollars saved while positive numbers in the costs columns indicate actual dollars spent; the aggregate row indicates savings less costs and does not include transfers. All numbers are in millions. Tables 42A, B, and C form the basis for Table 41 and for the calculation to the infinite horizon discounted to 2016 and mentioned in the conclusion.

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TABLE 42A: AGGREGATE SAVINGS, COST, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2021 THROUGH 2024

	2021 Savings	2021 Cost	2021 Transfers	2022 Savings	2022 Cost	2022 Transfers	2023 Savings	2023 cost	2023 Transfers	2024 Savings	2024 Cost	2024 Transfers
Total Savings	24.5			27.5			28.1			28.7		
Total Costs		34.0			21.3			21.3			21.3	
Aggregate Total	(9.5)			6.2			6.8			7.4		
Total Transfers			36.3			39.7			43.3			(322.2)
Health Plan Quality Rating System												(368.1)
MTMP		0.7			0.7			0.7			0.7	
SNP MOCs		0.3			0.3			0.3			0.3	
MLR Regulation			35.3			37.5			39.7			41.9
MSA MLR			1.0			2.2			3.6			4.0
PACE Service Delivery Requests	18.7			19.8			20.4			20.9		

	2021 Savings	2021 Cost	2021 Transfers	2022 Savings	2022 Cost	2022 Transfers	2023 Savings	2023 cost	2023 Transfers	2024 Savings	2024 Cost	2024 Transfers
Fraud & Abuse Pt C, D		15.0			9.5			9.5			9.5	
Educating At-Risk Enrollees		0.1										
RTBT		4.6			0.4			0.4			0.4	
Pharmacy Performance Measures		0.2			0.2			0.2			0.2	
Mandatory DMP					0.1			0.1			0.1	
DMP Paperwork		3.1			0.1			0.1			0.1	
DMP Case Management		9.9			10.0			10.0			10.0	
DMP Drug Savings	5.8			7.7			7.7			7.7		

TABLE 42B: AGGREGATE SAVINGS, COST, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2025 THROUGH 2028

	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers
Total Savings	29.2			29.8			30.3			30.8		
Total Costs		21.3			21.3			21.3			21.3	
Aggregate Total	7.9			8.5			9.0			9.5		
Total Transfers			(489.3)			(555.4)			(561.3)			(717.0)
Health Plan Quality Rating System			(537.9)			(606.7)			(615.3)	-		(773.7)
MTMP		0.7			0.7			0.7			0.7	
SNP MOCs		0.3			0.3			0.3			0.3	
MLR Regulation			44.2			46.5			48.8			51.1
MSA MLR			4.4			4.8			5.2			5.6
PACE Service Delivery Requests	21.5			22.0			22.5			23.0		

	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers
Fraud & Abuse Pt C, D		9.5			9.5			9.5			9.5	
Educating At-Risk Enrollees												
RTBT		0.4			0.4			0.4			0.4	
Pharmacy Performance Measures		0.2			0.2			0.2			0.2	
Mandatory DMP		0.1			0.1			0.1			0.1	
DMP Paperwork		0.1			0.1			0.1			0.1	
DMP Case Management		10.0			10.0			10.0			10.0	
DMP Drug Savings	7.7			7.7			7.7			7.7		

TABLE 42C: AGGREGATE SAVINGS, COST, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2029 THROUGH 2030 AND RAW TOTALS

	2029 Savings	2029 Cost	2029 Transfers	2030 Savings	2030 Costs	2030 Transfers	Raw 10 Year Totals (Savings)	Raw 10 Year Totals (Costs)	Raw 10 year totals (Transfers)
Total Savings	31.22			31.7			291.7		
Total Costs		21.3			21.3			225.5	
Aggregate Total	9.9			10.4			66.2		(4,359.4)
Total Transfers			(897.0)			(936.6)			
Health Plan Quality Rating System			(956.8)			(999.4)			(4,857.8)
MTMP		0.7			0.7			7.0	
SNP MOCs		0.3			0.3			3.4	
MLR Regulation			53.8			56.4			455.2
MSA MLR			6.0			6.4			43.2
PACE Service Delivery Requests	23.5			23.9			216.3		

	2029 Savings	2029 Cost	2029 Transfers	2030 Savings	2030 Costs	2030 Transfers	Raw 10 Year Totals (Savings)	Raw 10 Year Totals (Costs)	Raw 10 year totals (Transfers)
Fraud & Abuse Pt C, D		9.5			9.5			100.1	
Educating At-Rrisk Enrollees								0.1	
RTBT		0.4			0.4			8.0	
Pharmacy Performance Measures		0.2			0.2			2.4	
Mandatory DMP		0.1			0.1			0.8	
DMP Paperwork		0.1			0.1			3.9	
DMP Case Management		10.0			10.0			99.9	
DMP Drug Savings	7.7			7.7			75.4		

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The following information supplements Table 42 and also identifies how impacts calculated in section IX of this proposed rule affect the calculations of this section and the tables.

- For two provisions, DMP and PACE, this Regulatory Impact Analysis provides tables summarizing a variety of impacts with line items for the paperwork burdens of section IX of this proposed rule. Thus the section IX impacts are reflected both in Table 42 (summary table) and 40 (monetized table) as well as in special tables in this section.
- For five provisions, MTMP, RTBT, SNP MOCs, pharmacy, and Fraud and Abuse, the only impacts are calculated in section IX of this proposed rule. These five provisions have those section IX impacts listed in Table 42.
- For outreach to at risk beneficiaries, which was estimated in section IX of this proposed rule, only the system updates and preparation of outreach are listed in Table 42. Although Table 19 of section IX of this proposed rule does list additional impacts, the mailing of material to beneficiaries, since CMS was not given the authority to decide on the

cohort of beneficiaries to whom to send this information, we have omitted mailing costs from Table 42 and instead solicited stakeholder feedback.

• For two provisions, Parts C and D SEPs, and ESRD enrollment, calculations of impact, either paperwork or on the Medicare Trust Fund have been provided in the narrative along with tables providing 10-year summaries. However, since these impacts are already reflected in current spending, in other words, since the provisions do not change current spending, these impacts have not been included in Table 42.

• There is a cost of $0.7 million arising from burden to beneficiaries for filling out enrollment forms as a result of allowing ESRD beneficiaries to join plans and expected increased in MSA enrollment. These costs have been duly noted in section IX of this proposed rule but were not included in Table 42 since it deals mainly with impacts on the Medicare Trust Fund and industry.

• For two provisions, D–SNP look alike and MSA MLR, the impact calculated in section IX of this proposed rule is $0.0 million and hence these amounts are not included in Table 42. They are however included in Table 10 of section IX of this proposed rule.

F. Conclusion

As indicated in Table 41, we estimate that this proposed rule generates annualized cost savings of approximately $5.8 to 6.3 million per year over 2021 through 2030. As indicated in Table 42, the primary driver of savings are (i) proposed revisions to the PACE program resulting in greater efficiencies and (ii) increased vigilance for at-risk beneficiaries with a consequent reduction in drug costs. These savings are offset by costs from Fraud and Abuse efforts and a variety of outreach efforts to at-risk beneficiaries.

As indicated in Table 42, the government agencies have a net reduction in spending of $4.4 billion over 10 years. The primary driver of reduction is the use of the Tukey outlier deletion for Star Ratings. This reduction in Medicare Trust Fund spending is offset by several items increasing spending such as the MLR provisions which reduce civil penalties to the Treasury, and the MSA provisions which may result in increased enrollment in MSA plans and consequent increased spending by the Trust Fund,

G. Reducing Regulation and Controlling Regulatory Costs

This proposed rule, if finalized, is tentatively expected to be a deregulatory action under Executive Order 13771. The Department preliminarily estimates that this rule generates $4.4 million in annualized savings at a 7 percent discount rate, discounted relative to 2016, over a perpetual time horizon.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, 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 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to reads as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.370(a) is amended by—

■ a. Revising paragraph (1) of the definition of ''Credible allegation of fraud''; and

■ b. Adding the definition for ''Fraud hotline tip'' in alphabetical order.

The revision and addition read as follows:

§ 405.370 Definitions.

(a) * * *

Credible allegation of fraud. * * *

(1) Fraud hotline tips verified by further evidence.

* * * * *

Fraud hotline tip. A complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 3. The authority citation for part 417 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, 42 U.S.C. 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

■ 4. Section 417.416 is amended by adding paragraph (e)(3) to read as follows:

§ 417.416 Qualifying condition: Furnishing of services.

* * * * *

(e) * * *

(3) The HMO or CMP must meet network adequacy standards specified in § 422.116 of this chapter.

■ 5. Section 417.496 is added to read as follows:

§ 417.496 Cost plan crosswalk.

(a) *General rules*—(1) *Definition.* Crosswalk means the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a cost plan contract between the CMP or HMO and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibition.* (i) Crosswalks are prohibited between different contracts.

(ii) Crosswalks are prohibited between different plan IDs unless the crosswalk to a different plan ID meets the requirements in paragraph (c)(1)(i) of this section.

(3) *Compliance with renewal/nonrenewal rules.* The cost plan must comply with renewal and nonrenewal rules in §§ 417.490 and 417.492 in order to complete plan crosswalks.

(b) *Allowable crosswalk types.* All cost plans may perform a crosswalk in the following circumstances:

(1) *Renewal.* A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(2) *Consolidated renewal.* A plan in the following contract year that combines 2 or more PBPs. The plan ID for the following contract year must retain one of the current contract year plan IDs.

(3) *Renewal with a service area expansion (SAE).* A plan in the following contract year plan that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(4) *Renewal with a service area reduction (SAR).* A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area.

(c) *Exception.* (1) In order to perform a crosswalk that is not specified in paragraph (b) of this section, a cost organization must request an exception. CMS reviews requests and permits a crosswalk exception in the following circumstance:

(i) Except as specified in paragraph (c)(1)(ii) of this section, terminating cost plans offering optional benefits may transfer enrollees from one of the PBPs under its contract to another PBP under its contract, including new PBPs that have no optional benefits or optional benefits different than those in the terminating PBP.

(ii) A terminating cost plan cannot move an enrollee from a PBP that does not include Part D to a PBP that does include Part D.

(iii) If the terminated supplemental benefit includes Part D and the new PBP does not, enrollees must receive written notification about the following:

(A) That they are losing Part D coverage;

(B) The options for obtaining Part D; and

(C) The implications of not getting Part D through some other means.

(2) [Reserved]

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 6. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 7. Section 422.2 is amended by revising the definition of ''Institutionalized'' and adding the definition of ''Parent organization'' in alphabetical order to read as follows:

§ 422.2 Definitions.

* * * * *

Institutionalized means, for the purposes of defining a special needs individual and for the open enrollment period for institutionalized individuals at § 422.62(a)(4), an MA eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in one of the following long-term care facility settings:

(1) Skilled nursing facility (SNF) as defined in section 1819 of the Act (Medicare).

(2) Nursing facility (NF) as defined in section 1919 of the Act (Medicaid).

(3) Intermediate care facility for individuals with intellectual and developmental disabilities as defined in section 1905(d) of the Act.

(4) Psychiatric hospital or unit as defined in section 1861(f) of the Act.

(5) Rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act.

(6) Long-term care hospital as defined in section 1886(d)(1)(B) of the Act.

(7) Hospital which has an agreement under section 1883 of the Act (a swing-bed hospital).

(8) Subject to CMS approval, a facility that is not listed in paragraphs (1) through (7) of this definition but meets both of the following:

(i) Furnishes similar long-term, healthcare services that are covered under Medicare Part A, Medicare Part B, or Medicaid; and

(ii) Whose residents have similar needs and healthcare status as residents of one or more facilities listed in paragraphs (1) through (7) of this definition.

* * * * *

Parent organization means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

* * * * *

■ 8. Section 422.3 is added to read as follows:

§ 422.3 MA organizations' use of reinsurance.

(a) An MA organization may obtain insurance or make other arrangements for the cost of providing basic benefits to an individual enrollee that either:

(1) The aggregate value of which exceeds an aggregate level that is greater than or equal to $10,000 during a contract year; or

(2) If the MA organization uses insurance or makes arrangements for sharing such costs proportionately on a first dollar basis, the value of the insured risk does not exceed a value which is actuarially equivalent to the costs described in paragraph (a)(1) of this section.

(b) [Reserved]

§ 422.50 [Amended]

■ 9. Section 422.50 is amended in paragraph (a)(2) introductory text by removing the phrase ''Has not been'' and adding in its place the phrase ''For coverage before January 1, 2021, has not been''.

§ 422.52 [Amended]

■ 10. Section 422.52 is amended in paragraph (c) by removing the phrase ''CMS may waive § 422.50(a)(2)'' and adding in its place the phrase ''For plan years beginning before January 1, 2021, CMS may waive § 422.50(a)(2)''.

■ 11. Section 422.62 is amended by—

■ a. Revising paragraphs (b) introductory text and (b)(3) introductory text;

■ b. Redesignating paragraph (b)(4) as paragraph (b)(26); and

■ c. Adding a new paragraph (b)(4) and paragraphs (b)(5) through (25).

The revisions and additions read as follows:

§ 422.62 Election of coverage under an MA plan.

* * * * *

(b) *Special election periods (SEPs).* An individual may at any time (that is, not limited to the annual coordinated election period) discontinue the election of an MA plan offered by an MA organization and change his or her election from an MA plan to original Medicare or to a different MA plan under any of the following circumstances:

* * * * *

(3) The individual demonstrates to CMS that—

* * * * *

(4) The individual is making an MA enrollment request into or out of an employer sponsored MA plan, is disenrolling from an MA plan to take employer sponsored coverage of any kind, or is disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan. This SEP is available to individuals who have (or are enrolling in) an employer or union

sponsored MA plan and ends 2 months after the month the employer or union coverage of any type ends. The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to 3 months after the month in which the election is made.

(5) The individual is enrolled in an MA plan offered by an MA organization that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction.

(i) Consistent with disclosure requirements at § 422.111(g), CMS may require the MA organization to notify current enrollees that if the enrollees believe they are affected by the matter(s) that gave rise to the sanction, the enrollees are eligible for a SEP to elect another MA plan or disenroll to original Medicare and enroll in a PDP.

(ii) The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

(6)(i) The individual is enrolled in a section 1876 cost contract that is not renewing its contract for the area in which the enrollee resides.

(ii) This SEP begins December 8 of the then-current contract year and ends on the last day of February of the following year.

(7) The individual is disenrolling from an MA plan to enroll in a Program of All-inclusive Care for the Elderly (PACE) organization or is enrolling in an MA plan after disenrolling from a PACE organization.

(i) An individual who disenrolls from PACE has a SEP for 2 months after the effective date of PACE disenrollment to elect an MA plan.

(ii) An individual who disenrolls from an MA plan has a SEP for 2 months after the effective date of MA disenrollment to elect a PACE plan.

(8) The individual terminated a Medigap policy upon enrolling for the first time in an MA plan and is still in a ''trial period'' and eligible for ''guaranteed issue'' of a Medigap policy, as outlined in section 1882(s)(3)(B)(v) of the Act.

(i) This SEP allows an eligible individual to make a one-time election to disenroll from his or her first MA plan to join original Medicare at any time of the year.

(ii) This SEP begins upon enrollment in the MA plan and ends after 12 months of enrollment or when the individual disenrolls from the MA plan, whichever is earlier.

(9) Until December 31, 2020, the individual became entitled to Medicare based on ESRD for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA plan during his or her Initial Coverage Election Period (ICEP).

(i) The individual may prospectively elect an MA plan offered by an MA organization, provided—

(A) The individual was enrolled in a health plan offered by the same MA organization the month before their entitlement to Parts A and B;

(B) The individual developed ESRD while a member of that health plan; and

(C) The individual is still enrolled in that health plan.

(ii) This SEP begins the month the individual receives the notice of the Medicare entitlement determination and continues for 2 additional calendar months after the month the notice is received.

(10) The individual became entitled to Medicare for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA plan during their initial coverage election period (ICEP). This SEP begins the month the individual receives the notice of the retroactive Medicare entitlement determination and continues for 2 additional calendar months after the month the notice is received. The effective date would be the first of the month following the month in which the election is made but would not be earlier than the first day of the month in which the notice of the Medicare entitlement determination is received by the individual.

(11)(i) The individual enrolled in an MA special needs plan (SNP) and is no longer eligible for the SNP because he or she no longer meets the applicable special needs status.

(ii) This SEP begins the month the individual's special needs status changes and ends when the individual makes an enrollment request or 3 calendar months after the effective date of involuntary disenrollment from the SNP, whichever is earlier.

(12) The individual belongs to a qualified State Pharmaceutical Assistance Program (SPAP) and is requesting enrollment in an MA–PD plan.

(i) The individual may make one MA election per year.

(ii) This SEP is available while the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after either the month of the loss of eligibility or notification of the loss, whichever is later.

(13)(i) The individual has severe or disabling chronic conditions and is eligible to enroll into a Chronic Care SNP designed to serve individuals with those conditions. The SEP is for an enrollment election that is consistent with the individual's eligibility for a Chronic Care SNP. Individuals enrolled in a Chronic Care SNP who have a severe or disabling chronic condition which is not a focus of their current SNP are eligible for this SEP to request enrollment in a Chronic Care SNP that focuses on this other condition. Individuals who are found after enrollment not to have the qualifying condition necessary to be eligible for the Chronic Care SNP are eligible for a SEP to enroll in a different MA plan.

(ii) This SEP is available while the individual has the qualifying condition and ends upon enrollment in the Chronic Care SNP. This SEP begins when the MA organization notifies the individual of the lack of eligibility and extends through the end of that month and the following 2 calendar months. The SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

(14) The individual is enrolled in an MA–PD plan and requests to disenroll from that plan to enroll in or maintain other creditable prescription drug coverage.

(i) This SEP is available while the individual is enrolled in an MA–PD plan. The effective date of disenrollment from the MA plan is the first day of the month following the month a disenrollment request is received by the MA organization.

(ii) Permissible enrollment changes during this SEP are to disenroll from an MA–PD plan and elect original Medicare or to elect an MA-only plan, resulting in disenrollment from the MA–PD plan.

(15) The individual is requesting enrollment in an MA plan offered by an MA organization with a Star Rating of 5 Stars. An individual may use this SEP only once for the contract year in which the MA plan was assigned a 5-star overall performance rating, beginning the December 8th before that contract year through November 30th of that contract year.

(16) The individual is a non-U.S. citizen who becomes lawfully present in the United States.

(i) This SEP begins the month the individual attains lawful presence status and ends the earlier of when the

individual makes an enrollment election or 2 calendar months after the month the individual attains lawful presence status.

(ii) [Reserved]

(17) The individual was adversely affected by having requested, but not received, required notices or information in an accessible format, as outlined in section 504 of the Rehabilitation Act of 1973 within the same timeframe that the MA organization or CMS provided the same information to individuals who did not request an accessible format.

(i) The SEP begins at the end of the election period during which the individual was seeking to make an enrollment election and the length is at least as long as the time it takes for the information to be provided to the individual in an accessible format.

(ii) MA organizations may determine eligibility for this SEP when the criterion is met, ensuring adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of the requested materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

(18) Individuals affected by a Federal Emergency Management Agency (FEMA)-declared weather-related emergency or major disaster are eligible for a SEP to make an MA enrollment or disenrollment election. The SEP is available from the start of the incident period and for 4 calendar months after the start of the incident period. And individual is eligible for this SEP provided the individual—

(i)(A) Resides, or resided at the start of the incident period, in an area for which FEMA has declared an emergency or a major disaster and has designated affected counties as being eligible to apply for individual or public level assistance; or

(B) Does not reside in the affected areas but relies on help making healthcare decisions from one or more individuals who reside in the affected areas; and

(ii) Was eligible for an election period at the time of incident period; and

(iii) Did not make an election during that election period due to the weather-related emergency or major disaster.

(19) The individual experiences an involuntary loss of creditable prescription drug coverage, including a reduction in the level of coverage so that it is no longer creditable and excluding any loss or reduction of creditable coverage that is due to a failure to pay premiums.

(i) The individual is eligible to request enrollment in an MA–PD plan.

(ii) The SEP begins when the individual is notified of the loss of creditable coverage and ends 2 calendar months after the later of the loss (or reduction) or the individual's receipt of the notice.

(iii) The effective date of this SEP is the first of the month after the enrollment election is made or, at the individual's request, may be up to 3 months prospective.

(20) The individual was not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage. CMS determines eligibility for this SEP on a case-by-case basis, based on its determination that an entity offering prescription drug coverage failed to provide accurate and timely disclosure of the loss of creditable prescription drug coverage or whether the prescription drug coverage offered is creditable.

(i) The individual is eligible for one enrollment in, or disenrollment from, an MA–PD plan.

(ii) This SEP begins the month of CMS' determination and continues for 2 additional calendar months following the determination.

(21) The individual's enrollment or non-enrollment in an MA–PD plan is erroneous due to an action, inaction, or error by a Federal employee.

(i) The individual is permitted enrollment in, or disenrollment from, the MA–PD plan, as determined by CMS.

(ii) This SEP begins the month of CMS approval of this SEP on the basis that the individual's enrollment was erroneous due to an action, inaction, or error by a Federal employee and continues for 2 additional calendar months following this approval.

(22) The individual is eligible for an additional Part D Initial Election Period, such as an individual currently entitled to Medicare due to a disability and who is attaining age 65.

(i) The individual is eligible to make an MA election to coordinate with the additional Part D Initial Election Period.

(ii) The SEP may be used to disenroll from an MA plan, with or without Part D benefits, to enroll in original Medicare, or to enroll in an MA plan that does not include Part D benefits, regardless of whether the individual uses the Part D Initial Election Period to enroll in a PDP.

(iii) The SEP begins and ends concurrently with the additional Part D Initial Election Period.

(23) Individuals affected by a significant change in plan provider network are eligible for a SEP that permits disenrollment from the MA plan that has changed its network to another MA plan or to original Medicare. This SEP can be used only once per significant change in the provider network.

(i) The SEP begins the month the individual is notified of eligibility for the SEP and extends an additional 2 calendar months thereafter.

(ii) An enrollee is affected by a significant network change when the enrollee is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated from the provider network.

(iii) When instructed by CMS, the MA plan that has significantly changed its network must issue a notice, in the form and manner directed by CMS, that notifies enrollees who are eligible for this SEP of their eligibility for the SEP and how to use the SEP.

(24) The individual is enrolled in a plan offered by an MA organization that has been placed into receivership by a state or territorial regulatory authority. The SEP begins the month the receivership is effective and continues until it is no longer in effect or until the enrollee makes an election, whichever occurs first. When instructed by CMS, the MA plan that has been placed under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for this SEP and how to use the SEP.

(25) The individual is enrolled in a plan that has been identified with the low performing icon in accordance with § 422.166(h)(1)(ii). This SEP exists while the individual is enrolled in the low performing MA plan.

* * * * *

■ 12. Section 422.68 is amended by revising paragraph (d) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(d) *Special election periods.* For an election or change of election made during a special election period as described in § 422.62(b), the coverage or change in coverage is effective the first day of the calendar month following the month in which the election is made, unless otherwise noted.

* * * * *

■ 13. Section 422.100 is amended by—

■ a. Revising paragraphs (c)(1) and (2);

■ b. Redesignating paragraph (d)(2) as paragraph (d)(2)(i);

■ c. Adding paragraph (d)(2)(ii); and

■ d. Revising paragraphs (f)(4) through (6), (j), and (m)(5)(iii).

The revisions and addition read as follows:

§ 422.100 General requirements.

* * * * *

(c) * * *

(1) Basic benefits are all items and services (other than hospice care or, beginning in 2021, coverage for organ acquisitions for kidney transplants) for which benefits are available under Parts A and B of Medicare, including additional telehealth benefits offered consistent with the requirements at § 422.135.

(2) Supplemental benefits are benefits offered under § 422.102.

(i) Supplemental benefits consist of—

(A) Mandatory supplemental benefits are services not covered by Medicare that an MA enrollee must purchase as part of an MA plan that are paid for in full, directly by (or on behalf of) Medicare enrollees, in the form of premiums or cost sharing.

(B) Optional supplemental benefits are health services not covered by Medicare that are purchased at the option of the MA enrollee and paid for in full, directly by (or on behalf of) the Medicare enrollee, in the form of premiums or cost sharing. These services may be grouped or offered individually.

(ii) Supplemental benefits must meet the following requirements:

(A) Except in the case of special supplemental benefit for the chronically ill (SSBCI) offered in accordance with § 422.102(f) that are not primarily health related, the benefits diagnose, compensate for physical impairments or act to ameliorate the functional or psychological impact of injuries or health conditions, or reduce avoidable emergency and health care utilization;

(B) The MA organization incurs a non-zero direct medical cost, except that in the case of a SSBCI that is not primarily health related that is offered in accordance with § 422.102, the MA organization may instead incur a non-zero direct non-administrative cost; and

(C) The benefits are not covered by Medicare.

(d) * * *

(2) * * *

(ii) MA plans may provide supplemental benefits (such as specific reductions in cost sharing or additional services or items) that are tied to disease state or health status in a manner that ensures that similarly situated individuals are treated uniformly; there must be some nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state.

* * * * *

(f) * * *

(4) Except as provided in paragraph (f)(5) of this section, for each year beginning on or after January 1, 2022, MA local plans (as defined in § 422.2) must establish a maximum out-of-pocket (MOOP) limit for basic benefits that is consistent with this paragraph (f)(4). MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee, and must alert enrollees and contracted providers when the MOOP limit is reached.

(i) CMS sets up to three MOOP limits using projections of beneficiary spending that are based on the most recent, complete Medicare Fee-for-Service (FFS) data subject to paragraph (f)(4)(vii) of this section.

(ii) An MA organization that establishes a plan's MOOP limit at a dollar amount within the range specified in paragraphs (f)(4)(ii)(A) through (C) of this section is considered to have the corresponding mandatory, intermediate, or lower MOOP limit for purposes of paragraphs (f)(6) and (j) of this section:

(A) *Mandatory MOOP limit:* Above the intermediate MOOP limit and up to and including the mandatory MOOP limit.

(B) *Intermediate MOOP limit:* Above the lower MOOP limit and up to and including the intermediate MOOP limit.

(C) *Lower MOOP limit:* Between $0.00 and up to and including the lower MOOP limit.

(iii) Each MOOP limit CMS sets is rounded to the nearest $50 increment and in cases where the MOOP limit is projected to be exactly in between two $50 increments, CMS rounds to the lower $50 increment.

(iv) For 2022, CMS sets the MOOP limits as follows, subject to the rounding rules in paragraph (f)(4)(iii) of this section and ESRD cost transition schedule in paragraph (f)(4)(vii) of this section:

(A) The mandatory MOOP limit is set at the 95th percentile of projected Medicare FFS beneficiary out-of-pocket spending.

(B) The intermediate MOOP is set at the numeric midpoint of the mandatory and lower MOOP limits.

(C) The lower MOOP limit is set at the 85th percentile of projected Medicare FFS beneficiary out-of-pocket spending.

(v) For 2023 and 2024 or, if later, until the end of the ESRD cost transition, CMS sets the MOOP limits as follows, subject to the rounding rules in paragraph (f)(4)(iii) of this section and ESRD cost transition schedule in paragraph (f)(4)(vii) of this section:

(A) The mandatory MOOP limit does not continue the ESRD cost transition if the prior year's projected 95th percentile (including costs incurred by all Medicare FFS beneficiaries with and without diagnoses of ESRD) is more than two percentiles above or below the projected 95th percentile for the upcoming contract year. Instead, the mandatory MOOP limit increases or decreases by up to 10 percent of the prior year's MOOP limit and the ESRD cost transition schedule resumes at the rate that was scheduled to occur once the prior year's projected 95th percentile remains within the range of two percentiles above or below the projected 95th percentile for the upcoming contract year.

(B) The intermediate MOOP is either maintained at the prior year's limit or updated to the new numeric midpoint if the mandatory or lower MOOP limit changes for the year.

(C) The lower MOOP limit does not continue the ESRD cost transition if the prior year's projected 85th percentile (including costs incurred by all Medicare FFS beneficiaries with and without diagnoses of ESRD) is more than two percentiles above or below the projected 85th percentile for the upcoming contract year. Instead, the lower MOOP limit increases or decreases by up to 10 percent of the prior year's MOOP limit and the ESRD cost transition schedule resumes at the rate that was scheduled to occur once the prior year's projected 85th percentile remains within the range of two percentiles above or below the projected 85th percentile for the upcoming contract year.

(vi) For 2025 or following the ESRD transition schedule in paragraph (f)(4)(vii) of this section and for subsequent years, CMS sets the MOOP limits as follows, subject to the rounding rules in paragraph (f)(4)(iii) of this section:

(A) The prior year's mandatory MOOP limit is maintained for the upcoming contract year if:

(*1*) The prior year's MOOP limit amount is within the range of two percentiles above or below the projected 95th percentile of Medicare FFS beneficiary out-of-pocket spending for the upcoming year incurred by beneficiaries with and without diagnoses of ESRD; and

(*2*) The projected 95th percentile did not increase or decrease for three consecutive years in a row. If the prior year's mandatory MOOP limit is not maintained, CMS increases or decreases the MOOP limit by up to 10 percent of

the prior year's MOOP amount annually until the MOOP limit reaches the projected 95th percentile for the applicable year.

(B) The prior year's intermediate MOOP limit is maintained or updates to the new numeric midpoint if the mandatory or lower MOOP limit changes as outlined in this section.

(C) The prior year's lower MOOP limit is maintained for the upcoming contract year if:

(*1*) The prior year's MOOP limit amount is within the range of two percentiles above or below the projected 85th percentile of Medicare FFS beneficiary out-of-pocket spending for the upcoming year incurred by beneficiaries with and without diagnoses of ESRD; and

(*2*) The projected 85th percentile did not increase or decrease for three consecutive years in a row. If the prior year's lower MOOP limit is not maintained, CMS increases or decreases the MOOP limit by up to 10 percent of the prior year's MOOP amount annually until the MOOP limit reaches the projected 85th percentile for the applicable year.

(vii) For purposes of this section, the *ESRD cost differential* is the difference between, first, for the mandatory MOOP limit, $7,175 and for the lower MOOP limit, $3,360 and second, the projected out-of-pocket costs for beneficiaries using Medicare FFS data (including the costs incurred by beneficiaries with ESRD diagnoses) for each year between 2022 and 2024 or the final year of transition. Subject to the MOOP calculation methodology in paragraphs (f)(4)(iv) through (vi) of this section, CMS transitions to using the most recent, complete Medicare FFS data of beneficiary out-of-pocket spending incurred by beneficiaries with and without diagnoses of ESRD by factoring in a percentage of the ESRD cost differential on the following schedule:

(A) For 2022, CMS factors in 60 percent of the ESRD cost differential.

(B) For 2023 or the next year of ESRD cost transition, CMS factors in 80 percent of the ESRD cost differential.

(C) For 2024 or the final year of the ESRD cost transition and beyond, CMS uses the most recent, complete Medicare FFS data that includes the out-of-pocket costs incurred by beneficiaries with and without diagnoses of ESRD.

(5) With respect to a local PPO plan, the MOOP limits specified under paragraph (f)(4) of this section apply only to use of network providers.

(i) Such local PPO plans must establish a total combined limit on beneficiary out-of-pocket expenditures for basic benefits that are provided in-network and out-of-network that is no greater than the total combined limit applicable to regional plans under § 422.101(d)(3)(ii).

(ii) The type of in-network MOOP limit dictates the type of combined MOOP limit the MA plan may use; MA PPO plans must have the same MOOP type (lower, intermediate, or mandatory) for the in-network MOOP limit and combined limit on in-network and out-of-network out-of-pocket expenditures.

(iii) MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee, and must alert enrollees and contracted providers when the MOOP limit is reached.

(6) For each year beginning on or after January 1, 2022, a MA organization must establish cost sharing for basic benefits (which may be coinsurance or copayments) that comply with the cost sharing limits in this paragraph (f)(6), which are in addition to any other limits and rules applicable to MA cost sharing, including that MA cost sharing for basic benefits be actuarially equivalent to Medicare FFS cost sharing.

(i)(A) For in-network basic benefits that are not specifically addressed in this paragraph (f)(6)(i) and for out-of-network basic benefits, MA plans may not pay less than 50 percent of the total MA plan financial liability, regardless of the MOOP limit established.

(B) If the MA plan establishes a coinsurance method of cost sharing, then the coinsurance cannot exceed 50 percent.

(C) If the MA plan establishes a copay method of cost sharing, then the copay for out-of-network benefits cannot exceed 50 percent of the average Medicare FFS allowable cost for that service area and the copay for in-network benefits cannot exceed 50 percent of the MA organization's average contracted rate of that benefit (item or service).

