

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 417, 422, 423, and 498

[CMS-4182-P]

RIN 0938-AT08

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act; improve program quality, accessibility, and affordability; improve the CMS customer experience; address program integrity policies related to payments based on prescriber, provider and supplier status in Medicare Advantage, Medicare cost plan, Medicare Part D and the PACE programs; provide a proposed update to the official Medicare Part D electronic prescribing standards; and clarify program requirements and certain technical changes regarding treatment of Medicare Part A and Part B appeal rights related to premiums adjustments.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 16, 2018.

ADDRESSES: In commenting, please refer to file code CMS-4182-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four 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-4182-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-4182-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

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

FOR FURTHER INFORMATION CONTACT:

Theresa Wachter, (410) 786-1157, Part C Issues.

Marie Manteuffel, (410) 786-3447, Part D Issues.

Kristy Nishimoto, (206) 615-2367, Beneficiary Enrollment and Appeals Issues.

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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 Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site 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.

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- ACA Affordable Care Act
- ACS American Community Survey
- AEP Annual Election Period
- ANDA Abbreviated New Drug Application
- ANOC Annual Notice of Change
- AMA American Medical Association
- AO Accrediting Organization
- ASPE Office of the Assistant Secretary for Planning and Evaluation
- AWP Any Willing Pharmacy
- CAI Categorical Adjustment Index
- CARA Comprehensive Addiction and Recovery Act
- CCIP Chronic Care Improvement Program
- CMS Centers for Medicare & Medicaid Services
- CPT Current Procedural Terminology
- DAB Departmental Appeals Board
- DE Dual Eligible
- DIR Direct or Indirect Remuneration
- DME Durable Medical Equipment
- DSMO Designated Standards Maintenance Organization
- D-SNP Dual-Eligible Special Needs Plan
- EDM Enhanced Disease Management
- EHR Electronic Health Record
- EOC Evidence of Coverage
- EP Eligible Professionals
- FFS Fee-for-Service
- ePA Electronic Prior Authorization
- eRx Electronic Prescription (e-prescribing)
- FDA Food and Drug Administration
- FIDE Fully Integrated Dual Eligible
- FMV Fair Market Value
- FPL Federal Poverty Level
- HPMS Health Plan Management System
- ICD-10 ICD-10-CM
- IRE Independent Review Entity
- LIS Low Income Subsidy
- LPPO Local Preferred Provider Organization
- LTC Long Term Care
- MA Medicare Advantage
- MADP Medicare Advantage Disenrollment Period
- MA-PD Medicare Advantage Prescription Drug
- MAO Medicare Advantage Organizations
- MIPPA Medicare Improvements for Patients and Providers Act
- MLR Medical Loss Ratio
- MOOP Maximum Out-of-Pocket
- NCPDP National Council of Prescription Drug Programs
- NCQA National Committee for Quality Assurance
- NDC National Drug Code
- NSO National Standard Organization
- OIG Office of Inspector General
- OEP Open Enrollment Period
- OMHA Office of Medicare Hearings and Appeals
- OOPC Out-of-Pocket Cost
- PA Prior Authorization
- PBM Pharmacy Benefit Manager
- PBP Plan Benefit Package
- PDP Prescription Drug Plan
- PHSA Public Health Service Act

PIP Physician Incentive Plan
 PQA Pharmacy Quality Alliance
 PSO Provider Sponsored Organization
 PSP Provider Specific Plan
 QBP Quality Bonus Payment
 QI Quality Improvement
 QIA Quality Improvement Activities
 QIP Quality Improvement Project
 REMS Risk Evaluation and Mitigation Strategies
 RFI Request for Information
 RHC Rural Health Center
 RI Rewards and Incentives
 RPPO Regional Preferred Provider Organization
 RRB Railroad Retirement Board
 SE Standard Error
 SEP Special Enrollment/Election Period
 SES Socio-Economic Status
 SNP Special Needs Plan
 SSA Social Security Administration
 TMP Timeliness Monitoring Project

I. Executive Summary

A. Purpose

The primary purpose of this proposed rule is to make revisions to the Medicare Advantage (MA) program (Part C) and Prescription Drug Benefit Program (Part D) regulations based on our continued experience in the administration of the Part C and Part D programs and to implement certain provisions of the Comprehensive Addiction and Recovery Act and the 21st Century Cures Act. The proposed changes are necessary to—(1) Support Innovative Approaches to Improving Quality, Accessibility, and Affordability; (2) Improve the CMS Customer Experience; and (3) Implement Other Changes. In addition, this rule proposes technical changes related to treatment of Part A and Part B premium adjustments and updates the Script standard used for Part D electronic prescribing. While the Part D program has high satisfaction among users, we continually evaluate program policies and regulations to remain responsive to current trends and newer technologies. Specifically, this regulation meets the Administration's priorities to reduce burden and provide the regulatory framework to develop MA and Part D products that better meet the individual beneficiary's healthcare needs. Additionally, this regulation includes a number of provisions that will help address the opioid epidemic and mitigate the impact of increasing drug prices in the Part D program.

B. Summary of the Major Provisions

1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions

This proposed regulatory provision would implement statutory provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA), enacted

into law on July 22, 2016, which amended the Social Security Act and includes new authority for Medicare Part D drug management programs, effective on or after January 1, 2019. Through this provision, CMS proposes a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse, or "at-risk beneficiaries." CMS proposes that, under such programs, sponsors may limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are "frequently abused drugs" to a selected prescriber(s) and/or network pharmacy(ies). CMS also proposes to limit the use of the special enrollment period (SEP) for dually- or other low income subsidy (LIS)-eligible beneficiaries who are identified as at-risk or potentially at-risk for prescription drug abuse under such a drug management program. Finally, this provision proposes to codify the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) by integrating this current policy with our proposals for implementing the drug management program provisions. The current policy involves Part D prescription drug benefit plans engaging in case management with prescribers when an enrollee is found to be taking a very high dose of opioids and obtaining them from multiple prescribers and multiple pharmacies who may not know about each other. Through the adoption of this policy, from 2011 through 2016, there was a 61 percent decrease (over 17,800 beneficiaries) in the number of Part D beneficiaries identified as potential very high risk opioid overutilizers.¹ Thus, this proposal expands upon an existing, innovative, successful approach to reduce opioid overutilization in the Part D program by improving quality of care through coordination while maintaining access to necessary pain medications.

2. Updating the Part D E-Prescribing Standards (§ 423.160)

This provision proposes an update to the electronic standards to be used by Medicare Part D prescription drug plans. This includes the proposed adoption of the NCPDP SCRIPT Standard Version 2017071, and retirement of the current NCPDP SCRIPT Version 10.6, as the official electronic prescribing standard for transmitting prescriptions and prescription-related information using electronic media for covered Part D

drugs for Part D eligible individuals. These changes would become effective January 1, 2019. The NCPDP SCRIPT standards are used to exchange information between prescribers, dispensers, intermediaries and Medicare prescription drug plans.

Although e-prescribing is optional for physicians and pharmacies, the Medicare Part D statute and regulations require drug plans participating in the prescription benefit to support electronic prescribing, and physicians and pharmacies who elect to transmit e-prescriptions and related communications electronically must utilize the adopted standards. The proposed updated NCPDP SCRIPT standards have been requested by the industry and could provide a number of efficiencies which the industry and CMS supports.

In order to facilitate this change, we propose to update § 423.160, and also make a number of conforming technical changes to other sections of part 423. In addition, we are proposing to correct a typographical error that occurred in the regulatory text listing the applicability dates of the standards by changing the reference in § 423.160(b)(1)(iv) to reference (b)(2)(iii) instead of (b)(2)(ii) to correctly cite to the present use of the currently adopted NCPDP SCRIPT Standard Version 10.

3. Revisions to Timing and Method of Disclosure Requirements

We are proposing to allow the electronic delivery of certain information normally provided in hard copy documents such as the Evidence of Coverage (EOC). Additionally, we are proposing to change the timeframe for delivery of the EOC in particular to the first day of the Annual Election Period (AEP) rather than fifteen days prior to that date. Allowing plans to provide the EOC electronically would alleviate plan burden related to printing and mailing, and simultaneously would reduce the number of paper documents that beneficiaries receive from plans. This would allow beneficiaries to focus on materials, like the Annual Notice of Change (ANOC), that drive decision making. Changing the date by which plans must provide the EOC to members would allow plans more time to finalize the formatting and ensure the accuracy of the information, as well as further distance it from the ANOC, which must still be delivered 15 days prior to the AEP. We see this proposed change as an overall reduction of impact that our regulations have on plans and beneficiaries. In aggregate, we estimate a savings (to plans for not producing

¹ CY 2018 Final Parts C&D Call Letter, April 3, 2017.

and mailing hard-copy EOCs) of approximately \$51 million.

4. Preclusion List

a. Part D

This proposed rule would rescind the current provisions in § 423.120(c)(6) that require physicians and eligible professionals (as defined in section 1848(k)(3)(B) of the Act) to enroll in or validly opt-out of Medicare in order for a Part D drug prescribed by the physician or eligible professional to be covered. As a replacement, we propose that a Part D plan sponsor must reject, or must require its pharmacy benefit manager to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the “preclusion list,” which would be defined in § 423.100 and would consist of certain prescribers who are currently revoked from the Medicare program under § 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have

revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program. We recognize, however, the need to minimize interruptions to Part D beneficiaries’ access to needed medications. Therefore, we also propose to prohibit plan sponsors from rejecting claims or denying beneficiary requests for reimbursement for a drug on the basis of the prescriber’s inclusion on the preclusion list, unless the sponsor has first covered a 90-day provisional supply of the drug and provide individualized written notice to the beneficiary that the drug is being covered on a provisional basis.

b. Part C

This proposed rule would rescind the current provisions in § 422.222 stating that providers or suppliers that are types of individuals or entities that can enroll

in Medicare in accordance with section 1861 of the Act must be enrolled in Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. As a replacement, we propose that an MA organization shall not make payment for an item or service furnished by an individual or entity that is on the “preclusion list.” The preclusion list, which would be defined in § 422.2, would consist of certain individuals and entities that are currently revoked from the Medicare program under § 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or would have led, to the revocation is detrimental to the best interests of the Medicare program.

C. Summary of Costs and Benefits

Provision	Savings
Implementation of the Comprehensive Addiction and Recovery Act of 2016.	Besides the benefits of preventing opioid dependency in beneficiaries we estimate a net savings in 2019 of \$13 million to the Trust Fund because of reduced scripts, modestly increasing to a savings of \$14 million in 2023. The cost to industry is estimated at about \$2.8 million per year.
Revisions to Timing and Method of Disclosure Requirements.	We estimate 67% of the current 47.8 million beneficiaries will prefer use of the internet vs. hard copies. This will result in savings of \$55 million in 2019 and growing due to inflation to \$67 million in 2023.

II. Provisions of the Proposed Regulations

A. Supporting Innovative Approaches to Improving Quality, Accessibility, and Affordability

1. Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions

a. Medicare Part D Drug Management Programs

The Comprehensive Addiction and Recovery Act of 2016 (CARA), enacted into law on July 22, 2016, amended the Social Security Act and includes new authority for the establishment of drug management programs in Medicare Part D, effective on or after January 1, 2019. In accordance with section 704(g)(3) of CARA and revised section 1860D–4(c) of the Act, CMS must establish through notice and comment rulemaking a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at-risk for prescription drug abuse, or “at-risk beneficiaries.” Under such a Part D drug management program, sponsors may limit at-risk beneficiaries’

access to coverage of controlled substances that CMS determines are “frequently abused drugs” to a selected prescriber(s) and/or network pharmacy(ies). While such programs, commonly referred to as “lock-in programs,” have been a feature of many state Medicaid programs for some time, prior to the enactment of CARA, there was no statutory authority to allow Part D plan sponsors to require beneficiaries to obtain controlled substances from a certain pharmacy or prescriber in the Medicare Part D program.