(ii)(A) In setting copayment limits, CMS rounds to the nearest whole $5 increment for professional services and nearest whole $1 for inpatient acute and psychiatric and skilled nursing facility cost sharing limits.

(B) For all cases in which the copayment limit is projected to be exactly between two increments, CMS rounds to the lower dollar amount.

(iii)(A) For in-network basic benefits that are professional services, including primary care services, physician specialist services, partial hospitalization, and rehabilitation services, an MA plan may not establish cost sharing that exceeds the limits established by CMS pursuant to this paragraph (f)(6)(ii) for the MOOP limit established by the MA plan.

(B) CMS uses projections of out-of-pocket costs representing beneficiaries with and without diagnoses of ESRD based on the most recent, complete Medicare FFS data for basic benefits that are professional services to set the cost sharing limits.

(C) The professional service cost sharing limits, subject to the rounding rules at paragraph (f)(6)(ii)(A) of this section are as follows:

(*1*) *Mandatory MOOP limit:* 30 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 70 percent of the total MA plan financial liability.

(*2*) *Intermediate MOOP limit:* 40 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 60 percent of the total MA plan financial liability.

(*3*) *Lower MOOP limit:* 50 percent coinsurance or actuarially equivalent copayment values. The MA plan must not pay less than 50 percent of the total MA plan financial liability.

(iv)(A) For in-network basic benefits that are inpatient acute and psychiatric services, an MA plan may not establish cost sharing that exceeds the limits established by CMS pursuant to this paragraph (f)(6)(iv) for the MOOP limit established by the MA plan.

(B) The cost sharing limits are set for the following seven inpatient stay scenarios in an inpatient facility for a period for which cost sharing would apply under original Medicare: inpatient hospital acute stay scenarios of 3 days, 6 days, 10 days, and 60 days and psychiatric inpatient hospital stay scenarios of 8 days, 15 days, and 60 days.

(C) CMS sets the inpatient acute and psychiatric cost sharing limits annually using projections of out-of-pocket costs and utilization based on the most recent, complete Medicare FFS data that factors in out-of-pocket costs representing all beneficiaries with diagnoses of ESRD on the transition schedule described in paragraphs (f)(4)(vii)(A) through (D) of this section (without application of the exceptions for MOOP limit calculations in paragraphs (f)(4)(v)(A) and (C) of this section), and may also use patient utilization information from MA encounter data.

(D) The cost sharing limits applicable to inpatient acute and psychiatric services are as follows:

(*1*) *Mandatory MOOP limit:* cost sharing must not exceed 100 percent of estimated Medicare Fee-for-Service cost sharing, including the Part A deductible and related Part B costs, for each length of stay scenario.

(*2*) *Intermediate MOOP limit:* cost sharing must not exceed the numeric mid-point between the cost sharing limits established in paragraphs (f)(6)(iv)(D)(*1*) and (*3*) of this section.

(*3*) *Lower MOOP limit:* cost sharing must not exceed 125 percent of estimated Medicare Fee-for-Service cost sharing, including the Part A deductible and related Part B costs, for each the length of stay scenario. For inpatient acute 60 day length of stays, MA plans that establish a lower MOOP limit have the flexibility to set cost sharing above 125 percent of estimated Medicare Fee-for-Service cost sharing as long as the total cost sharing for the inpatient benefit does not exceed the MOOP limit or cost sharing for inpatient benefits in original Medicare on an per member per month actuarially equivalent basis.

* * * * *

(j) *Cost sharing and actuarial equivalence standards for basic benefits*—(1) *Specific benefits for which cost sharing may not exceed cost sharing under original Medicare.* For each year beginning on or after January 1, 2022, for the following basic benefits, in-network cost sharing established by an MA plan may not exceed the cost sharing required under original Medicare:

(i) Chemotherapy administration services to include chemotherapy/radiation drugs integral to the treatment regimen.

(ii) Renal dialysis services as defined at section 1881(b)(14)(B) of the Act.

(iii) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare, when the MA plan establishes the mandatory MOOP limit; when the MA plan establishes the lower or intermediate MOOP limit, the MA plan may establish cost sharing for the first 20 days of a SNF stay.

(A) Regardless of the MOOP limit established by the MA plan, the per-day cost sharing for days 21 through 100 must not be greater than the projected original Medicare SNF amount.

(B) Total cost sharing for the overall SNF benefit must be no higher than the actuarially equivalent cost sharing for the SNF benefit in original Medicare.

(iv) Home health services (as defined in section 1861(m) of the Act), when the MA plan establishes a mandatory or intermediate MOOP limit; when the MA plan establishes the lower MOOP limit, the MA plan may have cost sharing up to 20 percent of the total MA plan financial liability.

(v) Durable medical equipment (DME), when the MA plan establishes the mandatory MOOP limit; when the MA plan establishes the lower or intermediate MOOP limit, the MA plan may establish cost sharing on specific categories or items of DME as long as the total cost sharing for the overall DME benefit is no higher than the per member per month actuarially equivalent cost sharing for the DME benefit in original Medicare.

(2) *Actuarially equivalent cost sharing for categories of basic benefits in the aggregate.* For each year beginning on or after January 1, 2022, total MA cost sharing for all basic benefits, excluding out of network benefits covered by a regional MA plan, must not exceed cost sharing for those benefits in original Medicare on a per member per month actuarially equivalent basis.

(i) MA cost sharing for the following specific benefit categories must not exceed the cost sharing for those benefit categories in original Medicare on a per member per month actuarially equivalent basis:

(A) Inpatient hospital acute and psychiatric services, defined as services provided during a covered stay in an inpatient facility during the period for which cost sharing would apply under original Medicare.

(B) Durable medical equipment (DME).

(C) Drugs and biologics covered under Part B of original Medicare (including both chemotherapy/radiation drugs integral to the treatment regimen and other drugs covered under Part B).

(D) Skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility during the period for which cost sharing would apply under original Medicare.

(ii) CMS may extend flexibility for MA plans when evaluating actuarial equivalent cost sharing limits for those service categories to the extent that the per member per month cost sharing limit is actuarially justifiable based on generally accepted actuarial principles and supporting documentation included in the bid, provided that the cost sharing for specific services otherwise satisfies published cost sharing standards.

* * * * *

(m) * * *

(5) * * *

(iii) Provide the information described in paragraphs (m)(1), (2), and (3) and (m)(5)(i) of this section on its website.

■ 14. Section 422.101 by—

■ a. Revising paragraphs (d)(2) and (3), (f)(1) introductory text, and (f)(1)(i) and (iii); and

■ b. Adding paragraph (f)(1)(iv);

■ c. Revising paragraph (f)(2) introductory text; and

■ d. Adding paragraph (f)(3).

The revisions and additions read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(d) * * *

(2) *Catastrophic limit.* For each year beginning on or after January 1, 2022, MA regional plans must establish a catastrophic limit on beneficiary out-of-pocket expenditures for basic benefits that are furnished by in-network providers that is consistent with § 422.100(f)(4) subject to the rounding rules in paragraph (f)(4)(iii) of this section.

(i) The type of catastrophic (in-network) limit dictates the total catastrophic MOOP range for MA regional plans under paragraph (d)(3) of this section, MA regional plans must have the same MOOP type (lower, intermediate, or mandatory) for the in-network MOOP limit and combined catastrophic limit on in-network and out-of-network out-of-pocket expenditures.

(ii) MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee, and must alert enrollees and contracted providers when the MOOP limit is reached.

(3) *Total catastrophic limit.* For each year beginning on or after January 1, 2022, MA regional plans must establish a total catastrophic limit on beneficiary out-of-pocket expenditures for basic benefits that are provided in-network and out-of-network that is consistent with this paragraph (d)(3).

(i) The total catastrophic limit for both in-network and out-of-network benefits may not be used to increase the limit described in paragraph (d)(2) of this section.

(ii) CMS sets the total catastrophic limit by multiplying the respective in-network MOOP limits by 1.5 for the relevant year, subject to the rounding rules in paragraph (f)(4)(iii) of this section.

(iii) MA organizations are responsible for tracking out-of-pocket spending incurred by the enrollee, and must alert enrollees and contracted providers when the MOOP limit is reached.

* * * * *

(f) * * *

(1) MA organizations offering special needs plans (SNP) must implement an evidence-based model of care with appropriate networks of providers and specialists designed to meet the specialized needs of the plan's targeted enrollees. The MA organization must, with respect to each individual enrolled, do all of the following:

(i) Conduct a comprehensive initial health risk assessment of the individual's physical, psychosocial, and functional needs as well as annual health risk reassessment, using a comprehensive risk assessment tool that CMS may review during oversight activities, and ensure that results from the initial assessment and annual reassessment conducted for each individual enrolled in the plan are addressed in the individual's individualized care plan as required under paragraph (f)(1)(ii) of this section.

* * * * *

(iii) In the management of care, use an interdisciplinary team that includes a team of providers with demonstrated expertise and training, and, as applicable, training in a defined role appropriate to their licensure in treating individuals similar to the targeted population of the plan.

(iv) Provide for face-to-face encounters between each enrollee and a member of the enrollee's interdisciplinary team or the plan's case management and coordination staff on at least an annual basis, beginning within the first 12 month of enrollment, as feasible and with the individual's consent. A face-for-face encounter must be either in person or through a visual, real-time, interactive telehealth encounter.

(2) MA organizations offering SNPs must also develop and implement the following model of care components to assure an effective care management structure:

* * * * *

(3)(i) All MA organizations wishing to offer or continue to offer a SNP will be required to be approved by the National Committee for Quality Assurance (NCQA) effective January 1, 2012 and subsequent years. All SNPs must submit their model of care (MOC) to CMS for NCQA evaluation and approval in accordance with CMS guidance.

(ii) As part of the evaluation and approval of the SNP model of care, NCQA must evaluate whether goals were fulfilled from the previous model of care.

(A) Plans must provide relevant information pertaining to the MOC's goals as well as appropriate data pertaining to the fulfillment the previous MOC's goals.

(B) Plans submitting an initial model of care must provide relevant information pertaining to the MOC's goals for review and approval.

(C) If the SNP model of care did not fulfill the previous MOC's goals, the plan must indicate in the MOC submission how it will achieve or revise the goals for the plan's next MOC.

(iii) Each element of the model of care of a plan must meet a minimum benchmark score of 50 percent, and a plan's model of care will only be approved if each element of the model of care meets the minimum benchmark.

■ 15. Section 422.102 is amended—

■ a. In paragraph (a)(4) by removing the phrase ''only as a mandatory'' and adding in its place the phrase ''for Part A and B benefits only as a mandatory''; and

■ b. Adding paragraphs (a)(5) and (6) and (f).

The revisions and additions read as follows:

§ 422.102 Supplemental benefits.

(a) * * *

(5) An MA plan may reduce the cost sharing for items and services that are not basic benefits only as a mandatory supplemental benefit.

(6) An MA plan may offer mandatory supplemental benefits in the following forms:

(i) Reductions in cost sharing through the use of reimbursement, through a debit card or other means, for cost sharing paid for covered benefits. Reimbursements must be limited to the specific plan year.

(ii) Use of a uniform dollar amount as a maximum plan allowance for a package of supplemental benefits, including reductions in cost sharing or coverage of specific items and services, available to enrollees on a uniform basis for enrollee use for any supplemental benefit in the package. Allowance must be limited to the specific plan year.

* * * * *

(f) *Special supplemental benefits for the chronically ill (SSBCI)*—(1) *Requirements*—(i) *Chronically-ill enrollee.* (A) A chronically ill enrollee is an individual enrolled in the MA plan who has one or more comorbid and medically complex chronic conditions that meet all of the following:

(*1*) Is life threatening or significantly limits the overall health or function of the enrollee;

(*2*) Has a high risk of hospitalization of other adverse health outcomes; and

(*3*) Requires intensive care coordination.

(B) CMS may publish a non-exhaustive list of conditions that are medically complex chronic conditions that are life threatening or significantly limit the overall health or function of an individual.

(ii) *SSBCI definition.* A special supplemental benefit for the chronically ill (SSBCI) is a supplemental benefit that has, with respect to a chronically ill enrollee, a reasonable expectation of improving or maintaining the health or overall function of the enrollee; an SSBCI that meets this standard may also include a benefit that is not primarily health related, as defined in § 422.100(c)(2)(ii).

(2) *Offering SSBCI.* (i) An MA plan may offer SSBCI to a chronically ill enrollee only as a mandatory supplemental benefit.

(ii) Upon approval by CMS, an MA plan may offer SSBCI that are not uniform for all chronically ill enrollees in the plan.

(iii) An MA plan may consider social determinants of health as a factor to help identify chronically ill enrollees whose health or overall function or could be improved or maintained with SSBCI. An MA plan may not use social determinants of health as the sole basis for determining eligibility for SSBCI.

(3) *Plan responsibilities.* An MA plan offering SSBCI must do all of the following:

(i) Must have written policies for determining enrollee eligibility and must document its determination that an enrollee is a chronically ill enrollee based on the definition in paragraph (f)(1)(i) of this section.

(ii) Make information and documentation related to determining enrollee eligibility available to CMS upon request.

(iii) Must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and must document this criteria.

(iv) Document each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request.

§ 422.110 [Amended]

■ 16. Section 422.110 is amended in paragraph (b) by removing the phrase ''An MA organization'' and adding in its place the phrase ''For coverage before January 1, 2021, an MA organization''.

■ 17. Section 422.111 is amended by—

■ a. Removing paragraph (b)(12);

■ b. Revising paragraphs (h)(1)(i), (ii) and (iii); and

■ c. Adding paragraphs (h)(1)(iv) and (v), (j), and (k).

The revisions and additions read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(h) * * *

(1) * * *

(i) Is open at least from 8:00 a.m. to 8:00 p.m. in all service areas served by the Part C plan.

(ii) At a minimum, provides customer telephone service access, in accordance with the following business practices:

(A) Limits average hold time to no longer than 2 minutes. The hold time is defined as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person.

(B) Answers 80 percent of incoming calls within 30 seconds after the Interactive Voice Response (IVR), touch-tone response system, or recorded greeting interaction.

(C) Limits the disconnect rate of all incoming calls to no higher than 5 percent. The disconnect rate is defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center.

(iii)(A) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(B) Interpreters must be available within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

(iv) Responds to TTY-to-TTY calls as defined in 47 CFR part 64, subpart F, in accordance with the mandatory minimum standards delineated in 47 CFR 64.604.

(v) Provides effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of Federal Communication Commission-approved telecommunications relay systems, when using automated-attendant systems. See 28 CFR 35.161 and 36.303(d).

* * * * *

(j) *Safe disposal of certain prescription drugs.* Information regarding the safe disposal of prescription drugs that are controlled substances and drug takeback programs must be provided in the case of an individual enrolled under an MA plan who is furnished an in-home health risk assessment on or after January 1, 2021.

(1) As part of the in-home health risk assessment, the enrollees must be furnished written supporting materials describing how to safely dispose of medications that are controlled substances as well as a verbal summary when possible. The written information furnished to enrollees about the safe disposal of medications and takeback programs must include the following information for enrollees:

(i) Unused medications should be disposed of as soon as possible.

(ii) The US Drug Enforcement Administration (DEA) allows unused prescription medications to be mailed back to pharmacies and other authorized sites using packages made available at such pharmacies or such other locations.

(iii) Community take back sites are the preferred method of disposing of unused controlled substances.

(iv) Location of take back sites available in the MA plan service area where the enrollee resides or that are nearest to the enrollee's residence.

(v) Instructions on how to safely dispose of medications in household trash or of cases when a medication can be safely flushed. Include instructions on removing personal identification information when disposing of prescription containers.

(vi) Include a web link to the information available on the United States Department of Health and Human Services website identifying methods for the safe disposal of drugs available at the following web address: *www.hhs.gov/opioids/prevention/safely-dispose-drugs/index.html*

(k) *Claims information.* MA organizations must furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under this part.

(1) *Information requirements for the reporting period.* Claims data elements presented on the explanation of benefits must include all of the following for the reporting period:

(i) The descriptor and billing code for the item or service billed by the provider, and the corresponding amount billed.

(ii) The total cost approved by the plan for reimbursement.

(iii) The share of total cost paid for by the plan.

(iv) The share of total cost for which the enrollee is liable.

(2) *Information requirements for year-to-date totals.* Claims data elements presented on the explanation of benefits must include specific year-to-date totals as follows:

(i) The cumulative amount billed by all providers.

(ii) The cumulative total costs approved by the plan.

(iii) The cumulative share of total cost paid for by the plan.

(iv) The cumulative share of total cost for which the enrollee is liable.

(v) The amount an enrollee has incurred toward the MOOP limit, as applicable.

(vi) The amount an enrollee has incurred toward the deductible, as applicable.

(3) *Additional information requirements.* (i) Each explanation of benefits must include clear contact information for enrollee customer service.

(ii) Each explanation of benefits must include instructions on how to report fraud.

(iii) Each EOB that includes a denied claim must clearly identify the denied claim and provide information about enrollee appeal rights, but the EOB does not replace the notice required by §§ 422.568 and 422.570.

(4) *Reporting cycles for explanation of benefits.* MA organizations must send an explanation of benefits on either a monthly cycle or a quarterly cycle with per-claim notifications.

(i) A monthly explanation of benefits must include all claims processed in the prior month and, for each claim, the information in paragraphs (k)(1) and (2) of this section as of the last day of the prior month.

(A) The monthly explanation of benefits must be sent before the end of each month that follows the month a claim was filed.

(B) [Reserved]

(ii) A quarterly explanation of benefits must include all claims processed in the quarter and, for each claim, the information in paragraphs (k)(1) and (2) of this section as of the last day of the quarter; a per-claim notification must include all claims processed in the prior month and, for each claim, the information specified in paragraph (k)(1) of this section as of the last day of the prior month.

(A) MA organizations that send the explanation of benefits on a quarterly cycle with per-claim notifications must send the quarterly explanation of benefits before the end of each month that follows the quarter in which a claim was filed.

(B) MA organizations that send the explanation of benefits on a quarterly cycle with per-claim notifications must send the per-claim notification before the end of each month that follows the month in which a claim was filed.

■ 18. Section 422.113 is amended by—

■ a. Revising paragraph (b)(2)(v); and

■ b. Adding paragraph (b)(2)(vi).

The revision and addition read as follows:

§ 422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

* * * * *

(b) * * *

(2) * * *

(v) For each year beginning on or after January 1, 2022, with a dollar limit on emergency services including post-stabilization services costs for enrollees that is the lower of—

(A) The cost sharing established by the MA plan if the emergency services

were provided through the MA organization; or

(B) A maximum cost sharing limit permitted per visit that corresponds to the MA plan MOOP limit as follows:

(*1*) $115 for MA plans with a mandatory MOOP limit.

(*2*) $130 for MA plans with an intermediate MOOP limit.

(*3*) $150 for MA plans with a lower MOOP limit.

(vi) For each year beginning on or after January 1, 2022, with a cost sharing limit on urgently needed services that does not exceed the limits specified for professional services in § 422.100(f)(6)(iii).

* * * * *

■ 19. Section 422.116 is added to read as follows:

§ 422.116 Network adequacy.

(a) *General rules*—(1) *Access.* A network-based MA plan, as described in § 422.114(a)(3)(ii) but not including MSA plans, must demonstrate that it has an adequate contracted provider network that is sufficient to provide access to covered services in accordance with access standards described in section 1852(d)(1) of the Act and in §§ 422.112(a) and 422.114(a)(1) and by meeting the standard in paragraph (a)(2) of this section. When required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year.

(2) *Standards.* An MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility-specialty type.

(i) Each contract provider type must be within maximum time and distance of at least one beneficiary in order to count toward the minimum number.

(ii) The minimum number criteria and the time and distance criteria vary by the county type.

(3) *Applicability of MA network adequacy criteria.* (i) The following providers and facility types do not count toward meeting network adequacy criteria:

(A) Specialized, long-term care, and pediatric/children's hospitals.

(B) Providers that are only available in a residential facility.

(C) Providers and facilities contracted with the organization only for its commercial, Medicaid, or other products.

(ii) For the facility type of outpatient dialysis, hospital-based dialysis may count in network adequacy criteria.

(4) *Annual updates by CMS.* CMS annually updates and makes the following available:

(i) A Health Service Delivery (HSD) Reference file that identifies the following:

(A) All minimum provider and facility number requirements.

(B) All provider and facility time and distance standards.

(C) Ratios established in paragraph (e) of this section in advance of network reviews for the applicable year.

(ii) A Provider Supply file that lists available providers and facilities and their corresponding office locations and specialty types.

(A) The Provider Supply file is updated annually based on information in the Integrated Data Repository (IDR), which has comprehensive claims data, and information from public sources.

(B) CMS may also update the Provider Supply file based on findings from validation of provider information submitted on Exception Requests to reflect changes in the supply of health care providers and facilities.

(b) *Provider and facility-specialty types.* The provider and facility-specialty types to which the network adequacy evaluation under this section applies are specified in this paragraph (b).

(1) *Provider-specialty types.* The provider-specialty types are as follows:

(i) Primary Care.

(ii) Allergy and Immunology.

(iii) Cardiology.

(iv) Chiropractor.

(v) Dermatology.

(vi) Endocrinology.

(vii) ENT/Otolaryngology.

(viii) Gastroenterology.

(ix) General Surgery.

(x) Gynecology, OB/GYN.

(xi) Infectious Diseases.

(xii) Nephrology.

(xiii) Neurology.

(xiv) Neurosurgery.

(xv) Oncology—Medical, Surgical.

(xvi) Oncology—Radiation/Radiation Oncology.

(xvii) Ophthalmology.

(xviii) Orthopedic Surgery.

(xix) Physiatry, Rehabilitative Medicine.

(xx) Plastic Surgery.

(xxi) Podiatry.

(xxii) Psychiatry.

(xxiii) Pulmonology.

(xxiv) Rheumatology.

(xxv) Urology.

(xxvi) Vascular Surgery.

(xxvii) Cardiothoracic Surgery.

(2) *Facility-specialty types.* The facility specialty types are as follows:

(i) Acute Inpatient Hospitals.

(ii) Cardiac Surgery Program.

(iii) Cardiac Catheterization Services.

(iv) Critical Care Services—Intensive Care Units (ICU).

(v) Outpatient Dialysis (including hospital-based outpatient dialysis).

(vi) Surgical Services (Outpatient or ASC).

(vii) Skilled Nursing Facilities.

(viii) Diagnostic Radiology.

(ix) Mammography.

(x) Physical Therapy.

(xi) Occupational Therapy.

(xii) Speech Therapy.

(xiii) Inpatient Psychiatric Facility Services.

(xiv) Outpatient Infusion/Chemotherapy.

(3) *Removal of a provider or facility-specialty type.* CMS may remove a specialty or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file.

(c) *County type designations.* Counties are designated as a specific type using the following population size and density parameters:

(1) *Large metro.* A large metro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 1,000,000 persons with a population density greater than or equal to 1,000 persons per square mile.

(ii) A population size greater than or equal to 500,000 and less than or equal to 999,999 persons with a population density greater than or equal to 1,500 persons per square mile.

(iii) Any population size with a population density of greater than or equal to 5,000 persons per square mile.

(2) *Metro.* A metro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 1,000,000 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 999.9 persons per square mile.

(ii) A population size greater than or equal to 500,000 persons and less than or equal to 999,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 1,499.9 persons per square mile.

(iii) A population size greater than or equal to 200,000 persons and less than or equal to 499,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 4,999.9 persons per square mile.

(iv) A population size greater than or equal to 50,000 persons and less than or equal to 199,999 persons with a population density greater than or equal

to 100 persons per square mile and less than or equal to 4999.9 persons per square mile.

(v) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density greater than or equal to 1,000 persons per square mile and less than or equal to 4999.9 persons per square mile.

(3) *Micro.* A micro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 50,000 persons and less than or equal to 199,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 99.9 persons per square mile.

(ii) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density greater than or equal to 50 persons per square mile and less than 999.9 persons per square mile.

(4) *Rural.* A rural designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density of greater than or equal to 10 persons per square mile and less than or equal to 49.9 persons per square mile.

(ii) A population size less than 10,000 persons with a population density greater than or equal 50 persons per square mile and less than or equal to 999.9 persons per square mile.

(5) *Counties with extreme access considerations (CEAC).* For any population size with a population density of less than 10 persons per square mile.

(d) *Maximum time and distance standards*—(1) *General rule.* CMS determines and annually publishes maximum time and distance standards for each combination of provider or facility specialty type and each county type in accordance with paragraphs (d)(2) and (3) of this section.

(i) Time and distance metrics measure the relationship between the approximate locations of beneficiaries and the locations of the network providers and facilities.

(ii) [Reserved]

(2) *By county designation.* The following base maximum time (in minutes) and distance (in miles) standards apply for each county type designation, unless modified through customization as described in paragraph (d)(3) of this section.

TABLE 1 TO PARAGRAPH (d)(2)

Provider/Facility Type	Large Metro		Metro		Micro		Rural		CEAC	
	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance
Primary Care	10	5	15	10	30	20	40	30	70	60
Allergy and Immunology	30	15	45	30	80	60	90	75	125	110
Cardiology	20	10	30	20	50	35	75	60	95	85
Chiropractor	30	15	45	30	80	60	90	75	125	110
Dermatology	20	10	45	30	60	45	75	60	110	100
Endocrinology	30	15	60	40	100	75	110	90	145	130
ENT/Otolaryngology	30	15	45	30	80	60	90	75	125	110
Gastroenterology	20	10	45	30	60	45	75	60	110	100
General Surgery	20	10	30	20	50	35	75	60	95	85
Gynecology, OB/GYN	30	15	45	30	80	60	90	75	125	110
Infectious Diseases	30	15	60	40	100	75	110	90	145	130
Nephrology	30	15	45	30	80	60	90	75	125	110
Neurology	20	10	45	30	60	45	75	60	110	100
Neurosurgery	30	15	60	40	100	75	110	90	145	130
Oncology—Medical, Surgical	20	10	45	30	60	45	75	60	110	100
Oncology—Radiation/Radiation Oncology	30	15	60	40	100	75	110	90	145	130
Ophthalmology	20	10	30	20	50	35	75	60	95	85
Orthopedic Surgery	20	10	30	20	50	35	75	60	95	85
Physiatry, Rehabilitative Medicine	30	15	45	30	80	60	90	75	125	110
Plastic Surgery	30	15	60	40	100	75	110	90	145	130
Podiatry	20	10	45	30	60	45	75	60	110	100
Psychiatry	20	10	45	30	60	45	75	60	110	100
Pulmonology	20	10	45	30	60	45	75	60	110	100
Rheumatology	30	15	60	40	100	75	110	90	145	130
Urology	20	10	45	30	60	45	75	60	110	100
Vascular Surgery	30	15	60	40	100	75	110	90	145	130
Cardiothoracic Surgery	30	15	60	40	100	75	110	90	145	130
Acute Inpatient Hospitals	20	10	45	30	80	60	75	60	110	100
Cardiac Surgery Program	30	15	60	40	160	120	145	120	155	140
Cardiac Catheterization Services	30	15	60	40	160	120	145	120	155	140
Critical Care Services—Intensive Care Units (ICU)	20	10	45	30	160	120	145	120	155	140

TABLE 1 TO PARAGRAPH (d)(2)—Continued

Provider/Facility Type	Large Metro		Metro		Micro		Rural		CEAC	
	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance
Outpatient Dialysis	20	10	45	30	65	50	55	50	100	90
Surgical Services (Outpatient or ASC)	20	10	45	30	80	60	75	60	110	100
Skilled Nursing Facilities	20	10	45	30	80	60	75	60	95	85
Diagnostic Radiology	20	10	45	30	80	60	75	60	110	100
Mammography	20	10	45	30	80	60	75	60	110	100
Physical Therapy	20	10	45	30	80	60	75	60	110	100
Occupational Therapy	20	10	45	30	80	60	75	60	110	100
Speech Therapy	20	10	45	30	80	60	75	60	110	100
Inpatient Psychiatric Facility Services	30	15	70	45	100	75	90	75	155	140
Outpatient Infusion/Chemotherapy	20	10	45	30	80	60	75	60	110	100

(3) *By customization.* CMS may set maximum time and distance standards for provider or facility types for specific counties by customization in accordance with the following rules:

(i) CMS maps provider location data from the Provider Supply file against its MA Medicare Sample Census (which provides MA enrollee population distribution data) or uses claims data to identify the distances beneficiaries travel according to the usual patterns of care for the county.

(ii) CMS identifies the distance at which 90 percent of the population would have access to at least one provider or facility in the applicable specialty type.

(iii) The resulting distance is then rounded up to the next multiple of 5, and a multiplier specific to the county designation is applied to determine the analogous maximum time.

(iv) Customization may only be used to increase the base time and distance standards specified in paragraph (d)(2) of this section and may not be used to decrease the base time and distance standards.

(4) *Percentage of beneficiaries residing within maximum time and distance standards.* MA plans must ensure both of the following:

(i) At least 85 percent of the beneficiaries residing in micro, rural, or CEAC counties have access to at least one provider/facility of each specialty type within the published time and distance standards.

(ii) At least 90 percent of the beneficiaries residing in large metro and metro counties have access to at least one provider/facility of each specialty type within the published time and distance standards.

(5) *MA telehealth providers.* An MA plan receives a 10 percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the applicable provider specialty type and county when the plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted networks for the following provider specialty types:

(i) Dermatology.

(ii) Psychiatry.

(iii) Cardiology.

(iv) Neurology.

(v) Otolaryngology.

(6) *State Certificate of Need (CON) laws.* In a state with CON laws, or other state imposed anti-competitive restrictions that limit the number of providers or facilities in the state or a county in the state, CMS may award the MA organization a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected providers and facilities in paragraph (b) of this section or, where appropriate, specifically customize the base time and distance standards based on the effects of CON laws.

(e) *Minimum number standard.* CMS annually determines the minimum number standard for each provider and facility-specialty type as follows:

(1) *General rule.* The provider or facility must—

(i) Be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number standard (requirement); and

(ii) Not be a telehealth-only provider.

(2) *Minimum number requirement for provider and facility-specialty types.* The minimum number for provider and facility-specialty types are as follows:

(i) For provider-specialty types described in paragraph (b)(1) of this section, CMS calculates the minimum number as specified in paragraph (e)(3) of this section.

(ii) For facility-specialty types described in paragraph (b)(2)(i) of this section, CMS calculates the minimum number as specified in paragraph (e)(3) of this section.

(iii) For facility-specialty types described in paragraphs (b)(2)(ii) through (xiv) of this section, the minimum requirement number is 1.

(3) *Determination of the minimum number of for certain provider and facility-specialty types.* For specialty types in paragraphs (b)(1) and (b)(2)(i) of this section, CMS multiplies the minimum ratio by the number of beneficiaries required to cover, divides the resulting product by 1,000, and rounds it up to the next whole number.

(i)(A) The minimum ratio for provider specialty types represents the minimum number of providers per 1,000 beneficiaries.

(B) The minimum ratio for facility specialty type specified in paragraph (b)(2)(i) of this section (acute inpatient hospital) represents the minimum number of beds per 1,000 beneficiaries.

(C) The minimum ratios are as follows:

TABLE 2 TO PARAGRAPH (e)(3)(i)(C)

Minimum ratio	Large metro	Metro	Micro	Rural	CEAC
Primary Care	1.67	1.67	1.42	1.42	1.42
Allergy and Immunology	0.05	0.05	0.04	0.04	0.04
Cardiology	0.27	0.27	0.23	0.23	0.23
Chiropractor	0.10	0.10	0.09	0.09	0.09
Dermatology	0.16	0.16	0.14	0.14	0.14
Endocrinology	0.04	0.04	0.03	0.03	0.03
ENT/Otolaryngology	0.06	0.06	0.05	0.05	0.05
Gastroenterology	0.12	0.12	0.10	0.10	0.10
General Surgery	0.28	0.28	0.24	0.24	0.24
Gynecology, OB/GYN	0.04	0.04	0.03	0.03	0.03
Infectious Diseases	0.03	0.03	0.03	0.03	0.03
Nephrology	0.09	0.09	0.08	0.08	0.08
Neurology	0.12	0.12	0.10	0.10	0.10
Neurosurgery	0.01	0.01	0.01	0.01	0.01
Oncology—Medical, Surgical	0.19	0.19	0.16	0.16	0.16
Oncology—Radiation/Radiation Oncology	0.06	0.06	0.05	0.05	0.05
Ophthalmology	0.24	0.24	0.20	0.20	0.20
Orthopedic Surgery	0.20	0.20	0.17	0.17	0.17
Physiatry, Rehabilitative Medicine	0.04	0.04	0.03	0.03	0.03
Plastic Surgery	0.01	0.01	0.01	0.01	0.01
Podiatry	0.19	0.19	0.16	0.16	0.16
Psychiatry	0.14	0.14	0.12	0.12	0.12
Pulmonology	0.13	0.13	0.11	0.11	0.11
Rheumatology	0.07	0.07	0.06	0.06	0.06
Urology	0.12	0.12	0.10	0.10	0.10
Vascular Surgery	0.02	0.02	0.02	0.02	0.02
Cardiothoracic Surgery	0.01	0.01	0.01	0.01	0.01
Acute Inpatient Hospitals	12.2	12.2	12.2	12.2	12.2

(ii)(A) *Number of beneficiaries required to cover.* (*1*) The number of beneficiaries required to cover is calculated by multiplying the 95th percentile base population ratio by the total number of Medicare beneficiaries residing in a county.

(*2*) CMS uses its MA State/County Penetration data to calculate the total beneficiaries residing in a county.

(B) *95th percentile base population ratio.* (*1*) The 95th percentile base population ratio is:

(*i*) Calculated annually for each county type and varies over time as MA market penetration and plan enrollment change across markets; and

(*ii*) Represents the proportion of Medicare beneficiaries enrolled in the 95th percentile MA plan (that is, 95 percent of plans have enrollment lower than this level).

(*2*) CMS calculates the 95th percentile base population ratio as follows:

(*i*) Uses its most recent List of PFFS Network Counties to exclude any PFFS plans in non-networked counties from the calculation at the county-type level.

(*ii*) Uses its most recent MA State/County Penetration data to determine the number of eligible Medicare beneficiaries in each county.

(*iii*) Uses its Monthly MA Enrollment By State/County/Contract data to determine enrollment at the contract ID and county level, including only enrollment in RPPO, LPPO, HMO, HMO/POS, healthcare prepayment plans under section 1833 of the Act, and network PFFS plan types.

(*iv*) Calculates penetration at the contract ID and county level by dividing the number of enrollees for a given contract ID and county by the number of eligible beneficiaries in that county.

(*v*) Groups counties by county designation to determine the 95th percentile of penetration among MA plans for each county type.

(f) *Exception requests.* (1) An MA plan may request an exception to network adequacy criteria in paragraphs (b) through (e) of this section when both of the following occur:

(i) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type.

(ii) The MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

(2) In evaluating exception requests, CMS considers whether—

(i) The current access to providers and facilities is different from the HSD reference and Provider Supply files for the year;

(ii) There are other factors present, in accordance with § 422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and

(iii) Approval of the exception is in the best interests of beneficiaries.

■ 20. Section 422.134 is revised to read as follows:

§ 422.134 Reward and incentive programs.

(a) *Definitions.* As used in this section, the following definitions are applicable:

Incentive item means the same things as reward item.

Incentive(s), R&I, and *rewards and incentives* mean the same things as reward(s).

Incentive(s) program, Reward(s) program, and *R&I program* means the same thing as rewards and incentives program.

Qualifying individual in the context of a plan-covered health benefit means any plan enrollee who would qualify for coverage of the benefit and satisfies the plan criteria to participate in the target activity. In the context of a non-plan-covered health benefit it means any plan enrollee who satisfies the plan criteria to participate in the target activity.

Reward and incentive program is a program offered by an MA plan to qualifying individuals to voluntarily perform specified target activities in exchange for reward items.

Reward item (or incentive item) means the item furnished to a qualifying individual who performs a target

activity as specified by the plan in the reward program.

Target activity means the activity for which the reward is provided to the qualifying individual by the MA plan.

(b) *Offering an R&I program.* An MA plan may offer R&I program(s) consistent with the requirements of this section.

(c) *Target activities.* (1) A target activity in an R&I program must meet all of the following:

(i) Directly involve the qualifying individual and performance by the qualifying individual.

(ii) Be specified, in detail, as to the level of completion needed in order to qualify for the reward item.

(iii) Be health-related by doing at least one of the following:

(A) Promoting improved health.

(B) Preventing injuries and illness,

(C) Promoting the efficient use of health care resources.

(2) The target activity in an R&I program must not do any of the following:

(i) Be related to Part D benefits.

(ii) Discriminate against enrollees. To assure that anti-discrimination requirements are met, an MA organization, in providing a rewards and incentives program, must comply with paragraph (f)(1) of this section and all the following:

(A) Uniformly offer any qualifying individual the opportunity to participate in the target activity.

(B) Provide accommodations to otherwise qualifying individuals who are unable to perform the target activity in a manner that satisfies the intended goal of the target activity.

(C) Not design a program based on the achievement of a health status measurement.

(d) *Reward items.* (1) The reward item for a target activity must meet all of the following:

(i) Be offered uniformly to any qualifying individual who performs the target activity.

(ii) Be a direct tangible benefit to the qualifying individual who performs the target activity.

(iii) Be provided, such as through transfer of ownership or delivery, to the enrollee in the contract year in which the activity is completed, regardless if the enrollee is likely to use the reward item after the contract year.

(2) The reward item for a target activity must not:

(i) Be offered in the form of cash, cash equivalents, or other monetary rebates (including reduced cost sharing or premiums). An item is classified as a cash equivalent if it either:

(A) Is convertible to cash (such as a check); or

(B) Can be used like cash (such as a general purpose debit card).

(ii) Have a value that exceeds the value of the target activity itself.

(iii) Involve elements of chance.

(3) Permissible reward items for a target activity may be reward items that:

(i) Consist of ''points'' or ''tokens'' that can be used to acquire tangible items.

(ii) Are offered in the form of a gift card that can be redeemed only at specific retailers or retail chains or for a specific category of items or services.

(e) *Marketing and communication requirements.* An MA organization that offers an R&I program must comply with all marketing and communications requirements in subpart V of this part.

(f) *R&I disclosure.* MA organization must make information available to CMS upon request about the form and manner of any rewards and incentives programs it offers and any evaluations of the effectiveness of such programs.

(g) *Miscellaneous.* (1) The MA organization's reward and incentive program must comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries. Additionally all MA program anti-discrimination prohibitions continue to apply. The R&I program may not discriminate against enrollees based on race, national origin, including limited English proficiency, gender, disability, chronic disease, whether a person resides or receives services in an institutional setting, frailty, health status, or other prohibited basis.

(2) Failure to comply with R&I program requirements may result in a violation of one or more of the basis for sanction at § 422.752(a).

(3) The reward and incentive program is classified as a non-benefit expense in the plan bid.

(i) If offering a reward and incentive program, the MA organization must include all costs associated with the reward and incentive program as an administrative cost and non-benefit expense in the bid for the year in which the reward and incentive program operates.

(ii) Disputes on rewards and incentives must be treated as a grievance under § 422.564.

(4) A reward and incentive program may not be changed mid-year.

■ 21. Section 422.162 is amended—

■ a. In paragraph (a) by adding a definition for ''Tukey outer fence outliers'' in alphabetical order;

■ b. By revising paragraphs (b)(3)(iv)(A) and (B); and

■ c. By adding paragraph (b)(4).

The additions and revisions read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Tukey outer fence outliers are measure scores that are below a certain point (first quartile − 3.0 × (third quartile − first quartile)) or above a certain point (third quartile + 3.0 × (third quartile − first quartile)).

(b) * * *

(3) * * *

(iv) * * *

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures and call center measures. The survey-based measures would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period.

(*2*) For contract consolidations approved on or after January 1, 2021, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(B)(*1*) For the second year after consolidation, CMS uses the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except for HEDIS, CAHPS, and HOS. HEDIS and HOS measure data are scored as reported. CMS ensures that the CAHPS survey sample includes enrollees in the sample frame from both the surviving and consumed contracts.

(*2*) For contract consolidations approved on or after January 1, 2021, for all measures except HEDIS, CAHPS, and HOS if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 422.164(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

* * * * *

(4) *Quality bonus payment ratings.* (i) For contracts that receive a numeric Star Rating, the final quality bonus payment (QBP) rating for the contract is released in April of each year for the following contract year. The QBP rating is the contract's highest rating from the Star Ratings published by CMS in October of the calendar year that is 2 years before

the contract year to which the QBP rating applies.

(ii) The contract QBP rating is applied to each plan benefit package offered under the contract.

* * * * *

■ 22. Section 422.164 is amended by revising paragraph (g)(1)(iii)(A) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(A)(*1*) The data submitted for the Timeliness Monitoring Project (TMP) or audit that aligns with the Star Ratings year measurement period is used to determine the scaled reduction.

(*2*) For contract consolidations approved on or after January 1, 2021, if there is a contract consolidation as described at § 422.162(b)(3), the TMP or audit data are combined for the consumed and surviving contracts before the methodology provided in paragraphs (g)(1)(iii)(B) through (O) of this section is applied.

* * * * *

■ 23. Section 422.166 is amended—

■ a. By revising paragraph (a)(2)(i);

■ b. By adding paragraph (d)(2)(vi);

■ c. In paragraphs (e)(1)(iii) and (iv) by removing the phrase ''weight of 2'' and adding in its place ''weight of 4''; and

■ d. By adding a sentence to the end of paragraph (i)(8).

The revision and additions read as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. Prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(d) * * *

(2) * * *

(vi) The QBP ratings for contracts that do not have sufficient data to calculate and assign ratings and do not meet the definition of low enrollment or new MA plans at § 422.252 are assigned as follows:

(A) For a new contract under an existing parent organization that has other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the QBP rating assigned is the enrollment-weighted average highest rating of the parent organization's other MA contract(s) that are active as of the April when the final QBP ratings are released under § 422.162(b)(4). The Star Ratings used in this calculation are the rounded stars (to the whole or half star) that are publicly displayed on *www.medicare.gov.*

(B) For a new contract under a parent organization that does not have other MA contract(s) with numeric Star Ratings in November when the preliminary QBP ratings are calculated for the contract year that begins 14 months later, the MA Star Ratings for the previous 3 years are used and the QBP rating is the enrollment-weighted average of the MA contract(s)'s highest ratings from the most recent year rated for that parent organization.

(*1*) The Star Ratings had to be publicly reported on *www.medicare.gov.*

(*2*) The Star Ratings used in this calculation are rounded to the whole or half star.

(C) The November enrollment is used in the enrollment-weighted calculations for the year the Star Ratings are released.

(D) The QBP ratings are updated for any changes in a contract's parent organization that are reflected in CMS records prior to the release of the final QBP ratings in April of each year.

(E) Once the QBP ratings are finalized in April of each year for the following contract year, no additional parent organization changes are used for purposes of assigning QBP ratings.

* * * * *

(i) * * *

(8) * * * Missing data includes data where there is a data integrity issue as defined at § 422.164(g)(1).

* * * * *

■ 24. Section 422.220 is revised to read as follows:

§ 422.220 Exclusion of payment for basic benefits furnished under a private contract.

(a) Unless otherwise authorized in paragraph (b) or (c) of this section, an MA organization may not pay, directly or indirectly, on any basis, for basic benefits furnished to a Medicare enrollee by a physician (as defined in paragraphs (1), (2), (3), and (4) of section 1861(r) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare contractor an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries.

(b) An MA organization must pay for emergency or urgently needed services furnished by a physician or practitioner described in paragraph (a) of this section who has not signed a private contract with the beneficiary.

(c) An MA organization may make payment to a physician or practitioner described in paragraph (a) of this section for services that are not basic benefits but are provided to a beneficiary as a supplemental benefit consistent with § 422.102.

■ 25. Section 422.252 is amended by revising the definition of ''New MA plan'' to read as follows:

§ 422.252 Terminology.

* * * * *

New MA plan means a plan that meets the following:

(1) Offered under a new MA contract.

(2) Offered under an MA contract that is held by a parent organization defined at § 422.2 that has not had an MA contract in the prior 3 years. For purposes of this definition, the parent organization is identified as of April of the calendar year before the payment year to which the final QBP rating applies, and contracts associated with that parent organization are also evaluated using contracts in existence as of April of the 3 calendar years before the payment year to which the final QBP rating applies. Under our current policy, we identify the parent organization for each MA contract in April of each year and then whether any MA contracts have been held by that parent organization in the immediately preceding 3 years to determine if the parent organization meets the 3-year standard.

* * * * *

§ 422.258 [Amended]

■ 26. Section 422.258 is amended in paragraphs (d)(3), (d)(5) introductory text, (d)(5)(i) introductory text, (d)(5)(ii), and (d)(6)(i) by removing the reference

''§ 422.306(c)'' and adding in its place the reference '' § 422.306(c) and (d)''.

■ 27. Section 422.306 is amended—

■ a. In the introductory text by:

■ i. Removing ''§§ 422.308(b) and 422.308(g)'' and adding in its place ''§ 422.308(b) and (g)''; and

■ ii. Removing the phrase ''year under paragraph (c) of this section'' and adding in its place the phrase ''year under paragraph (c) of this section and costs for kidney acquisitions in the area for the year under paragraph (d) of this section''; and

■ b. By adding paragraph (d).

The addition reads as follows:

§ 422.306 Annual MA capitation rates.

* * * * *

(d) *Exclusion of costs for kidney acquisitions from MA capitation rates.* Beginning with 2021, after the annual capitation rate for each MA local area is determined under paragraph (a) or (b) of this section, the amount is adjusted in accordance with section 1853(k)(5) of the Act to exclude the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d) of the Act) in the area for the year.

§ 422.312 [Amended]

■ 28. Section 422.312 is amended—

■ a. In paragraph (b)(1) by removing the phrase ''45 days'' and adding in its place the phrase ''60 days''; and

■ b. In paragraph (b)(2) by removing the phrase ''15 days'' and adding in its place the phrase ''30 days''.

■ 29. Section 422.322 is amended by adding paragraph (d) to read as follows:

§ 422.322 Source of payment and effect of MA plan election on payment.

* * * * *

(d) *FFS payment for expenses for kidney acquisitions.* Paragraphs (b) and (c) of this section do not apply with respect to expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act.

■ 30. Section 422.500 is amended in paragraph (b) by adding the definitions of ''Fraud hotline tip'', ''Inappropriate prescribing'', and ''Substantiated or suspicious activities of fraud, waste, or abuse'' in alphabetical order to read as follows:

§ 422.500 Scope and definitions.

* * * * *

(b) * * *

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Plan sponsors may consider any number of factors including, but not limited to the following:

(i) Documentation of a patient's medical condition.

(ii) Identified instances of patient harm or death.

(iii) Medical records, including claims (if available).

(iv) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.

(v) Levels of morphine milligram equivalent (MME) dosages prescribed.

(vi) Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.

(vii) State-level prescription drug monitoring program (PDMP) data.

(viii) Geography, time, and distance between a prescriber and the patient.

(ix) Refill frequency and factors associated with increased risk of opioid overdose.

* * * * *

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier—

(i) Engaged in a pattern of improper billing;

(ii) Submitted improper claims with suspected knowledge of their falsity;

(iii) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(iv) Is the subject of a fraud hotline tip verified by further evidence.

■ 31. Section 422.502 is amended by adding paragraphs (b)(1)(i) and (ii) to read as follows:

§ 422.502 Evaluation and determination procedures.

* * * * *

(b) * * *

(1) * * *

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction or civil money penalty under subpart O of this part, with the exception of a sanction imposed under § 422.752(d).

(B) Failed to maintain a Part C summary rating score of at least three stars consistent with § 422.504(b)(17).

(C) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(b)(14).

(ii) CMS may deny an application submitted by an organization that does not hold a Part C contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section.

* * * * *

■ 32. Section 422.503 is amended by adding paragraphs (b)(4)(vi)(G)(*4*) through (*7*) and (b)(5)(i) and (ii) to read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(G) * * *

(*4*) The MA organization must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

(*i*) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act.

(*ii*) Any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan.

(*5*) The MA organization must submit the data elements specified in paragraphs (b)(4)(G)(vi)(*5*)(*i*) through (*lxviii*) of this section in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the MA organization; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier

related to fraud, waste, or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data elements, as applicable, are as follows:

(*i*) Date of Referral.

(*ii*) Part C or Part D Issue.

(*iii*) Complainant Name.

(*iv*) Complainant Phone.

(*v*) Complainant Fax.

(*vi*) Complainant Email.

(*vii*) Complainant Organization Name.

(*viii*) Complainant Address.

(*ix*) Complainant City.

(*x*) Complainant State.

(*xi*) Complainant Zip.

(*xii*) Plan Name/Contract Number.

(*xiii*) Plan Tracking Number.

(*xiv*) Parent Organization.

(*xv*) Pharmacy Benefit Manager.

(*xvi*) Beneficiary Name.

(*xvii*) Beneficiary Phone.

(*xviii*) Beneficiary Health Insurance Claim Number (HICN).

(*xix*) Beneficiary Medicare Beneficiary Identifier (MBI).

(*xx*) Beneficiary Address.

(*xxi*) Beneficiary City.

(*xxii*) Beneficiary State.

(*xxiii*) Beneficiary Zip.

(*xxiv*) Beneficiary Date of Birth (DOB).

(*xxv*) Beneficiary Primary language.

(*xxvi*) Beneficiary requires Special Accommodations. If Yes, Describe.

(*xxvii*) Beneficiary Medicare Plan Name.

(*xxviii*) Beneficiary Member ID Number.

(*xxix*) Whether the Beneficiary is a Subject.

(*xxx*) Did the complainant contact the beneficiary. If Yes, is there a Report of the Contact?

(*xxxi*) Subject Name.

(*xxxii*) Subject Tax Identification Number (TIN).

(*xxxiii*) Does the Subject have Multiple TIN's. If Yes, provide.

(*xxxiv*) Subject NPI.

(*xxxv*) Subject DEA Number.

(*xxxvi*) Subject Medicare Provider Number.

(*xxxvii*) Subject Business.

(*xxxviii*) Subject Phone Number.

(*xxxix*) Subject Address.

(*xl*) Subject City.

(*xli*) Subject State.

(*xlii*) Subject Zip.

(*xliii*) Subject Business or Specialty Description.

(*xliv*) Secondary Subject Name.

(*xlv*) Secondary Subject Tax Identification Number (TIN)

(*xlvi*) Does the Secondary Subject have Multiple TIN's. If Yes, provide.

(*xlvii*) Secondary Subject NPI.

(*xlviii*) Secondary Subject DEA Number.

(*xlix*) Secondary Subject Medicare Provider Number.

(*l*) Secondary Subject Business.

(*li*) Secondary Subject Phone Number.

(*lii*) Secondary Subject Address.

(*liii*) Secondary Subject City.

(*liv*) Secondary Subject State.

(*lv*) Secondary Subject Zip.

(*lvi*) Secondary Subject Business or Specialty Description.

(*lvii*) Complaint Prior MEDIC Case Number.

(*lviii*) Period of Review.

(*lix*) Complaint Potential Medicare Exposure.

(*lx*) Whether Medical Records are Available.

(*lxi*) Whether Medical Records were Reviewed.

(*lxii*) Whether the submission has been Referred to Law Enforcement. Submission Accepted? If so, provide Date Accepted.

(*lxiii*) What Law Enforcement Agency(ies) has it been Referred to.

(*lxiv*) Whether HPMS Analytics and Investigations Collaboration Environment for Fraud, Waste, and Abuse (AICE–FWA) was Used.

(*lxv*) Whether the submission has indicated Patient Harm or Potential Patient Harm.

(*lxvi*) Whether the submission has been Referred. If so, provide Date Accepted.

(*lxvii*) What Agency was it Referred to.

(*lxviii*) Description of Allegations/Plan Sponsor Findings.

(*6*)(*i*) The MA organization is required to notify the Secretary, or its designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*4*)(*i*) of this section 14 days prior to implementation of the payment suspension.

(*ii*) The MA organization is required to submit the information described in paragraph (b)(4)(vi)(G)(*4*)(*ii*) of this section no later than January 15, April 15, July 15, and October 15 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. For the first reporting period (January 15, 2021), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31).

(*7*)(*i*) CMS will provide MA organizations with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*4*)(*i*) and (*ii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(*ii*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*iii*) Are anonymized information submitted by plans without identifying the source of such information.

(*iv*) For the first quarterly report (April 15, 2021), that the report reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 15, 2021.

(5) * * *

(i) Not accept, or share, a corporate parent organization owning a controlling interest in an entity that accepts new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(ii) Not accept, or be either the parent organization owning a controlling interest of, or subsidiary of, an entity that accepts new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

* * * * *

■ 33. Section 422.504 is amended by revising paragraph (a)(15) to read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(15) Through the CMS complaint tracking system, to address and resolve complaints received by CMS against the MA organization.

* * * * *

■ 34. Section 422.514 is amended by—

■ a. Revising the section heading and the heading for paragraph (a).

■ b. Adding paragraphs (d) and (e).

The revisions and additions read as follows:

§ 422.514 Enrollment requirements.

(a) *Minimum enrollment rules.* * * *

(d) *Rule on dual eligible enrollment.* In any state where there is a dual eligible special needs plan or any other plan authorized by CMS to exclusively enroll individuals entitled to medical assistance under a state plan under title XIX, CMS does not enter into or renew a contract under this subpart for plan year 2022 or subsequent years for an MA plan that is not a specialized MA plan for special needs individuals as defined in § 422.2 which does either of the following:

(1) Projects enrollment in its bid submitted under § 422.254 that 80 percent or more enrollees of the plan's total enrollment are enrollees entitled to

medical assistance under a state plan under title XIX.

(2) Has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under title XIX, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

(e) *Transition process and procedures.* (1) For coverage effective January 1 of the next year, and subject to the disclosure requirements described in paragraph (e)(2) of this section, an MA organization may transition enrollees in a plan specified in paragraph (d)(2) of this section into another MA plan or plans (including into a dual eligible special needs plan for enrollees who are eligible for such a plan) offered by the MA organization, or another MA organization that shares the same parent organization as the MA organization, for which the individual is eligible in accordance with §§ 422.50 through 422.53 if the MA plan or plans receiving such enrollment—

(i) Would not meet the criteria in paragraph (d)(2) of this section, as determined in the procedures described in paragraph (e)(3) of this section, with the addition of the newly enrolled individuals (unless such plan is a Specialized MA plan for Special Needs Individuals as defined in § 422.2);

(ii) Is an MA–PD plan described at § 422.2; and

(iii) Has a combined Part C and Part D premium of $0.00 for individuals eligible for the premium subsidy for full subsidy eligible individuals described in § 423.780(a) of this chapter.

(2) An MA organization may transition individuals under paragraph (e)(1) of this section without requiring the individual to file the election form under § 422.66(a) if—

(i) The enrolled individual is eligible to enroll in the MA plan; and

(ii) The MA organization describes changes to MA–PD benefits and information about the MA–PD plan into which the individual is enrolled in the Annual Notice of Change, which must be sent consistent with §§ 422.111(a), (d), and (e) and 422.2267(e)(3).

(3) For the purpose of approving a MA organization to transition enrollment under this paragraph (e), CMS determines whether a non-SNP MA plan would meet the criteria in paragraph (d)(2) of this section by adding the cohort of individuals identified by the MA organization for enrollment in a non-SNP MA plan to the April enrollment of such plan and calculating the resulting percentage of dual eligible enrollment.

(4) In cases where an MA organization does not transition current enrollees under paragraph (e)(1) of this section, the MA organization must send, consistent with § 422.506(a)(2), a written notice to enrollees who are not transitioned.

■ 35. Section 422.530 is added to subpart K to read as follows:

§ 422.530 Plan crosswalks.

(a) *General rules*—(1) *Definition of crosswalk.* A crosswalk is the movement of enrollees from one plan benefit package (PBP) to another PBP under a contract between the MA organization and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibitions.* Except as described in paragraph (c) of this section, crosswalks are prohibited between different contracts or different plan types (for example, HMO to PPO).

(3) *Compliance with renewal/nonrenewal rules.* The MA organization must comply with renewal and nonrenewal rules in §§ 422.505 and 422.506 in order to complete plan crosswalks.

(4) *Eligibility.* Enrollees must be eligible for enrollment under §§ 422.50 through 422.54 in order to be moved from PBP to another PBP.

(5) *Types of MA plans.* For purposes of crosswalk policy in this section, CMS considers the following plans as different plan types:

(i) Health maintenance organizations coordinated care plans.

(ii) Provider-sponsored organizations coordinated care plans.

(iii) Regional or local preferred provider organizations coordinated care plans.

(iv) Special needs plans.

(v) Private Fee-for-service plans.

(vi) MSA plans.

(b) *Allowable crosswalk types*—(1) *All MA plans.* All MA plans may perform a crosswalk in the following circumstances:

(i) *Renewal.* A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(ii) *Consolidated renewal.* A plan in the following contract year that combines 2 or more complete current contract year plans of the same plan type but not including when a current PBP is split among more than one PBP for the following contract year. The plan ID for the following contract year must be the same as one of the current contract year plan IDs.

(iii) *Renewal with a service area expansion (SAE).* A plan in the following contract year plan that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(iv) *Renewal with a service area reduction (SAR).* (A) A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area.

(B) While the MA organization may not affirmatively crosswalk enrollees in the locations that will no longer be part of the service area, the MA organization may offer the affected enrollees in the reduced portion of the service area a continuation in accordance with § 422.74(b)(3)(ii), provided that there are no other MA plan options in the reduced service area.

(C) If the MA organization offers another PBP in the locations that will no longer be part of the service area, current enrollees in the locations that will no longer be part of the service area must be disenrolled and the MA organization must send a non-renewal notice that includes notification of a special enrollment period under § 422.62 and, for applicable enrollees, Medigap guaranteed issue rights.

(D) The MA organization may offer current enrollees in the locations that will no longer be part of the service area the option of enrolling in the other plan(s) the MA organization offers in the location that is no longer part of the service area, however, no specific plan information for the following contract year may be shared with any beneficiaries prior to the plan marketing period for the next contract year.

(2) *Special needs plans (SNPs).* In addition to those described in paragraph (b)(1) of this section, SNPs may also perform the following types of crosswalks:

(i) *Chronic SNPs (C–SNPs).* (A) Renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP with a grouping that contains that same chronic condition.

(B) Non-renewing C–SNP with one chronic condition that transitions eligible enrollees into another C–SNP

with a grouping that contains that same chronic condition.

(C) Renewing C–SNP with a grouping that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping.

(D) Non-renewing C–SNP in a grouping that is transitioning eligible enrollees into a different grouping C–SNP if the new grouping contains at least one condition that the prior plan contained.

(ii) *Institutional SNP.* (A) Renewing Institutional SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(B) Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(C) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.

(D) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.

(E) Non-renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/Institutional Equivalent SNP.

(c) *Exceptions.* In order to perform a crosswalk that is not specified in paragraph (b) of this section, an MA organization must request an exception. Crosswalk exceptions are prohibited between different plan types. CMS reviews exception requests and permits a crosswalk exception in the following circumstances:

(1) When a non-network or partial network Private Fee-For-Service (PFFS) changes to either a partial network or to a full network PFFS plan, enrollees may be moved to the new plan when CMS determines it is in the interest of beneficiaries.

(2) When MA plans offered by two different MA organizations that share the same parent organization are consolidated such that the MA plans under separate contracts are consolidated under one surviving contract, the enrollees from the consolidating plans may be crosswalked to an MA plan under the surviving plan.

(3) When a renewing D–SNP in a multi-state service area reduces its service area to accommodate state contracting efforts in the service area, enrollees who are no longer in the service area may be moved into one or more new or renewing D–SNPs in their service area as CMS determines is necessary to accommodate changes to D–SNP state contracts.

(4) When a renewing D–SNP has another new or renewing D–SNP, and the two D–SNPs are offered to different populations, enrollees who are no longer eligible for their current D–SNP may be moved into the other new or renewing D–SNP if they meet the eligibility criteria for the new or renewing D–SNP and CMS determines it is in the best interests of the enrollees to move to the new or renewing D–SNP.

(5) Renewing C–SNP with a grouping that is transitioning eligible enrollees into another C–SNP with one of the chronic conditions from that grouping.

(d) *Procedures.* (1) An MA organization must submit all crosswalks in paragraph (b) of this section in writing through the bid submission process in HPMS by the bid submission deadline announced by CMS.

(2) An organization must submit all crosswalk exception requests in paragraph (c)(1) of this section in writing through the crosswalk exceptions process in HPMS by the crosswalk exception request deadline announced by CMS annually. CMS verifies the requests and notifies requesting organizations of the approval or denial after the crosswalk exception request deadline.

■ 36. Section 422.550 is amended by adding paragraph (f) to read as follows:

§ 422.550 General provisions.

* * * * *

(f) *Sale of beneficiaries not permitted.* (1) CMS only recognizes the sale or transfer of an organization's entire MA line of business, consisting of all MA contracts held by the MA organization with the exception of the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization, which is permitted.

(2) CMS does not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries, groups of beneficiaries enrolled in a plan benefit package, or one contract if the organization holds more than one MA contract.

■ 37. Section 422.562 is amended by adding paragraph (d)(3) to read as follows:

§ 422.562 General provisions.

* * * * *

(d) * * *

(3) For the sole purpose of applying the regulations at § 405.1038(c) of this chapter, an MA organization is included in the definition of ''contractors'' as it relates to stipulated decisions.

■ 38. Section 422.568 is amended by adding paragraphs (g) through (k) to read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

* * * * *

(g) *Dismissing a request.* The MA organization may dismiss an organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an organization determination under § 422.566(c).

(2) The MA organization determines the party failed to make out a valid request for an organization determination that substantially complies with paragraph (a) of this section.

(3) An enrollee or the enrollee's representative files a request for an organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the organization determination.

(4) A party filing the organization determination request submits a timely written request for withdrawal of their request for an organization determination with the MA organization.

(h) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the organization determination request to the parties. The notice must state the all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(i) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for an organization determination within 6 months from the date of the notice of dismissal.

(j) *Effect of dismissal.* The dismissal of a request for an organization determination is binding unless it is modified or reversed by the MA organization upon reconsideration or vacated under paragraph (i) of this section.

(k) *Withdrawing a request.* A party that requests an organization determination may withdraw its request at any time before the decision is issued by filing a written request with the MA organization.

■ 39. Section 422.570 is amended by adding paragraph (g) to read as follows:

§ 422.570 Expediting certain organization determinations.

* * * * *

(g) *Dismissing a request.* The MA organization may dismiss an expedited organization request in accordance with § 422.568.

■ 40. Section 422.582 is amended by adding paragraphs (f) through (i) to read as follows:

§ 422.582 Request for a standard reconsideration.

* * * * *

(f) *Dismissing a request.* The MA organization may dismiss a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting a reconsideration is not a proper party under § 422.578.

(2) The MA organization determines the party failed to make a valid request for a reconsideration that substantially complies with paragraph (a) of this section.

(3) The party fails to file the reconsideration request within the proper filing time frame in accordance with paragraph (b) of this section.

(4) The enrollee or the enrollee's representative files a request for a reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the reconsideration.

(5) A party filing the reconsideration request submits a timely written request for withdrawal of the request for a reconsideration with the MA organization.

(g) *Notice of dismissal.* The MA organization must mail or otherwise transmit a written notice of the dismissal of the reconsideration request to the parties. The notice must state the all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(h) *Vacating a dismissal.* If good cause is established, the MA organization may vacate its dismissal of a request for reconsideration within 6 months from the date of the notice of dismissal.

(i) *Effect of dismissal.* The MA organization's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h) or the decision is vacated under paragraph (h) of this section.

■ 41. Section 422.584 is amended by adding paragraph (g) to read as follows:

§ 422.584 Expediting certain reconsiderations.

* * * * *

(g) *Dismissing a request.* The MA organization may dismiss an expedited reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting an expedited reconsideration is not a proper party under paragraph (a) of this section.

(2) When the MA organization determines the party failed to make a valid request for an expedited reconsideration that substantially complies with paragraph (b) of this section.

(3) When the party fails to file the expedited reconsideration request within the proper filing time frame in accordance with § 422.572(a).

(4) When the enrollee or the enrollee's representative files a request for an expedited reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the expedited reconsideration.

(5) When a party filing the expedited reconsideration request submits a timely written request for withdrawal of their request for an expedited reconsideration with the MA organization.

■ 42. Section 422.590 is amended by adding paragraph (i) to read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

* * * * *

(i) *Requests for review of a dismissal by the independent entity.* If the MA organization dismisses a request for a reconsideration in accordance with §§ 422.582(f) and 422.584(g), the enrollee or other party has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the MA organization's dismissal notice.

■ 43. Section 422.592 is amended by revising paragraph (a) and adding paragraphs (d) through (i) to read as follows:

§ 422.592 Reconsideration by an independent entity.

(a) When the MA organization affirms, in whole or in part, its adverse organization determination, the issues that remain in dispute must be reviewed and resolved by an independent, outside entity that contracts with CMS. In accordance with § 422.590(h), the independent entity is responsible for reviewing MA organization dismissals of reconsideration requests.

* * * * *

(d) The independent entity may dismiss a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting a reconsideration is not a proper party under § 422.578(c).

(2) The independent entity determines the party failed to make out a valid request for a reconsideration that substantially complies with § 422.582(a) or (b).