In summary, this proposed rule would implement the CARA Part D drug management program provisions by integrating them with the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) (“current policy”). As explained in more detail later in this section, this integration would mean that Part D sponsors implementing a drug management program could limit an at-risk beneficiary’s access to coverage of opioids beginning 2019 through a point-of-sale (POS) claim edit and/or by requiring the beneficiary to obtain opioids from a selected

pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary. To do so, the beneficiary would have to meet clinical guidelines that factor in that the beneficiary is taking a high-risk dose of opioids over a sustained time period and that the beneficiary is obtaining them from multiple prescribers and multiple pharmacies. This proposed rule would also implement a limitation on the use of the special enrollment period (SEP) for low income subsidy (LIS)-eligible beneficiaries who are identified as potential at-risk beneficiaries.

b. Stakeholder Input Informing This Notice of Proposed Rulemaking

Section 704(g)(2) of CARA required us to convene stakeholders to provide input on specific topics so that we could take such input into account in promulgating regulations governing Part D drug management programs. Stakeholders include Medicare beneficiaries with Part A or Part B, advocacy groups representing Medicare beneficiaries, physicians, pharmacists, and other clinicians (particularly other lawful prescribers of controlled

substances), retail pharmacies, Part D plan sponsors and their delegated entities (such as pharmacy benefit managers), and biopharmaceutical manufacturers.

We hosted a Listening Session on the CARA drug management program provisions via a public conference call on November 14, 2016 that was announced in the October 26, 2016 **Federal Register** (81 FR 74388). We sought stakeholder input on specific topics enumerated in sections 704(a)(1) and 704(g)(2)(B) of the CARA and other related topics of concern to the stakeholders.

In developing this proposed rule, we considered the stakeholders' comments provided during the Listening Session, as well as written comments submitted afterward, including those submitted in response to the Request for Information associated with the publication of the Plan Year 2018 Medicare Parts C&D Final Call Letter. We refer to this input in this preamble using the terms "stakeholders," "commenters" and "comments."

c. Integration of CARA and the Current Part D Opioid DUR Policy and OMS

As noted in section II.A.1. of this proposed rule previously, we are proposing to implement the CARA Part D drug management program provisions by integrating them with our current policy that is not currently codified, but would be under this proposal. In using the term "current policy", we refer to the aspect of our current Part D opioid overutilization policy that is based on retrospective DUR.² Specifically, we are proposing a regulatory framework for Part D plan sponsors to voluntarily adopt drug management programs through which they address potential overutilization of frequently abused drugs identified retrospectively through the application of clinical guidelines/criteria that identify potential at-risk beneficiaries and conduct case management which incorporates clinical contact and prescriber verification that a beneficiary is an at-risk beneficiary. If deemed necessary, a sponsor could limit at-risk beneficiaries' access to coverage for such drugs through pharmacy lock-in, prescriber lock-in, and/or a beneficiary-specific point-of-sale (POS) claim edit. Finally, sponsors would report to CMS the status and results of their case management to OMS and any beneficiary coverage

²Please refer to the CMS Web site, "Improving Drug Utilization Review Controls in Part D" at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html> which contains CMS communications regarding the current policy.

limitations they have implemented to MARx, CMS' system for payment and enrollment transactions. While plan sponsors would have the option to implement a drug management program, our proposal codifies a framework that would place requirements upon such programs. We foresee that all plan sponsors will implement such drug management programs based on our experience that all plan sponsors' are complying with the current policy as laid out in guidance, the fact that our proposal largely incorporates the CARA drug management provisions into existing CMS and sponsor operations, and especially, in light of the national opioid epidemic and the declaration that the opioid crisis is a nationwide Public Health Emergency.

Because we propose to integrate the CARA Part D drug management program provisions with the current policy and codify them both, we describe the current policy in section II.A.1.c.(1) of this proposed rule, noting where our proposal incorporates changes to the current policy in order to comply with CARA and achieve operational consistency. Where we do not note a change, 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. CMS communications regarding the current policy can be found at the CMS Web site, "Improving Drug Utilization Review Controls in Part D" at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>.

Then we set forth our proposal for codification of the regulatory framework for drug management programs in section II.A.1.c.(2) of this proposed rule, which includes provisions specific to lock-in, which is not a feature of the current policy.

(1) Current Part D Opioid DUR Policy and OMS

CMS is actively engaged in addressing the opioid epidemic and committed to implementing effective tools in Medicare Part D. We will work across all stakeholder, beneficiary and advocacy groups, health plans, and other federal partners to help address this devastating epidemic. CMS has worked with plan sponsors and other stakeholders to implement Medicare Part D opioid overutilization policies with multiple initiatives to address opioid overutilization in Medicare Part D through a medication safety approach. These initiatives include better formulary and utilization management;

real-time safety alerts at the pharmacy aimed at coordinated care; retrospective identification of high risk opioid overutilizers who may need case management; and regular actionable patient safety reports based on quality metrics to sponsors.

The goal of the current policy and OMS is to reduce opioid overutilization in Part D. In conjunction with related Part D opioid overutilization policies that address prospective opioid use, the current policy has played a key role in reducing high risk opioid overutilization in the Part D program by 61 percent (representing over 17,800 beneficiaries) from 2011 (pre-policy pilot) through 2016, even as the number of beneficiaries enrolled in Part D increased overall during this period from 31.5 million to 43.6 million enrollees, or a 38 percent increase.³

The purpose of the current policy is to provide Part D plan sponsors with specific guidance about compliance with § 423.153(b)(2) as to opioid overutilization, which requires a Part D plan sponsor to have a reasonable and appropriate drug utilization management program that maintains policies and systems to assist in preventing overutilization of prescribed medications. We adopted the current policy on January 1, 2013, and it has evolved over time in scope in several ways with stakeholder feedback and support, including through the addition of the OMS in July 2013, primarily via the annual Parts C&D Call Letter process.

The current policy has two aspects. First, in the CY 2013 final Call Letter and subsequent supplemental guidance, we provided guidance about our expectations for Part D plan sponsors to retrospectively identify beneficiaries who are at high risk for potential opioid overutilization and provide appropriate case management aimed at coordinated care.⁴ More specifically, we currently expect Part D plan sponsors' Pharmacy and Therapeutics (P&T) committees to establish criteria consistent with CMS guidance to retrospectively identify potential opioid overutilizers at high risk for an adverse event enrolled in their plans who may warrant case management because they are receiving opioid prescriptions from multiple prescribers and pharmacies. Enrollees

³Final CY 2018 Parts C&D Call Letter, April 3, 2017.

⁴An excerpt from the Final 2013 Call Letter, the supplemental guidance, and additional information about the policy and OMS are available on the CMS Web page, "Improving Drug Utilization Controls in Part D" at <https://www.cms.gov/Medicare/Prescription-Drug/PrescriptionDrugCovContra/RxUtilization.html>.

with cancer or in hospice are excluded from the current policy, because the benefit of their high opioid use may outweigh the risk associated with such use. This exclusion was supported by stakeholder feedback on the current policy.

Once such enrollees are identified through retrospective prescription drug claims review, we expect the Part D plan sponsors to diligently assess each case, and if warranted, have their clinical staff conduct case management with the beneficiary's opioid prescribers until the case is resolved. According to the supplemental guidance,⁵ case management entails:

- The personnel communicating with prescribers have appropriate credentials.
- Written inquiries to the prescribers of the opioid medications about the appropriateness, medical necessity and safety of the apparent high dosage for their patient.
- Attempts to schedule telephone conversations with the prescribers (separately or together) within a reasonable period from the issuance of the written inquiry notification, if necessary.
- The clinician-to-clinician communication includes information about the existence of multiple prescribers and the beneficiary's total opioid utilization, and the plan's clinician elicits the information necessary to identify any complicating factors in the beneficiary's treatment that are relevant to the case management effort.
- After discussion or communication about the appropriate level of opioid use, the consensus reached by the prescribers is implemented by the sponsor, with a beneficiary-specific opioid POS claim edit, as deemed appropriate by the prescribers, to prevent further Part D coverage of an unsafe level of drug.
- In cases of non-responsive prescribers, the sponsor may also implement a beneficiary-specific opioid POS claim edit to prevent further coverage of an unsafe level of drug and to encourage the prescribers to participate in case management.

Thus, we expect case management to confirm that the beneficiary's opioid use is medically necessary or resolve an overutilization issue.

As part of the current policy, and because the Food and Drug Administration (FDA)-approved labeling for opioids generally does not

include maximum daily doses, CMS developed specific criteria to identify beneficiaries at high risk through retrospective review of their opioid use in order to assist Part D sponsors in identifying such beneficiaries. These criteria incorporate a morphine milligram equivalent (MME)⁶ approach, which is a method to uniformly calculate the total daily dosage of opioids across all of a patient's opioid prescription drug claims. Beginning with plan year 2018, we adjusted these criteria to align with the Centers for Disease Control (CDC) Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline)⁷ issued in March 2016 in terms of using 90 MME as a threshold to identify beneficiaries who appear to be at high risk due to their opioid use. In its guideline, after considering information from relevant studies and experts, the CDC identifies 50 MME daily dose as a threshold for increased risk of opioid overdose, and to generally avoid increasing the daily dosage to 90 MME. Our criteria, which we will discuss more fully later in the preamble, also incorporate a multiple prescriber and pharmacy count to focus on beneficiaries who appear to be not only overutilizing opioids but who also are at increased risk due to potential coordination of care issues, such that the providers who are prescribing or dispensing opioids to these beneficiaries may not know that other providers are also doing so.

The second aspect of the current policy came into place in July 2013, when CMS launched the OMS as a tool to monitor Part D plan sponsors' effectiveness in complying with § 423.153(b)(2) to address opioid overutilization. Through the OMS, CMS sends sponsors quarterly reports about their Part D enrollees who meet the criteria for being at high risk of opioid overutilization. Then, we expect sponsors to address each case through the case management process previously described and respond to CMS through the OMS using standardized responses. In addition, we expect sponsors to provide information to their regional CMS representatives and the MARx system about beneficiary-specific opioid POS claim edits that they intend to or have implemented.⁸

⁶ Please note that CMS will use the term "MME" going forward instead of morphine equivalent dose (MED), which CMS has used to date. CMS used the term MED in a manner that was equivalent to MME. We will update CMS documents that currently refer to MED as soon as practicable.

⁷ Please see <https://www.cdc.gov/drugoverdose/prescribing/guideline.html>.

⁸ Please refer to the CMS Web site, "Improving Drug Utilization Review Controls in Part D" at

Because case management is very resource intensive for sponsors and PBMs, we have limited the scope of the current policy in terms of the number of beneficiaries identified by OMS, and when expanding that number, we have made changes incrementally through annual Parts C&D Call Letter process.

(2) Proposed Requirements for Part D Drug Management Programs (§§ 423.100 and 423.153)

We first propose several definitions for terms we propose to use in establishing requirements for Part D drug management programs.

(i) Definitions (§ 423.100)

(A) Definition of "Potential At-Risk Beneficiary" and "At-Risk Beneficiary" (§ 423.100)

Section 1860D-4(c)(5)(C) of the Act contains a definition for "at-risk beneficiary" that we propose to codify at § 423.100. In addition, although the section 1860D-4(c)(5) of the Act does not explicitly define a "potential at-risk beneficiary," it contemplates a beneficiary who is potentially at-risk. Accordingly, we propose to define these two terms at § 423.100 as follows: Potential at-risk beneficiary means a Part D eligible individual—(1) Who is identified using clinical guidelines (as defined in § 423.100); or (2) 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, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification. At-risk beneficiary means 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 under a Part D plan sponsor's drug management program in accordance with the requirements of § 423.153(f); or (2) 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 an at-risk beneficiary (as defined in paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most

<https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html> which contains CMS communications regarding the current policy.

⁵ September 6, 2012 HPMS memo, "Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D."

recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification. The distinction between a “potential at-risk beneficiary” and an “at-risk beneficiary” is important for a few reasons that we will explain later in this preamble. Also, we added the phrase, “and the new plan has adopted the identification” to both definitions for cases where a beneficiary has been identified as a potential at-risk or at-risk beneficiary by the immediately prior plan to indicate that the beneficiary’s status in the subsequent plan is not automatic.

(B) Definition of “Frequently Abused Drug”, “Clinical Guidelines”, “Program Size”, and “Exempted Beneficiary” (§ 423.100)

Because we use these terms in the proposed definitions of “potential at-risk beneficiary” and “at-risk beneficiary,” we propose to define “frequently abused drug,” “clinical guidelines”, “program size”, and “exempted beneficiary” at § 423.100 as follows:

- Frequently Abused Drug

Section 1860D–4(c)(5)(G) of the Act defines “frequently abused drug” as a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted. Consistent with the statutory definition, we propose to define “Frequently abused drug” at § 423.100 to mean a controlled substance under the federal Controlled Substances Act that the Secretary determines is frequently abused or diverted, taking into account the following factors: (1) The drug’s schedule designation by the Drug Enforcement Administration; (2) Government or professional guidelines that address that a drug is frequently abused or misused; and (3) An analysis of Medicare or other drug utilization or scientific data. This definition is intended to provide enough specificity for stakeholders to know how the Secretary will determine a frequently abused drug, while preserving flexibility to update which drugs CMS considers to be frequently abused drugs based on relevant factors, such as actions by the Drug Enforcement Administration and/or trends observed in Medicare or scientific data.