(3) The enrollee or the enrollee's representative files a request for a reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the reconsideration.

(4) The party filing the reconsideration request submits with the independent review entity a timely written request for withdrawal of the request for reconsideration.

(e) The independent entity mails or otherwise transmits a written notice of the dismissal of the reconsideration request to the parties. The notice must state the following:

(1) The reason for the dismissal.

(2) That there is a right to request that the independent entity vacate the dismissal action.

(3) The right to a review of the dismissal under §§ 422.600 and 422.602.

(f) If good cause is established, the independent entity may vacate its dismissal of a request for reconsideration within 6 months from the date of the notice of dismissal.

(g) The independent entity's dismissal is binding and not subject to further review unless a party meets the requirements in § 422.600 and files a proper and timely request under § 422.602 or the dismissal is vacated under paragraph (f) of this section.

(h) The party or physician acting on behalf of an enrollee who files a request for reconsideration may withdraw the request by filing a written request for

withdrawal with the independent entity.

(i) If the independent entity determines that the MA organization's dismissal was in error, the independent entity vacates the dismissal and remands the case to the plan for reconsideration. The independent entity's decision regarding an MA organization's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review.

■ 44. Section 422.600 is amended by revising paragraph (b) to read as follows:

§ 422.600 Right to a hearing.

* * * * *

(b) The amount remaining in controversy, which can include any combination of Part A and Part B services, is computed in accordance with part 405 of this chapter. For purposes of calculating the amount remaining in controversy under this section, references to coinsurance in § 405.1006(d) of this chapter should be read to include coinsurance and copayment amounts.

* * * * *

■ 45. Section 422.629, as added on April 16, 2019 (84 FR 15835) effective January 1, 2021, is amended by revising paragraph (k)(4)(ii) to read as follows:

§ 422.629 General requirements for applicable integrated plans.

* * * * *

(k) * * *

(4) * * *

(ii) If deciding an appeal of a denial that is based on lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), are a physician or other appropriate health care professional who have the appropriate clinical expertise in treating the enrollee's condition or disease, and knowledge of Medicare and Medicaid coverage criteria, before the applicable integrated plan issues the integrated organization determination decision.

* * * * *

■ 46. Section 422.631, as added on April 16, 2019 (84 FR 15835) effective January 1, 2021, is amended by adding paragraphs (e) through (i) to read as follows:

§ 422.631 Integrated organization determinations.

* * * * *

(e) *Dismissing a request.* The applicable integrated plan may dismiss a standard or expedited integrated organization determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The individual or entity making the request is not permitted to request an integrated organization determination under § 422.629(l).

(2) The applicable integrated plan determines the party failed to make out a valid request for an integrated organization determination that substantially complies with paragraph (b) of this section.

(3) An enrollee or the enrollee's representative files a request for an integrated organization determination, but the enrollee dies while the request is pending, and both of the following apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated organization determination.

(4) A party filing the integrated organization determination request submits a timely written request for withdrawal of their request for an integrated organization determination with the applicable integrated plan.

(f) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated organization determination request to the parties. The notice states that there is a right to request that the applicable integrated plan vacate the dismissal action.

(g) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for an integrated organization determination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal.* The dismissal of a request for an integrated organization determination is binding unless it is modified or reversed by the applicable integrated plan or vacated under paragraph (g) of this section.

(i) *Withdrawing a request.* A party that requests an integrated organization determination may withdraw its request at any time before the decision is issued by filing a written request with the applicable integrated plan.

§ 422.632 [Amended]

■ 47. Section 422.632, as added on April 16, 2019 (84 FR 15835) effective January 1, 2021, is amended in paragraph (b)(1) by removing the reference ''§ 422.633(e)'' and adding in its place the reference ''§ 422.633(d)''.

■ 48. Section 422.633, as added on April 16, 2019 (84 FR 15835) effective January 1, 2021, is amended by adding paragraphs (g) through (k) to read as follows:

§ 422.633 Integrated reconsideration.

* * * * *

(g) *Withdrawing a request.* The party or physician acting on behalf of an enrollee who files a request for integrated reconsideration may withdraw it by filing a written request for withdrawal with the applicable integrated plan.

(h) *Dismissing a request.* The applicable integrated plan may dismiss an expedited or standard integrated reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) The person or entity requesting an integrated reconsideration is not a proper party to request an integrated reconsideration under § 422.629(l).

(2) The applicable integrated plan determines the party failed to make a valid request for an integrated reconsideration that substantially complies with § 422.629(l) of this section.

(3) The party fails to file the integrated reconsideration request within the proper filing timeframe in accordance with paragraph (d) of this section.

(4) The enrollee or the enrollee's representative files a request for an integrated reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) No other individual or entity with a financial interest in the case wishes to pursue the integrated reconsideration.

(5) A party filing the reconsideration request submits a timely written request for withdrawal of their request for an integrated reconsideration with the applicable integrated plan.

(i) *Notice of dismissal.* The applicable integrated plan must mail or otherwise transmit a written notice of the dismissal of the integrated reconsideration request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the applicable integrated plan vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(j) *Vacating a dismissal.* If good cause is established, the applicable integrated plan may vacate its dismissal of a request for integrated reconsideration within 6 months from the date of the notice of dismissal.

(k) *Effect of dismissal.* The applicable integrated plan's dismissal is binding unless the enrollee or other party requests review by the independent entity in accordance with § 422.590(h).

■ 49. Section 422.760 is amended by redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5), respectively, and adding a new paragraph (b)(3) to read as follows:

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

* * * * *

(b) * * *

(3) CMS calculates the minimum penalty amounts under paragraphs (b)(1) and (2) of this section using the following criteria:

(i) *Definitions for calculating penalty amounts*—(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination penalty amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(E) *Cost-of-living multiplier.* The percent change between each year's published October consumer price index for all urban consumers (United States city average), which is released by The Office of Management and Budget (OMB) annually.

(ii) *Calculation of minimum penalty amounts.* (A) Per determination and per enrollee minimum penalty amounts increases by multiplying the current standard minimum penalty and aggravating factor amounts by the cost-of-living multiplier.

(B) The minimum penalty and aggravating factor amounts is updated no more often than every 3 years.

(C) CMS does the following:

(*1*) Tracks the calculation and accrual of the standard minimum penalty and aggravating factor amounts.

(*2*) Announces the penalties and amounts described in paragraph (b) of this section on an annual basis.

* * * * *

■ 50. Section 422.2260 is revised to read as follows:

§ 422.2260 Definitions.

The definitions in this section apply for this subpart unless the context indicates otherwise.

Advertisement (Ad) means a read, written, visual, oral, watched, or heard bid for call to attention. Advertisements can be considered communications or marketing based on the intent and content of the message.

Alternate format means a format used to convey information to individuals with visual, speech, physical, hearing, and intellectual disabilities (for example, braille, large print, audio).

Banner means a type of advertisement feature typically used in television ads that is intended to be brief, and flashes limited information across a screen for the sole purpose of enticing a prospective enrollee to contact the MA plan (for example, obtain more information) or to alert the viewer that information is forthcoming.

Banner-like advertisement is an advertisement that uses a banner-like feature, that is typically found in some media other than television (for example, outdoors and on the internet).

Communications means activities and use of materials created or administered by the MA organization or any downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.

Marketing means communications materials and activities that meet both the following standards for intent and content:

(1) Intended, as determined under paragraph (1)(ii) of this definition, to do any of the following:

(i)(A) Draw a beneficiary's attention to a MA plan or plans.

(B) Influence a beneficiary's decision-making process when making a MA plan selection.

(C) Influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).

(ii) In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, and timing and other context of the activity or material and is not limited to the MA organization's stated intent.

(2) Include or address content regarding any of the following:

(i) The plan's benefits, benefits structure, premiums, or cost sharing.

(ii) Measuring or ranking standards (for example, star ratings or plan comparisons).

(iii) Rewards and incentives as defined under § 422.134(a).

Outdoor advertising (ODA) means outdoor material intended to capture the attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be communications or marketing material.

■ 51. Section 422.2261 is added to read as follows:

§ 422.2261 Submission, review, and distribution of materials.

(a) *General requirements.* MA organizations must submit all marketing materials, all election forms, and certain designated communications materials for CMS review.

(1) The Health Plan Management System (HPMS) Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for review.

(2) Materials must be submitted to the HPMS directly by the MA organization. Third party and downstream entities are not permitted to submit materials directly to CMS.

(b) *CMS review of marketing materials and election forms.* MA organizations may not distribute or otherwise make available any marketing materials (as defined in § 422.2260) or election forms unless one of the following occurs:

(1) CMS has reviewed and approved the material.

(2) The material has been deemed approved; that is, CMS has not rendered a disposition for the material within 45 days (or 10 days if using CMS model or standardized marketing materials as outlined in § 422.2267(e)) of submission to CMS; or

(3) The material has been accepted under File and Use, as follows:

(i) The MA organization may distribute certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission.

(ii) The MA organization must certify that the material meets all applicable CMS communications and marketing requirements in §§ 422.2260 through 422.2267.

(c) *CMS review of communications materials.* CMS does not generally require submission and approval of communications materials prior to use, with the exception of certain designated communications materials that are critical to the beneficiary understanding or accessing their benefits (for example, the Evidence of Coverage (EOC)).

(d) *Standards for CMS review.* CMS reviews materials to ensure the following:

(1) Compliance with all applicable requirements under §§ 422.2260 through 422.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the MA organization's bid.

■ 52. Section 422.2262 is revised to read as follows:

§ 422.2262 General communications materials and activities requirements.

MA organizations may not mislead, confuse, or provide inaccurate information to current or potential enrollees.

(a) *General rules.* MA organizations must ensure their statements and the terminology used in communications activities and materials adhere to the following requirements:

(1) MA organizations may not do any of the following:

(i) Provide information that is inaccurate or misleading.

(ii) Make unsubstantiated statements, including superlatives or pejoratives.

(iii) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization.

(iv) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas, or vice versa.

(v) Target potential enrollees based on income levels, unless it is a dual eligible special needs plan or comparable plan as determined by the Secretary.

(vi) Target potential enrollees based on health status, unless it is a special needs plan or comparable plan as determined by the Secretary.

(vii) State or imply plans are only available to seniors rather than to all Medicare beneficiaries.

(viii) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries, unless it is a special needs plan or comparable plan as determined by the Secretary. This prohibition does not apply to MA plan names in effect prior to July 31, 2000.

(ix) Display the names or logos or both of co-branded network providers on the organization's member identification card, unless the provider names or logos or both are related to the member selection of specific provider organizations (for example, physicians or hospitals).

(x) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name, for example, ''Super Medicare Advantage (HMO).''

(xi) Claim they are recommended or endorsed by CMS, Medicare, or the HHS.

(xii) Convey that a failure to pay premium will not result in disenrollment.

(xiii) Use the term ''free'' to describe a $0 premium, any type of reduction in premium, reduction in deductibles or cost sharing, low-income subsidy, or cost sharing for dual eligible individuals.

(xiv) Imply that the plan operates as a supplement to Medicare.

(xv) State or imply a plan is available only to or is designed for beneficiaries who are dually eligible for Medicare and Medicaid, unless it is a dual-eligible special needs plan or comparable plan as determined by the Secretary.

(xvi) Market a non-dual eligible special needs plan as if it were a dual-eligible special needs plan.

(xvii) Target marketing efforts primarily to dual eligible individuals, unless the plan is a dual eligible special needs plan or comparable plan as determined by the Secretary.

(xviii) Claim a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for that plan is in place.

(2) MA organizations may do the following:

(i) State that the MA organization is approved to participate in Medicare programs or is contracted to administer Medicare benefits or both.

(ii) Use the term ''Medicare-approved'' to describe benefits or services in materials or both.

(iii) Use the term ''free'' in conjunction with mandatory, supplemental, and preventative benefits provided at a zero cost share for all enrollees.

(b) *Product endorsements and testimonials.* (1) Product endorsements and testimonials may take any of the following forms:

(i) Television or video ads.

(ii) Radio ads.

(iii) Print ads.

(iv) Social media ads. In cases of social media, the use of a previous post, whether or not associated with or originated by the MA organization, is considered a product endorsement or testimonial.

(v) Other types of ads.

(2) MA organizations may use individuals to endorse the MA organization's product provided the endorsement or testimonial adheres to the following requirements:

(i) The speaker must identify the MA organization's product or company by name.

(ii) Medicare beneficiaries endorsing or promoting the MA organization must have been an enrollee at the time the endorsement or testimonial was created.

(iii) The endorsement or testimonial must clearly state that the individual was paid for the endorsement or testimonial, if applicable.

(iv) If an individual is used (for example, an actor) to portray a real or fictitious situation, the endorsement or testimonial must state that it is an actor portrayal.

(c) *Requirements when including certain telephone numbers in materials.* (1) MA organizations must adhere to the following requirements for including certain telephone numbers in materials:

(i) When a MA organization includes its customer service number, the hours of operation must be included the first time (at a minimum) the number appears.

(ii) When a MA organization includes its customer service number, it must provide a toll-free TTY number in conjunction with the customer service number in the same font size.

(iii) On every material where 1–800–MEDICARE or Medicare TTY appears, the MA organization must include the hours and days of operation for 1–800–MEDICARE (that is, 24 hours a day/7 days a week).

(2) The following advertisement types are exempt from these requirements:

(i) Outdoor advertising.

(ii) Banners or banner-like ads.

(iii) Radio advertisements and sponsorships.

(d) *Standardized material identification (SMID).* (1) MA organizations must use a standardized method of identification for oversight and tracking of materials beneficiaries receive.

(2) The SMID consists of the following three parts:

(i) The MA organization contract or Multi-Contract Entity (MCE) number (that is, ''H'' for MA or Section 1876 Cost Plans, ''R'' for Regional PPO plans (RPPOs), or ''Y'' for MCE identifier) followed by an underscore, except that the SMID for multi-plan marketing materials must begin with the word ''MULTI–PLAN'' instead of the MA organization's contract number (for example, H1234_abc123_C or MULTI–PLAN_efg456_M).

(ii) A series of alpha numeric characters (chosen at the MA organization's discretion) unique to the material followed by an underscore.

(iii) An uppercase ''C'' for communications materials or an uppercase ''M'' for marketing materials (for example, H1234_abc123_C or H5678_efg456_M).

(3) The SMID is required on all materials except the following:

(i) Membership ID card.

(ii) Envelopes, radio ads, outdoor advertisements, banners, banner-like

ads, and social media comments and posts.

(iii) OMB-approved forms/documents, except those materials included in § 422.2267.

(iv) Corporate notices or forms (that is, not MA/Part D specific) meeting the definition of communications (see § 422.2260) such as privacy notices and authorization to disclose protected health information (PHI).

(v) Agent-developed communications materials that are not marketing.

(4) Non-English and alternate format materials, based on previously created materials, may have the same SMID as the material on which they are based.

■ 53. Section 422.2263 is added to read as follows:

§ 422.2263 General marketing requirements.

Marketing is a subset of communications and therefore must follow the requirements outlined in § 422.2262 as well as this section. Marketing (as defined in § 422.2260) must additionally meet the following requirements:

(a) MA organizations may begin marketing prospective plan year offerings on October 1 of each year for the following contract year. MA organizations may market the current and prospective year simultaneously provided materials clearly indicate what year is being discussed.

(b) In marketing, MA organizations may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to potential enrollees, unless the gifts are of nominal value (as governed by guidance published by the HHS OIG), are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Provide meals to potential enrollees regardless of value.

(4) Market non-health care related products to prospective enrollees during any MA sales activity or presentation. This is considered cross-selling and is prohibited.

(5) Compare their plan to other plans, unless the information is accurate, not misleading, and can be supported by the MA organization making the comparison.

(6) Display the names or logos or both of provider co-branding partners on marketing materials, unless the materials clearly indicate via a disclaimer or in the body that ''Other providers are available in the network.''

(7) Knowingly target or send unsolicited marketing materials to any MA enrollee during the Open Enrollment Period (OEP).

(i) During the OEP, an MA organization may do any of the following:

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment SEP, and marketing to dual-eligible and LIS beneficiaries who, in general, may make changes once per calendar quarter during the first 9 months of the year;

(B) Send marketing materials when a beneficiary makes a proactive request;

(C) At the beneficiary's request, have one-on-one meetings with a sales agent; and

(D) At the beneficiary's request, provide information on the OEP through the call center.

(ii) During the OEP, an MA organization may not:

(A) Send unsolicited materials advertising the ability/opportunity to make an additional enrollment change or referencing the OEP;

(B) Specifically target beneficiaries who are in the OEP because they made a choice during Annual Enrollment Period (AEP) by purchase of mailing lists or other means of identification;

(C) Engage in or promote agent/broker activities that intend to target the OEP as an opportunity to make further sales; or

(D) Call or otherwise contact former enrollees who have selected a new plan during the AEP.

(c) The following requirements apply to how MA organizations must display CMS issued Star Ratings:

(1) References to individual Star Rating measure(s) must also include references to the overall Star Rating.

(2) May not use an individual underlying category or measure to imply overall high Star Ratings.

(3) Must be clear that the rating is out of 5 stars.

(4) Must clearly identify the Star Rating contract year.

(5) May only market the Star Ratings in the service area in which the Star Rating is applicable.

(6) The following requirements apply to all 5 Star MA contracts:

(i) May not market the 5 star special enrollment period, as defined in § 422.62(b)(15), after November 30 of each year if the contract has not received an overall 5 star for the next contract year.

(ii) May use CMS' 5 star icon or may create their own icon.

(7) The following requirements apply to all Low Performing MA contracts:

(i) The Low Performing Icon must be included on all materials about or referencing the specific contract's Star Ratings.

(ii) Must state the Low Performing Icon means that the MA organization's contract received a summary rating of 2.5 stars or below in Part C or Part D or both for the last 3 years.

(iii) May not attempt to refute or minimize Low Performing Status.

■ 54. Section 422.2264 is revised to read as follows:

§ 422.2264 Beneficiary contact.

For the purpose of this section, beneficiary contact applies to all outreach activities to a beneficiary or a beneficiary's caregivers by the MA organization or its agents and brokers.

(a) *Unsolicited contact.* Subject to the rules for contact for plan business in paragraph (b) of this section, the following rules apply when materials or activities are given or supplied to a beneficiary or their caregiver without prior request:

(1) MA organizations may make unsolicited direct contact by conventional mail and other print media (for example, advertisements and direct mail) or email (provided every email contains an opt-out option).

(2) MA organizations may not do any of the following:

(i) Use door to door solicitation, including leaving information of any kind, except that information may be left when an appointment is pre-scheduled but the beneficiary is not home.

(ii) Approach enrollees in common areas such as parking lots, hallways, and lobbies.

(iii) Unsolicited direct messages from social media platforms.

(iv) Use telephone solicitation (that is, cold calling), text messages, or voicemail messages, including, but not limited to, the following:

(A) Unsolicited calls based on referrals.

(B) Calls to former enrollees who have disenrolled or those in the process of disenrolling, except to conduct disenrollment surveys for quality improvement purposes.

(C) Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission to be contacted.

(D) Unsolicited calls to prospective enrollees to confirm receipt of mailed information.

(3) Calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. For example, returning phone calls or calling an individual who has

completed a business reply card requesting contact is not considered unsolicited.

(4) MA organizations are responsible for ensuring sales staff, including agents and brokers, abide by Federal and state laws related to consumer protection, including, but not limited to, do not call requirements.

(b) *Contact for plan business.* MA organizations may contact current, and to a more limited extent, former members, including those enrolled in other products offered by the parent organization, to discuss plan business, in accordance with the following requirements:

(1) An MA organization may conduct the following activities as plan business:

(i) Call current enrollees, including those in non-Medicare products, to discuss Medicare products. Examples of such calls include, but are not limited to the following:

(A) Enrollees aging into Medicare from commercial products.

(B) Existing enrollees, including Medicaid enrollees, to discuss other Medicare products or plan benefits.

(C) Members in a Part D plan to discuss other Medicare products.

(ii) Call beneficiaries who submit enrollment applications to conduct business related to enrollment.

(iii) With prior CMS approval, call LIS enrollees that a plan is prospectively losing to due reassignment. CMS decisions to approve calls are for limited circumstances based on the following:

(A) The proximity of cost of the losing plan as compared to the national benchmark; and

(B) The selection of plans in the service area that are below the benchmark.

(iv) Agents/brokers calling clients who are enrolled in other products they may sell, such as automotive or home insurance.

(v) MA organizations may not make unsolicited calls about other lines of business as a means of generating leads for Medicare plans.

(2) [Reserved]

(c) *Events with beneficiaries.* MA organizations and their agent/brokers may hold educational events, marketing or sales events, and personal marketing appointments to meet with Medicare beneficiaries, either face-to-face or virtually. The requirements for each type of event are as follows:

(1) Educational events must be advertised as such and be designed to generally inform beneficiaries about Medicare, including Medicare Advantage, Prescription Drug programs, or any other Medicare program.

(i) At educational events, MA organizations and agents/brokers may not market specific MA plans or benefits.

(ii) MA organizations holding or participating in educational events may do any of the following:

(A) Distribute communications materials.

(B) Answer beneficiary-initiated questions pertaining to MA plans.

(C) Set up future personal marketing appointments.

(D) Distribute business cards.

(E) Obtain beneficiary contact information, including Scope of Appointment forms.

(iii) MA organizations holding or participating in educational events may not conduct sales or marketing presentations or distribute or accept plan applications.

(2) Marketing or sales events are group events that fall within the definition of marketing at § 422.2260.

(i) If a marketing event directly follows an educational event, the MA organization or agent/broker must provide an opportunity for beneficiaries to determine if they want to continue onto the marketing event.

(ii) MA organizations holding or participating in marketing events may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Collect Scope of Appointment forms for future personal marketing appointments.

(D) Conduct marketing presentations.

(iii) MA organizations holding or participating in marketing events may not do any of the following:

(A) Require sign-in sheets or require attendees to provide contact information as a prerequisite for attending an event.

(B) Conduct activities, including health screenings, health surveys, or other activities that are used for or could be viewed as being used to target a subset of members (that is, ''cherry-picking'').

(C) Use information collected for raffles or drawings for any purpose other than raffles or drawings.

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple). Personal marketing appointments are not defined by the location.

(i) Prior to the personal marketing appointment beginning, the MA plan (or agent/broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).

(ii) MA organizations holding a personal marketing appointment may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Conduct marketing presentations.

(D) Review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

(iii) MA organizations holding a personal marketing appointment may not do any of the following:

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate Scope of Appointment identifying the additional lines of business to be discussed.

(C) Market non-health related products, such as annuities.

■ 55. Section 422.2265 is added to read as follows:

§ 422.2265 Websites.

As required under § 422.111(h)(2), MA organizations must have a website.

(a) *General website requirements.* (1) MA organization websites must meet the all of the following requirements:

(i) Maintain current year contract content through December 31 of each year.

(ii) Notify users when they will leave the MA organization's Medicare site.

(iii) Include or provide access to (for example, through a hyperlink) applicable disclaimers with corresponding content. Overarching disclaimers, such as the Federal Contracting Statement, are not required on every page.

(iv) Be updated to reflect the most current information within 30 days of any information on the website changing.

(v) Keep MA content separate and distinct from other lines of business, including Medicare Supplemental Plans.

(2) MA organization websites may not do any of the following:

(i) Require beneficiaries to enter any information other than zip code, county, or state for access to non-beneficiary-specific website content.

(ii) Provide links to foreign drug sales, including advertising links.

(iii) State that the MA organization is not responsible for the content of their social media pages or the website of any first tier, downstream, or related entity that provides information on behalf of the MA organization.

(b) *Required content.* MA organization's websites must include the following content:

(1) A toll-free customer service number, TTY number, and days and hours of operation.

(2) A physical or Post Office Box address.

(3) A PDF or copy of a printable provider directory.

(4) A searchable provider directory.

(5) When applicable, a searchable pharmacy directory combined with a provider directory.

(6) Information on enrollees' and MA organizations' rights and responsibilities upon disenrollment. MA organizations may either post this information or provide specific information on where it is located in the Evidence of Coverage together with a link to that document.

(7) A description of and information on how to file a grievance, organizational determination, and appeal.

(8) Prominently display a link to the *Medicare.gov* electronic complaint form.

(9) A Privacy Notice under the HIPAA Privacy Rule (45 CFR part 160).

(10) For PFFS plans, a link to the PFFS Terms and Conditions of Payment.

(11) For MSA plans, the following statements:

(i) ''You must file Form 1040, 'US Individual Income Tax Return,' along with Form 8853, 'Archer MSA and Long-Term Care Insurance Contracts' with the Internal Revenue Service (IRS) for any distributions made from your Medicare MSA account to ensure you aren't taxed on your MSA account withdrawals. You must file these tax forms for any year in which an MSA account withdrawal is made, even if you have no taxable income or other reason for filing a Form 1040. MSA account withdrawals for qualified medical expenses are tax free, while account withdrawals for non-medical expenses are subject to both income tax and a fifty (50) percent tax penalty.''

(ii) ''Tax publications are available on the IRS website at *http://www.irs.gov* or from 1–800–TAX–FORM (1–800–829–3676).''

(c) *Required posted materials.* MA organization's website must provide access to the following materials, in a printable format, within the timeframes noted in paragraphs (c)(1) and (2) of this section.

(1) The following documents for each plan year must be posted on the website by October 15 prior to the beginning of the plan year:

(i) Evidence of Coverage.

(ii) Annual Notice of Change (for renewing plans).

(iii) Summary of Benefits.

(iv) Provider Directory.

(v) Provider/Pharmacy Directory.

(2) The following documents must be posted on the website throughout the year and be updated as required:

(i) Prior Authorization Forms for physicians and enrollees.

(ii) When applicable, Part D Model Coverage Determination and Redetermination Request Forms.

(iii) Exception request forms for physicians (which must be posted by January 1 for new plans).

(iv) CMS Star Ratings document, which must be posted within 21 days after its release on the Medicare Plan Finder.

■ 56. Section 422.2266 is added to read as follows:

§ 422.2266 Activities with healthcare providers or in the healthcare setting.

(a) *Where marketing is prohibited.* The requirements in paragraphs (c) through (e) of this section apply to activities in the health care setting. Marketing activities and materials are not permitted in areas where care is being administered, including but not limited to the following:

(1) Exam rooms.

(2) Hospital patient rooms.

(3) Treatment areas where patients interact with a provider and clinical team (including dialysis treatment facilities).

(4) Pharmacy counter areas.

(b) *Where marketing is permitted.* Marketing activities and materials are permitted in common areas within the health care setting, including, are not limited to, the following:

(1) Common entryways.

(2) Vestibules.

(3) Waiting rooms.

(4) Hospital or nursing home cafeterias.

(5) Community, recreational, or conference rooms.

(c) *Provider-initiated activities.* Provider-initiated activities are activities conducted by a provider at the request of the patient, or as a matter of a course of treatment, and occur when meeting with the patient as part of the professional relationship between the provider and patient. Provider-initiated activities do not include activities conducted at the request of the MA organization or pursuant to the network participation agreement between the MA organization and the provider. Provider-initiated activities that meet the definition in this paragraph (c) fall outside of the definition of marketing in § 422.2260. Permissible provider-initiated activities include:

(1) Distributing unaltered, printed materials created by CMS, such as reports from Medicare Plan Finder, the ''Medicare & You'' handbook, or ''Medicare Options Compare'' (from *https://www.medicare.gov*), including in areas where care is delivered.

(2) Providing the names of MA organizations with which they contract or participate or both.

(3) Answering questions or discussing the merits of a MA plan or plans, including cost sharing and benefit information, including in areas where care is delivered.

(4) Referring patients to other sources of information, such as State Health Insurance Assistance Program (SHIP) representatives, plan marketing representatives, State Medicaid Office, local Social Security Offices, CMS' website at *https://www.medicare.gov,* or 1–800–MEDICARE.

(5) Referring patients to MA plan marketing materials available in common areas;

(6) Providing information and assistance in applying for the LIS.

(7) Announcing new or continuing affiliations with MA organizations, once a contractual agreement is signed. Announcements may be made through any means of distribution.

(d) *Plan-initiated provider activities.* Plan-initiated provider activities are those activities conducted by a provider at the request of an MA organization. During a plan-initiated provider activity, the provider is acting on behalf of the MA organization. For the purpose of plan-initiated activities, the MA organization is responsible for compliance with all applicable regulatory requirements.

(1) During plan-initiated provider activities, MA organizations must ensure that the provider does not:

(i) Accept or collect Scope of Appointment forms.

(ii) Accept Medicare enrollment applications.

(iii) Make phone calls or direct, urge, or attempt to persuade their patients to enroll in a specific plan based on financial or any other interests of the provider.

(iv) Mail marketing materials on behalf of the MA organization.

(v) Offer inducements to persuade patients to enroll in a particular MA plan or organization.

(vi) Conduct health screenings as a marketing activity.

(vii) Distribute marketing materials or enrollment forms in areas where care is being delivered.

(viii) Offer anything of value to induce enrollees to select the provider.

(ix) Accept compensation from the MA organization for any marketing or enrollment activities.

(2) During plan-initiated provider activities, the provider may do any of the following:

(i) Make available, distribute, and display communications materials, including in areas where care is being delivered.

(ii) Provide or make available marketing materials and enrollment forms in common areas.

(e) *MA organization activities in the health care setting.* MA organization activities in the health care setting are those activities, including marketing activities, that are conducted by MA organization staff or on behalf of the MA organization or any downstream entity, but not by a provider. All marketing must follow the requirements in paragraphs (a) and (b) of this section. However, during MA organization activities, the following is permitted:

(1) Accepting and collect Scope of Appointment forms.

(2) Accepting enrollment forms.

(3) Making available, distributing, and displaying communications materials, including in areas where care is being delivered.

■ 57. Section 422.2267 is added to read as follows:

§ 422.2267 Required materials and content.

For information CMS deems to be vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form. Such materials and content are collectively referred to as *required.*

(a) *Standards for required materials and content.* All required materials and content, regardless of categorization as standardized in paragraph (b) of this section or model in paragraph (c) of this section, must meet the following:

(1) Be in a 12pt font, Times New Roman or equivalent.

(2) For markets with a significant non-English speaking population, be in the language of these individuals. Specifically, MA organizations must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(3) Be provided to the beneficiary within CMS's specified timeframes.

(b) *Standardized materials.* Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

(1) When CMS issues standardized material or content, an MA organization must use the document without alteration except for the following:

(i) Populating variable fields.

(ii) Correcting grammatical errors.

(iii) Adding customer service phone numbers.

(iv) Adding plan name, logo, or both.

(v) Deleting content that does not pertain to the plan type (for example, removing Part D language for a MA-only plan).

(vi) Adding the SMID.

(vii) Adding the Privacy Notice under the HIPAA Privacy Rule.

(2) The MA organization may develop accompanying language for standardized material or content, provided it does not conflict with the standardized material or content. For example, CMS may issue standardized content associated with an appeal notification. MA organizations may draft a letter that includes the standardized content in the body of the letter. The remaining language in the letter is at the plan's discretion, provided it does not conflict with the standardized content.

(c) *Model materials.* Model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. When drafting required materials or content based on CMS models, MA organizations:

(1) Must accurately convey the vital information in the required material or content to the beneficiary, although the MA organization is not required to use CMS model materials or content verbatim; and

(2) Must follow CMS's specified order of content, when specified.

(d) *Delivery of required materials.* MA organizations must mail required materials in hard copy or provide them electronically, following the requirements in paragraphs (d)(1) and (2) of this section.

(1) For hard copy mailed materials, each enrollee must receive his or her own copy, except in cases of non-beneficiary-specific material(s) where the MA organization has determined multiple enrollees are living in the same household and it has reason to believe the enrollees are related. In that case, the MA organization may mail one copy to the household. The MA organization must provide all enrollees an opt-out process so the enrollees can each receive his or her own copy, instead of a copy to the household. Materials specific to an individual beneficiary must always be mailed to that individual.

(2) Materials may be delivered electronically following the requirements in paragraphs (d)(2)(i) and (ii) of this section.

(i) Without prior authorization, MA organizations may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: The Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The following requirements apply:

(A) The MA organization may mail one notice for all materials or multiple notices.

(B) Notices for prospective year documents may not be mailed prior to September 1 of each year, but must be sent in time for an enrollee to access the specified documents by October 15 of each year.

(C) The MA organization may send the notice throughout the year to new enrollees.

(D) The notice must include the website address to access the documents, the date the documents will be available if not currently available, and a phone number to request that hard copy documents be mailed.

(E) The notice must provide the enrollee with the option to request hardcopy materials. Requests may be materials specific, and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again.

(F) Hard copies of requested materials must be sent within three business days.

(ii) With prior authorization from the enrollee, MA organizations may provide any required material or content electronically. To do so, MA organizations must:

(A) Obtain prior consent from the enrollee. The consent must specify both the media type and the specific materials being provided in that media type.