We plan to publish and update a list of frequently abused drugs for purposes of Part D drug management programs. We propose that future designations of frequently abused drugs by the Secretary primarily be included in the annual Parts C&D Call Letter or in

similar guidance, which would be subject to public comment, if necessary to address midyear entries to the drug market or evolving government or professional guidelines. This approach would be consistent with our approach under the current policy and necessary for Part D drug management programs to be responsive to changing public health issues over time.

While this is the approach we propose for future designations of frequently abused drugs, we are including a discussion of the designation for plan year 2019 in this preamble. For plan year 2019, consistent with current policy, we propose that opioids are frequently abused drugs. Our proposal to designate opioids as frequently abused drugs illustrates how the proposed definition could work in practice:

First, the Secretary determines opioids are frequently abused or diverted, because they are controlled substances, and drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are so considered precisely because they have abuse potential. The Drug Enforcement Administration (DEA) divides controlled substances into five schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and their likelihood of causing dependence when abused. Most prescription opioids are Schedule II, where the DEA places substances with a high potential for abuse with use potentially leading to severe psychological or physical dependence.⁹ A few opioids are Schedule III or IV, where the DEA places substances that have a potential for abuse.

Second, on October 26, 2017, the President directed that executive agencies use all appropriate emergency authorities and other relevant authorities to address drug addiction and opioid abuse, and the Acting Secretary of Health and Human Services declared a nationwide Public Health Emergency to address the opioid crisis.¹⁰ In addition, the CDC has

⁹ The abuse rate is a determinate factor in the DEA’s scheduling of the drug; for example, Schedule I drugs have a high potential for abuse and the potential to create severe psychological and/or physical dependence. As the drug schedule changes— Schedule II, Schedule III, etc., so does the abuse potential— Schedule V drugs represents the least potential for abuse. See DEA Web site about Drug Scheduling: <https://www.dea.gov/druginfo/ds.shtml>.

¹⁰ See White House Web site <https://www.whitehouse.gov/the-press-office/2017/10/26/presidential-memorandum-heads-executive->

declared opioid overuse a national epidemic, both of which are relevant factors.¹¹ More than 33,000 people died from opioid overuse in 2015, which is the highest number per year on record. From 2000 to 2015, more than half a million people died from drug overdoses, and 91 Americans die every day from an opioid overdose. Nearly half of all opioid overdose deaths involve a prescription opioid. Given that opioids, including prescription opioids, are the main driver of drug overdose deaths in the U.S., it is reasonable for the Secretary to conclude that opioids are frequently abused and misused.

Third, government or professional guidelines support determining that opioids are frequently abused or misused. Consistent with current policy, we propose to designate all opioids as frequently abused drugs except buprenorphine for medication-assisted treatment (MAT) and injectables. The CDC MME Conversion Factor file¹² does not include all formulations of buprenorphine for MAT so that access is not limited, and injectables are not included due to low claim volume. Therefore, CMS cannot determine the MME. CMS will consider revisions to the CDC MME Conversion Factor file when updating the list of opioids designated as frequently abused drugs in future guidance.

Fourth, an analysis of Medicare data supports designating opioids as “frequently abused drugs,” at least initially. Over 727,000 Part D beneficiaries had an average MME of at least 90 mg during the 6-month period from July 1, 2015 to December 31, 2015 (“90 mg MME + users”), a number which excludes beneficiaries with cancer or in hospice, whom we propose to exempt from drug management programs, as we discuss later. As noted earlier, the CDC recommends prescribers generally avoid increasing the daily opioid dosage to 90 MME. Given that so many beneficiaries have an average MME above this threshold, it is reasonable that the Secretary consider this data to be a relevant factor in determining that opioids are frequently abused or diverted.

Most stakeholders recommended designating opioids as frequently abused drugs. In this regard, we note

departments-and-agencies, and the HHS Web site <https://www.hhs.gov/about/news/2017/10/26/hhs-acting-secretary-declares-public-health-emergency-address-national-opioid-crisis.html>.

¹¹ See CDC Web site <https://www.cdc.gov/drugoverdose/index.html> for all statistics in this paragraph.

¹² See <https://www.cdc.gov/drugoverdose/resources/data.html>.

that our current policy applies only to opioids and that we are integrating the drug management provisions of CARA with our current policy. Therefore, designating opioids as frequently abused drugs, at least in the initial implementation of drug management programs, would have the added benefit of allowing CMS and stakeholders to gain experience with the use of lock-in in the Part D program, before potentially designating other controlled substances as frequently abused drugs.

Some commenters expressed support for including other or all controlled substances, such as benzodiazepines, sedatives, and certain muscle relaxants as frequently abused drugs; however, we are not persuaded. Opioids are unique in that there is generally no maximum dose for them in the FDA labeling. Also, in the proposed Contract Year 2016 Parts C&D Call Letter, we solicited feedback on expanding the current policy to other drugs, and the comments were mixed. A few commenters suggested that we expand the current policy to benzodiazepines and muscle relaxants when used with opioids. In respond to the feedback, we did not expand the current policy beyond the opioid class but indicated that we would investigate. Subsequently, the CDC Guideline was published and it specifically recommends that clinicians avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible due to increased risk for overdose. Therefore, we added a concurrent benzodiazepine-opioid flag to OMS in October 2016 to alert Part D sponsors that concurrent use may be an issue that should be addressed during case management, and we will continue to do so.¹³

Other than conveying the concurrent benzodiazepine use information to sponsors, we have not expanded the current policy to address non-opioid medications. However, we have stated that if a sponsor chooses to implement the current policy for non-opioid medications, we would expect the sponsor to employ the same level of diligence and documentation with respect to non-opioid medications that we expect for opioid medications.¹⁴ We have taken this approach to the current policy so that we could focus on the opioid epidemic and also due to the difficulty in establishing overdose guidelines for non-opioid controlled

substances. For this reason our proposal would not identify benzodiazepines as frequently abused drugs. However, we solicit additional comment on our proposed approach to frequently abused drugs. Also, we propose that, if finalized, this rule would supersede our current policy, and sponsors would no longer be allowed to implement the current policy for non-opioid medications. We seek feedback on allowing sponsors to continue to implement the current policy for non-opioid medications with respect to beneficiary-specific claim edits.

- **Clinical Guidelines and Program Size**

Section 1860D–4(c)(5)(C)(i)(I) of the Act requires at-risk beneficiaries to be identified using clinical guidelines that indicate misuse or abuse of frequently abused drugs and that are developed in consultation with stakeholders. We propose to include a definition of “clinical guidelines” that cross references standards that we are proposing at § 423.153(f) for how the guidelines would be established and updated. Specifically, we propose to define clinical guidelines for purposes of a Part D drug management program as criteria to identify potential at-risk beneficiaries who may be determined to be at-risk beneficiaries under such programs, and that are developed in accordance with the proposed standards in § 423.153(f)(16) and published in guidance annually.

We also propose to add § 423.153(f)(16) to state that potential at-risk beneficiaries and at-risk beneficiaries are identified by CMS or the Part D sponsor using clinical guidelines that: (1) Are developed with stakeholder consultation; (2) Are based on the acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs, or any combination of these factors; (3) Are derived from expert opinion and an analysis of Medicare data; and (4) Include a program size estimate. This proposed approach to developing and updating the clinical guidelines is intended to provide enough specificity for stakeholders to know how CMS would determine the guidelines by identifying the standards we would apply in determining them.

This proposed approach indicates that the program size would be determined as part of the process to develop the clinical guidelines—a process into which stakeholders would provide input. Section 1860D–4(c)(5)(C)(iii) of the Act states that the Secretary shall establish policies, including the guidelines and exemptions, to ensure

that the population of enrollees in drug management programs could be effectively managed by plans. We propose to define “program size” in § 423.100 to mean the estimated population of potential at-risk beneficiaries in drug management programs (described in § 423.153(f)) operated by Part D plan sponsors that the Secretary determines can be effectively managed by such sponsors as part of the process to develop clinical guidelines.

This proposed approach to developing and updating the clinical guidelines would also be flexible enough to allow for updates to the guidelines outside of the regulatory process to address trends in Medicare with respect to the misuse and/or diversion of frequently abused drugs. We have determined this approach is appropriate to enable CMS to assist Part D drug management programs in being responsive to public health issues over time. This approach would also be consistent with how the OMS criteria have been established over time through the annual Medicare Parts C&D Call Letter process, which we plan to continue except for 2019.

For plan year 2019, we propose the clinical guidelines in this preamble to be the OMS criteria established for plan year 2018, which meet the proposed standards for the clinical guidelines for the following reasons: First, as described earlier, the OMS criteria incorporate a 90 MME threshold cited in a CDC Guideline, which was developed by experts as the level that prescribers should avoid reaching with their patients. This threshold does not function as a prescribing limit for the Part D program; rather, it identifies potentially risky and dangerous levels of opioid prescribing in terms of misuse or abuse. Second, the OMS criteria also incorporate a multiple prescriber and pharmacy count. A high MED level combined with multiple prescribers and/or pharmacies may also indicate the abuse or misuse of opioids due to the possible lack of care coordination among the providers for the patient. Third, the OMS criteria have been revised over time based on analysis of Medicare data and with stakeholder input via the annual Parts C&D Call Letter process. Indeed, many stakeholders recommended the use of the CDC Guideline as part of the clinical guidelines the Secretary must develop, with some noting that they would need to be used in a way that accounts for use of multiple providers, which the OMS criteria do. Fourth, these criteria are familiar to Part D sponsors—they will already have experience with them by

¹³ Please refer to the memo, “Medicare Part D Overutilization Monitoring System (OMS) Update: Addition of the Concurrent Opioid-Benzodiazepine Use Flag” dated October 21, 2016.

¹⁴ See “Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D,” dated September 6, 2012.

2019, and they were established with an estimate of program size.

Several stakeholders in their comments referred to various criteria used in state Medicaid lock-in programs to identify beneficiaries appropriate for lock-in, without suggesting that any particular ones be adopted. Other commenters suggested CMS consider other guidelines, such as the American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use and the Veterans Affairs/Department of Defense (VA/DoD) Clinical Practice Guideline on Opioid Therapy for Chronic Pain. However, these guidelines are similar to or moving toward an MME methodology which we currently use or address a more narrow population than persons who may be abusing or misusing frequently abused drugs, and they do not directly address situations involving multiple opioid providers. The VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain is similar to the scope of the CDC Guideline. The ASAM Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use was developed specifically for the evaluation and treatment of opioid use disorder and for the management of opioid overdose, which would not be applicable here because it serves a different purpose. Therefore, we do not see a reason to adopt these guidelines instead of the 2018 OMS criteria.

The clinical guidelines for use in drug management programs we are proposing for 2019 are: Use of opioids with an average daily MME greater than or equal to 90 mg for any duration during the most recent 6 months and either: 4 or more opioid prescribers and 4 or more opioid dispensing pharmacies *OR* 6 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. We note that we have described alternative clinical guidelines that we considered in the Regulatory Impact Analysis section of this rule. Stakeholders are invited to comment on those alternatives and any others which would involve identifying more or fewer potential at-risk beneficiaries.

We propose that under the proposed clinical guidelines, prescribers associated with the same single Tax Identification Number (TIN) be counted as a single prescriber. This is consistent with the current policy under which we have found that such prescribers are typically in the same group practice that is coordinating the care of the patients served by it. Thus, it is appropriate to count such prescribers as one, so as not

to identify beneficiaries who are not at-risk.

In this regard, in applying the OMS criteria, CMS counts prescribers with the same TIN as one prescriber, unless any of the prescribers are associated with multiple TINs. For example, under the criteria we have proposed, a beneficiary who meets the 90 MME criterion and received opioid prescriptions from 4 prescribers in the same group practice and 3 independent opioid prescribers (1 group practice + 3 prescribers = 4 prescribers) and filled the prescriptions at 4 opioid dispensing pharmacies, would still meet the criteria, which is appropriate. However, a beneficiary who meets that 90 MME criterion and received opioid prescriptions from 4 prescribers in the same group practice and 1 independent opioid prescriber (1 group practice + 1 prescriber = 2 prescribers) and filled the prescriptions at 4 opioid dispensing pharmacies would not meet the criteria, which is also appropriate at this time given program size concerns.

Section 1860D-4(c)(5)(D) of the Act specifies that for purposes of limiting access to coverage of frequently abused drugs to those obtained from a selected pharmacy, if the pharmacy has multiple locations that share real-time electronic data, all such locations of the pharmacy collectively are treated as one pharmacy. Given this provision, as well as our proposal to treat multiple prescribers from the same group practice as one prescriber under the clinical guidelines, we propose that where a pharmacy has multiple locations that share real-time electronic data, all locations of the pharmacy collectively be treated as one pharmacy under the clinical guidelines.

Because not all Part D plans' data systems may be able to account for group practice prescribers as we described above, or chain pharmacies through data analysis alone, or may not be able to fully account for them, we request information on sponsors' systems capabilities in this regard. Also, if a plan sponsor does not have the systems capability to automatically determine when a prescriber is part of a group or a pharmacy is part of a chain, the plan sponsor would have to make these determinations during case management, as they do with respect to group practices under the current policy. If through such case management, the Part D plan finds that the multiple prescribers who prescribed frequently abused drugs for the beneficiary are members of the same group practice, the Part D plan would treat those prescribers as one prescriber for purposes of identification of the

beneficiary as a potential at-risk beneficiary. Similarly, if through such case management, the Part D plan finds that multiple locations of a pharmacy used by the beneficiary share real-time electronic data, the Part D plan would treat those locations as one pharmacy for purposes of identification of the beneficiary as a potential at-risk beneficiary. Both of these scenarios may result in a Part D sponsor no longer conducting case management for a beneficiary because the beneficiary does not meet the clinical guidelines. We also note that group practices and chain pharmacies are important to consider for purposes of the selection of a prescriber(s) and pharmacy(ies) in cases when a Part D plan limits a beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) and/or prescriber(s), which we discuss in more detail later in this preamble.

Under the current policy, sponsors must use 90 MME as a "floor" for their own criteria to identify beneficiaries who may be overutilizing opioids, but they may vary the prescriber and pharmacy count. This means sponsors may review beneficiaries who do not meet the OMS criteria but meet the sponsors' internal criteria for review, or they may not review beneficiaries who meet the OMS criteria but do not meet the sponsors' internal criteria for review. However, under our proposal to adopt the 2018 OMS criteria as the 2019 clinical guidelines for Part D drug management programs, we also propose to mostly eliminate this feature of the current policy. Under our proposal, Part D plan sponsors would not be able to vary the criteria of the guidelines to include more or fewer beneficiaries in their drug management programs, except that we propose to continue to permit plan sponsors to apply the criteria more frequently than CMS would apply them through OMS in 2018, which can result in sponsors identifying beneficiaries earlier. This is because CMS evaluates enrollees quarterly using a 6-month look back period, whereas sponsors may evaluate enrollees more frequently (for example, monthly).

While several commenters stated that Part D plan sponsors should have flexibility in developing their own criteria for identifying at-risk beneficiaries in their plans, a more conservative and uniform approach is warranted for the initial implementation of Part D drug management programs. While we already have experience with how frequently Part D plan sponsors use beneficiary-specific opioid POS claim edits to prevent opioid overutilization, we wish to learn how sponsors will use

lock-in as a tool to address this issue before adopting clinical guidelines that might include parameters for permissible variations of the criteria. We plan to monitor compliance of drug management programs as we monitor compliance with the current policy through various CMS data sources, such as OMS, MARx, beneficiary complaints and appeals.

Also, we note that despite sponsors' additional identification of some beneficiaries currently, in practice, we have found that CMS identifies the vast majority of beneficiaries who are reviewed by Part D sponsors through OMS. CMS identifies over 80 percent of the cases reviewed through OMS, and about 20 percent are identified by sponsors based on their internal criteria. We understand that most of the beneficiaries representing the 20 percent were reported to OMS due to the sponsors averaging the MME calculations across all opioid prescriptions, which has subsequently been changed in the 2018 OMS criteria. The 2018 OMS criteria also have a lower MME threshold and account for additional beneficiaries who receive their opioids from many prescribers regardless of the number of pharmacies, which will result in the identification of more beneficiaries through OMS. Thus, our proposal would not substantially change the current practice.

Furthermore, in approximately 39 percent of current OMS cases, sponsors respond that the case does not meet the sponsor's internal criteria for review.¹⁵ We found that the original OMS criteria generated false positives that some sponsors' internal criteria did not because these sponsors used a shorter look back period or were able to group prescribers within the same practice or chain pharmacies. These best practices have also been incorporated into the revised 2018 OMS criteria, which are the basis of the proposed 2019 clinical guidelines. Thus, while our proposal will prevent sponsors from voluntarily reviewing more potential at-risk beneficiaries than CMS identifies through OMS, it will likely require sponsors to review more beneficiaries than they currently do.

Table 1 shows that in 2015 approximately 33,000 beneficiaries would have met the proposed 2019 clinical guidelines, which is approximately 0.08 percent of the 42 million beneficiaries enrolled in Part D in 2015. We think this population would constitute a manageable program size because this is the estimated OMS population we finalized during the Plan Year 2018 Parts C&D Call Letter process. Moreover, we have no evidence to suggest that this program size will be problematic for sponsors.

In addition, current Medicaid lock-in programs support the notion that this

program size would be manageable by Part D plan sponsors. In 2015, an average 0.37 percent of Medicaid recipients were locked-in and the percentage of recipient's locked-in by state programs ranged from 0.01 percent to 1.8 percent.¹⁶

To derive this estimated population of potential at-risk beneficiaries, we analyzed prescription drug event data (PDE) from 2015,¹⁷ using the CDC opioid drug list and MME conversion factors, and applying the criteria we proposed earlier as the clinical guidelines. This estimate is over-inclusive because we did not exclude beneficiaries in long-term care (LTC) facilities who would be exempted from drug management programs, as we discuss later in this section. However, based on similar analyses we have conducted, this exclusion would not result in a noteworthy reduction to our estimate. Also, we were unable to count all locations of a pharmacy that has multiple locations that share real-time electronic data as one, which is a topic we discussed earlier and will return to later. Thus, there likely are beneficiaries counted in our estimate who would not be identified as potential at-risk beneficiaries because they are in an LTC facility or only use multiple locations of a retail chain pharmacy that share real-time electronic data.

TABLE 1—CLINICAL GUIDELINES OR IDENTIFYING POTENTIAL AT-RISK BENEFICIARIES

Criteria applied	Impact to Part D program
≥90 mg MED and either: 4+ opioid prescribers AND 4+ opioid dispensing pharmacies OR 6+ opioid prescribers (regardless of the number of opioid dispensing pharmacies).	33,053 beneficiaries in 2015 (76.3% were LIS). Represents 0.08% of 41,835,016 Part D beneficiaries in 2015. LTC beneficiaries included in estimate but are exempt. Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber.

We note that the alternatives for clinical guidelines that we considered, which are described in the Regulatory Impact Analysis (RIA) section of this rule, also include estimated population of potential at-risk beneficiaries for each alternative. Most of the options include a 90 MME threshold with varying prescriber and pharmacy counts and range from identifying 33,053 to 319,133 beneficiaries. Again, stakeholders are invited to comment on these alternatives. We are particularly interested in receiving comments on

whether CMS should adjust the clinical guidelines so that more or fewer potential at-risk beneficiaries are identified, and if more are identified, whether the additional number would result in a manageable program size for plan sponsors (or too few beneficiaries to be meaningful).

• Exempted Beneficiary

Section 1860D–4(c)(5)(C)(ii) of the Act defines an exempted individual as one who receives hospice care, who is a resident of a long-term care facility for

which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, or who the Secretary elects to treat as an exempted individual. Consistent with this, we propose that an exempted beneficiary, with respect to a drug management program, would mean an enrollee who: (1) Has elected to receive hospice care; (2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents

¹⁵ We noted in the final CY Parts C&D Call Letter, for the January 2014 OMS reports, 67 percent of the potential opioid overutilization responses were that the beneficiary did not meet the sponsor's internal criteria. We explained the reasons for this figure and the actions we took to reduce it.

¹⁶ Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2015 Annual Report: Prescription Drug-Fee-For-Service Programs (December 2016), pg. 26.

¹⁷ Unique count of beneficiaries who met the criteria in any 6 month measurement period (January 2015–June 2015; April 2015–September 2015; or July 2015–December 2015).

through a contract with a single pharmacy; or (3) Has a cancer diagnosis.

While the first two exceptions are required under CARA, we propose to exercise the authority in section 1860D-4(c)(5)(C)(ii)(III) of the Act to treat a beneficiary who has a cancer diagnosis as an exempted individual for two reasons. First, many commenters recommended that the Secretary exempt beneficiaries who have a cancer diagnosis, because a Part D drug management program should not be able to interfere administratively with their pain control regimen in the form of additional notices from their prescription drug benefit plans and limitations on their access to coverage for frequently abused drugs. We agree with these commenters. Second, exempting beneficiaries with a cancer diagnosis would be consistent with current policy. Under the current policy, which has been developed through stakeholder feedback, beneficiaries with cancer are excluded because the benefit of their opioid use may outweigh the risk associated with their opioid use. Also, as noted previously, some commenters requested that implementation of the drug management program provisions of CARA be as consistent as possible with the current policy for operational ease. We also agree with these commenters.

Some commenters recommended against exempting beneficiaries with cancer diagnoses, stating that there is no standard clinical reason why a beneficiary with cancer should be receiving opioids from multiple prescribers and/or multiple pharmacies, and that such situations warrant further review. While we understand the concern of these commenters, we maintain that beneficiaries who have a cancer diagnosis should be exempted for the reasons stated just above. Moreover, our experience with this exemption under the current policy suggests that the exemption is workable and appropriate. We understand beneficiaries with cancer diagnoses are identifiable by Part D plan sponsors either through recorded diagnoses, their drug regimens or case management, and no major concerns have been expressed about this exemption under our current policy, including from standalone Part D plan sponsors who may not have access to their enrollees' medical records.

A few commenters suggested exempting beneficiaries who are receiving palliative and end-of-life care, since not all patients receiving this type of care are necessarily enrolled in hospice or reside in an LTC facility. Two commenters suggested exempting

beneficiaries in assisted living. Other commenters suggested exempting beneficiaries in various other health care facilities, such as group homes and adult day care centers, where medication is supervised. Other commenters suggested exempting beneficiaries with debilitating disorders or receiving medication-assisted treatment for substance abuse disorders.

We have not proposed to exempt these additional categories of beneficiaries but we seek specific comment on whether to do so and our rationale. First, we have not exempted these other beneficiaries under the current policy, and we thus do not think it is necessary to exempt them from drug management programs. Second, unlike with cancer diagnoses, we are not able to determine administratively through CMS data who these beneficiaries are to exempt them from OMS reporting. Consequently, it could be burdensome for Part D sponsors to attempt to exempt these beneficiaries, by definition, from their drug management programs. Third, it is important to remember that the proposed clinical guidelines would only identify potential at-risk beneficiaries in the Part D program who are receiving potentially unsafe doses of opioids from multiple prescribers and/or multiple pharmacies who typically do not know about each other in terms of providing services to the beneficiary. Thus, it is likely that a plan would discover during case management that a potential at-risk beneficiary is receiving palliative and end-of-life care during case management. Absent a compelling reason, we would expect the plan not to seek to implement a limit on such beneficiary's access to coverage of opioids under the current policy nor a drug management program, as it would seem to outweigh the medication risk in such circumstances. Moreover, in cases where a prescriber is cooperating with case management, we would not expect the prescriber to agree to such a limitation, again, absent a compelling reason. With respect to beneficiaries receiving medication-assisted treatment for substance abuse for opioid use disorder, we decline to propose to treat these individuals as exempted individuals. It is these beneficiaries who are among the most likely to benefit from a drug management program.

(ii) Requirements of Drug Management Programs (§§ 423.153, 423.153(f))

As noted previously, we are proposing to codify a regulatory framework under which Part D plan sponsors may adopt drug management programs to address overutilization of

frequently abused drugs. Therefore, we propose to amend § 423.153(a) by adding this sentence at the end: "A Part D plan sponsor may establish a drug management program for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs, as described in paragraph (f) of this section," in accordance with our authority under revised section 1860D-4(c)(5)(A) of the Act.