(B) Provide instructions on how and when enrollees can access the materials.

(C) Have a process through which an enrollee can request hard copies be mailed, providing the beneficiary with the option of a one-time request or a permanent request (which must stay in place until the enrollee chooses to receive electronic materials again), and with the option of requesting hard copies for all or a subset of materials. Hard copies must be mailed within three business days.

(D) Have a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable.

(e) *CMS required materials and content.* The following are required materials that must be provided to current and or perspective enrollees, as applicable, in the form and manner outlined in this section:

(1) *Evidence of Coverage (EOC).* The EOC is a standardized communications material through which certain required information (under § 422.111(b)) must be provided annually.

(i) Must be provided to current enrollees of plan by October 15 of each Year.

(ii) Must be provided to new enrollees within ten (10) calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(2) *Part C explanation of benefits (EOB).* The EOB is a model communications material through which plans must provide the information required under § 422.111(k). MA organizations may send this monthly or per claim with a quarterly summary.

(3) *Annual notice of change (ANOC).* The ANOC is a standardized marketing material through which plans must provide the information required under § 422.111(d)(2) annually.

(i) Must send for enrollee receipt no later than September 30 of each year.

(ii) Enrollees with an October 1, November 1, and December 1 effective date must receive within ten (10) calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(4) *Pre-Enrollment checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form and Summary of Benefits (SB), so that the enrollees understand important plan benefits and rules. It references information on the following:

(i) The EOC.

(ii) Provider directory.

(iii) Pharmacy directory.

(iv) Formulary.

(v) Premiums/copayments/coinsurance.

(vi) Emergency/urgent coverage.

(vii) Plan-type rules.

(5) *Summary of Benefits (SB).* MA organizations must disseminate a summary of highly utilized coverage that include benefits and cost sharing to prospective Medicare beneficiaries, known as the SB. The SB is a model marketing material. It must be in a clear and accurate form.

(i) The SB must be provided with an enrollment form that meets the following:

(A) In hard copy with a paper enrollment form.

(B) For online enrollment, the SB must be made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the SB.

(ii) The SB must include the following information:

(A) Medical benefits:

(*1*) Monthly Plan Premium.

(*2*) Deductible/Out-of-pocket limits.

(*3*) Inpatient/Outpatient Hospital coverage.

(*4*) Ambulatory Surgical Center (ASC).

(*5*) Doctor Visits (Primary Care Providers and Specialists).

(*6*) Preventive Care.

(*7*) Emergency Care/Urgently Needed Services.

(*8*) Diagnostic Services/Labs/Imaging.

(*9*) Hearing Services/Dental Services/Vision Services.

(*10*) Mental Health Services.

(B) Prescription drug expense including (tiers/levels):

(*1*) Deductible, the initial coverage phase, coverage gap, and catastrophic coverage.

(*2*) A note that costs may differ based on pharmacy type or status (for example, preferred/non-preferred, mail order, long-term care (LTC) or home infusion, and 30- or 90-day supply), when applicable.

(C) For Medicare Medical Savings Account Plans (MSAs), the SB must include the following:

(*1*) The amount Medicare deposits into the beneficiaries MSA account.

(*2*) Language that the beneficiary pays nothing once the deductible is met.

(D) For dual eligible special needs plan (D–SNP)s, the SB must provide the Medicaid benefits to prospective enrollees. This may be done by either of the following:

(*1*) Including the Medicaid benefits in the SB.

(*2*) Providing a separate document with the Medicaid benefits that accompanies the SB.

(E) For D–SNPs open to dually eligible enrollees with differing levels of cost, the SB must:

(*1*) State how cost sharing and benefits differ depending on the level of Medicaid eligibility.

(*2*) Describe the Medicaid benefits, if any, provided by the plan.

(F) Fully integrated dual eligible SNPs (FIDE SNPs) and highly integrated D–SNPs, as defined in § 422.2, that provide Medicaid benefits have the option to display integrated Medicare and Medicaid benefits in the SB.

(G) MA organizations may include other health related benefits with the SB.

(6) *Enrollment/Election form.* This is model communications material through which plans must provide the information required under § 422.60(c).

(7) *Enrollment Notice.* This is a model communications material through which plans must provide the information required under § 422.60(e)(3).

(8) *Disenrollment Notice.* This is a model communications material through which plans must provide the information required under § 422.74(b).

(9) *Mid-Year Change Notification.* This is a model communications material through which plans must provide a notice to enrollees when there is a mid-year change in benefits or plan rules, under the following timelines:

(i) Notices of changes in plan rules, unless otherwise addressed elsewhere in this part, must be provided 30 days in advance.

(ii) For National Coverage Determination (NCD) changes announced or finalized less than 30 days before their effective date, a notification is required as soon as possible.

(iii) Mid-year NCD or legislative changes must be provided no later than 30 days after the NCD is announced.

(A) Plans may include the change in next plan mass mailing (for example, newsletter), provided it is within 30 days.

(B) The notice must also appear on the MA organization's website.

(10) *Non-renewal Notice.* This is a model communications material through which plans must provide the information required under § 422.506.

(i) The Non-renewal Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees in special needs plans (SNPs).

(ii) The Non-renewal Notice must do all of the following:

(A) Inform the enrollee that their plan will no longer be offered and told when their plan will end.

(B) Identify the last day the enrollee has to make a Medicare health plan selection and include any applicable open enrollment periods or special election periods or both (for example, Medicare open enrollment, non-renewal special election period).

(C) Explain what they must do to continue receiving Medicare coverage and what will happen if the enrollee chooses to do nothing.

(D) Include all available health plan options must be included in the enrollee's notice along with an explanation of how to obtain each option.

(E) Specify when coverage will start after a new Medicare plan is chosen.

(F) List 1–800–MEDICARE contact information together with other organizations that may be able to assist with comparing plans (for example, SHIPs).

(G) Explain Medigap to applicable enrollees and the special right to buy a Medigap policy and include a Medigap fact sheet with the non-renewal notice that explains Medigap coverage, policy, options to compare Medigap policies, and options to buy a Medigap policy.

(H) Include the MA organization's telephone number, TTY number, and hours and days of operation.

(11) *Provider Directory.* This is a model communications material through which plans must provide the information under § 422.111(b)(3). The Provider Directory must:

(i) Be provided to current enrollees of the plan by October 15 of each year.

(ii) Be provided to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(iii) Be provided to current enrollees upon request, within three 3 business days of the request.

(iv) Be updated any time the MA organization becomes aware of changes.

(A) Updates to the online provider directories must be completed within 30 days of receiving information requiring update.

(B) Updates to hardcopy provider directories must be completed within 30 days; hard copy directories that include separate updates via addenda are considered up-to-date.

(12) *Provider Termination Notice.* This is a model communications material through which plans must provide the information required under § 422.111(e). The provider termination notice must do both of the following:

(i) Be provided in hard copy.

(ii) Be sent via U.S. mail (first class postage is recommended, but not required).

(13) *Star Ratings Document.* This is a standardized marketing material through which Star Ratings information is conveyed to prospective enrollees.

(i) The Star Ratings Document is generated through HPMS.

(ii) The Star Ratings Document must be provided with an enrollment form, as follows:

(A) In hard copy with a paper enrollment form.

(B) For online enrollment, made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the Star Ratings Document.

(iii) New MA organization that have no Star Ratings are not required to provide the Star Ratings Document until the following contract year.

(iv) Updated Star Ratings must be used within 21 calendar days of release of updated information on Medicare Plan Finder.

(v) Updated Star Ratings must not be used until CMS releases Star Ratings on Medicare Plan Finder.

(14) *Organization Determination Notice.* This is a model communications material through which plans must provide the information under § 422.568.

(15) *Excluded Provider Notice.* This is a model communications material through which plans must notify members when a provider they use has been excluded from participating in the Medicare program based on an OIG exclusion or the CMS preclusion list.

(16) *Notice of Denial of Medical Coverage or Payment (NDMCP) (also known as the Integrated Denial Notice (IDN)).* This is a standardized material used to convey beneficiary appeal rights when a plan has denied a service as non-covered or excluded from benefits.

(17) *Notice of Medicare Non-Coverage (NOMNC).* This is a standardized material used to convey termination of previously-approved coverage.

(18) *Detailed Explanation of Non-Coverage (DENC).* This is a standardized material used to convey plan receipt of a request for an appeal on a beneficiary's behalf from the Beneficiary and Family Centered Care Quality Improvement Organization (BFCC–QIO).

(19) *Appointment of Representative (AOR).* This is a standardized material used to assign an individual to act on behalf of a beneficiary for the purpose of a specific appeal, grievance, or organization determination.

(20) *An Important Message From Medicare About Your Rights (IM).* This is a standardized material used to convey a beneficiary's discharge rights in an inpatient hospital setting.

(21) *Detailed Notice of Discharge Form (DND).* This is a standardized material used to convey a detailed explanation of an appellant's discharge rights from an inpatient hospital setting.

(22) *Medicare Outpatient Observation Notice (MOON).* This is a standardized material used to inform a beneficiary of outpatient status after an inpatient stay.

(23) *Appeal and Grievance Data Form.* This is a standardized material used to convey organization-specific grievance and appeals data.

(24) *Request for Administrative Law Judge (ALJ) Hearing.* This is a standardized material used to formally request a reconsideration of the independent review entity's determination.

(25) *Attorney Adjudicator Review in Lieu of ALJ Hearing.* This is a standardized material used to request that an attorney adjudicator review a previously determined decision rather than having an ALJ do so.

(26) *Notice of Right to an Expedited Grievance.* This is a model communications material used to convey a Medicare enrollee's rights to request that a decision be made on a grievance or appeal within a shorter timeframe.

(27) *Waiver of Liability Statement.* This is a model communications material used by providers to waive beneficiary liability for payment for denied services.

(28) *Notice of Appeal Status.* This is a model communications material used to inform a beneficiary of the denial of an appeal and additional appeal rights.

(29) *Notice of Dismissal of Appeal.* This is a model communications material used to convey the rationale by an MA organization to dismiss beneficiary's appeal.

(30) *Federal Contracting Statement.* This is model content through which plans must convey that they have a contract with Medicare and that enrollment in the plan depends on contract renewal.

(i) The Federal Contracting Statement must include all of the following:

(A) Legal or marketing name of the organization.

(B) Type of plan (for example, HMO, HMO SNP, PPO, PFFS, PDP).

(C) A statement that the organization has a contract with Medicare (when applicable, MA organizations may incorporate a statement that the organization has a contract with the state/Medicaid program).

(D) A statement that enrollment depends on contract renewal.

(ii) MA organizations must include the Federal Contracting Statement on all marketing materials with the exception of the following:

(A) Banners and banner-like advertisements.

(B) Outdoor advertisements.

(C) Text messages.

(D) Social media.

(31) *Star Ratings Disclaimer.* This is standardized content. The disclaimer consists of the statement ''Every year, Medicare evaluates plans based on a 5-star rating system,'' and must be present whenever Star Ratings are mentioned in marketing materials, with the exception of when Star Ratings are published on small objects (that is, a give-away items such as a pens or rulers).

(32) *Availability of Non-English Translations Disclaimer.* This is standardized content. The disclaimer consists of the statement ''ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–XXX–XXX–XXXX (TTY: 1–XXX–XXX–XXXX).''

(i) The disclaimer must be placed in non-English languages that meet the 5 percent threshold for language translation under paragraph (a)(2) of this section.

(ii) The disclaimer must be added to all required materials in this section.

(33) *Accommodations Disclaimer.* This is standardized content. The disclaimer consists of the statement ''For accommodations of persons with special needs at meetings call '' and must be present on all advertisements and invitations to all events described under § 422.2264(c).

(34) *Mailing Statements.* This is standardized content. It consists of statements on envelopes that MA organizations must include when mailing information to current members, as follows:

(i) MA organizations must include the following statement when mailing information about the enrollee's current plan: ''Important [Insert Plan Name] information.''

(ii) MA organizations must include the following statement when mailing health and wellness information: ''Health and wellness or prevention information.''

(iii) The MA organization must include the plan name; however, if the plan name is elsewhere on the envelope, the plan name does not need to be repeated in the disclaimer.

(iv) Delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a multiple MA organizations must also comply with this requirement; however, they do not have to include a plan name.

(35) *Promotional Give-Away Disclaimer.* This is model content. The disclaimer consists of a statement that must make clear that there is no obligation to enroll in a plan, and must be included when offering a promotional give-away such as a drawing, prizes, or a free gift.

(36) *Provider Co-Branded Material Disclaimer.* This is standardized content. The disclaimer consists of the statement: ''Other Pharmacies/Physicians/Providers are available in our network,'' and must be included on materials that identify co-branding relationships with network provider or pharmacies. This disclaimer is not required when co-branding with a provider network or health system that represents 90 percent or more of the network as a whole.

(37) *Out of Network Non-Contracted Provider Disclaimer.* This is standardized content. The disclaimer consists of the statement: ''Out-of-network/non-contracted providers are under no obligation to treat <Plan> members, except in emergency situations. Please call our customer service number or see your Evidence of Coverage for more information, including the cost- sharing that applies to out-of-network services,'' and must be included whenever materials reference out-of-network/non-contracted providers.

(38) *NCQA SNP Approval Statement.* This is standardized content and must be used by SNPs who have received NCQA approval. It consists of the following statement: ''[Insert Plan Name] has been approved by the National Committee for Quality Assurance (NCQA) to operate as a Special Needs Plan (SNP) until [insert last contract year of NCQA approval] based on a review of [insert Plan Name's] Model of Care.'' MA organizations are prohibited from including numeric SNP approval scores, and no other language referencing NCQA approval may be used.

§ 422.2268 [Removed]

■ 58 Section 422.2268 is removed.

■ 59. Section 422.2274 is revised to read as follows:

§ 422.2274 Agent, broker, and other third party requirements.

If an MA organization uses agents and brokers to sell its Medicare plans, the requirements in paragraphs (a) through (e) of this section are applicable. If an MA organization makes payments to third parties, the requirements in paragraph (f) of this section are applicable.

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a plan or product offered by an MA organization including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(E) Referral or Finder fees.

(ii) Does not include any of the following:

(A) Payment of fees to comply with State appointment laws, training, certification, and testing costs.

(B) Reimbursement for mileage to, and from, appointments with beneficiaries.

(C) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Fair market value (FMV) means, for purposes of evaluating agent/broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into an MA plan. FMV for an upcoming year is calculated by adding the current year FMV and the product of the current year FMV and MA Growth Percentage for aged and disabled beneficiaries, which is published for each year in the rate announcement issued pursuant to § 422.312.

Initial enrollment year means the first year that a beneficiary is enrolled in a plan vs. subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA–PD replaced with another MA or MA–PD.

(iii) Cost plan replaced with another cost plan.

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

Unlike plan type means one of the following:

(i) An MA or, MA–PD plan to a PDP or Section 1876 Cost Plan.

(ii) A PDP to a Section 1876 Cost Plan or an MA or MA–PD plan.

(iii) A Section 1876 Cost Plan to an MA or MA–PD plan or PDP.

(b) *Agent/broker requirements.* Agents and brokers who represent MA organizations must follow the requirements in paragraphs (b)(1) through (3) of this section. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

(1) Be licensed and appointed under State law (if required under applicable State law).

(2) Be trained and tested annually as required under paragraph (c)(4) of this section, and achieve an 85 percent or higher on all forms of testing.

(3) Secure and document a Scope of Appointment prior to meeting with potential enrollees.

(c) *MA organization oversight.* MA organizations must oversee first tier, downstream, and related entities that represent the MA organization to ensure agents/brokers abide by all applicable State and Federal laws, regulations, and requirements. MA organizations must do all of the following:

(1) As required under applicable State law, employ as marketing representatives only individuals who are licensed by the State to conduct marketing (as defined in this subpart) in that State, and whom the MA organization has informed that State it has appointed, consistent with the appointment process provided for under State law.

(2) As required under applicable State law, report the termination of an agent/broker to the State and the reason for termination.

(3) Report to CMS all enrollments made by unlicensed agents/brokers and for-cause terminations of agent/brokers.

(4) On an annual basis, provide agent/broker training and testing on Medicare rules and regulations, the plan products that agents and brokers will sell including any details specific to each plan product, and relevant State and Federal requirements.

(5) On an annual basis by the last Friday in July, report to CMS whether the MA organization intends to use employed, captive, and/or independent agents/brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents/brokers. Following the reporting deadline, MA organizations may not change their decisions related to agent/broker type, or their compensation rates and ranges, until the next plan year.

(6) On an annual basis by October 1, have in place full compensation structures for the following plan year. The structure must include details on compensation dissemination, including specifying payment amounts for initial enrollment year and renewal year compensation.

(7) Submit agent/broker marketing materials to CMS through HPMS prior to use, following the requirements for marketing materials in this subpart.

(8) Ensure agents and brokers do not charge beneficiaries a marketing fee.

(9) Establish and maintain a system for confirming that:

(i) Beneficiaries enrolled by agents/brokers understand the product, including the rules applicable under the plan.

(ii) Agent/brokers appropriately complete Scope of Appointment records for all marketing appointments (including telephonic and walk-in).

(10) Demonstrate that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(11) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(d) *Compensation requirements.* MA organizations must ensure they meet the requirements in paragraphs (d)(1) through (5) of this section in order to pay compensation. These compensation requirements only apply to independent agent/brokers.

(1) *General rules.* (i) MA organizations may only pay agents/brokers who meet the requirements in paragraph (b) of this section.

(ii) MA organizations may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section.

(iii) MA organizations may determine their payment schedule (for example, monthly or quarterly). Payments (including payments for AEP enrollments) must be made during the year of the beneficiary's enrollment.

(iv) MA organizations may only pay compensation for the number of months a member is enrolled.

(2) *Initial enrollment year compensation.* For each enrollment in an initial enrollment year, MA organizations may pay compensation at or below FMV.

(i) MA organizations may pay either a full or pro-rated initial enrollment year compensation for:

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) MA organizations must pay pro-rate initial enrollment year compensation for:

(A) A beneficiary's plan change(s) during their initial enrollment year.

(B) A beneficiary's selection of an ''unlike plan type'' change. In that case, the new plan would only pay the months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(3) *Renewal compensation.* For each enrollment in a renewal year, MA plans may pay compensation at an amount up to 50 percent of FMV.

(i) MA plans may pay compensation for a renewal year:

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new ''like plan type''.

(ii) [Reserved]

(4) *Other compensation scenarios.* (i) When a beneficiary enrolls in an MA–PD, MA organizations may pay only the MA compensation (and not compensation for Part D enrollment under § 423.2274 of this chapter).

(ii) When a beneficiary enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor must pay compensation for the Part D enrollment.

(iii) When a beneficiary enrolls in a MA-only plan and a PDP plan, the MA plan sponsor may pay for the MA plan enrollment and the Part D plan may pay for the PDP plan enrollment.

(iv) When a beneficiary changes from two plans (for example, a MA plan and a stand-alone PDP) (dual enrollments) to one plan (MA–PD), the MA organization may only pay compensation at the renewal rate for the MA–PD product.

(5) *Additional compensation, payment, and compensation recovery requirements (Charge-backs).* (i) MA organizations must retroactively pay or recoup funds for retroactive beneficiary changes for the current and previous calendar years. MA organizations may choose to recoup or pay compensation for years prior to the previous calendar year, but they must do both (recoup amounts owed and pay amounts due during the same year).

(ii) Compensation recovery is required when:

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first 3 months of enrollment (known as rapid disenrollment), except as noted in paragraph (d)(5)(iii) of this section.

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1.

(B) A beneficiary's enrollment change is not in the best interests of the

Medicare program, including for the following reasons:

(*1*) Other creditable coverage (for example, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation (whether paid for an initial enrollment year or renewal year) from an agent/broker equal to the number of months not enrolled.

(*1*) If a plan has paid full initial compensation, and the enrollee disenrolls prior to the end of the enrollment year, the total number of months not enrolled (including months prior to the effective date of enrollment) must be recovered from the agent/broker.

(*2*) Example: A beneficiary enrolls upon turning 65 effective April 1 and disenrolls September 30 of the same year. The plan paid full initial enrollment year compensation. Recovery is equal to 6/12ths of the initial enrollment year compensation (for January through March and October through December).

(e) *Payments to third parties.* (1) Payments made to third parties (that is, entities other than individual agents/brokers) for services other than enrollment of beneficiaries (for example, training customer service, agent recruitment, or operational overhead) must not exceed FMV.

(2) Administrative payments to third parties can be based on enrollment, provided payments are at or below FMV.

■ 60. Section 422.2420 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 422.2420 Calculation of the medical loss ratio.

* * * * *

(b) * * *

(2) * * *

(i) Amounts that the MA organization pays (including under capitation contracts) for covered services, described at paragraph (a)(2) of this section, provided to all enrollees under the contract.

* * * * *

■ 61. Section 422.2440 is revised to read as follows:

§ 422.2440 Credibility adjustment.

(a) An MA organization may add the credibility adjustment specified under paragraph (e) of this section to a contract's MLR if the contract's experience is partially credible, as defined in paragraph (d)(1) of this section.

(b) An MA organization may not add a credibility adjustment to a contract's MLR if the contract's experience is fully credible, as defined in paragraph (d)(2) of this section.

(c) For those contract years for which a contract has non-credible experience, as defined in paragraph (d)(3) of this section, sanctions under § 422.2410(b) through (d) will not apply.

(d)(1) A contract's experience is partially credible if it is based on the experience of at least 2,400 member months and fewer than or equal to 180,000 member months.

(2) A contract's experience is fully credible if it is based on the experience of more than 180,000 member months.

(3) A contract's experience is non-credible if it is based on the experience of fewer than 2,400 member months.

(e)(1) The credibility adjustment for a partially credible MA contract, other than an MSA contract, is equal to the base credibility factor determined under paragraph (f) of this section.

(2) The credibility adjustment for a partially credible MA MSA contract is the product of the base credibility factor, as determined under paragraph (f) of this section, multiplied by the deductible factor, as determined under paragraph (g) of this section.

(f) The base credibility factor for partially credible experience is determined based on the number of member months for all enrollees under the contract and the factors shown in Table 1 of this section. When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 of this section, the value associated with that number of member months is the base credibility factor. The base credibility factor for a number of member months between the values shown in Table 1 of this section is determined by linear interpolation.

(g) The deductible factor is based on the enrollment-weighted average deductible for all MSA plans under the MA MSA contract, where the deductible for each plan under the contract is weighted by the plan's portion of the total number of member months for all plans under the contract. When the weighted average deductible exactly matches a deductible category listed in Table 2 of this section, the value associated with that deductible is the deductible factor. The deductible factor for a weighted average deductible between the values shown in Table 2 of section is determined by linear interpolation.

TABLE 1 TO § 422.2440—BASE CREDIBILITY FACTORS FOR MA CONTRACTS

Member months	Base credibility factor (additional percentage points)
<2,400	N/A (Non-credible).
2,400	8.4%.
6,000	5.3%.
12,000	3.7%.
24,000	2.6%.
60,000	1.7%.
120,000	1.2%.
180,000	1.0%.
>180,000	0.0% (Fully credible).

TABLE 2 TO § 422.2440—DEDUCTIBLE FACTORS FOR MA MSA CONTRACTS

Weighted average deductible	Deductible factor
<$2,500	1.000
$2,500	1.164
$5,000	1.402
≥$10,000	1.736

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 62. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh.

■ 63. Section 423.4 is amended by adding definitions for ''Credible allegation of fraud'', ''Fraud hotline tip'', ''Inappropriate prescribing'', ''Parent organization'', and ''Substantiated or suspicious activities of fraud, waste, or abuse'' in alphabetical order to read as follows:

§ 423.4 Definitions.

* * * * *

Credible allegation of fraud means an allegation from any source, including but not limited to the following:

(1) Fraud hotline tips verified by further evidence.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

* * * * *

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by Medicare Advantage (MA) organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Plan sponsors may consider any number of factors including, but not limited, to the following:

(1) Documentation of a patient's medical condition.

(2) Identified instances of patient harm or death.

(3) Medical records, including claims (if available).

(4) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.

(5) Levels of morphine milligram equivalent (MME) dosages prescribed.

(6) Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.

(7) State-level prescription drug monitoring program (PDMP) data.

(8) Geography, time, and distance between a prescriber and the patient.

(9) Refill frequency and factors associated with increased risk of opioid overdose.

* * * * *

Parent organization means the legal entity that exercises a controlling interest, through the ownership of shares, the power to appoint voting board members, or other means, in a Part D sponsor or MA organization, directly or through a subsidiary or subsidiaries, and which is not itself a subsidiary of any other legal entity.

* * * * *

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier;

(1) Engaged in a pattern of improper billing;

(2) Submitted improper claims with suspected knowledge of their falsity;

(3) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(4) Is the subject of a fraud hotline tip verified by further evidence.

* * * * *

■ 64. Section 423.38 is amended by revising paragraph (c)(8) and adding paragraphs (c)(11) through (33) to read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that the PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to the following—

(i) Failure to provide the individual on a timely basis benefits available under the plan;

(ii) Failure to provide benefits in accordance with applicable quality standards; or

(iii) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communications as outlined in subpart V of this part.

* * * * *

(11) The individual is making an enrollment request into or out of an employer sponsored Part D plan, is disenrolling from a Part D plan to take employer sponsored coverage of any kind, or is disenrolling from employer sponsored coverage (including Consolidated Omnibus Budget Reconciliation Act (COBRA) coverage) to elect a Part D plan.

(i) This special election period (SEP) is available to individuals who have (or are enrolling in) an employer or union sponsored Part D plan and ends two months after the month the employer or union coverage of any type ends.

(ii) The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to three months after the month in which the election is made.

(12) The individual is enrolled in a Part D plan offered by a Part D plan sponsor that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction.

(i) Consistent with the disclosure requirements at § 423.128(f), CMS may require the sponsor to notify current enrollees that if the enrollees believe they are affected by the matter(s) that gave rise to the sanction, the enrollees are eligible for a SEP to elect another PDP.

(ii) The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

(13) The individual is enrolled in a section 1876 cost contract that is non-renewing its contract for the area in which the enrollee resides.

(i) Individuals eligible for this SEP must meet Part D plan eligibility requirements.

(ii) This SEP begins December 8 of the then-current contract year and ends on the last day of February of the following year.

(14) The individual is disenrolling from a PDP to enroll in a Program of All-inclusive Care for the Elderly (PACE) organization or is enrolling in a PDP after disenrolling from a PACE organization.

(i) An individual who disenrolls from PACE has a SEP for 2 months after the effective date of PACE disenrollment to elect a PDP.

(ii) An individual who disenrolls from a PDP has a SEP for 2 months after the effective date of PDP disenrollment to elect a PACE plan.

(15) The individual moves into, resides in, or moves out of an institution, as defined by CMS, and elects to enroll in, or disenroll from, a Part D plan.

(16) The individual is not entitled to premium free Part A and enrolls in Part B during the General Enrollment Period for Part B (January through March) for an effective date of July 1st are eligible to request enrollment in a Part D plan that begins April 1st and ends June 30th, with a Part D plan enrollment effective date of July 1st.

(17) The individual belongs to a qualified State Pharmaceutical Assistance Program (SPAP) and is requesting enrollment in a Part D plan.

(i) The individual is eligible to make one enrollment election per year.

(ii) This SEP is available while the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after either the month of the loss of eligibility or notification of the loss, whichever is later.

(18) The individual is enrolled in a Part D plan and elects to disenroll from that Part D plan to enroll in or maintain other creditable prescription drug coverage.

(19)(i) The individual is enrolled in a section 1876 cost contract and an optional supplemental Part D benefit under that contract and elects a Part D plan upon disenrolling from the cost contract.

(ii) The SEP begins the month the individual requests disenrollment from the cost contract and ends when the individual makes an enrollment election or on the last day of the second month following the month the cost contract enrollment ended, whichever is earlier.

(20) The individual is requesting enrollment in a Part D plan offered by a Part D plan sponsor with a Star Rating of 5 Stars. An individual may use this SEP only once for the contract year in which the Part D plan was assigned a 5-star overall performance rating, beginning the December 8 before that contract year through November 30 of that contract year.

(21)(i) The individual is a non-U.S. citizen who becomes lawfully present in the United States.

(ii) This SEP begins the month the enrollee attains lawful presence status and ends the earlier of when the individual makes an enrollment election or 2 calendar months after the month the enrollee attains lawful presence status.

(22) The individual was adversely affected by having requested, but not received, required notices or information in an accessible format, as outlined in section 504 of the Rehabilitation Act of 1973, within the same timeframe that the Part D plan sponsor or CMS provided the same information to individuals who did not request an accessible format.

(i) The SEP begins at the end of the election period during which the individual was seeking to make an election and the length is at least as long as the time it takes for the information to be provided to the individual in an accessible format.

(ii) Part D plan sponsors may determine eligibility for this SEP when the criterion is met, ensuring adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

(23) Individuals affected by a FEMA-declared weather-related emergency or major disaster are eligible for a SEP to make a Part D enrollment or disenrollment election. The SEP is available from the start of the incident period and for 4 calendar months after the start of the incident period. The individual is eligible for this SEP provided the individual—

(i)(A) Resides, or resided at the start of the incident period, in an area for which Federal Emergency Management Agency (FEMA) has declared an emergency or a major disaster and has designated affected counties as being eligible to apply for individual or public level assistance; or

(B) Does not reside in the affected areas but relies on help making healthcare decisions from one or more individuals who reside in the affected areas; and

(ii) Was eligible for an election period at the time of incident period; and

(iii) Did not make an election during that election period due to the weather-related emergency or major disaster.

(24) The individual is using the SEP at § 422.62(b)(8) of this chapter to disenroll from a MA plan that includes Part D benefits.

(i) This SEP permits a one-time election to enroll in a Part D plan.

(ii) This SEP begins upon disenrollment from the MA plan and continues for 2 calendar months.

(25)(i) An individual using the MA Open Enrollment Period for Institutionalized Individuals (OEPI) to disenroll from a MA plan that includes Part D benefits plan is eligible for a SEP to request enrollment in a Part D plan.

(ii) The SEP begins with the month the individual requests disenrollment from the MA plan and ends on the last day of the second month following the month MA enrollment ended.

(26) An individual using the Medicare Advantage Open Enrollment Period (MA OEP) to elect original Medicare is eligible for a SEP to make a Part D enrollment election.

(27)(i) The individual is enrolled in a MA special needs plan (SNP) and is no longer eligible for the SNP because he or she no longer meets the specific special needs status.

(ii) The individual may request enrollment in a Part D plan that begins the month the individual's special needs status changes and ends the earlier of when he or she makes an election or 3 months after the effective date of involuntary disenrollment from the SNP.

(28) The individual is found, after enrollment into a Chronic Care SNP, not to have the required qualifying condition.

(i) This individual is eligible to enroll prospectively in a Part D plan.

(ii) This SEP begins when the MA organization notifies the individual of the lack of eligibility for the Chronic Care SNP and extends through the end of that month and the following 2 calendar months.

(iii) The SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

(29) The individual uses the SEP at § 422.62(b)(15) of this chapter to enroll in a MA Private Fee-for-Service plan without Part D benefits, or enrolls in a section 1876 cost plan, is eligible to request enrollment in a PDP or the cost plan's optional supplemental Part D benefit, if offered.

(i) This SEP begins the month the individual uses the SEP at § 422.62(b)(15) of this chapter and continues for 2 additional months.

(ii) [Reserved]

(30) An individual who uses the SEP at § 422.62(b)(23) of this chapter to disenroll from a MA plan is eligible to request enrollment in a PDP.

(i) This SEP begins the month the individual is notified of eligibility for the SEP at § 422.62(b)(23) of this chapter and continues for an additional 2 calendar months.

(ii) This SEP permits one enrollment into a PDP.

(iii) This SEP ends when the individual has enrolled in the PDP.

(iv) An individual may use this SEP to request enrollment in a PDP subsequent to having submitted a disenrollment to the MA plan or may simply request enrollment in the PDP, resulting in automatic disenrollment from the MA plan.

(31) The individual is enrolled in a plan offered by a Part D plan sponsor that has been placed into receivership by a state or territorial regulatory authority. The SEP begins the month the receivership is effective and continues until it is no longer in effect or until the enrollee makes an election, whichever occurs first. When instructed by CMS, the MA plan that has been placed under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for this SEP and how to use the SEP.

(32) The individual is enrolled in a plan that has been identified with the low performing icon in accordance with § 423.186(h)(1)(ii). This SEP exists while the individual is enrolled in the low performing Part D plan.

(33) The individual meets other exceptional circumstances as CMS may provide.

* * * * *

■ 65. Section 423.40 is amended by revising paragraph (c) to read as follows:

§ 423.40 Effective dates.

* * * * *

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.38(c), the coverage or change in coverage is effective the first day of the calendar month following the month in which the election is made, unless otherwise noted.

* * * * *

■ 66. Section 423.100 is amended—

■ a. In the definition of ''Applicable drug'' by revising paragraph (1)(ii);

■ b. In the definition of ''Exempted beneficiary'' by:

■ i. Removing the word ''or'' at the end of paragraph (2);

■ ii. Removing the period at the end of paragraph (3) and adding ''; or'' in its place; and

■ iii. Adding paragraph (4); and

■ c. By revising the definition of ''Potential at-risk beneficiary''.

The revisions and addition read as follows:

§ 423.100 Definitions.

* * * * *

Applicable drug * * *

(1) * * *

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than, with respect to a plan year before 2019), a product licensed under subsection (k) of such section 351); and

* * * * *

Exempted beneficiary * * *

(4) Has sickle cell disease.

* * * * *

Potential at-risk beneficiary means a Part D eligible individual who meets any of the following:

(1) Is identified using clinical guidelines (as defined in this section).

(2) Who is identified by CMS as having a history of opioid-related overdose on the following basis:

(i) At least one recent Medicare fee-for-service claim has been submitted that contains a principal diagnosis code indicating opioid overdose.

(ii) At least one recent PDE for an opioid medication has been submitted.

(3) With respect to whom a Part D plan sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as a potential at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment.

* * * * *

■ 67. Section 423.104 is amended by adding paragraph (d)(2)(iv) to read as follows:

§ 423.104 Requirements related to qualified prescription drug coverage.

* * * * *

(d) * * *

(2) * * *

(iv) Specialty tier means a formulary cost sharing tier dedicated to high-cost Part D drugs with ingredient costs for a 30-day equivalent supply (as described in paragraph (d)(2)(iv)(A)(*2*) of this section) that are greater than the specialty tier cost threshold specified in paragraph (d)(2)(iv)(A) of this section.

(A) *Specialty-tier cost threshold.* CMS sets the specialty-tier cost threshold for a plan year in accordance with this paragraph (d)(2)(iv)(A), using the following steps:

(*1*) *30-day equivalent ingredient cost.* Using the PDE data as specified in paragraph (d)(2)(iv)(C) of this section, CMS uses the ingredient cost reflected on the prescription drug event (PDE) to determine the ingredient cost in dollars for a 30-day equivalent supply of the Part D drug.

(*2*) *30-day equivalent supply.* CMS determines the 30-day equivalent supply as follows: If the days' supply reported on a PDE is less than or equal to 34, the number of 30-day equivalent supplies equals one. If the days' supply reported on a PDE is greater than 34, the number of 30-day equivalent supplies is equal to the number of days' supply reported on each PDE divided by 30.

(*3*) *Top 1 percent.* CMS determines the amount that equals the lowest 30-day equivalent ingredient cost that is within the top 1 percent of all 30-day equivalent ingredient costs reflected in the PDE data.

(*4*) *Determination.* Except as provided in paragraph (d)(2)(iv)(B) of this section, the amount determined in paragraph (d)(2)(iii) of this section is the specialty-tier cost threshold for the plan year.

(*5*) *Claims history.* Except for newly FDA-approved Part D drugs only recently available on the market for which Part D sponsors would have little or no claims data, CMS approves placement of a Part D drug on a specialty tier when that Part D sponsor's claims data from the time period specified in paragraph (d)(2)(iv)(C) of this section demonstrates that greater than 50 percent of the Part D sponsor's PDEs for a given Part D drug, when adjusted for 30-day equivalent supplies, have ingredient costs for 30-day equivalent supplies, as described in paragraph (d)(2)(iv)(A)(*2*) of this section, that exceed the specialty-tier cost threshold.

(B) *Limit on specialty-tier cost threshold adjustment.* (*1*) CMS increases the specialty-tier cost threshold for a plan year only if the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section for a plan year is at least 10 percent above the specialty tier cost threshold for the prior plan year.

(*2*) If an increase is made in accordance with this paragraph (d)(2)(iv)(B), CMS rounds the amount determined in paragraph (d)(2)(iv)(A)(*3*) of this section to the nearest $10, and the resulting dollar amount is the specialty-tier cost threshold for the plan year.

(C) *Data used to determine the specialty-tier cost threshold.* CMS uses PDEs from the plan year that ended 12 months prior to the applicable plan year.

(D) *Maximum number of specialty tiers and maximum allowable cost sharing.* A Part D plan may maintain up to two specialty tiers. CMS sets the maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost sharing specialty tier as follows:

(*1*) For Part D plans with the full deductible provided under the Defined Standard benefit, as specified in paragraph (d)(1) of this section, 25 percent coinsurance.

(*2*) For Part D plans with no deductible, 33 percent coinsurance.

(*3*) For Part D plans with a deductible that is greater than $0 and less than the deductible provided under the Defined Standard benefit, a coinsurance percentage that is determined by subtracting the plan's deductible from 33 percent of the initial coverage limit (ICL) under section 1860D–2(b)(3) of the Act, dividing this difference by the difference between the ICL and the plan's deductible, and rounding to the nearest 1 percent.

* * * * *

■ 68. Section 423.128 is amended by—

■ a. Revising paragraph (a)(1);

■ b. Adding paragraph (b)(11);

■ c. Revising paragraphs (d)(1)(i), (ii), and (iii); and

■ d. Adding paragraphs (d)(1)(v) and (vi) and (d)(4) and (5).

The revisions and additions read as follows:

§ 423.128 Dissemination of Part D plan information.

(a) * * *

(1) To each enrollee of a Part D plan offered by the Part D sponsor under this

part, except as provided in paragraph (b)(11)(ii) of this section;

* * * * *

(b) * * *

(11) *Opioid information.* (i) Subject to paragraph (b)(11)(ii) of this section, for plan year 2021 and each subsequent year, a Part D sponsor must disclose to each enrollee identified in paragraph (b)(11)(ii) of this section at least once per year the following:

(A) The risks associated with prolonged opioid use.

(B) Coverage of non-pharmacological therapies, devices, and non-opioid medications—

(*1*) In the case of an MA–PD, under such plan; and

(*2*) In the case of a PDP, under such plan and Medicare Parts A and B.

(ii) The Part D sponsor may elect to, in lieu of disclosing the information described in paragraph (b)(11)(i) of this section to each enrollee under each plan offered by the Part D sponsor under this part, disclose such information to a subset of enrollees, such as enrollees who have been prescribed an opioid in the previous 2-year period.

* * * * *

(d) * * *

(1) * * *

(i)(A) Is open at least from 8:00 a.m. to 8:00 p.m. in all regions served by the Part D plan.

(B) Any call center serving pharmacists or pharmacies must be open so long as any network pharmacy in that region is open.

(ii) At a minimum provides customer telephone service, including to pharmacists, in accordance with the following business practices:

(A) Limits average hold time to 2 minutes. The hold time is defined as the time spent on hold by callers following the interactive voice response (IVR) system, touch-tone response system, or recorded greeting, before reaching a live person.

(B) Answers 80 percent of incoming calls within 30 seconds after the Interactive Voice Response (IVR), touch-tone response system, or recorded greeting interaction.

(C) Limits the disconnect rate of all incoming calls to 5 percent. The disconnect rate is defined as the number of calls unexpectedly dropped divided by the total number of calls made to the customer call center.

(iii)(A) Provides interpreters for non-English speaking and limited English proficient (LEP) individuals.

(B) Interpreters must be available within 8 minutes of reaching the customer service representative and be made available at no cost to the caller.

* * * * *

(v)(A) Responds to TTY-to-TTY calls as defined in 47 CFR part 64, subpart F, in accordance with the mandatory minimum standards delineated in 47 CFR 64.604.

(B) Provides effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of Federal Communication Commission-approved telecommunications relay systems, when using automated-attendant systems. See 28 CFR 35.161 and 36.303(d).

(vi) Provides the information described in paragraph (d)(4) of this section to enrollees who call the customer service call center.

* * * * *

(4) A Part D sponsor must implement, and make available directly to enrollees, in an easy to understand manner, the following accurate, timely, clinically appropriate, patient-specific formulary and benefit real-time information in their beneficiary-specific portal or computer application:

(i) Enrollee cost sharing amounts.

(ii) Clinically appropriate formulary medication alternatives for a given condition, which are not excluded based on cost implications.

(iii) Formulary status, including utilization management requirements applicable to each alternative medication, as appropriate for each enrollee and medication presented.

(5) The Part D sponsor may provide rewards and incentives to enrollees who use the beneficiary real time benefit tool (RTBT) described in paragraph (d)(4) of this section, provided the rewards and incentives comply with the requirements in paragraphs (d)(5)(i) through (iii) of this section, and the rewards and incentives information is made available to CMS upon request. Use is defined as logging into the RTBT, via portal or computer application, or calling the customer service call center to obtain the information described in paragraph (d)(4) of this section. The rewards and incentives must meet the following:

(i) Be of nominal value, both individually and in the aggregate.

(ii) Be offered to enrollees for no more than one login per month.

(iii) Be designed so that all enrollees are eligible to earn rewards and incentives, and that there is no discrimination based on race, national origin, gender, disability, chronic disease, health status, or basis prohibited by any applicable law.

(iv) Not be offered in the form of cash or other cash equivalents.

(v) Not be used to target potential enrollees.

(vi) Be earned solely for logging onto the beneficiary RTBT and not for any other purpose.

(vii) Otherwise comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil money penalty prohibiting inducements to beneficiaries.

* * * * *

■ 69. Section 423.153 is amended—

■ a. By revising the section heading;

■ b. In paragraph (a) by removing the phrase ''A Part D plan sponsor may establish a drug management'' and adding in its place the phrase ''No later than January 1, 2022, a Part D plan sponsor must have established a drug management'';

■ c. By adding paragraphs (d)(1)(vii)(E) and (F);

■ d. By revising paragraph (d)(2);

■ e. In paragraph (f)(3)(ii) introductory text by removing the phrase ''paragraphs (f)(10) and (11) of this section'' and adding in its place the phrase ''paragraphs (f)(9) through (13) of this section'';

■ f. In paragraph (f)(4)(ii)(A) by:

■ i. Removing the phrase ''paragraph (f)(2)(ii)(B) of this section'' and adding in its place the phrase ''paragraph (f)(3)(ii)(A) of this section'';

■ ii. Removing the phrase ''paragraph (f)(4)(i)(B) of this section'' and adding in its place the phrase ''paragraph (f)(2)(i)(B) of this section'';

■ g. Revising paragraphs (f)(5)(ii)(C)(*3*), (f)(6)(ii)(C)(*4*), and (f)(8)(i);

■ h. In paragraph (f)(15)(ii)(C) by removing the phrase ''any potential at-risk beneficiary'' and adding in its place the phrase ''any potential at-risk beneficiary or at-risk beneficiary''; and

■ i. By revising the heading of paragraph (g).

The revisions and additions read as follows:

§ 423.153 Drug utilization management, quality assurance, medication therapy management programs (MTMPs), and access to Medicare Parts A and B claims data extracts.

* * * * *

(d) * * *

(1) * * *

(vii) * * *

(E) For enrollees targeted in paragraph (d)(2) of this section, provide at least annually as part of the comprehensive medication review, a targeted medication review, or another follow up service, information about safe disposal of prescription drugs that are controlled substances, drug take back programs, in-home disposal and cost-effective means to safely dispose of such drugs.

(F) The information to be provided under paragraph (d)(1)(vii)(E) of this

section must comply with all requirements of § 422.111(j) of this chapter.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the MTMP described in paragraph (d)(1) of this section are enrollees in the sponsor's Part D plan who meet the characteristics of at least one of the following two groups:

(i)(A) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment;

(B) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment; and

(C) Are likely to incur the following annual Part D drug costs:

(*1*) For 2011, costs for covered Part D drugs greater than or equal to $3,000.

(*2*) For 2012 and subsequent years, costs for covered Part D drugs in an amount greater than or equal to $3,000 increased by the annual percentage specified in § 423.104(d)(5)(iv); or

(ii) Beginning January 1, 2021, are at-risk beneficiaries as defined in § 423.100.

* * * * *

(f) * * *

(5) * * *

(ii) * * *

(C) * * *

(*3*) An explanation of the beneficiary's right to a redetermination if the sponsor issues a determination that the beneficiary is an at-risk beneficiary and the standard and expedited redetermination processes described at §§ 423.582 and 423.584, including notice that if on redetermination the plan sponsor affirms its denial, in whole or in part, the case must be automatically forwarded to the independent review entity contracted with CMS for review and resolution.

(6) * * *

(ii) * * *

(C) * * *

(*4*) An explanation of the beneficiary's right to a redetermination under § 423.580, including all of the following:

(*i*) A description of both the standard and expedited redetermination processes.

(*ii*) The beneficiary's right to, and conditions for, obtaining an expedited redetermination.

(*iii*) Notice that if on redetermination the plan sponsor affirms its denial, in whole or in part, the case must be automatically forwarded to the independent review entity contracted with CMS for review and resolution.

* * * * *

(8) * * *

(i) Subject to paragraph (f)(8)(ii) of this section, a Part D sponsor must provide the second notice described in paragraph (f)(6) of this section or the alternate second notice described in paragraph (f)(7) of this section, as applicable, on a date that is not less than 30 days after the date of the initial notice described in paragraph (f)(5) of this section and not more than the earlier of the following two dates:

(A) The date the sponsor makes the relevant determination.

(B) Sixty days after the date of the initial notice described in paragraph (f)(5) of this section.

* * * * *

(g) *Prescription drug plan sponsors' access to Medicare Parts A and B claims data extracts*—* * *

* * * * *

■ 70. Section 423.182 is amended—

■ a. In paragraph (a) by adding a definition for ''Tukey outer fence outliers'' in alphabetical order; and

■ b. By revising paragraphs (b)(3)(ii)(A) and (B).

The additions and revisions read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) * * *

Tukey outer fence outliers are measure scores that are below a certain point (first quartile − 3.0 × (third quartile × first quartile)) or above a certain point (third quartile + 3.0 × (third quartile − first quartile)).

(b) * * *

(3) * * *

(ii) * * *

(A)(*1*) For the first year after consolidation, CMS uses enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except survey-based measures and call center measures. The survey-based measures would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. The call center measures would use average enrollment during the study period.

(*2*) For contract consolidations approved on or after January 1, 2021, if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

(B)(*1*) For the second year after consolidation, CMS uses the enrollment-weighted measure scores using the July enrollment of the measurement year of the consumed and surviving contracts for all measures except those from CAHPS. CMS ensures that the CAHPS survey sample includes enrollees in the sample frame from both the surviving and consumed contracts.

(*2*) For contract consolidations approved on or after January 1, 2021, for all measures except CAHPS if a measure score for a consumed or surviving contract is missing due to a data integrity issue as described in § 423.184(g)(1)(i) and (ii), CMS assigns a score of zero for the missing measure score in the calculation of the enrollment-weighted measure score.

* * * * *

■ 71. Section 423.184 is amended by revising paragraph (g)(1)(ii)(A) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(g) * * *

(1) * * *

(ii) * * *

(A)(*1*) The data submitted for the Timeliness Monitoring Project (TMP) or audit that aligns with the Star Ratings year measurement period is used to determine the scaled reduction.

(*2*) For contract consolidations approved on or after January 1, 2021, if there is a contract consolidation as described at § 423.182(b)(3), the TMP or audit data are combined for the consumed and surviving contracts before the methodology, as provided in paragraphs (g)(1)(ii)(B) through (M) of this section, is applied.

* * * * *

■ 72. Section 423.186 is amended—

■ a. By revising paragraph (a)(2)(i);

■ b. In paragraphs (e)(1)(iii) and (iv) by removing the phrase ''weight of 2'' and adding in its place ''weight of 4''; and

■ c. By adding a sentence to the end of paragraph (i)(6).

The revision and additions read as follows:

§ 423.186 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data, and a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. Prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute

percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

(i) * * *

(6) * * * Missing data includes data where there is a data integrity issue as defined at § 423.184(g)(1).

* * * * *

■ 73. Section 423.265 is amended by revising paragraph (b)(2) to read as follows:

§ 423.265 Submission of bids and related information.

* * * * *

(b) * * *

(2) *Limit on number of plan offerings.* Potential Part D sponsors' bid submissions may include no more than three stand-alone prescription drug plan offerings in a service area and must include only one basic prescription drug plan offering.

* * * * *

■ 74. Section 423.286 is amended by revising paragraph (d)(4)(ii) to read as follows:

§ 423.286 Rules regarding premiums.

* * * * *

(d) * * *

(4) * * *

(ii) *Calculating the income-related monthly adjustment amount.* The income-related monthly adjustment is equal to the product of the standard base beneficiary premium, as determined under paragraph (c) of this section, and the ratio of the applicable premium percentage specified in 20 CFR 418.2120, reduced by 25.5 percent; divided by 25.5 percent (that is, premium percentage − 25.5 percent)/ 25.5 percent).

* * * * *

■ 75. Section 423.329 is amended by revising paragraph (b)(4) to read as follows:

§ 423.329 Determination of payments.

* * * * *

(b) * * *

(4) *Publication.* CMS publishes the risk adjustment factors established under paragraph (b)(1) of this section for the upcoming calendar year in the Advance Notice and Rate Announcement publications specified under § 422.312 of this chapter.

* * * * *

■ 76. Section 423.502 is amended by adding paragraphs (b)(1)(i) and (ii) to read as follows:

§ 423.502 Application requirements.

* * * * *

(b) * * *

(1) * * *

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant does any of the following:

(A) Was subject to the imposition of an intermediate sanction or civil money penalty under to subpart O of this part.

(B) Failed to maintain a Part D summary rating score of at least three stars consistent with § 423.505(b)(26).

(C) Failed to maintain a fiscally sound operation consistent with the requirements of § 423.505(b)(23).

(ii) CMS may deny an application submitted by an organization that does not hold a Part D contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section.

* * * * *

■ 77. Section 423.503 is amended by revising paragraph (a)(3) to read as follows:

§ 423.503 Evaluation and determination procedures for applications to be determined qualified to act as a sponsor.

(a) * * *

(3) CMS does not approve an application when it would result in the applicant's parent organization, directly or through its subsidiaries, holding more than one PDP sponsor contract in the PDP Region for which the applicant is seeking qualification as a PDP sponsor.

* * * * *

■ 78. Section 423.504 is amended by adding paragraphs (b)(4)(vi)(G)(*4*) through (*7*) to read as follows:

§ 423.504 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(G) * * *

(*4*) The Part D plan sponsor must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(*4*) through (*6*) of this section:

(*i*) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act.

(*ii*) Any information related to the inappropriate prescribing of opioids and concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan.

(*5*) The Part D plan sponsor must submit the data elements, as specified in this section, in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan sponsor; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data elements, as applicable, are as follows:

(*i*) Date of Referral.

(*ii*) Part C or Part D Issue.

(*iii*) Complainant Name.

(*iv*) Complainant Phone.

(*v*) Complainant Fax.

(*vi*) Complainant Email.

(*vii*) Complainant Organization Name.

(*viii*) Complainant Address.

(*ix*) Complainant City.

(*x*) Complainant State.

(*xi*) Complainant Zip.

(*xii*) Plan Name/Contract Number.

(*xiii*) Plan Tracking Number.

(*xiv*) Parent Organization.

(*xv*) Pharmacy Benefit Manager.

(*xvi*) Beneficiary Name.

(*xvii*) Beneficiary Phone.

(*xviii*) Beneficiary Health Insurance Claim Number (HICN).

(*xix*) Beneficiary Medicare Beneficiary Identifier (MBI).

(*xx*) Beneficiary Address.

(*xxi*) Beneficiary City.

(*xxii*) Beneficiary State.

(*xxiii*) Beneficiary Zip.

(*xxiv*) Beneficiary Date of Birth (DOB).

(*xxv*) Beneficiary Primary language.

(*xxvi*) Beneficiary requires Special Accommodations. If Yes, Describe.

(*xxvii*) Beneficiary Medicare Plan Name.

(*xxviii*) Beneficiary Member ID Number.

(*xxix*) Whether the Beneficiary is a Subject.

(*xxx*) Did the complainant contact the beneficiary. If Yes, is there a Report of the Contact?

(*xxxi*) Subject Name.
(*xxxii*) Subject Tax Identification Number (TIN).
(*xxxiii*) Does the Subject have Multiple TIN's. If Yes, provide.
(*xxxiv*) Subject NPI.
(*xxxv*) Subject DEA Number.
(*xxxvi*) Subject Medicare Provider Number.
(*xxxvii*) Subject Business.
(*xxxviii*) Subject Phone Number.
(*xxxix*) Subject Address.
(*xl*) Subject City.
(*xli*) Subject State.
(*xlii*) Subject Zip.
(*xliii*) Subject Business or Specialty Description.
(*xliv*) Secondary Subject Name.
(*xlv*) Secondary Subject Tax Identification Number (TIN)
(*xlvi*) Does the Secondary Subject have Multiple TIN's. If Yes, provide.
(*xlvii*) Secondary Subject NPI.
(*xlviii*) Secondary Subject DEA Number.
(*xlix*) Secondary Subject Medicare Provider Number.
(*l*) Secondary Subject Business.
(*li*) Secondary Subject Phone Number.
(*lii*) Secondary Subject Address.
(*liii*) Secondary Subject City.
(*liv*) Secondary Subject State.
(*lv*) Secondary Subject Zip.
(*lvi*) Secondary Subject Business or Specialty Description.
(*lvii*) Complaint Prior MEDIC Case Number.
(*lviii*) Period of Review.
(*lix*) Complaint Potential Medicare Exposure.
(*lx*) Whether Medical Records are Available.
(*lxi*) Whether Medical Records were Reviewed.
(*lxii*) Whether the submission has been Referred to Law Enforcement. Submission Accepted? If so, provide Date Accepted.
(*lxiii*) What Law Enforcement Agency(ies) has it been Referred to.
(*lxiv*) Whether HPMS Analytics and Investigations Collaboration Environment for Fraud, Waste, and Abuse (AICE–FWA) was Used.
(*lxv*) Whether the submission has indicated Patient Harm or Potential Patient Harm.
(*lxvi*) Whether the submission has been Referred. If so, provide Date Accepted.
(*lxvii*) What Agency was it Referred to.
(*lxviii*) Description of Allegations/Plan Sponsor Findings.

(*6*)(*i*) The plan sponsor is required to notify the Secretary, or its designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*4*) of this section 14 days prior to implementation of the payment suspension.

(*ii*) The plan sponsor is required to submit the information described in paragraph (b)(4)(vi)(G)(*4*)(*ii*) of this section no later than January 15, April 15, July 15, and October 15 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. For the first reporting period (January 15, 2021), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31).

(*7*)(*i*) CMS provides plan sponsors with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*4*)(*i*) and (*ii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(*ii*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*iii*) Are anonymized information submitted by plans without identifying the source of such information.

(*iv*) For the first quarterly report (April 15, 2021), that the report reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 15, 2021.

* * * * *

■ 79. Section 423.505 is amended by revising paragraph (b)(22) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(22) Through the CMS complaint tracking system, address and resolve complaints received by CMS against the MA organization.

* * * * *

■ 80. Section 423.514 is amended by redesignating paragraph (a)(5) as paragraph (a)(6) and adding a new paragraph (a)(5) to read as follows:

§ 423.514 Validation of Part D reporting requirements.

(a) * * *

(5) Pharmacy performance measures.

* * * * *

■ 81. Section 423.560 is amended by—
■ a. Removing the definition of ''Appointed representative'';
■ b. Adding the definition of ''Representative'' in alphabetical order; and
■ c. Revising the definition of ''Specialty tier''.

The addition and revision read as follows:

§ 423.560 Definitions.

* * * * *

Representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the representative has all of the rights and responsibilities of an enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M, of this chapter.

Specialty tier has the meaning given the term in § 423.104.

■ 82. Section 423.566 is amended by revising paragraph (c)(2) to read as follows:

§ 423.566 Coverage determinations.

* * * * *

(c) * * *

(2) The enrollee's representative, on behalf of the enrollee; or

* * * * *

■ 83. Section 423.568 is amended by adding paragraphs (i) through (m) to read as follows:

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

* * * * *

(i) *Dismissing a request.* The Part D plan sponsor may dismiss a coverage determination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the individual making the request is not permitted to request a coverage determination under § 423.566(c).

(2) When the Part D plan sponsor determines the party failed to make out a valid request for a coverage determination that substantially complies with paragraph (a) of this section.

(3) When an enrollee or the enrollee's representative files a request for a coverage determination, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to pursue the request for coverage.

(4) When a party filing the coverage determination request submits a timely written request for withdrawal of the request for a coverage determination with the Part D plan sponsor.

(j) *Notice of dismissal.* The Part D plan must mail or otherwise transmit a written notice of the dismissal of the coverage determination request to the parties. The notice must state the all of the following:

(1) The reason for the dismissal.

(2) The right to request that the MA organization vacate the dismissal action.

(3) The right to request reconsideration of the dismissal.

(k) *Vacating a dismissal.* If good cause is established, the Part D plan sponsor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(l) *Effect of dismissal.* The Part D plan sponsor's dismissal is binding unless it is modified or reversed by the Part D plan sponsor or vacated under paragraph (k) of this section.

(m) *Withdrawing a request.* A party that requests a coverage determination may withdraw its request at any time before the decision is issued by filing a written request with the Part D plan sponsor.

■ 84. Section 423.570 is amended by adding paragraph (f) to read as follows:

§ 423.570 Expediting certain coverage determinations.

* * * * *

(f) *Dismissing a request.* The Part D plan sponsor may dismiss an expedited coverage determination in accordance with § 423.568.

■ 85. Section 423.578 is amended—

■ a. By revising paragraph (a)(6)(iii); and

■ b. In paragraph (b)(4) by removing the phrase ''the enrollee's appointed representative'' and adding in its place the phrase ''the enrollee's representative''.

The revision reads as follows:

§ 423.578 Exceptions process.

(a) * * *

(6) * * *

(iii) If a Part D plan sponsor maintains one or two specialty tiers, as defined in § 423.104, the Part D sponsor may design its exception process so that Part D drugs on the specialty tier(s) are not eligible for tiering exception(s) to non-specialty tiers.

* * * * *

■ 86. Section 423.582 is amended by adding paragraphs (e) through (h) to read as follows:

§ 423.582 Request for a standard redetermination.

* * * * *

(e) *Dismissing a request.* A Part D plan sponsor may dismiss a redetermination request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a redetermination is not a proper party under § 423.580.

(2) When the Part D plan sponsor determines the party failed to make out a valid request for redetermination that substantially complies with paragraph (a) of this section.

(3) When the party fails to file the redetermination request within the proper filing time frame in accordance with paragraph (b) of this section.

(4) When the enrollee or the enrollee's representative files a request for redetermination, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to pursue the request for coverage.

(5) When a party filing the redetermination request submits a timely written request for withdrawal of the request for a redetermination with the Part D plan sponsor.

(f) *Notice of dismissal.* The Part D plan sponsor must mail or otherwise transmit a written notice of the dismissal of the redetermination request to the parties. The notice must state all of the following:

(1) The reason for the dismissal.

(2) The right to request that the Part D plan sponsor vacate the dismissal action.

(3) The right to request review of the dismissal by the independent entity.

(g) *Vacating a dismissal.* If good cause is established, a Part D sponsor may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(h) *Effect of dismissal.* The dismissal of a request for redetermination is binding unless the enrollee or other party requests review by the IRE or the decision is vacated under paragraph (g) of this section.

■ 87. Section 423.584 is amended by adding paragraph (f) to read as follows:

§ 423.584 Expediting certain redeterminations.

* * * * *

(f) *Dismissing a request.* The Part D plan sponsor may dismiss an expedited redetermination in accordance with § 423.582.

■ 88. Section 423.590 is amended by adding paragraphs (i) and (j) to read as follows:

§ 423.590 Timeframes and responsibility for making redeterminations.

* * * * *

(i) *Automatic forwarding of redeterminations made under a drug management program.* If on redetermination the plan sponsor affirms, in whole or in part, its denial related to an at-risk determination under a drug management program in accordance with § 423.153(f), the Part D plan sponsor must forward the case to the IRE contracted with CMS by the expiration of the applicable adjudication timeframe under paragraph (a)(2), (b)(2), or (d)(1) of this section.

(j) *Requests for review of a dismissal by the independent entity.* If the Part D plan sponsor dismisses a request for a reconsideration in accordance with § 423.582(e) or § 423.584(f), the enrollee or other party has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity within 60 calendar days from the date of the Part D plan sponsor's dismissal notice.

■ 89. Section 423.600 is amended by—

■ a. Revising paragraph (b); and

■ b. Adding paragraphs (f) through (k).

The revision and additions read as follows:

§ 423.600 Reconsideration by an independent review entity (IRE).

* * * * *

(b) When an enrollee, or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee), files an appeal or a determination is forwarded to the IRE by a Part D plan sponsor, the IRE is required to solicit the views of the prescribing physician or other prescriber.

(1) The IRE may solicit the views of the prescribing physician or other prescriber orally or in writing.

(2) A written account of the prescribing physician's or other prescriber's views (prepared by either the prescribing physician, other prescriber, or IRE, as appropriate) must be contained in the IRE record.

* * * * *

(f) The party who files a request for reconsideration may withdraw it by filing a written request with the IRE.

(g) The independent entity may dismiss a reconsideration request, either entirely or as to any stated issue, under any of the following circumstances:

(1) When the person or entity requesting a reconsideration is not a proper party under paragraph (a) of this section.

(2) When the IRE determines the party failed to make out a valid request for reconsideration that substantially complies with paragraph (a) of this section.

(3) When the party fails to file the reconsideration request within the

proper filing time frame in accordance with paragraph (a) of this section.

(4) When an enrollee or the enrollee's representative files a request for reconsideration, but the enrollee dies while the request is pending, and both of the following criteria apply:

(i) The enrollee's surviving spouse or estate has no remaining financial interest in the case.

(ii) The enrollee's representative, if any, does not wish to continue the appeal.

(5) When a party filing the reconsideration request submits a timely written request for withdrawal of the request for a reconsideration with the IRE.

(h) The IRE mails or otherwise transmits a written notice of the dismissal of the reconsideration request to the parties. The notice must state the all of the following:

(1) The reason for the dismissal.

(2) That there is a right to request that the IRE vacate the dismissal action.

(3) The right to a review of the dismissal in accordance with § 423.2004.

(i) If good cause is established, the IRE may vacate its dismissal of a request for redetermination within 6 months from the date of the notice of dismissal.

(j) An enrollee has a right to have an IRE's dismissal reconsidered in accordance with § 423.2004.

(k) If the IRE determines that the Part D plan sponsor's dismissal was in error, the IRE vacates the dismissal and remands the case to the Part D plan sponsor for reconsideration. The IRE's decision regarding an Part D plan sponsor's dismissal, including a decision to deny a request for review of a dismissal, is binding and not subject to further review.

■ 90. Section 423.760 is amended by—

■ a. Redesignating paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5); and

■ b. Adding a new paragraph (b)(3).

The addition reads as follows:

§ 423.760 Determinations regarding the amount of civil money penalties and assessments imposed by CMS.

* * * * *

(b) * * *

(3) CMS calculates the minimum penalty amounts under paragraphs (b)(1) and (2) of this section using the following criteria:

(i) *Definitions for calculating penalty amounts*—(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(E) *Cost-of-living multiplier.* The percent change between each year's published October consumer price index for all urban consumers (United States city average), which is released by the Office of Management and Budget (OMB) annually.

(ii) *Calculation of penalty amounts.* (A) Per determination and per enrollee penalty amounts are increased by multiplying the current standard minimum penalty and aggravating factor amounts by the cost-of-living multiplier.

(B) The minimum penalty and aggravating factor amounts will be updated no more often than every 3 years.

(C) CMS tracks the calculation and accrual of the standard minimum penalty and aggravating factor amounts and announce them on an annual basis.

* * * * *

■ 91. Section 423.2006 is amended by redesignating paragraphs (c)(1) and (2) as paragraphs (c)(2) and (3) and adding a new paragraph (c)(1) to read as follows:

§ 423.2006 Amount in controversy required for an ALJ hearing and judicial review.

* * * * *

(c) * * *

(1) The amount remaining in controversy is computed as the projected value described in paragraph (c)(2) or (3) of this section, reduced by any cost sharing amounts, including deductible, coinsurance, or copayment amounts that may be collected from the enrollee for the Part D drug(s).

* * * * *

§ 423.2014 [Amended]

■ 92. Section 423.2014 is amended in paragraph (a)(1)(ii) by removing the phrase ''appointed representative'' and adding in its place the phrase ''representative''.

§ 423.2036 [Amended]

■ 93. Section 423.2036 is amended in paragraphs (c) and (d) by removing the phrase ''appointed representative'' and adding in its place the phrase ''representative'' each time it appears.