We also propose to revise § 423.153 by adding a new paragraph (f) about drug management programs for which the introductory sentence would read: "(f) Drug Management Programs. A drug management program must meet all the following requirements." Thus, the requirements that a Part D plan sponsor must meet to operate a drug management program would be codified in various provisions under subsection § 423.153(f).

(iii) Written Policies and Procedures (§ 423.153(f)(1))

We propose to require Part D sponsors document their programs in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate, which is consistent with the current policy. Also consistent with the current policy, we would require these policies and procedures to address the appropriate credentials of the personnel conducting case management and the necessary and appropriate contents of files for case management. We additionally propose to require sponsors to monitor information about incoming enrollees who would meet the definition of a potential at-risk and an at-risk beneficiary in proposed § 423.100 and respond to requests from other sponsors for information about potential at-risk and at-risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plans. We discuss potential at-risk and at-risk beneficiaries who are identified as such in their most recent Part D plan later in this preamble.

To codify these requirements, we propose that section § 423.153(f)(1) read as follows: (1) Written policies and procedures. A sponsor must document its drug management program in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate. The policies and procedures must address all aspects of the sponsor's drug management program, including but not limited to the following: (i) The appropriate credentials of the personnel conducting case management required under

paragraph (f)(2); (ii) The necessary and appropriate contents of files for case management required under paragraph (f)(2); and (iii) Monitoring reports and notifications about incoming enrollees who meet the definition of an at-risk beneficiary and a potential at-risk beneficiary in § 423.100 and responding to requests from other sponsors for information about at-risk beneficiaries and potential at-risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plans. Thus, Part D sponsors would have flexibility—as they do today under the current policy—to adopt specific policies and procedures for their drug management programs, as long as they are consistent with the requirements of § 423.153, as finalized.

(iv) Case Management/Clinical Contact/Prescriber Verification (§ 423.153(f)(2))

As discussed earlier, case management is a key feature of the current policy, under which we currently expect Part D plan sponsors' clinical staff to diligently engage in case management with the relevant opioid prescribers to coordinate care with respect to each beneficiary reported by OMS until the case is resolved (unless the beneficiary does not meet the sponsor's internal criteria). We propose that the second requirement for drug management programs in a new § 423.153(f)(2) reflect the current policy with some adjustment to the current policy to require all beneficiaries reported by OMS to be reviewed by sponsors.

Our proposal for a new § 423.153(f)(2) also meets the requirements of section 1860D–4I(5)(C) of the Act. This section of the Act requires that, with respect to each at-risk beneficiary, the sponsor shall contact the beneficiary's providers who have prescribed frequently abused drugs regarding whether prescribed medications are appropriate for such beneficiary's medical conditions. Further, our proposal meets the requirements of Section 1860D–4(c)(5)(B)(i)(II) of the Act, which requires that a Part D sponsor first verify with the beneficiary's providers that the beneficiary is an at-risk beneficiary, if the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs.

Specifically, we propose that a new § 423.153(f)(2) read as follows: Case Management/Clinical Contact/Prescriber Verification. (i) General Rule. The sponsor's clinical staff must conduct case management for each potential at-risk beneficiary for the purpose of engaging in clinical contact with the prescribers of frequently abused drugs

and verifying whether a potential at-risk beneficiary is an at-risk beneficiary. Proposed § 423.153(f)(2)(i) would further state that, except as provided in paragraph (f)(2)(ii) of this section, the sponsor must do all of the following: (A) Send written information to the beneficiary's prescribers that the beneficiary meets the clinical guidelines and is a potential at-risk beneficiary; (B) Elicit information from the prescribers about any factors in the beneficiary's treatment that are relevant to a determination that the beneficiary is an at-risk beneficiary, including whether prescribed medications are appropriate for the beneficiary's medical conditions or the beneficiary is an exempted beneficiary; and (C) In cases where the prescribers have not responded to the inquiry described in (i)(B), make reasonable attempts to communicate telephonically with the prescribers within a reasonable period after sending the written information.

Given the “Except as provided in paragraph (f)(2)(ii) of this section”, we propose to add paragraph (ii) to § 423.153(f)(2) that would read: (ii) Exception for identification by prior plan. If a beneficiary was identified as a potential at-risk or an at-risk beneficiary by his or her most recent prior plan, and such identification has not been terminated in accordance with paragraph (f)(14) of this section, the sponsor meets the requirements in paragraph (f)(2)(i) of this section, so long as the sponsor obtains case management information from the previous sponsor and such information is still clinically adequate and up to date. This proposal is to avoid unnecessary burden on health care providers when additional case management outreach is not necessary. This is consistent with the current policy under which sponsors are expected to enter information into MARx about pending, implemented and terminated beneficiary-specific POS claim edits, which is transferred to the next sponsor, if applicable. Pending and implemented POS claim edits are actions that sponsors enter into MARx after case management. We discuss potential at-risk and at-risk beneficiaries who change plans again later in this preamble.

The information that the plan sends to the prescribers and elicits from them is intended to assist a Part D sponsor to understand why the beneficiary meets the clinical guidelines and if a plan intervention is warranted for the safety of the beneficiary. Also, sponsors use this information to choose standardized responses in OMS and provide information to MARx about plan interventions that were referenced

earlier. We will address required reporting to OMS and MARx by sponsors again later.

We note that, currently, OMS standardized responses generally fall into four categories: First, in approximately 18 percent of cases, the enrollee's opioid use is medically necessary. Second, approximately 38 percent of cases are resolved without a beneficiary-specific POS opioid claim edit, for example, when the sponsor takes a “wait and see” approach to observe if the prescribers adjust their management of, and the opioid prescriptions they are writing for, their patient due to the written information they received from the sponsor about their patient. Third, a small subset of cases—on average 1.3 percent—need a beneficiary-specific opioid POS claim edit to resolve the beneficiary's opioid overutilization issue. From 2013 through of July 4, 2017, CMS received 4,617 contract-beneficiary-level opioid POS claim edit notifications through MARx for 3,961 unique beneficiaries. Fourth, as previously mentioned, approximately 39 percent of cases do not meet the sponsor's internal criteria for review. We expect adjustment to these percentages under our proposal, particularly since we anticipate that plans will no longer be able to respond that a case does not meet its internal criteria for review. In addition, the revised 2018 OMS criteria which are the basis of the proposed 2019 clinical guidelines should reduce “false positives” which may have been reported through OMS but not identified through sponsors' internal criteria due to a shorter look back period and ability to group prescribers within the same practice.

We also note that under the current policy, sponsors are expected to make “at least three (3) attempts to schedule telephone conversations with the prescribers (separately or together) within a reasonable period (for example, a 10 business day period) from the issuance of the written inquiry notification.” If the prescribers are unresponsive to case management, under our current policy, a sponsor may also implement a beneficiary-specific POS claim edit for opioids as a last resort to encourage prescriber engagement with case management.

By contrast, our proposed § 423.153(f)(2) uses the terms “reasonable attempts” and “reasonable period” rather than a specific number of attempts or a specific timeframe for plan to call prescribers. The reason for this proposed adjustment to our policy is because our current policy also states that “[s]ponsors are not required to

automatically contact prescribers telephonically,” but those that “employ a wait-and-see approach” should understand that “we expect sponsors to address the most egregious cases of opioid overutilization without unreasonable delay, and that we do not believe that all such cases can be addressed through a prescriber letter campaign.” Our guidance further states that, “to the extent that some cases can be addressed through written communication to prescribers only, we would acknowledge the benefit of not aggravating prescribers with unnecessary telephonic communications.” Finally, our guidance states that, “[s]ponsors must determine for themselves the usefulness of attempting to call or contact all opioid prescribers when there are many, particularly when they are emergency room physicians.”¹⁸

Given the competing priorities of sponsors’ diligently addressing opioid overutilization in the Part D program through case management, which may necessitate telephone calls to the prescribers, while being cognizant of the need to be judicious in contacting prescribers telephonically in order to not unnecessarily disrupt their practices, we wish to leave flexibility in the regulation text for sponsors to balance these priorities on a case-by-case basis in their drug management programs, particularly since this flexibility exists under the current policy. We note however, that we propose a 3 attempts/10 business days requirement for sponsors to conclude that a prescriber is unresponsive to case management in § 423.153(f)(4) discussed later in this section.

(v) Limitations on Access to Coverage for Frequently Abused Drugs (§ 423.153(f)(3))

As described earlier, under the current policy, Part D sponsors may implement a beneficiary-specific opioid POS claim edit to prevent continued overutilization of opioids, with prescriber agreement or in the case of an unresponsive prescriber during case management. If a sponsor implements a POS claim edit, the sponsor thereafter does not cover opioids for the beneficiary in excess of the edit, absent a subsequent determination, including a successful appeal.

As noted earlier, revised section 1860D–4(c)(5)(A) of the Act provides

additional tools commonly known as “lock-in”, for Part D plans to limit an at-risk beneficiary’s access to coverage for frequently abused drugs. Prescriber lock-in would limit an at-risk beneficiary’s access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers, and pharmacy lock-in would restrict an at-risk beneficiary’s access to coverage for frequently abused drugs to those that are dispensed to the beneficiary by one or more network pharmacies.

If the sponsor uses a lock-in tool(s), the sponsor must generally cover frequently abused drugs for the beneficiary only when they are obtained from the selected pharmacy(ies) and/or prescriber(s), as applicable, absent a subsequent determination, including a successful appeal. Pursuant to section 1860D–4(c)(5)(D)(i)(II) of the Act, a sponsor would also have to cover frequently abused drugs from a non-selected pharmacy or prescriber, if such coverage were necessary in order to provide reasonable access. We discuss selection of pharmacies and prescribers and reasonable access later.

We propose to describe all the tools that would be available to sponsors to limit an at-risk beneficiary’s access to coverage for frequently abused drugs through a drug management program in § 423.153(f)(3) as follows: Limitation on Access to Coverage for Frequently Abused Drugs. Subject to the requirements of paragraph (f)(4) of this section, a Part D plan sponsor may do all of the following: (i) Implement a point-of-sale claim edit for frequently abused drugs that is specific to an at-risk beneficiary; or (ii) In accordance with paragraphs (f)(10) and (f)(11) of this section, limit an at-risk beneficiary’s access to coverage for frequently abused drugs to those that are (A) Prescribed for the beneficiary by one or more prescribers; (B) Dispensed to the beneficiary by one or more network pharmacies; or (C) Specified in both paragraphs (3)(ii)(B)(1) and (2) of this paragraph. Paragraph (iii)(A) would state that if the sponsor implements an edit as specified in paragraph (f)(3)(i) of this section, the sponsor must not cover frequently abused drugs for the beneficiary in excess of the edit, unless the edit is terminated or revised based on a subsequent determination, including a successful appeal. Paragraph (iii)(B) would state that if the sponsor limits the at-risk beneficiary’s access to coverage as specified in paragraph (f)(3)(ii) of this section, the sponsor must cover frequently abused drugs for the beneficiary only when they are obtained from the selected

pharmacy(ies) and/or prescriber(s), or both, as applicable, (1) in accordance with all other coverage requirements of the beneficiary’s prescription drug benefit plan, unless the limit is terminated or revised based on a subsequent determination, including a successful appeal, and (2) except as necessary to provide reasonable access in accordance with paragraph (f)(12) of this section.

(vi) Requirements for Limiting Access to Coverage for Frequently Abused Drugs (§ 423.153(f)(4))

We propose that before a Part D plan sponsor could limit the access of at-risk beneficiary to coverage for frequently abused drugs, the sponsor must first take certain actions, consistent with current policy. We propose that a sponsor must first conduct the case management discussed earlier, which includes clinical contact to determine whether prescribed medications are appropriate for the potential at-risk beneficiary’s medical conditions and prescriber verification that the beneficiary is an at-risk beneficiary. We also propose that the sponsor must first obtain the agreement of the prescribers of frequently abused drugs with the limitation, unless the prescribers were not responsive to the required case management, in light of the risk to the beneficiary’s health. We further propose that the sponsor must first provide notice to the beneficiary in accordance with section 1860D–4(c)(5)(B)(i)(I) of the Act.

We propose to require the additional step of prescriber agreement, which is consistent with the current policy as discussed earlier, because a prescriber may verify that the beneficiary is an at-risk beneficiary but may not view a limitation on the beneficiary’s access to coverage for frequently abused drugs as appropriate. Given the additional information the prescribers would have from the Part D sponsor through case management about the beneficiary’s utilization of frequently abused drugs, the prescribers’ professional opinion may be that an adjustment to their prescribing for, and care of, the beneficiary is all that is needed to safely manage the beneficiary’s use of frequently abused drugs going forward. We invite stakeholders to comment on not requiring prescriber agreement to implement pharmacy lock-in. We could foresee a case in which the prescriber is responsive, but does not agree with pharmacy lock-in.

We also propose language that would provide an exception to the case management requirement in § 423.153(f)(2) when an at-risk

¹⁸ See “Supplemental Guidance Relating to Improving Drug Utilization Review Controls in Part D”, September 6, 2012 (pp. 5, 19–20) at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html>.

beneficiary was identified as an at-risk beneficiary by the beneficiary's most recent prior prescription drug benefit plan. We discuss such cases more later in this section. Given the foregoing, we propose to add a paragraph (f)(4) to § 423.153 that reads: Requirements for Limiting Access to Coverage for Frequently Abused Drugs. (i) A sponsor may not limit the access of an at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section, unless the sponsor has done all of the following: (A) Conducted the case management required by paragraph (f)(2) of this section and updated it, if necessary; (B) Obtained the agreement of the prescribers of frequently abused drugs for the beneficiary that the specific limitation is appropriate; and (C) Provided the notices to the beneficiary in compliance with paragraphs (f)(5) and (6) of this section. We would also state in subsection (ii) that if the sponsor complied with the requirement of paragraph (f)(2)(i)(C) of this section, and the prescribers were not responsive after 3 attempts by the sponsor to contact them by telephone within 10 business days, then the sponsor has met the requirement of paragraph (f)(4)(i)(B) of this section. Finally, we would state in a subsection (iii) that if the beneficiary meets paragraph (2) of the definition of a potential at-risk beneficiary or an at-risk beneficiary, and the sponsor has obtained the applicable case management information from the sponsor of the beneficiary's most recent plan and updated it as appropriate, the sponsor has met the case management requirement in paragraph (f)(2)(i).

(vii) Beneficiary Notices and Limitation of Special Enrollment Period (§§ 423.153(f)(5), 423.153(f)(6), 423.38)

(A) Initial Notice to Beneficiary and Sponsor Intent To Implement Limitation on Access to Coverage for Frequently Abused Drugs (§ 423.153(f)(5))

The notices referred to in proposed § 423.153(f)(4)(i)(C) are the initial and second notice that section 1860D-4(c)(5)(B)(i)(I) of the Act requires Part D sponsors to send to potential at-risk and at-risk beneficiaries regarding their drug management programs. We remind Part D sponsors that under Section 504 of the Rehabilitation Act of 1973, effective communications requirements would apply to both these notices. We first discuss the initial notice.

We propose in § 423.153(f)(5) that if a Part D plan sponsor intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs, the sponsor would be required to

provide an initial written notice to the potential at-risk beneficiary. We also propose that the language be approved by the Secretary and be in a readable and understandable form that contains the language required by section 1860D-4(c)(5)(B)(ii) of the Act to which we propose to add detail in the regulation text. Finally, we propose that the sponsor be required to make reasonable efforts to provide the prescriber(s) of frequently abused drugs with a copy of the notice.

We propose that § 423.153(f)(5)(i) read as follows: Initial Notice to Beneficiary. A Part D sponsor that intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section must provide an initial written notice to the beneficiary. Paragraph (f)(5)(ii) would require that the notice use language approved by the Secretary and be in a readable and understandable form that provides the following information: (1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as a potential at-risk beneficiary; (2) A description of all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health and other counseling services and information on how to access such services, including any such services covered by the plan under its Medicare benefits, supplemental benefits, or Medicaid benefits (if the plan integrates coverage of Medicare and Medicaid benefits); (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 § 423.580 *et seq.*; (4) A request that the beneficiary submit to the sponsor within 30 days of the date of this initial notice any information that the beneficiary believes is relevant to the sponsor's determination, including which prescribers and pharmacies the beneficiary would prefer the sponsor to select if the sponsor implements a limitation under § 423.153(f)(3)(ii); (5) An explanation of the meaning and consequences of being identified as an at-risk beneficiary, including an explanation of the sponsor's drug management program, the specific limitation the sponsor intends to place on the beneficiary's access to coverage for frequently abused drugs under the program, the timeframe for the sponsor's decision, and if

applicable, any limitation on the availability of the special enrollment period described in § 423.38; (6) Clear instructions that explain how the beneficiary can contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(5)(ii)(C)(4); (7) Contact information for other organizations that can provide the beneficiary with assistance regarding the sponsor's drug management program; and (8) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

We propose to require at § 423.153(f)(5)(iii) that the Part D plan sponsor make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required under paragraph (f)(5)(i).

The content of the initial notice we propose in § 423.153(f)(5) closely follows the content required by section 1860D-4(c)(5)(B)(ii) of the Act, but as noted previously, we have proposed to add some detail to the regulation text. In proposed paragraph (f)(5)(ii)(C)(2)—which would require a description of public health resources that are designed to address prescription drug abuse—we propose to require that the notice contain information on how to access such services. We also included a reference in proposed paragraph (ii)(C)(4) to the fact that a beneficiary would have 30 days to provide information to the sponsor, which is a timeframe we discuss later in this preamble. We propose an additional requirement in paragraph (ii)(C)(5) that the sponsor include the limitation the sponsor intends to place on the beneficiary's access to coverage for frequently abused drugs, the timeframe for the sponsor's decision, and, if applicable, any limitation on the availability of the SEP. Finally, we proposed a requirement in paragraph (ii)(C)(8) that the notice contain other content that CMS determines is necessary for the beneficiary to understand the information required in the initial notice.

We note that our proposed implementation of the statutory requirements for the initial notice would permit the notice also to be used when the sponsor intends to implement a beneficiary-specific POS claim edit for frequently abused drugs. This is consistent with our current policy and would streamline beneficiary notices about opioids since we propose frequently abused drugs to consist of opioids for 2019.

Although section 1860D–4(c)(5) is silent as to the sequence of the steps of clinical contact, prescriber verification, and the initial notice, we propose to implement these requirements such that they would occur in the following order: First, the plan sponsor would conduct the case management which encompasses clinical contact and prescriber verification required by § 423.153(f)(2) and prescriber agreement required by § 423.153(f)(4), and second would, as applicable, indicate the sponsor's intent to limit the beneficiary's access to frequently abused drugs by providing the initial notice. In our view, a sponsor cannot reasonably intend to limit the beneficiary's access unless it has first undertaken case management to make clinical contact and obtain prescriber verification and agreement. Further, under our proposal, although the proposed regulatory text of (f)(4)(i) states that the sponsor must verify with the prescriber(s) that the beneficiary is an at-risk beneficiary in accordance with the applicable statutory language, the beneficiary would still be a potential at-risk beneficiary from the sponsor's perspective when the sponsor provides the beneficiary the initial notice. This is because the sponsor has yet to solicit information from the beneficiary about his or her use of frequently abused drugs, and such information may have a bearing on whether a sponsor identifies a potential at-risk beneficiary as an at-risk beneficiary.

Moreover, we believe that in general, a sponsor should not send a potential at-risk beneficiary an initial notice until after the sponsor has been in contact with the beneficiary's prescribers of frequently abused drugs, so as to avoid unnecessarily alarming the beneficiary, considering that a sponsor may learn from the prescribers that the beneficiary's use of the drugs is medically necessary, or that the beneficiary is an exempted beneficiary. This proposed approach is also consistent with our current policy and stakeholder comments. Therefore, under this approach, a sponsor would provide an initial notice to a potential at-risk beneficiary if the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs, and the sponsor would provide a second notice to an at-risk beneficiary when it actually limits the beneficiary's access to coverage for frequently abused drugs. Alternatively, the sponsor would provide an alternate second notice if it decides not to limit the beneficiary's access to coverage for frequently abused drugs. We discuss the second notice and

alternate second notice later in this preamble.

We intend to develop language for the initial notice. Therefore, the proposed regulatory text states that the notice must use language approved by the Secretary.

(B) Limitation on the Special Enrollment Period for LIS Beneficiaries With an At-Risk Status (§ 423.38)

In addition to providing relevant information to a potential at-risk beneficiary, we propose that the initial notice will notify dually- and other low income subsidy (LIS)-eligible beneficiaries, that they will be unable to use the special enrollment period (SEP) for LIS beneficiaries due to their at-risk status. (Hereafter, this SEP is referred to as the "duals' SEP"). Section 1860D–1(b)(3)(D) of the Act requires the Secretary to establish a Part D SEP for full-benefit dually eligible (FBDE) beneficiaries. This SEP, codified at § 423.38(c)(4), was later extended to all other subsidy-eligible beneficiaries (75 *FR* 19720) so that all LIS-eligible beneficiaries were treated uniformly. The duals' SEP currently allows such individuals to make Part D enrollment changes (that is, enroll in, disenroll from, or change Part D plans) throughout the year, unlike other Part D enrollees who generally may make enrollment changes only during the annual election period (AEP). Individuals using this SEP can enroll in either a stand-alone Part D prescription drug plan (PDP) or a Medicare Advantage plan with prescription drug coverage.

Section 704(a)(3) of CARA gives the Secretary the discretion to limit the SEP for FBDE beneficiaries outlined in section 1860D–1(b)(3)(D) of the Act. This limitation is related to, but distinct from, other changes to the duals' SEP proposed in section III.A.11 of this proposed rule (as discussed later). A limitation under a sponsor's drug management program can only be effective as long as the individual is enrolled in that plan or another plan that also has a drug management program. Therefore, this proposed SEP limitation would be an important tool to reduce the opportunities for LIS-eligible beneficiaries designated as at-risk to switch plans. If an individual is determined to be an at-risk beneficiary, and is permitted to change plans using the duals' SEP, he or she could avoid the drug management program by leaving the plan before the program can be started or by enrolling in a PDP that does not have a drug management program. This would allow the beneficiary to circumvent the lock-in

program and not receive the care coordination such a program provides. Even if an at-risk beneficiary joined another plan that had a drug management program in place, there would be challenges in terms of preventing a gap managing their potential or actual overutilization of frequently abused drugs due to timing of information sharing between the plans and possible difference in provider networks.

Accordingly, we are proposing to revise § 423.38(c)(4), so that it is not available to potential at-risk beneficiaries or at-risk beneficiaries. Once an individual is identified as a potential at-risk beneficiary and the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs, the sponsor would provide an initial notice to the beneficiary and the duals' SEP would no longer be available to the otherwise eligible individual. This means that he or she would be unable to use the duals' SEP to enroll in a different plan or disenroll from the current Part D plan. The limitation would be effective as of the date the Part D plan sponsor identifies an individual to be potentially at-risk. Limiting the duals' SEP concurrent with the plan's identification of a potential at-risk beneficiary would reduce the opportunities for such beneficiaries to use the interval between receipt of the initial notice and application of the limitation (for example, pharmacy or prescriber lock-in, beneficiary-specific POS claim edit) as an opportunity to change plans before the restriction takes effect.

Based on the 2015 data in CMS' OMS, more than 76 percent of all beneficiaries estimated to be potential at-risk beneficiaries are LIS-eligible individuals. Based on this data, without an SEP limitation at the initial point of identification, the notification of a potential drug management program may prompt these individuals to switch plans immediately after receiving the initial notice. In effect, under the current regulations, if unchanged, the dually- or other LIS-eligible individual, could keep changing plans and avoid being subject to any drug management program.

We propose that, consistent with the timeframes discussed in proposed paragraph § 423.153(f)(7), if the Part D plan sponsor takes no additional action to identify the individual as an at-risk beneficiary within 90 days from the initial notice, the "potentially at-risk" designation and the duals' SEP limitation would expire. If the sponsor determines that the potential at-risk beneficiary is an at-risk beneficiary, the

duals' SEP would not be available to that beneficiary until the date the beneficiary's at-risk status is terminated based on a subsequent determination, including a successful appeal, or at the end of a 12-month period calculated from the effective date the sponsor provided the beneficiary in the second notice as proposed at § 423.153(f)(6) whichever is sooner.