■ 94. Section 423.2260 is revised to read as follows:

§ 423.2260 Definitions.

The definitions in this section apply for this subpart unless the context indicates otherwise.

Advertisement (Ad) means a read, written, visual, oral, watched, or heard call to attention. Advertisements can be considered communication or marketing based on the intent and content of the message.

Alternate format means used to convey information to individuals with visual, speech, physical, hearing, and intellectual disabilities (for example, braille, large print, audio).

Banner means a type of advertisement feature typically used in television ads that is intended to be brief, and flashes limited information across a screen for the sole purpose of enticing a prospective enrollee to contact the MA plan (for example, obtain more information) or to alert the viewer that information is forthcoming.

Banner-like advertisement is an advertisement that uses a banner-like feature, that is typically found in some media other than television (for example, outdoors and on the internet).

Communications means activities and use of materials created or administered by the Part D sponsor or any downstream entity to provide information to current and prospective enrollees. Marketing is a subset of communications.

Marketing means communications materials and activities that meet both the following standards for intent and content:

(1) Intended to do any of the following:

(i) Draw a beneficiary's attention to a Part D plan or plans.

(ii) Influence a beneficiary's decision making process when making a Part D plan selection.

(iii) Influence a beneficiary's decision to stay enrolled in a Part D plan (that is, retention-based marketing).

(2) Include or address content regarding any of the following:

(i) The plan's benefits, benefits structure, premiums or cost sharing.

(ii) Measuring or ranking standards (for example, star ratings or plan comparisons).

(3) In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, and timing and other context of the activity or material and is not limited to the MA organization's stated intent.

Outdoor advertising (ODA) means outdoor material intended to capture the

attention of a passing audience (for example, billboards, signs attached to transportation vehicles). ODA may be a communication or marketing material.

■ 95. Section 423.2261 is added to read as follows:

§ 423.2261 Submission, review, and distribution of materials.

(a) *General requirements.* MA organizations must submit all marketing materials, all election forms, and certain designated communications materials for CMS review.

(1) The Health Plan Management System (HPMS) is the primary system of record for the collection, review, and storage of materials that must be submitted for review.

(2) Materials must be submitted to the HPMS Marketing Module directly by the Part D sponsor. Third party and downstream entities are not permitted to submit materials directly to CMS.

(b) *CMS review of marketing materials and election forms.* Except as provided in paragraph (b) of this section, a Part D sponsor may not distribute or otherwise make available any marketing materials (as defined in § 423.2260) or election forms unless one of the following occurs:

(1) CMS has reviewed and approved the material.

(2) The material has been deemed approved; that is, CMS has not rendered a disposition for the material within 45 days (or 10 days if using CMS model or standardized marketing materials as outlined in § 422.2267(e) of this chapter) of submission to CMS. Materials that have been deemed may be used by the Part D sponsor.

(3) The material has been accepted under Files and Use, as follows:

(i) The MA organization may distribute certain types of marketing materials, designated by CMS based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary, 5 days following the submission.

(ii) The Part D sponsor must certify that the material meets all applicable CMS communications and marketing requirements in §§ 423.2260 through 423.2267.

(c) *CMS review of communications materials.* CMS does not generally require submission and approval of communications materials prior to use, with the exception of certain designated communications that are critical to the beneficiary understanding or accessing their benefits (for example, the Evidence of Coverage (EOC)).

(d) *Standards for CMS review.* CMS reviews materials to ensure the following:

(1) Compliance with all applicable requirements under §§ 423.2260 through 423.2267.

(2) Benefit and cost information is an accurate reflection of what is contained in the Part D sponsor's bid.

(3) CMS may determine, upon review of such materials, that the materials must be modified, or may no longer be used.

■ 96. Section 423.2262 is revised to read as follows:

§ 423.2262 General communications materials and activity requirements.

Part D sponsors may not mislead, confuse, or provide inaccurate information to current or potential enrollees.

(a) *General rules.* Part D sponsors must ensure their statements and the terminology used in communications activities and materials adhere to the following requirements:

(1) Part D sponsors may not do any of the following:

(i) Provide information that is inaccurate or misleading.

(ii) Make unsubstantiated statements, including superlatives or pejoratives.

(iii) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor.

(iv) Engage in any discriminatory activity such as attempting to recruit Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas, or vice versa.

(v) Target potential enrollees based on higher or lower income levels.

(vi) Target potential enrollees based on health status.

(vii) State or imply plans are only available to seniors rather than to all Medicare beneficiaries.

(viii) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(ix) Display the names or logos or both of co-branded network pharmacies on the sponsor's member identification card, unless the pharmacy names or logos or both are related to the member selection of specific pharmacies.

(x) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name, for example, ''Super Medicare Drug Plan (PDP)''.

(xi) Claim they are recommended or endorsed by CMS, Medicare, or the HHS.

(xii) Convey that a failure to pay premium will not result in disenrollment.

(xiii) Use the term ''free'' to describe a $0 premium, any type of reduction in premium, reduction in deductibles or cost sharing, low-income subsidy, or cost sharing for dual eligible individuals.

(xiv) State or imply a plan is available only to or is designed for Medicaid beneficiaries.

(xv) Market a Part D plan not designed to serve dual eligible beneficiaries as if it were a plan designed to serve dual eligible beneficiaries.

(xvi) Target marketing efforts primarily to dual eligible individuals.

(xvii) Claim a relationship with the state Medicaid agency, unless a contract to coordinate Medicaid services for that plan is in place.

(2) Part D sponsors may do the following:

(i) State that the Part D sponsor is approved to participate in Medicare programs or is contracted to administer Medicare benefits or both.

(ii) Use the term ''Medicare-approved'' to describe benefits or services in materials or both.

(b) *Product endorsements and testimonials.* (1) Product endorsements and testimonials may take any of the following forms:

(i) Television or video ads.

(ii) Radio ads.

(iii) Print ads.

(iv) Social media ads. In cases of social media, the use of a previous post, whether or not associated with or originated by the Part D sponsor, is considered a product endorsement or testimonial.

(v) Other types of ads.

(2) Part D sponsors may use individuals to endorse the Part D sponsor's product provided the endorsement or testimonial adheres to the following requirements:

(i) The speaker must identify the Part D sponsor's product or company by name.

(ii) Medicare beneficiaries endorsing or promoting the Part D sponsor must have been an enrollee at the time the endorsement or testimonial was created.

(iii) The endorsement or testimonial must clearly state that the individual was paid for the endorsement or testimonial, if applicable.

(iv) If an individual is used (for example, an actor) to portray a real or fictitious situation, the advertisement must state that it is an actor portrayal.

(c) *Requirements when including certain telephone numbers in materials.* (1) Part D sponsors must adhere to the following requirements for including certain telephone numbers in materials:

(i) When a Part D sponsor includes its customer service number, the hours of operation must be included the first time (at a minimum) the number appears.

(ii) When a Part D sponsor includes its customer service number, it must provide a toll-free TTY number in conjunction with the customer service number in the same font size.

(iii) On every material where 1–800–MEDICARE or Medicare TTY appears, the Part D sponsor must include the hours and days of operation for 1–800–MEDICARE (that is, 24 hours a day/7 days a week).

(2) The following advertisement types are exempt from these requirements:

(i) Outdoor advertising.

(ii) Banners or banner-like ads.

(iii) Radio advertisements and sponsorships.

(d) *Standardized material identification (SMID).* (1) Part D sponsors must use a standardized method of identification for oversight and tracking of materials beneficiaries receive.

(2) The SMID consists of the following three parts:

(i) The Part D sponsor's contract or Multi-Contract Entity (MCE) number, (that is, ''S'' for PDPs, or ''Y'' for MCE identifier) followed by an underscore, except that the SMID for multi-plan marketing materials must begin with the word ''MULTI–PLAN'' instead of the Part D sponsor's contract number (for example, S1234_abc123_C or MULTI–PLAN_efg456_M).

(ii) A series of alpha numeric characters (at the Part D sponsor's discretion) unique to the material followed by an underscore.

(iii) An uppercase ''C'' for communication materials or an uppercase ''M'' for marketing materials (for example, S1234_abc123_C or S5678_efg456_M).

(3) The SMID is required on all materials except the following:

(i) Membership ID card.

(ii) Envelopes, radio ads, outdoor advertisements, banners, banner-like ads, and social media comments and posts.

(iii) OMB-approved forms/documents, except those materials included in § 423.2267.

(iv) Corporate notices or forms (that is, not Part D-specific) meeting the definition of communications such as privacy notices and authorization to disclose protected health information (PHI).

(v) Agent-developed communications materials that are not marketing.

(4) Non-English and alternate format materials, based on previously created materials, may have the same SMID as the material on which they are based.

■ 97. Section 423.2263 is added to read as follows.

§ 423.2263 General marketing requirements.

Marketing is a subset of communications and therefore must follow the requirements outlined in § 423.2262 as well as this section. Marketing (as defined in § 423.2260) must additionally meet the following requirements:

(a) Part D sponsors may begin marketing prospective plan year offerings on October 1 of each year for the following contract year. Part D sponsors may market the current and prospective year simultaneously provided materials clearly indicate what year is being discussed.

(b) In marketing, Part D sponsors may not do any of the following:

(1) Provide cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Offer gifts to potential enrollees, unless the gifts are of nominal value (as governed by guidance published by the Department of Health and Human Services Office of Inspector General (HHS OIG)), are offered to all potential enrollees without regard to whether or not the beneficiary enrolls, and are not in the form of cash or other monetary rebates.

(3) Provide meals to potential enrollees regardless of value.

(4) Market non-health care related products to prospective enrollees during any Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(5) Compare their plan to other plans, unless the information is accurate, not misleading, and can be supported by the Part D sponsor making the comparison.

(6) Display the names or logos or both of pharmacy co-branding partners on marketing materials, unless the materials clearly indicate via a disclaimer or in the body that ''Other pharmacies are available in the network.''

(7) Knowingly target or send unsolicited marketing materials to any Part D enrollee during the Open Enrollment Period (OEP).

(i) During the OEP, Plans/Part D sponsors may do any of the following:

(A) Conduct marketing activities that focus on other enrollment opportunities, including but not limited to marketing to age-ins (who have not yet made an enrollment decision), marketing by 5-star plans regarding their continuous enrollment special election period (SEP), and marketing to dual-eligible and LIS beneficiaries who, in general, may make changes once per calendar quarter during the first nine months of the year.

(B) Send marketing materials when a beneficiary makes a proactive request;

(C) At the beneficiary's request, have one-on-one meetings with a sales agent; and

(D) At the beneficiary's request, provide information on the OEP through the call center.

(ii) During the OEP, Plans/Part D sponsors may not:

(A) Send unsolicited materials advertising the ability/opportunity to make an additional enrollment change or referencing the OEP;

(B) Specifically target beneficiaries who are in the OEP because they made a choice during Annual Enrollment Period (AEP) by purchase of mailing lists or other means of identification;

(C) Engage in or promote agent/broker activities that intend to target the OEP as an opportunity to make further sales; or

(D) Call or otherwise contact former enrollees who have selected a new plan during the AEP.

(c) The following requirements apply to how Part D sponsors must display CMS issued Star Ratings:

(1) References to individual Star Rating measure(s) must also include references to the contract's overall Star Rating.

(2) May not use an individual underlying category or measure to imply overall high Star Ratings.

(3) Must be clear that the rating is out of 5 stars.

(4) Must clearly identify the Star Rating contract year.

(5) May only market the Star Ratings in the service area in which the Star Rating is applicable.

(6) The following requirements apply to all 5 Star PDP contracts:

(i) May not market the 5 star special enrollment period, as defined in § 423.38(c)(20), after November 30 of each year if the contract has not received an overall 5 star for the next contract year.

(ii) May use CMS' 5 star icon or may create their own icon.

(7) The following requirements apply to all Low Performing MA contracts:

(i) The Low Performing Icon must be included on all materials about or referencing the specific contract's Star Ratings.

(ii) Must state the Low Performing Icon means that the Part D sponsor's contract received a summary rating of 2.5 stars or below in Part D for the last 3 years.

(iii) May not attempt to refute or minimize Low Performing Status.

■ 98. Section 423.2264 is revised to read as follows:

§ 423.2264 Beneficiary contact.

For the purpose of this section, beneficiary contact applies to all outreach activities to a beneficiary or their caregivers by the Part D sponsor or its agents and brokers.

(a) *Unsolicited contact.* Subject to the rules for contact for plan business in paragraph (b) of this section, the following rules apply when materials or activities are given or supplied to a beneficiary or their caregiver without prior request:

(1) Part D sponsors may make unsolicited direct contact by conventional mail and other print media (for example, advertisements and direct mail) or email (provided every email contains an opt-out option).

(2) Part D sponsors may not do any of the following:

(i) Use door to door solicitation, including leaving information of any kind, except that information may be left when an appointment is pre-scheduled but the beneficiary is not home.

(ii) Approach enrollees in common areas such as parking lots, hallways, lobbies.

(iii) Send unsolicited direct messages from social media platforms.

(iv) Use telephone solicitation (that is, cold calling), text messages, or voicemail messages, including, but not limited to the following:

(A) Unsolicited calls based on referrals.

(B) Calls to former enrollees who have disenrolled or those in the process of disenrolling, except to conduct disenrollment surveys for quality improvement purposes.

(C) Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission to be contacted.

(D) Unsolicited calls to prospective enrollees to confirm receipt of mailed information.

(3) Calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. For example, returning phone calls or calling an individual who has completed a business reply card requesting contact is not considered unsolicited.

(4) Part D sponsors are responsible to ensure sales staff, including agents and brokers, abide by Federal and state laws related to consumer protection, including but not limited to do not call list requirements.

(b) *Contact for plan business.* Part D sponsors may contact current, and to a more limited extent, former members, including those enrolled in other products offered by the parent organization, to discuss plan business, in accordance with the following requirements:

(1) A Part D sponsor may conduct the following activities as plan business:

(i) Call current enrollees, including those in non-Medicare products, to discuss Medicare products. Examples of such calls include, but are not limited to the following:

(A) Enrollees aging into Medicare from commercial products.

(B) Existing enrollees, including Medicaid enrollees, to discuss other Medicare products or plan benefits.

(C) Members in an MA or cost plan to discuss other Medicare products.

(ii) Call beneficiaries who submit enrollment applications to conduct business related to enrollment.

(iii) With prior CMS approval, call LIS enrollees that a plan is prospectively losing to due reassignment. CMS decisions to approve calls are for limited circumstances based on the following:

(A) The proximity of cost of the losing plan as compared to the national benchmark, and

(B) The selection of plans in the service area that are below the benchmark.

(iv) Agents/brokers calling clients who are enrolled in other products they may sell, such as automotive or home insurance.

(v) Part D sponsors may not make unsolicited calls about other lines of business as a means of generating leads for Medicare plans.

(2) [Reserved]

(c) *Events with beneficiaries.* Part D sponsors and their agent/brokers may hold educational events, marketing or sales events, and personal marketing appointments to meet with Medicare beneficiaries, either face-to-face or virtually. The requirements for each type of event are as follows:

(1) Educational events must be advertised as such and be designed to generally inform beneficiaries about Medicare, including Medicare Advantage, Prescription Drug programs, or any other Medicare program.

(i) At educational events, Part D sponsors and agents/brokers may not market specific Part D sponsors or benefits.

(ii) Part D sponsors holding or participating in educational events may do any of the following:

(A) Distribute communication materials.

(B) Answer beneficiary initiated questions pertaining to Part D sponsors.

(C) Set up future personal marketing appointments.

(D) Distribute business cards.

(E) Obtain beneficiary contact information, including Scope of Appointment forms.

(iii) Part D sponsors holding or participating in educational events may not conduct sales or marketing presentations or distribute or accept plan applications.

(2) Marketing or sales events are group events that fall within the definition of marketing at § 423.2260.

(i) If a marketing event directly follows an educational event, the Part D sponsor or agent/broker must provide an opportunity for beneficiaries to determine if they want to continue with the marketing event.

(ii) Part D sponsors holding or participating in marketing events may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Collect Scope of Appointment forms for future personal marketing appointments.

(D) Conduct marketing presentations.

(iii) Part D sponsors holding or participating in marketing events may not do any of the following:

(A) Require sign in sheets or require attendees to provide contact information as a prerequisite for attending an event.

(B) Conduct activities, including health screenings, health surveys, or other activities that are used for or could be viewed as being used to target a subset of members (that is ''cherry-picking'').

(C) Use information collected for raffles or drawings for any purpose other than raffles or drawings.

(3) Personal marketing appointments are those appointments that are tailored to an individual or small group (for example, a married couple). Personal marketing appointments are not defined by the location.

(i) Prior to the personal marketing appointment beginning, the Part D sponsor (or the agent/broker, as applicable) must agree upon and record the Scope of Appointment with the beneficiary(ies).

(ii) Part D sponsors holding a personal marketing appointment may do any of the following:

(A) Provide marketing materials.

(B) Distribute and accept plan applications.

(C) Conduct marketing presentations.

(D) Review the individual needs of the beneficiary including, but not limited to, health care needs and history, commonly used medications, and financial concerns.

(iii) Part D sponsors holding a personal marketing appointment may not do any of the following:

(A) Market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

(B) Market additional health related lines of plan business not identified prior to an individual appointment without a separate scope of appointment identifying the additional lines of business to be discussed.

(C) Market non-health related products such as annuities.

■ 99. Section 423.2265 is added to read as follows:

§ 423.2265 Websites.

As required under § 423.128(d)(2), Part D sponsors must have a website.

(a) *General website requirements.* (1) Part D sponsor websites must meet the all of the following requirements:

(i) Maintain current year contract content through December 31 of each year.

(ii) Notify users when they will leave the Part D sponsor's Medicare site.

(iii) Include or provide access to (for example, through a hyperlink) applicable disclaimers with corresponding content. Overarching disclaimers, such as the Federal Contracting Statement, are not required on every page.

(iv) Be updated to reflect the most current information within 30 days of any information on the website changing.

(v) Keep PDP content separate and distinct from other lines of business, including Medicare Supplemental Plans.

(2) Part D sponsor websites may not do any of the following:

(i) Require beneficiaries to enter any information other than zip code, county, or state for access to non-beneficiary-specific website content.

(ii) Provide links to foreign drug sales, including advertising links.

(iii) State that the Part D sponsor is not responsible for the content of their social media pages or the website of any first tier, downstream, or related entity that provides information on behalf of the Part D sponsor.

(b) *Required content.* A Part D sponsor's websites must include the following content:

(1) A toll-free customer service number, TTY number, and days and hours of operation.

(2) A physical or Post Office Box address.

(3) A PDF or copy of a printable pharmacy directory.

(4) A searchable pharmacy directory.

(5) A searchable formulary.

(6) Information on enrollees' and Part D sponsors' rights and responsibilities upon disenrollment. Part D sponsors may either post this information or provide specific information on where it is located in the Evidence of Coverage together with a link to that document.

(7) A description of and information on how to file a grievance, organizational determination, and appeal.

(8) Prominently display a link to the *Medicare.gov* electronic complaint.

(9) Privacy Notice under the HIPAA Privacy Rule (45 CFR part 160).

(10) Prescription Drug Transition Policy.

(11) LIS Premium Summary Chart.

(12) Prescription Drug Transition Policy.

(c) *Required posted materials.* A Part D sponsor's website must provide access to the following materials, in a printable format, within the timeframes noted in paragraphs (c)(1) and (2) of this section.

(1) The following documents for each plan year must be posted on the website by October 15 prior to the beginning of the plan year:

(i) Evidence of Coverage.

(ii) Annual Notice of Change (for renewing plans).

(iii) Summary of Benefits.

(iv) Pharmacy Directory.

(v) Formulary.

(vi) Utilization Management Forms for physicians and enrollees.

(2) The following documents must post on the website throughout the year and be updated as required:

(i) Prior Authorization Forms for Physicians and Enrollees.

(ii) Part D Model Coverage Determination and Redetermination Request Forms.

(iii) Exception request forms for physicians (which must be posted by January 1 for new plans).

(iv) CMS Star Ratings document, which must be posted within 21 days after its release on the Medicare Plan Finder.

■ 100. Section 423.2266 is added to read as follows:

§ 423.2266 Activities with healthcare providers or in the healthcare setting.

(a) *Where marketing is prohibited.* The requirements in paragraphs (c) through (e) of this section apply to activities in the health care setting. Marketing activities and materials are not permitted in areas where care is being administered, including but not limited to the following:

(1) Exam rooms.

(2) Hospital patient rooms.

(3) Treatment areas where patients interact with a provider and his/her clinical team and receive treatment (including dialysis treatment facilities).

(4) Pharmacy counter areas.

(b) *Where marketing is permitted.* Marketing activities and materials are permitted in common areas within the health care setting, including, not limited to, the following:

(1) Common entryways.

(2) Vestibules.

(3) Waiting rooms.

(4) Hospital or nursing home cafeterias.

(5) Community, recreational, or conference rooms.

(c) *Provider-initiated activities.* Provider-initiated activities are activities conducted by a provider at the request of the patient, or as a matter of a course of treatment, and occur when meeting with the patient as part of the professional relationship between the provider and patient. Provider-initiated activities do not include activities conducted at the request of the Part D sponsor or pursuant to the network participation agreement between the Part D sponsor and the provider. Provider-initiated activities that meet this definition fall outside of the definition of marketing in § 423.2260. Permissible provider-initiated activities include:

(1) Distributing unaltered, printed materials created by CMS, such as reports from Medicare Plan Finder, the ''Medicare & You'' handbook, or ''Medicare Options Compare'' (from *https://www.medicare.gov*) including in areas where care is delivered.

(2) Providing the names of Part D sponsors with which they contract.

(3) Answering questions or discussing the merits of a Part D plan or plans, including cost sharing and benefit information including in areas where care is delivered.

(4) Referring patients to other sources of information, such as State Health Insurance Assistance Program (SHIP) representatives, plan marketing representatives, State Medicaid Office, local Social Security Offices, CMS' website at *https://www.medicare.gov,* or 1–800–MEDICARE.

(5) Referring patients to Part D marketing materials available in common areas.

(6) Providing information and assistance in applying for the LIS.

(7) Announcing new or continuing affiliations with Part D sponsors, once a contractual agreement is signed. Announcements may be made through any means of distribution.

(d) *Plan-initiated provider activities.* Plan-initiated provider activities are those activities conducted by a provider at the request of a Part D sponsor.

During a plan-initiated provider activity, the provider is acting on behalf of the Part D sponsor. For the purpose of plan-initiated activities, the Part D sponsor is responsible for compliance with all applicable regulatory requirements.

(1) During plan-initiated provider activities, Part D sponsors must ensure that the provider does not:

(i) Accept/collect scope of appointment forms.

(ii) Accept Medicare enrollment applications.

(iii) Make phone calls or direct, urge, or attempt to persuade their patients to enroll in a specific plan based on financial or any other interests of the provider.

(iv) Mail marketing materials on behalf of a Part D sponsor.

(v) Offer inducements to persuade patients to enroll with a particular Part D sponsor.

(vi) Conduct health screenings as a marketing activity.

(vii) Distribute marketing materials or enrollment forms in areas where care is being delivered.

(viii) Offer anything of value to induce enrollees to select the provider.

(ix) Accept compensation from the Part D sponsor for any marketing or enrollment activities.

(2) During plan-initiated provider activities, the provider may do any of the following:

(i) Make available, distribute, and display communications materials, including in areas where care is being delivered.

(ii) Provide or make available marketing materials and enrollment forms in common areas.

(e) *Part D sponsor activities in the healthcare setting.* Part D sponsor activities in the health care setting are those activities, including marketing activities, that are conducted by Part D sponsor or any downstream entity, but not by a provider. All marketing must follow the requirements in paragraphs (a) and (b) of this section. However, during Part D sponsor activities, the following is permitted:

(1) Accepting and collect Scope of Appointment forms.

(2) Accepting enrollment forms.

(3) Making available, distributing, and displaying communications materials, including in areas where care is being delivered.

■ 101. Section 423.2267 is added to read as follows:

§ 423.2267 Required materials and content.

For information CMS deems to be vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form. Such materials and content are collectively referred to as required.

(a) *Standards for required materials and content.* All required materials and content, regardless of categorization as standardized in paragraph (b) of this section or model in paragraph (c) of this section, must meet the following:

(1) Be in a 12pt font (Times New Roman or equivalent).

(2) For markets with a significant non-English speaking population, be in the language of these individuals. Part D sponsors must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(3) Be provided to the beneficiary within CMS's specified timeframes.

(b) *Standardized materials.* Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

(1) When CMS issues standardized material or content, a Part D sponsor must use the document without alteration except for the following:

(i) Populating variable fields.

(ii) Correcting grammatical errors.

(iii) Adding customer service phone numbers.

(iv) Adding plan name, logo, or both.

(v) Deleting content that does not pertain to the plan type (for example, removing Part D language for a MA-only plan).

(vi) Adding the SMID.

(vii) Adding the Privacy Notice under the HIPAA Privacy Rule.

(2) When CMS issues standardized content, Part D sponsors—

(i) Must use the language provided without alteration.

(ii) May develop accompanying language for standardized material or content, provided it does not conflict with the standardized material or content. For example, CMS may issue standardized content associated with an appeal notification. Part D sponsors may draft a letter that includes the standardized content in the body of the letter. The remaining language in the letter is at the plan's discretion, provided it does not conflict with the standardized content.

(c) *Model materials.* Model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. When drafting required materials or content based on CMS models, MA organizations—

(1) Must accurately convey the vital information in the required material or content to the beneficiary, although the Part D sponsor is not required to use CMS model materials or content verbatim; and

(2) Must follow CMS's specified order of content, when specified.

(d) *Delivery of required materials.* Part D sponsor must mail required materials in hard copy or provide them electronically, following the requirements in paragraphs (d)(1) and (2) of this section.

(1) For hard copy mailed materials, each enrollee must receive his or her own copy, except in cases of non-beneficiary-specific material(s) where the Part D sponsor has determined multiple enrollees are living in the same household and it has reason to believe the enrollees are related. In that case, the Part D sponsor may mail one copy to the household. The Part D sponsor must provide all enrollees an opt-out process so the enrollees can each receive his or her own copy, instead of a copy to the household. Materials specific to an individual beneficiary must always be mailed to that individual.

(2) Materials may be delivered electronically following the requirements in paragraphs (d)(2)(i) and (ii) of this section.

(i) Without prior authorization, Part D sponsor may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: The Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The following requirements apply:

(A) The Part D sponsor may mail one notice for all materials or multiple notices.

(B) Notices for prospective year documents may not be mailed prior to September 1 of each year, but must be sent in time for an enrollee to access the specified documents by October 15 of each year.

(C) The Part D sponsor may send the notice throughout the year to new enrollees.

(D) The notice must include the website address to access the documents, the date the documents will be available if not currently available, and a phone number to request that hard copy documents be mailed.

(E) The notice must provide the enrollee with the option to request hardcopy materials. Requests may be materials specific, and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again.

(F) Hard copies of requested materials must be sent within three business days.

(ii) With prior authorization from the enrollee, the Part D sponsor may provide any required material or content electronically. To do so, the Part D sponsor must do all of the following:

(A) Obtain prior consent from the enrollee. The consent must specify both the media type and the specific materials being provided in that media type.

(B) Provide instructions on how and when enrollees can access the materials.

(C) Have a process through which an enrollee can request hard copies be mailed, providing the beneficiary with the option of a one-time request or a permanent request (which must stay in place until the enrollee chooses to receive electronic materials again), and with the option of requesting hard copies for all or a subset of materials. Hard copies must be mailed within 3 business days.

(D) Have a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable.

(e) *CMS required materials and content.* The following are required materials that must be provided to current and or perspective enrollees, as applicable, in the form and manor outlined in this section:

(1) *Evidence of Coverage (EOC).* The EOC is a standardized communications material through which certain required information (under § 423.128(b)) must be provided annually.

(i) Must be provided to current enrollees of plan by October 15 of each Year.

(ii) Must be provided to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(2) *Annual Notice of Change (ANOC).* The ANOC is a standardized marketing material through which plans must provide the information required under § 423.128(g)(2) annually.

(i) Must send for enrollee receipt no later than September 30 of each year.

(ii) Enrollees with an October 1, November 1, and December 1 effective date must receive within ten (10) calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(3) *Pre-Enrollment Checklist (PECL).* The PECL is a standardized communications material that plans must provide to prospective enrollees with the enrollment form and Summary of Benefits (SB) so that the enrollees understand important plan benefits and rules. The PECL references information on the following:

(i) The EOC.

(ii) Provider directory.

(iii) Pharmacy directory.

(iv) Formulary.

(v) Premiums/copayments/coinsurance.

(vi) Emergency/urgent coverage.

(vii) Plan-type rules.

(4) *Summary of Benefits (SB).* Part D sponsors must disseminate a summary of highly utilized coverage that include benefits and cost sharing to prospective Medicare beneficiaries, known as the SB. The SB is a model marketing material. It must be in a clear and accurate format.

(i) The SB must be provided with an enrollment form that meets the following:

(A) In hardcopy with a paper enrollment form.

(B) For online enrollment, the SB must be made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the SB.

(ii) The SB must include the following information:

(A) The prescription drug expense (tiers/levels) as follows:

(*1*) Deductible, the initial coverage phase, coverage gap, and catastrophic coverage.

(*2*) A note that costs may differ based on pharmacy type or status (for example, preferred/non-preferred, mail order, long-term care (LTC) or home infusion, and 30- or 90-day supply), when applicable.

(*3*) For dual eligible enrollees with differing levels of cost must state how cost sharing and benefits differ depending on the level of Medicaid eligibility.

(B) The SB may include other health related benefits.

(5) *Enrollment/Election form.* This is the model communications material through which plans must provide the information required under § 423.32(b).

(6) *Enrollment Notice.* This is a model communications material through which plans must provide the information required under § 423.32(d).

(7) *Disenrollment Notice.* This is a model communications material through which plans must provide the information required under § 423.36(b)(2).

(8) *Formulary.* This is a model communications material through which Part D sponsors must provide information required under § 423.128(b)(4).

(i) Must be provided to current enrollees of plan by October 15 of each year.

(ii) Must also provide to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(9) *Low Income Subsidy (LIS) Notice.* This is a model communications content through which Part D sponsors must notify potential enrollees of what their plan premium will be once they are eligible for Extra Help and receive the low-income subsidy.

(10) *Low Income Subsidy (LIS) Rider.* This is a model communications material provided to all enrollees who qualify for Extra Help. In the LIS Rider, the Part D sponsors must convey how much help the beneficiary will receive in the benefit year toward their Part D premium, deductible, and copayments provide to all beneficiaries who qualify for Extra Help.

(i) The LIS Rider must be provided at least once per year by September 30.

(ii) The LIS Rider must be sent to enrollees who qualify for Extra Help or have a change in LIS levels within 30 days of receiving notification from CMS.

(11) *Midyear Change Notification.* This is a model communications material through which plans must provide a notice to enrollees when there is a midyear change in benefits or plan rules, under the following timelines:

(i) Notices of changes in plan rules, unless otherwise addressed elsewhere in the regulation, must be provided 30 days in advance.

(ii) National Coverage Determination (NCD) changes announced or finalized less than 30 days before effective date, a notification is required as soon as possible.

(iii) Midyear NCD or legislative changes must be provided no later than 30 days after the NCD is announced.

(A) Plans may include the change in next plan mass mailing (for example, newsletter), provided it is within 30 days.

(B) The notice must also appear on the MA organization's website.

(12) *Non-renewal Notice.* This is a model communications material through which plans must provide the information required under § 423.507.

(i) The Non-renewal Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees

in Medicare-Medicaid Plans (MMPs) and special needs plans (SNPs).

(ii) The Non-renewal Notice must do all of the following:

(A) Inform the enrollee that their plan will no longer be offered and told when their plan will end.

(B) Identify the last day the enrollee has to make a Part D sponsor selection. Include any applicable open enrollment periods or special election periods or both (for example, Medicare open enrollment, non-renewal special election period).

(C) Explain what they must do to continue receiving Medicare coverage and what will happen if the enrollee chooses to do nothing.

(D) Include all available health plan options must be included in the enrollee's notice along with an explanation of how to obtain each option.

(E) Specify when coverage will start after a new Medicare plan is chosen.

(F) List 1–800–MEDICARE contact information together with other organizations that may be able to assist with comparing plans (for example, SHIPs).

(H) Include the Part D sponsor's organization's telephone number, TTY number, and hours and days of operation.

(13) *Part D Transition Letter.* This is a model communications material that must be provided to the beneficiary when they receive a transition fill for a nonformulary drug. The Part D Transition Letter must be sent within 3 days of adjudication of temporary transition fill.

(14) *Pharmacy Directory.* This is a model communications material through which Part D sponsors must provide the information required under § 423.128. The pharmacy directory must meet all of the following:

(i) Be provided to current enrollees by October 15 of each year and upon request, within 3 business days of the request.

(ii) Be provided to new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(iii) Plan sponsors must update directory information any time the Part D sponsor becomes aware of changes.

(A) All updates to the online provider directories are expected to be completed within 30 days of receiving information requiring update.

(B)(*1*) Updates to hardcopy provider directories must be completed within 30 days.

(*2*) Hardcopy directories that include separate updates via addenda are considered up-to-date.

(15) *Prescription transfer letter.* This is a model communications material must be sent when a Part D sponsor requests permission from an enrollee to fill a prescription at a different network pharmacy than the one currently being used by enrollee.

(16) *Star Ratings Document.* This is a standardized marketing material through which Star Ratings information is conveyed to prospective enrollees.

(i) The Star Ratings Document is generated through HPMS.

(ii) The Star Ratings Document must be provided with an enrollment form as follows:

(A) In hardcopy with a paper enrollment form.

(B) For online enrollment, made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the Star Ratings Document.

(iii) New Part D sponsor that have no Star Ratings are not required to provide the Star Ratings Document until the following contract year.

(iv) Updated Star Ratings must be used within 21 calendar days of release of updated information on Medicare Plan Finder.

(v) Updated Star Ratings must not be used until CMS releases Star Ratings on Medicare Plan Finder.

(17) *Coverage Determination Notices.* This is a model communications material through which plans must provide the information under § 423.568.

(18) *Excluded Provider Notices.* This is a model communications material through which plans must notify members when a provider they use has been excluded from participating in the Medicare program based on an OIG exclusion or the CMS preclusion list.

(19) *Notice of Denial of Medicare Prescription Drug Coverage.* This is a standardized material used to convey detailed descriptions of denied drug coverage and appeal rights.

(20) *Medicare Prescription Drug Coverage and Your Rights.* This is a standardized material used to convey a beneficiary's appeal rights when a drug cannot be filled at point-of-sale.

(21) *Medicare Part D Coverage Determination Request Form.* This is a model material used to collect additional information from a prescriber.

(22) *Request for Additional Information.* This is a standardized material used by the Part D sponsor to request a beneficiary obtain additional information from the prescriber regarding a beneficiary's exception request.

(23) *Notice of Right to an Expedited Grievance.* This is a model communications material used to convey a Medicare beneficiary's rights to request that a decision be made on a grievance or appeal within a shorter timeframe.

(24) *Notice of Inquiry.* This is a model communication from a prescription drug plan informing a beneficiary if a drug is covered by the formulary.

(25) *Notice of Case Status.* This is a model communications material used to inform a beneficiary of the denial of an appeal and additional appeal rights.

(26) *Request for Reconsideration of Medicare Prescription Drug Denial.* This is a model notice used to inform the beneficiary of rights to an independent review of a Part D sponsor's decision.

(27) *Notice of Redetermination.* This is a model communications material used to convey instructions for requesting an appeal of an adverse coverage determination.

(28) *Part D LEP Reconsideration Notice.* This is a model communication used to convey detailed instructions on how to request a reconsideration of an assessed Part D late enrollment penalty.

(29) *LEP Reconsideration Request Form.* This is a model communication used to request an appeal of a decision on an LEP by the independent review entity.

(30) *Request for Administrative Law Judge (ALJ) Hearing or Review of Dismissal.* This is a model communication used by an enrollee to request a hearing by the ALJ or a review of the IRE dismissal.

(31) *Appointment of Representative (AOR).* This is a standardized material used to assign an individual to act on behalf of a beneficiary for the purpose of an appeal, grievance, or coverage determination.

(32) *Federal Contracting Statement.* This is model content through which plans must convey that they have a contract with Medicare and that enrollment in the plan depends on contract renewal.

(i) The Federal Contracting Statement must include all of the following:

(A) Legal or marketing name of the organization.

(B) Type of plan (for example PDP).

(C) A statement that the organization has a contract with Medicare (when applicable, Part D sponsors may incorporate a statement that the organization has a contract with the State/Medicaid program).

(D) A statement that enrollment depends on contract renewal.

(ii) Part D sponsors must include the Federal Contracting Statement on all

marketing materials with the exception of the following:

(A) Banner and banner-like advertisements.

(B) Outdoor advertisements.

(C) Text messages.

(D) Social media.

(33) *Star Ratings Disclaimer.* This is standardized content. The disclaimer consists of the statement ''Every year, Medicare evaluates plans based on a 5-star rating system,'' and must be present whenever Star Ratings are mentioned in marketing materials, with the exception of when Star Ratings are published on small objects (that is, a give-away items such as a pens or rulers).

(34) *Availability of Non-English Translations Disclaimer.* This is standardized content. The disclaimer consists of the statement ''ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–XXX–XXX–XXXX (TTY: 1–XXX–XXX–XXXX).''

(i) The disclaimer must be placed in non-English languages that meet the 5 percent threshold for language translation under paragraph (a)(2) of this section.

(ii) The disclaimer must be added to all required materials in this section.

(35) *Accommodations Disclaimer.* This is standardized content. The disclaimer consists of the statement ''For accommodations of persons with special needs at meetings call <phone and TTY number>'' and must be present on all advertisements and invitations to all events as described under § 423.2264(b).

(36) *Mailing Statements.* This is standardized content. It consists of statements on envelopes that Part D sponsor must include when mailing information to current members, as follows:

(i) Part D sponsors must include the following statement when mailing information about the enrollee's current plan: ''Required on all advertisements and invitations to events (educational and marketing).''

(ii) Part D sponsors must include the following statement when mailing health and wellness information ''Health and wellness or prevention information.''

(iii) The Part D sponsor must include the plan name; however, if the plan name is elsewhere on the envelope, the plan name does not need to be repeated in the disclaimer.

(iv) Delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a multiple Part D sponsors must also comply with this requirement, however, they do not have to include a plan name.

(37) *Promotional Give-Away Disclaimer.* This is model content. The disclaimer consists of a statement that must make clear that there is no obligation to enroll in a plan, and must be included when offering a promotional give-away such as a drawing, prizes, or a free gift.

(38) *Provider Co-branded Material Disclaimer.* This is standardized content. The disclaimer consists of the statement: ''Other Pharmacies/Physicians/Providers are available in our network,'' and must be included on materials that identify co-branding relationships with network provider or pharmacies.

§ 423.2268 [Removed]

■ 102 Section 423.2268 is removed.

■ 103. Section 423.2274 is revised to read as follows:

§ 423.2274 Agent, broker, and other third party requirements.

If a Part D sponsor uses agents and brokers to sell its Medicare Part D plans, the requirements in paragraphs (a) through (e) of this section are applicable. If a Part D sponsor makes payments to third parties, the requirements in paragraph (f) of this section are applicable.

(a) *Definitions.* For purposes of this section, the following definitions are applicable:

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a plan or product offered by a Part D sponsor including, but not limited to the following:

(A) Commissions.

(C) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(E) Referral or Finder fees.

(ii) Does not include any of the following:

(A) Payment of fees to comply with State appointment laws, training, certification, and testing costs.

(B) Reimbursement for mileage to, and from, appointments with beneficiaries.

(C) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Fair market value (FMV) means, for purposes of evaluating agent and broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into a Part D plan. FMV for an upcoming year is calculated by adding the current year FMV and the product of the current year FMV and the Annual Percentage Increase for Part D, which is published for each year in the rate announcement issued pursuant to § 422.312 of this chapter.

Initial enrollment year means the first year that a beneficiary is enrolled in a plan vs. subsequent years (c.f., *renewal year*) that a beneficiary remains enrolled in a plan.

Like plan type means one of the following:

(i) PDP replaced with another PDP.

(ii) MA or MA–PD replaced with another MA or MA–PD.

(iii) Cost plan replaced with another cost plan.

Plan year and *enrollment year* mean the year beginning January 1 and ending December 31.

Renewal year means all years following the initial enrollment year in the same plan or in different plan that is a like plan type.

Unlike plan type means one of the following:

(i) An MA or MA–PD plan to a PDP or Section 1876 Cost Plan.

(ii) A PDP to a Section 1876 Cost Plan or an MA or MA–PD plan.

(iii) A Section 1876 Cost Plan to an MA or MA–PD plan or PDP.

(b) *Agent/broker requirements.* Agents and brokers who represent Part D sponsors must follow the requirements in paragraphs (b)(1) through (3) of this section. Representation includes selling products (including Medicare Advantage plans, Medicare Advantage-Prescription Drug plans, Medicare Prescription Drug plans, and section 1876 Cost plans) as well as outreach to existing or potential beneficiaries and answering or potentially answering questions from existing or potential beneficiaries.

(1) Be licensed and appointed under State law (if required under applicable State law).

(2) Be trained and tested annually as required under paragraph (c)(4) of this section, and achieve an 85 percent or higher on all forms of testing.

(3) Secure and document a Scope of Appointment prior to meeting with potential enrollees.

(c) *Part D sponsor oversight.* Part D sponsors must oversee first tier, downstream, and related entities that represent Part D sponsor to ensure agents/brokers abide by all applicable State and Federal laws, regulations, and requirements. Part D sponsors must do all of the following:

(1) As required under applicable State law, employ as marketing representatives only individuals who are licensed by the State to conduct marketing (as defined in this subpart) in that State, and whom the Part D sponsor has informed that State it has appointed,

consistent with the appointment process provided for under State law.

(2) As required under applicable State law, report the termination of an agent/broker to the State and the reason for termination if required by state law.

(3) Report to CMS all enrollments made by unlicensed agents/brokers and for-cause terminations of agent/brokers.

(4) On an annual basis, provide agent/broker training and testing on Medicare rules and regulations, the plan products that agents and brokers will sell including any details specific to each plan product, and relevant State and Federal requirements.

(5) On an annual basis by the last Friday in July, report to CMS whether the Part D sponsor intends to use employed, captive, and/or independent agents/brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents/brokers. Following the reporting deadline, Part D sponsor may not change their decisions related to agent/broker type, or their compensation rates and ranges, until the next plan year.

(6) On an annual basis by October 1, have in place full compensation structures for the following plan year. The structure must include details on compensation dissemination, including specifying payment amounts for initial enrollment year and renewal year compensation.

(7) Submit agent/broker marketing materials to CMS through HPMS prior to use, following the requirements for marketing materials in this subpart.

(8) Ensure agents and brokers do not charge beneficiaries a marketing fee.

(9) Establish and maintain a system for confirming that:

(i) Beneficiaries enrolled by agents/brokers understand the product, including the rules applicable under the plan.

(ii) Agent/brokers appropriately complete Scope of Appointment records for all marketing appointments (including telephonic and walk-in).

(10) Demonstrate that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(11) Must comply with State requests for information about the performance of a licensed agent or broker as part of a state investigation into the individual's conduct. CMS will establish and maintain a memorandum of understanding (MOU) to share compliance and oversight information with States that agree to the MOU.

(d) *Compensation requirements.* Part D sponsors must ensure they meet the requirements in paragraphs (d)(1) through (5) of this section in order to pay compensation. These compensation requirements only apply to independent agent/brokers.

(1) *General rules.* (i) MA organizations may only pay agents/brokers who meet the requirements in paragraph (b) of this section.

(ii) Part D sponsors may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section.

(iii) Part D sponsors may determine their payment schedule (for example, monthly or quarterly). Payments (including payments for AEP enrollments) must be made during the year of the beneficiary's enrollment.

(iv) Part D sponsors may only pay compensation for the number of months a member is enrolled.

(2) *Initial enrollment year compensation.* For each enrollment in an initial enrollment year, Part D sponsors may pay compensation at or below FMV.

(i) Part D sponsors may pay either a full or pro-rated initial enrollment year compensation for:

(A) A beneficiary's first year of enrollment in any plan; or

(B) A beneficiary's move from an employer group plan to a non-employer group plan (either within the same parent organization or between parent organizations).

(ii) Part D sponsors must pay pro-rate initial enrollment year compensation for:

(A) A beneficiary's plan change(s) during their initial enrollment year.

(B) A beneficiary's selection of an ''unlike plan type'' change. In that case, the new plan would only pay the months that the beneficiary is enrolled, and the previous plan would recoup the months that the beneficiary was not in the plan.

(3) *Renewal compensation.* For each enrollment in a renewal year, Part D sponsors may pay compensation at an amount up to 50 percent of FMV.

(i) Part D sponsors may pay compensation for a renewal year:

(A) In any year following the initial enrollment year the beneficiary remains in the same plan; or

(B) When a beneficiary enrolls in a new ''like plan type''.

(ii) [Reserved]

(4) *Other compensation scenarios.* (i) When a beneficiary enrolls in a PDP, the Part D sponsor may pay only the PDP compensation (and not compensation for MA enrollment under § 422.2274 of this chapter).

(ii) When a beneficiary enrolls in both a section 1876 Cost Plan and a stand-alone PDP, the 1876 Cost Plan sponsor may pay compensation for the cost plan enrollment and the Part D sponsor must pay compensation for the Part D enrollment.

(iii) When a beneficiary enrolls in a MA-only plan and a PDP, the MA plan may pay for the MA plan enrollment and the Part D sponsor may pay for the PDP enrollment.

(5) *Additional compensation, payment, and compensation recovery requirements (Charge-backs).* (i) Part D sponsors must retroactively pay or recoup funds for retroactive beneficiary changes for the current and previous calendar years. Part D sponsors may choose to recoup or pay compensation for years prior to the previous calendar year, but they must do both (recoup amounts owed and pay amounts due during the same year).

(ii) Compensation recovery is required when:

(A) A beneficiary makes any plan change (regardless of the parent organization) within the first 3 months of enrollment (known as rapid disenrollment), except as noted in paragraph (d)(5)(iii) of this section.

(B) Any other time period a beneficiary is not enrolled in a plan, but the plan paid compensation based on that time period.

(iii) Rapid disenrollment compensation recovery does not apply when:

(A) A beneficiary enrolls effective October 1, November 1, or December 1 and subsequently uses the Annual Election Period to change plans for an effective date of January 1.

(B) A beneficiary's enrollment change is not in the best interests of the Medicare program, including for the following reasons:

(*1*) Other creditable coverage (for example, an employer plan).

(*2*) Moving into or out of an institution.

(*3*) Gain or loss of employer/union sponsored coverage.

(*4*) Plan termination, non-renewal, or CMS imposed sanction.

(*5*) To coordinate with Part D enrollment periods or the State Pharmaceutical Assistance Program.

(*6*) Becoming LIS or dually eligible for Medicare and Medicaid.

(*7*) Qualifying for another plan based on special needs.

(*8*) Due to an auto, facilitated, or passive enrollment.

(*9*) Death.

(*10*) Moving out of the service area.

(*11*) Non-payment of premium.

(*12*) Loss of entitlement or retroactive notice of entitlement.

(*13*) Moving into a 5-star plan.

(*14*) Moving from an LPI plan into a plan with three or more stars.

(iv)(A) When rapid disenrollment compensation recovery applies, the entire compensation must be recovered.

(B) For other compensation recovery, plans must recover a pro-rated amount of compensation (whether paid for an initial enrollment year or renewal year) from an agent/broker equal to the number of months not enrolled.

(*1*) If a plan has paid full initial compensation, and the enrollee disenrolls prior to the end of the enrollment year, the total number of months not enrolled (including months prior to the effective date of enrollment) must be recovered from the agent/broker.

(*2*) Example: A beneficiary enrolls upon turning 65 effective April 1 and disenrolls September 30 of the same year. The plan paid full initial enrollment year compensation. Recovery is equal to 6/12ths of the initial enrollment year compensation (for January through March and October through December).

(e) *Payments to third parties.* (1) Payments made to third parties (that is, entities other than individual agents/brokers) for services other than enrollment of beneficiaries (for example, training customer service, agent recruitment, or operational overhead) must not exceed FMV.

(2) Administrative payments to third parties can be based on enrollment, provided payments are at or below FMV.

■ 104. Section 423.2305 is amended by revising the definition for ''Applicable discount'' to read as follows.

§ 423.2305 Definitions.

* * * * *

Applicable discount means 50 percent or, with respect to a plan year after plan year 2018, 70 percent of the portion of the negotiated price (as defined in this section) of the applicable drug of a manufacturer that falls within the coverage gap and that remains after such negotiated price is reduced by any supplemental benefits that are available.

* * * * *

■ 105. Section 423.2440 is revised to read as follows:

§ 423.2440 Credibility adjustment.

(a) A Part D sponsor may add the credibility adjustment specified under paragraph (e) of this section to a contract's MLR if the contract's experience is partially credible, as defined in paragraph (d)(1) of this section.

(b) A Part D sponsor may not add a credibility adjustment to a contract's MLR if the contract's experience is fully credible, as defined in paragraph (d)(2) of this section.

(c) For those contract years for which a contract has non-credible experience, as defined in paragraph (d)(3) of this section, sanctions under § 423.2410(b) through (d) will not apply.

(d)(1) A contract's experience is partially credible if it is based on the experience of at least 4,800 member months and fewer than or equal to 360,000 member months.

(2) A contract's experience is fully credible if it is based on the experience of more than 360,000 member months.

(3) A contract's experience is non-credible if it is based on the experience of fewer than 4,800 member months.

(e) The credibility adjustment for partially credible experience is determined based on the number of member months for all enrollees under the contract and the factors shown in Table 1 of this section. When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 of this section, the value associated with that number of member months is the credibility adjustment. The credibility adjustment for a number of member months between the values shown in Table 1 of this section is determined by linear interpolation.

TABLE 1 TO § 423.2440—CREDIBILITY ADJUSTMENTS FOR PART D CONTRACTS

Member months	Credibility adjustment (additional percentage points)
<4,800	N/A (Non-credible).
4,800	8.4%.
12,000	5.3%.
24,000	3.7%.
48,000	2.6%.
120,000	1.7%.
240,000	1.2%.
360,000	1.0%.
>360,000	0.0% (Fully credible).

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 106. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 107. Section 455.2 is amended by—

■ a. In the definition of ''Credible allegation of fraud,'' revising paragraph (1); and

■ b. Adding the definition of ''Fraud hotline tip'' in alphabetical order.

The revision and addition read as follows:

§ 455.2 Definitions.

* * * * *

Credible allegation of fraud. * * *

(1) Fraud hotline tips verified by further evidence.

* * * * *

Fraud hotline tip. A fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 108. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 109. Section 460.6 is amended by revising the definition of ''Services'' to read as follows:

§ 460.6 Definitions.

* * * * *

Service, as used in this part, means all services that could be required under § 460.92, including items and drugs.

* * * * *

■ 110. Section 460.56 is added to subpart D to read as follows:

§ 460.56 Procedures for imposing sanctions and civil money penalties.

CMS provides notice and a right to request a hearing according to the procedures set forth in either of the following:

(a) Section 422.756(a) and (b) of this chapter if CMS imposes a suspension of enrollment or payment under § 460.42 or § 460.48(b).

(b) Section 422.756(e)(2)(v) of this chapter if CMS imposes civil money penalties under § 460.46.

■ 111. Section 460.92 is revised to read as follows:

§ 460.92 Required services.

(a) The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(1) All Medicare-covered services.

(2) All Medicaid-covered services, as specified in the State's approved Medicaid plan.

(3) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.

(b) Decisions by the interdisciplinary team to provide or deny services under paragraph (a) of this section must be based on an evaluation of the participant that takes into account:

(1) The participant's current medical, physical, emotional, and social needs; and

(2) Current clinical practice guidelines and professional standards of care applicable to the particular service.

§ 460.96 [Amended]

■ 112. Section 460.96 is amended by—
■ a. Removing paragraphs (a) and (b); and
■ b. Redesignating paragraphs (c) through (e) as paragraphs (a) through (c).
■ 113. Section 460.98 is amended by—
■ a. Revising paragraph (a);
■ b. Adding a sentence to the end of paragraph (b)(1); and
■ c. Adding paragraphs (b)(4) and (5).

The revision and additions read as follows:

§ 460.98 Service delivery.

(a) *Access to services.* A PACE organization is responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and must establish and implement a written plan to ensure that care is appropriately furnished.

(b) * * *

(1) * * * These services must be furnished in accordance with § 460.70(a).

* * * * *

(4) Services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs.

(5) The PACE organization must document, track, and monitor the provision of services across all care settings in order to ensure the interdisciplinary team remains alert to the participant's medical, physical, emotional, and social needs regardless of whether services are formally incorporated into the participant's plan of care.

* * * * *

■ 114. Section 460.l02 is amended by revising paragraphs (d)(1) and (d)(2)(ii) to read as follows:

§ 460.102 Interdisciplinary team.

* * * * *

(d) * * *

(1) The interdisciplinary team is responsible for the following:

(i) The initial assessment, periodic reassessments, plan of care, and coordination of 24-hour care delivery.

(ii) Documenting all recommendations for care or services and the reason(s) for not approving or providing recommended care or services, if applicable, in accordance with § 460.210(b).

(2) * * *

(ii) Remaining alert to pertinent input from any individual with direct knowledge of or contact with the participant, including the following:

(A) Other team members.
(B) Participants.
(C) Caregivers.
(D) Employees.
(E) Contractors.
(F) Specialists.

* * * * *

■ 115. Section 460.104 is amended by revising paragraph (d)(2) to read as follows:

§ 460.104 Participant assessment.

* * * * *

(d) * * *

(2) *In response to a service delivery request.* In accordance with § 460.121(h), the PACE organization must conduct an in-person reassessment if it expects to deny or partially deny a service delivery request, and may conduct reassessments as determined necessary for approved services.

* * * * *

■ 116. Section 460.112 is amended by—
■ a. Adding paragraph (b)(4);
■ b. Redesignating paragraph (c)(3) as paragraph (c)(5); and
■ c. Adding new paragraphs (c)(3) and (4).

The additions read as follows:

§ 460.112 Specific rights to which a participant is entitled.

* * * * *

(b) * * *

(4) To contact 1–800–MEDICARE for information and assistance, including to make a complaint related to the quality of care or the delivery of a service.

(c) * * *

(3) To have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines.

(4) To receive necessary care in all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer provide the services necessary to maintain the participant safely in the community.

* * * * *

■ 117. Section 460.121 is added to read as follows:

§ 460.121 Service delivery requests.

(a) *Written procedures.* Each PACE organization must have formal written procedures for identifying and processing service delivery requests in accordance with the requirements of this section.

(b) *What is a service delivery request*—(1) *Requests that constitute a service delivery requests.* Except as provided in paragraph (b)(2) of this section, the following requests constitute service delivery requests:

(i) A request to initiate a service.

(ii) A request to modify an existing service, including to increase, reduce, eliminate, or otherwise change a service.

(iii) A request to continue coverage of a service that the PACE organization is recommending be discontinued or reduced.

(2) *Requests that do not constitute a service delivery request.* Requests to initiate, modify, or continue a service do not constitute a service delivery request if the request is made prior to development of the initial care plan.

(c) *Who can make a service delivery request?* Any of the following individuals can make a service delivery request:

(1) The participant.

(2) The participant's designated representative.

(3) The participant's caregiver.

(d) *Method for making a service delivery request.* An individual may make a service delivery request as follows:

(1) Either orally or in writing.

(2) To any employee or contractor of the PACE organization that provides direct care to a participant.

(e) *Processing a service delivery request.* (1) Except as provided in paragraph (e)(2) of this section, the PACE organization must bring a service delivery request to the interdisciplinary team as expeditiously as the participant's condition requires, but no later than 3 calendar days from the time the request is made.

(2) If a member of the interdisciplinary team is able to approve the service delivery request in full at the time the request is made, the PACE organization—

(i) Must fulfill all of the following:

(A) Notice of the decision to approve a service delivery request requirements specified in paragraph (j)(1) of this section.

(B) Effectuation requirements specified in paragraph (k) of this section.

(C) Recordkeeping requirements specified in paragraph (m) of this section.

(ii) Is not required to process the service delivery request in accordance with paragraphs (f) through (i), (j)(2), and (l) of this section.

(f) *Who must review a service delivery request?* The full interdisciplinary team must review and discuss each service delivery request and decide to approve, deny, or partially deny the request based on that review.

(g) *Interdisciplinary team decision making.* The interdisciplinary team

must consider all relevant information when evaluating a service delivery request, including, but not limited to, the findings and results of any reassessments required in paragraph (h) of this section, as well as the criteria specified in § 460.92(b).

(h) *Reassessments in response to a service delivery request.* (1) If the interdisciplinary team expects to deny or partially deny a service delivery request, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person reassessment before the interdisciplinary team makes a final decision. The team members performing the reassessment must evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs.

(2) The interdisciplinary team may conduct a reassessment prior to approving a service delivery request, either in-person or through the use of remote technology, if the team determines that a reassessment is necessary.

(i) *Notification timeframe.* Except as provided in paragraph (i)(1) of this section, when the interdisciplinary team receives a service delivery request, it must make its decision and notify the participant or their designated representative of its decision as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the interdisciplinary team receives the request.

(1) *Extensions.* The interdisciplinary team may extend the timeframe for review and notification by up to 5 calendar days if either of the following occur:

(i) The participant or other requestor listed in paragraph (c)(2) or (3) of this section requests the extension.

(ii) The extension is in the participant's interest because the interdisciplinary team needs additional information from an individual not directly employed by the PACE organization that may change the interdisciplinary team's decision to deny a service. The interdisciplinary team must document the circumstances that led to the extension and demonstrate how the extension is in the participant's best interest.

(2) *Notice of extension.* When the interdisciplinary team extends the timeframe, it must notify the participant or their designated representative in writing. The notice must explain the reason(s) for the delay and must be issued as expeditiously as the participant's condition requires, but no later than 24 hours after the IDT decides to extend the timeframe.

(j) *Notification requirements*—(1) *Notice of decisions to approve a service delivery request.* If the interdisciplinary team makes a determination to approve a service delivery request, it must provide the participant or the designated representative either oral or written notice of the determination. Notice of any decision to approve a service delivery request must explain the conditions of the approval in understandable language, including when the participant may expect to receive the approved service.

(2) *Notice of decisions to deny a service delivery request.* If the interdisciplinary team decides to deny or partially deny a service, it must provide the participant or the designated representative both oral and written notice of the determination. Notice of any denial must—

(i) State the specific reason(s) for the denial, including why the service is not necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, and the results of the reassessment(s) in understandable language.

(ii) Inform the participant or designated representative of his or her right to appeal the decision under § 460.122.

(iii) Describe the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in § 460.122.

(iv) For a Medicaid participant, inform the participant of both of the following, as specified in § 460.122(e)(1):

(A) His or her right to continue receiving disputed services during the appeals process until issuance of the final determination.

(B) The conditions for continuing to receive disputed services.

(k) *Effectuation requirements.* If the interdisciplinary team approves a service delivery request, in whole or in part, the PACE organization must provide the approved service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. The interdisciplinary team must explain when the participant may expect to receive the service in accordance with paragraph (j)(1) of this section.

(l) *Effect of failure to meet the processing timeframes.* If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with § 460.122.

(m) *Recordkeeping.* The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for service delivery requests received both orally and in writing. These records must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.

■ 118. Section 460.122 is amended by—

■ a. Revising the introductory text and paragraphs (b) and (c)(1), (2), and (4);

■ b. Redesignating paragraphs (c)(5) and (6) as paragraphs (c)(6) and (7), respectively;

■ c. Adding a new paragraph (c)(5);

■ d. Revising paragraph (d);

■ e. Redesignating paragraphs (g) through (i) as paragraphs (h) through (j), respectively;

■ f. Adding a new paragraph (g); and

■ g. Revising newly redesignated paragraph (h).

The revisions and additions read as follows:

§ 460.122 PACE organization's appeals process.

For purposes of this section, an appeal is a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services. A request to initiate, modify or continue a service must first be processed as a service delivery request under § 460.121 before the PACE organization can process an appeal under this section.

* * * * *

(b) *Notification of participants.* Upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a service delivery request or other request for services or payment, the PACE organization must give a participant written information on the appeals process.

(c) * * *

(1) Timely preparation and processing of a written denial of coverage or payment as provided in § 460.121(g).

(2) How a participant or their designated representative files an appeal, including procedures for accepting oral and written appeal requests.

* * * * *

(4) Review of an appeal by an appropriate third party reviewer or committee. An appropriate third party reviewer or member of a review committee must be an individual who meets all of the following:

(i) Appropriately credentialed in the field(s) or discipline(s) related to the appeal.

(ii) An impartial third party who meets both of the following:

(A) Was not involved in the original action.

(B) Does not have a stake in the outcome of the appeal.

(5) The distribution of written or electronic materials to the third party reviewer or committee that, at a minimum, explain all of the following:

(i) Services must be provided in a manner consistent with the requirements in §§ 460.92 and 460.98.

(ii) The need to make decisions in a manner consistent with how determinations under section 1862(a)(1)(A) of the Act are made.

(iii) The rules in § 460.90(a) that specify that certain limitations and conditions applicable to Medicare or Medicaid or both benefits do not apply.

* * * * *

(d) *Opportunity to submit evidence.* A PACE organization must give all parties involved in the appeal a reasonable opportunity to present evidence related to the dispute, in person, as well as in writing.

* * * * *

(g) *Notification.* A PACE organization must give all parties involved in the appeal appropriate written notification of the decision to approve or deny the appeal.

(1) *Notice of a favorable decision.* Notice of any favorable decision must explain the conditions of the approval in understandable language.

(2) *Notice of adverse decisions.* (i) If an appeal decision is partially or fully adverse to a participant, the PACE organization must provide the participant with written notification of the decision. Notice of any denial must—

(A) State the specific reason(s) for the denial;

(B) Explain the reason(s) why the service would not improve or maintain the participant's overall health status;

(C) Inform the participant of his or her right to appeal the decision; and

(D) Describe the external appeal rights under § 460.124.

(ii) If an appeal decision is partially or fully adverse to a participant, at the same time the decision is made, the PACE organization must notify the following:

(A) CMS.

(B) The State administering agency.

(C) The participant.

(h) *Actions following a favorable decision.* A PACE organization must furnish the disputed service as expeditiously as the participant's health condition requires if a determination is made in favor of the participant on appeal.

* * * * *

■ 119. Section 460.124 is revised to read as follows:

§ 460.124 Additional appeal rights under Medicare or Medicaid.

A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity.

(a) *Appeal rights under Medicare.* Medicare participants have the right to a reconsideration by an independent review entity.

(1) A written request for reconsideration must be filed with the independent review entity within 60 calendar days from the date of the decision by the third party reviewer under § 460.122.

(2) The independent outside entity must conduct the review as expeditiously as the participant's health condition requires but must not exceed the deadlines specified in the contract.

(3) If the independent review entity conducts a reconsideration, the parties to the reconsideration are the same parties described in § 460.122(c)(2), with the addition of the PACE organization.

(b) *Appeal rights under Medicaid.* Medicaid participants have the right to a State Fair Hearing as described in part 431, subpart E, of this chapter.

(c) *Appeal rights for dual eligible participants.* Participants who are eligible for both Medicare and Medicaid have the right to external review by means of either the Independent Review Entity described in paragraph (a) of this section or the State Fair Hearing process described in paragraph (b) of this section.

■ 120. Section 460.200 is amended by—

■ a. Redesignating paragraphs (b) introductory text and (b)(1) through (4) as paragraphs (b)(1) introductory text and (b)(1)(i) through (iv), respectively;

■ b. Adding a new paragraph (b)(2); and

■ c. Revising paragraph (d).

The addition and revision read as follows:

§ 460.200 Maintenance of records and reporting of data.

* * * * *

(b) * * *

(2) CMS and the State administering agency must be able to obtain, examine or retrieve the information specified at paragraph (b)(1) of this section, which may include reviewing information at the PACE site or remotely. PACE organizations may also be required to upload or electronically transmit information, or send hard copies of required information by mail.

* * * * *

(d) *Safeguarding data and records.* PACE organization must do all of the following:

(1) Establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(2) Maintain all written communications received from participants or other parties in their original form when the communications relate to a participant's care, health, or safety in accordance with § 460.210(b)(6).

* * * * *

■ 121. Section 460.210 is amended by—

■ a. Redesignating paragraphs (b)(4) through (12) as (b)(7) through (15); and

■ b. Adding new paragraphs (b)(4) through (6).

The additions read as follows:

§ 460.210 Medical records.

* * * * *

(b) * * *

(4) All recommendations for services made by employees or contractors of the PACE organization, including specialists.

(5) If a service recommended by an employee or contractor of the PACE organization, including a specialist, is not approved or provided, the reason(s) for not approving or providing that service.

(6) Original documentation of any written communication the PACE organization receives relating to the care, health or safety of a participant, in any format (for example, emails, faxes, letters, etc.) and including, but not limited to the following:

(i) Communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's health or safety or both.

(ii) Communications from an advocacy or governmental agency such as Adult Protective Services.

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Dated: January 13, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: January 24, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–02085 Filed 2–5–20; 4:15 pm]

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