As discussed in section III.A.11 of this proposed rule, we are also proposing to revise § 423.38(c)(4) to make the SEP for FBDE or other subsidy-eligible individuals available only in certain circumstances. As further explained in section III.A.11, we also are proposing to establish a new SEP at § 423.38(c)(9) to permit any beneficiary to make an enrollment change when he or she has a gain, loss, or change in Medicaid or LIS eligibility.

We propose not to limit the availability of this new SEP to potential at-risk and at-risk beneficiaries. In situations where an individual is designated as a potential at-risk beneficiary or an at-risk beneficiary and later determined to be dually-eligible for Medicaid or otherwise eligible for LIS, that beneficiary should be afforded the ability to receive the subsidy benefit to the fullest extent for which he or she qualifies and therefore should be able to change to a plan that is more affordable, or that is within the premium benchmark amount if desired. Likewise, if an individual with an "at-risk" designation loses dual-eligibility or LIS status, or has a change in the level of extra help, he or she would be afforded an opportunity to elect a different Part D plan, as discussed in section III.A.11 of this proposed rule. This is also a life changing event that may have a financial impact on the individual, and could necessitate an individual making a plan change in order to continue coverage.

We note that auto- and facilitated enrollment of LIS eligible individuals and plan annual reassignment processes would still apply to dual- and other LIS-eligible individuals who were identified as an at-risk beneficiary in their previous plan. This is consistent with CMS's obligation and general approach to ensure Part D coverage for LIS-eligible beneficiaries and to protect the individual's access to prescription drugs. Furthermore, we note that the proposed enrollment limitations for Medicaid or other LIS-eligible individuals designated as at-risk beneficiaries would not apply to other Part D enrollment periods, including the AEP or other SEPs. As discussed previously, we propose that the ability to use the duals' SEP, as outlined in

section III.A.11. of this proposed rule, would not be permissible once the individual is enrolled in a plan that has identified him or her as a potential at-risk beneficiary or at-risk beneficiary, for a dual or other LIS-eligible who meets the definition of at-risk beneficiary or potential at-risk beneficiary under proposed § 423.100.

(C) Second Notice to Beneficiary and Sponsor Implementation of Limitation on Access to Coverage for Frequently Abused Drugs by Sponsor (§ 423.153(f)(6))

As previously noted, section 1860D-4(c)(5)(B)(i)(I) of the Act requires Part D sponsors to provide a second written notice to at-risk beneficiaries when they limit their access to coverage for frequently abused drugs. Also, as with the initial notice, our proposed implementation of this statutory requirement for the second notice would permit the second notice to be used when the sponsor implements a beneficiary-specific POS claim edit for frequently abused drugs.

We propose to codify this requirement in § 423.153(f)(6)(i). Specifically, we propose to require the sponsor to provide the second notice when it determines that the beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs. We further propose to require the second notice to include the effective and end date of the limitation. Thus, this second notice would function as a written confirmation of the limitation the sponsor is implementing with respect to the beneficiary, and the timeframe of that limitation.

We also propose that the second notice, like the initial notice, contain language required by section 1860D-4(c)(5)(B)(iii) of the Act to which we propose to add detail in the regulation text. We also propose that the second notice, like the initial notice, be approved by the Secretary and be in a readable and understandable form, as well as contain other content that CMS determines is necessary for the beneficiary to understand the information required in this notice. Finally, in § 423.153(f)(6)(iii), we propose that the sponsor be required to make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice, as we proposed with the initial notice.

Proposed § 423.153(f)(6)(i) would read as follows: Second notice. Upon making a determination that a beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs under

paragraph (f)(3) of this section, a Part D sponsor must provide a second written notice to the beneficiary. Paragraph (f)(6)(ii) would require that the second notice use language approved by the Secretary and be in a readable and understandable form that contains the following information: (1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as an at-risk beneficiary; (2) An explanation that the beneficiary is subject to the requirements of the sponsor's drug management program, including the limitation the sponsor is placing on the beneficiary's access to coverage for frequently abused drugs and the effective and end date of the limitation; and, if applicable, any limitation on the availability of the special enrollment period described in § 423.38 *et seq.*; (3) The prescriber(s) and/or pharmacy(ies) or both, if and as applicable, from which the beneficiary must obtain frequently abused drugs in order for them to be covered by the sponsor; (4) An explanation of the beneficiary's right to a redetermination under § 423.580 *et seq.*, including a description of both the standard and expedited redetermination processes, with the beneficiary's right to, and conditions for, obtaining an expedited redetermination; (5) An explanation that the beneficiary may submit to the sponsor, if the beneficiary has not already done so, the prescriber(s) and pharmacy(ies), as applicable, from which the beneficiary would prefer to obtain frequently abused drugs; (6) Clear instructions that explain how the beneficiary may contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(6)(ii)(C)(5) of this section; and (7) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

The content of the second notice we propose in § 423.153(f)(6) closely follows the content required by section 1860D-4(c)(5)(B)(iii) of the Act, but as noted previously, we have proposed to add some detail to the regulation text. In proposed paragraph (2), we have proposed language that would require a sponsor to include the limitation the sponsors is placing on the beneficiary's access to coverage for frequently abused drugs, the effective and end date of the limitation, and if applicable, any limitation on the availability of the SEP. We propose an additional requirement in paragraph (6) that the sponsor include instructions how the beneficiary

may submit information to the sponsor in response to the request described in paragraph (4). Finally, we proposed a requirement in paragraph (7) that the notice contain other content that CMS determines is necessary for the beneficiary to understand the information required in the initial notice.

We note that under our current policy, plan sponsors send only one notice to the beneficiary if they intend to implement a beneficiary-specific POS opioid claim edit, which generally provides the beneficiary with a 30-day advance written notice and opportunity to provide additional information, as well as to request a coverage determination if the beneficiary disagrees with the edit. If our proposal is finalized, the implementation of a beneficiary-specific POS claim edit or a limitation on the at-risk beneficiary's coverage for frequently abused drugs to a selected pharmacy(ies) or prescriber(s) would be an at-risk determination (a type of initial determination that would confer appeal rights). Also, the sponsor would generally be required to send two notices—the first signaling the sponsor's intent to implement a POS claim edit or limitation (both referred to generally as a “limitation”), and the second upon implementation of such limitation. Under our proposal, the requirement to send two notices would not apply in certain cases involving at-risk beneficiaries who are identified as such and provided a second notice by their immediately prior plan's drug management program.

(D) Alternate Second Notice When Limit on Access Coverage for Frequently Abused Drugs by Sponsor Will Not Occur (§ 423.153(f)(7))

We propose that if a sponsor does not implement the limitation on the potential at-risk beneficiary's access to coverage of frequently abused drugs it described in the initial notice, then the sponsor would be required to provide the beneficiary with an alternate second notice. Although not explicitly required by the statute, we believe this notice is consistent with the intent of the statute and is necessary to avoid beneficiary confusion and minimize unnecessary appeals. We propose generally that in such an alternate notice, the sponsor must notify the beneficiary that the sponsor no longer considers the beneficiary to be a potential at-risk beneficiary upon making such determination; will not place the beneficiary in its drug management program; will not limit the beneficiary's access to coverage for frequently abused

drugs; and if applicable, that the SEP limitation no longer applies.

Specifically, we propose that § 423.153(f)(7)(i) would read: Alternate second notice. (i) If, after providing an initial notice to a potential at-risk beneficiary under paragraph (f)(4) of this section, a Part D sponsor determines that the potential at-risk beneficiary is not an at-risk beneficiary, the sponsor must provide an alternate second written notice to the beneficiary. Paragraph (f)(7)(ii) would require that the notice use language approved by the Secretary in a readable and understandable form containing the following information: (1) The sponsor has determined that the beneficiary is not an at-risk beneficiary; (2) The sponsor will not limit the beneficiary's access to coverage for frequently abused drugs; (3) If applicable, the SEP limitation no longer applies; (4) Clear instructions that explain how the beneficiary may contact the sponsor; and (5) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

Again, as with the initial and second notices, we propose in a paragraph (f)(7)(iii) that the Part D sponsor be required to make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required by paragraph (f)(7)(i). Also, as with the initial and second notices, we propose in paragraph (ii) that the notice use language approved by the Secretary and be in a readable and understandable form; in paragraph (ii)(C)(4) that the notice contain clear instructions that explain how the beneficiary may contact the sponsor; and in paragraph (ii)(C)(5), that the notice contain other content that CMS determines is necessary for the beneficiary to understand the information required in the notice.

(E) Timing of Notices (§ 423.153(f)(8))

Section 1860D–4(c)(5)(B)(iv) of the Act requires a Part D sponsor to provide the second notice to the beneficiary on a date that is not less than 30 days after the sponsor provided the initial notice to the beneficiary. We interpret the purpose of this requirement to be that the beneficiary should have ample time to provide information to the sponsor that may alter the sponsor's intended action that is contained in the initial notice to the beneficiary, or to provide the sponsor with the beneficiary's pharmacy and/or prescriber preferences, if the sponsor's intent is to limit the beneficiary's access to coverage for frequently abused drugs from selected a pharmacy(ies) and/or prescriber(s).

In addition, we propose to impose a deadline by when a sponsor must provide the second notice or alternate second notice to the beneficiary, although not specifically required by CARA. Such a requirement should provide the sponsor with sufficient time to complete the administrative steps necessary to execute the action the sponsor intends to take that was explained in the initial notice to the beneficiary, while acknowledging that the sponsor would have already met in the case management, clinical contact and prescriber verification requirement.

In the case of an alternate second notice, the timeframe should provide the beneficiary with definitive notice that the sponsor has not identified the beneficiary as an at-risk beneficiary and that there will be no limitation on his/her access to coverage for frequently abused drugs. Accordingly, we propose that the sponsor would be required to send either the second notice or the alternate second notice, as applicable, when it makes its determination or no later than 90 calendar days after the date on the initial notice, whichever comes sooner.

Specifically, we propose to include at § 423.153(f)(8) the following: Timing of Notices. (i) Subject to paragraph (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 and not more than the earlier of the date the sponsor makes the relevant determination or 90 days after the date of the initial notice described in paragraph (f)(5) of this section. We intend this proposed timeframe for the sponsor to provide either the second notice or the alternate second notice, as applicable, to be reasonable for both Part D sponsors and the relevant beneficiaries and important to ensuring clear, timely and reasonable communication between the parties.

Section 1860D–4(c)(5)(B)(iv)(II) of the Act explicitly provides for an exception to the required timeframe for issuing a second notice. Specifically, the statute permits the Secretary to identify through rulemaking concerns regarding the health or safety of a beneficiary or significant drug diversion activities that would necessitate that a Part D sponsor provide the second written notice to the beneficiary before the 30 day time period normally required has elapsed. For this reason, we included the language, “subject to paragraph (ii),” at the beginning of proposed § 423.153(f)(8)(i).

We note that the proposed definition of at-risk beneficiary would include beneficiaries for whom a gaining Part D plan sponsor received a notice upon the beneficiary's enrollment that the beneficiary was identified as an at-risk beneficiary under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon enrollment. This proposed definition is based on the language in section 1860-D-4(c)(5)(C)(i)(II) of the Act.

Given that this provision allows an at-risk identification to carry forward to the next plan, we believe it is appropriate to propose to permit a gaining plan to provide the second notice to an at-risk beneficiary so identified by the most recent prior plan sooner than would otherwise be required. For the same reasons, we believe that it would be appropriate to permit the gaining plan to even send the beneficiary a combined initial and second notice, under certain circumstances. However, because the content of the initial notice would not be appropriate for an at-risk beneficiary, and because such beneficiary would have already received an initial notice from his or her immediately prior plan sponsor, the content of this combined notice should only consist of the required content for the second notice so as not to confuse the beneficiary. Thus, our interpretation of section 1860D-4(c)(5)(B)(iv)(II) of the Act in conjunction with section 1860D-4(c)(5)(C)(i)(II) of the Act is that a gaining Part D sponsor may send the second notice immediately to a beneficiary for whom the sponsor received a notice upon the beneficiary's enrollment that the beneficiary was identified as an at-risk beneficiary under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment. This is consistent with our current policy under which a gaining sponsor may immediately implement a beneficiary-specific opioid POS claim edit, if the gaining sponsor is notified that the beneficiary was subject to such an edit in the immediately prior plan and such edit had not been terminated.¹⁹

We propose that sending a second notice to an at-risk beneficiary so identified in the most recent plan would be permissible only if the new sponsor is implementing a beneficiary-specific POS claim edit for a frequently abused

drug, or if the sponsor is implementing a limitation on access to coverage for frequently abused drugs to a selected pharmacy(ies) or prescriber(s) and has the same location of pharmacy(ies) and/or the same prescriber(s) in its provider network, as applicable, that the beneficiary used to obtain frequently abused drugs in the most recent plan. Otherwise, we propose that the new sponsor would be required to provide the initial notice to the at-risk beneficiary, even though the initial notice is generally intended for potential at-risk beneficiaries, and could not provide the second notice until at least 30 days had passed. This is because even though there would also be a concern for the at-risk beneficiary's health and safety in this latter case as well, this concern would be outweighed by the fact that the beneficiary had not been afforded a chance to submit his or her preference for a pharmacy(ies) and/or prescriber(s), as applicable, from which he or she would have to obtain frequently abused drugs to obtain coverage under the new plan's drug management program.

We propose to codify this policy by adding a paragraph (ii) to § 423.153(f)(8), as noted earlier, to read as follows: Immediately upon the beneficiary's enrollment in the gaining plan, the gaining plan sponsor may provide a second notice described in paragraph (f)(6) to a beneficiary for whom the gaining sponsor received notice that the beneficiary was identified as an at-risk beneficiary by his or her most recent prior plan and such identification had not been terminated in accordance with § 423.153(f)(14), if the sponsor is implementing either of the following: (A) A beneficiary-specific point-of-sale claim edit as described in paragraph (f)(3)(i); or (B) A limitation on access to coverage as described in paragraph (f)(3)(ii), if such limitation would require the beneficiary to obtain frequently abused drugs from the same location of pharmacy and/or the same prescriber, as applicable, that was selected under the immediately prior plan under (f)(9).

Some stakeholders commented that sponsors should be allowed to expedite the second notice in cases of egregious and potentially dangerous overutilization or in cases involving an active criminal investigation when allowed by a court. However, given the importance of a beneficiary having advance notice of a pending limit on his or her access to coverage for frequently abused drugs and sufficient time to respond and/or prepare, we believe exceptions to the timing of the notices

should be very narrow. Therefore, we have only included a proposal for an exception to shorten the 30 day timeframe between the initial and second notice that is based on a beneficiary's status as an at-risk beneficiary in an immediately preceding plan. We note that is a status the drug management provisions of CARA explicitly requires to be shared with the next plan sponsor, if a beneficiary changes plans, which means there would be a concrete data point for this proposed exception to the timing of the notices. We discuss such sharing of information later in the preamble.

(viii) Provisions Specific to Limitations on Access to Coverage of Frequently Abused Drugs to Selected Pharmacies and Prescribers (§§ 423.153(f)(4), 423.153(f)(9), 423.153(f)(10), 423.153(f)(11), 423.153(f)(12), 423.153(f)(13))

Some of the drug management program provisions in CARA are only relevant to "lock-in". We propose several regulatory provisions to implement these provisions, as follows:

(A) Special Requirement To Limit Access to Coverage of Frequently Abused Drugs to Selected Prescriber(s) (§ 423.153(f)(4))

We believe prescriber lock-in should be a tool of last resort to manage at-risk beneficiaries' use of frequently abused drugs, meaning when a different approach has not been successful, whether that was a "wait and see" approach or the implementation of a beneficiary specific POS claim edit or a pharmacy lock-in. Limiting an at-risk beneficiary's access to coverage for frequently abused drugs from only selected prescribers impacts the beneficiary's relationship with his or her health care providers and may impose burden upon prescribers in terms of prescribing frequently abused drugs.

As a result, we propose that a sponsor may not limit an at-risk beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) until at least 6 months has passed from the date the beneficiary is first identified as a potential at-risk beneficiary. We propose that this date be the date of the first OMS report that identified the beneficiary, so long as the beneficiary was also reported in the most recent OMS report that the sponsor received. This is because limiting the beneficiary's access to coverage of frequently abused drugs from a selected prescriber would only be necessary if the beneficiary continues to meet the clinical guidelines despite any existing

¹⁹ See "Beneficiary-Level Point-of-Sale Claim Edits and Other Overutilization Issues," August 25, 2014.

intervention or limitation. We discuss OMS reports in more detail later.

We expect that the 6-month waiting period will provide the sponsor additional time to assess whether case management or another tool, such as a beneficiary-specific POS claim edit or pharmacy lock-in has failed to resolve the beneficiary's overutilization of frequently abused drugs. Sponsors have indicated in comments on the current policy that the case management process can take 3 to 6 months. Also, sponsors would need time to determine whether the beneficiary still meets the clinical guidelines and is thus continuing to be reported by OMS. Therefore, the time period we propose was chosen to account for time needed for the case management process and to align with the 6 month measurement period of the proposed clinical guidelines.

We seek comment on whether this 6-month waiting period would reduce provider burden sufficiently to outweigh the additional case management, clinical contact and prescriber verification that providers may experience if a sponsor believes a beneficiary's access to coverage of frequently abused drugs should be limited to a selected prescriber(s). Comments should include the additional operational considerations for sponsors to implement this proposal.

Given our proposal, we propose adding a paragraph (iv) to § 423.153(f)(4) that would state: (f)(4)(iv) A Part D sponsor must not limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers under § 423.153(f)(3)(ii)(A) unless—(A) At least 6 months has passed from the date the beneficiary was first identified as a potential at-risk beneficiary from the date of the applicable CMS identification report; and (B) The beneficiary meets the clinical guidelines and was reported by the most recent CMS identification report.

We note that in conducting the case management required under § 423.153(f)(4)(i)(A) in anticipation of implementing a prescriber lock-in, the sponsor would be expected to update any case management it had already conducted. Also, even if a sponsor had already obtained the prescriber's agreement to implement a limitation on the beneficiary's coverage of frequently abused drugs to a selected pharmacy to comply with § 423.153(f)(4)(i)(B), for example, the sponsor would have to obtain the agreement of the prescriber who would be selected to implement a limitation on a beneficiary's coverage of

frequently abused drugs to a selected prescriber. Finally, we note that even if a sponsor had already provided the beneficiary with the required notices to comply with § 423.153(f)(4)(i)(C), the sponsor would have to provide them again in order to remain compliant, because the beneficiary would not have been notified about the specific limitation on his or her access to coverage for frequently abused drugs to a selected prescriber(s) and has an opportunity to select the prescriber(s).

We foresee a scenario in which a sponsor may wish to implement a limitation on a beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) when the sponsor's first round of case management, clinical contact and prescriber verification resulted only in sending the prescribers of frequently abused drugs a written report about the beneficiary's utilization of frequently abused drugs and taking a "wait and see" approach, which did not result in the prescribers' adjusting their prescriptions for frequently abused drugs for their patient. In such a scenario, assuming the patient still meets the clinical guidelines and continues to be reported by OMS, the sponsor would need to try another intervention to address the opioid overuse. Another scenario could be that the sponsor implemented a pharmacy lock-in, but after 6-months, the beneficiary still meets the clinical guidelines due to receiving frequently abused drugs from additional prescribers.

(B) Selection of Pharmacies and Prescribers (§§ 423.153(f)(9), 423.153(f)(10), 423.153(f)(11), 423.153(f)(12), 423.153(f)(13))

(1) Beneficiary Preferences (§ 423.153(f)(9))

Section 1860D–4(c)(5)(D) of the Act provides that, if a sponsor intends to impose, or imposes, a limit on a beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) or prescriber(s), and the potential at-risk beneficiary or at-risk beneficiary submits preferences for a pharmacy(ies) or prescriber(s), the sponsor must select the pharmacy(ies) and prescriber(s) for the beneficiary based on such preferences, unless an exception applies, which we will address later in the preamble. We further propose that such pharmacy(ies) or prescriber(s) must be in-network, except if the at-risk beneficiary's plan is a stand-alone prescription drug benefit plan and the beneficiary's preference involves a prescriber. Because stand-

alone Part D plans (PDPs) do not have provider networks, and thus no prescriber would be in-network, the plan sponsor must generally select the prescriber that the beneficiary prefers, unless an exception applies. We discuss exceptions in the next section of this preamble. In our view, it is essential that an at-risk beneficiary must generally select in-network pharmacies and prescribers so that the plan is in the best possible position to coordinate the beneficiary's care going forward in light of the demonstrated concerns with the beneficiary's utilization of frequently abused drugs.

Accordingly, we propose § 423.153(f)(9) to read: Beneficiary preferences. Except as described in paragraph (f)(10) of this section, if a beneficiary submits preferences for prescribers or pharmacies or both from which the beneficiary prefers to obtain frequently abused drugs, the sponsor must do the following—(i) Review such preferences and (ii) If the beneficiary is—(A) Enrolled in a stand-alone prescription drug benefit plan and specifies a prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or network pharmacy(ies) or both for the beneficiary based on beneficiary's preference(s) or (B) Enrolled in a Medicare Advantage prescription drug benefit plan and specifies a network prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or pharmacy(ies) or both for the beneficiary based on the beneficiary's preference(s). If the beneficiary submits preferences for a non-network pharmacy(ies), or in the case of a Medicare Advantage prescription drug benefit plan a non-network prescriber(s), or both, the sponsor does not have to select or change the selection for the beneficiary to a non-network pharmacy or prescriber except if necessary to provide reasonable access.

In a paragraph (iii), we propose that the sponsor must inform the beneficiary of the selection in the second notice, or if not feasible due to the timing of the beneficiary's submission, in a subsequent written notice, issued no later than 14 days after receipt of the submission. Thus, this section would require a Part D plan sponsor to honor an at-risk beneficiary's preferences for in-network prescribers and pharmacies from which to obtain frequently abused drugs, unless the plan was a stand-alone PDP and the selection involves a prescriber. In other words, a stand-alone PDP or MA–PD does not have to honor a beneficiary's selection of a non-network pharmacy, except as necessary

to provide reasonable access, which we discuss later in this section. Also, under our proposal, the beneficiary could submit preferences at any time. Finally, the sponsor would be required to confirm the selection in writing either in the second notice, if feasible, or within 14 days of receipt of the beneficiary's submission.

(2) Exception to Beneficiary Preferences (§ 423.153(f)(10))

Section 1860D-4(c)(5)(D)(iv) of the Act, provides for an exception to an at-risk beneficiary's preference of prescriber or pharmacy from which the beneficiary must obtain frequently abused drugs, if the beneficiary's allowable preference of prescriber or pharmacy would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary. Section 1860D-4(c)(5)(D)(iv) of the Act requires the sponsor to provide the at-risk beneficiary with at least 30 days written notice and a rationale for not honoring his or her allowable preference for pharmacy or prescriber from which the beneficiary must obtain frequently abused drugs under the plan.

A few commenters asserted there should be limits to how many times beneficiaries can submit their preferences. Other commenters stated there should be a strong evidence of inappropriate action before a sponsor can change a beneficiary's selection.

We are not proposing to place a limit on how many times beneficiaries can submit their preferences, but we are open to additional comments on this topic. We agree with commenters who stated that there should be a strong evidence of inappropriate action before a sponsor can change a beneficiary's selection, but we note that because such a situation would often involve a network pharmacy or prescriber, we would expect that the sponsor would also take appropriate action with respect to the pharmacy or prescriber, such as termination from the network.

Given the foregoing, we propose to add the following: § 423.153(f)(10) Exception to Beneficiary Preferences. (i) If the Part D sponsor determines that the selection or change of a prescriber or pharmacy under paragraph (f)(9) of this section would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary, the sponsor may change the selection without regard to the beneficiary's preferences if there is strong evidence of inappropriate action by the prescriber, pharmacy or beneficiary. (ii) If the sponsor changes the selection, the sponsor must provide the beneficiary with (A) At least 30 days

advance written notice of the change; and (B) A rationale for the change.

(3) Reasonable Access (§§ 423.100, 423.153(f)(11), 423.153(f)(12))

If a potential at-risk beneficiary or at-risk beneficiary does not submit pharmacy or prescriber preferences, section 1860D-4(c)(5)(D)(i) of the Act provides that the Part D sponsor shall make the selection. Section 1860D-4(c)(5)(D)(ii) of the Act further provides that, in making the selection, the sponsor shall ensure that the beneficiary continues to have reasonable access to frequently abused drugs, taking into account geographic location, beneficiary preference, impact on cost-sharing, and reasonable travel time.

We propose to add the following at § 423.153(f)(11): Reasonable access. In making the selections under paragraph (f)(12) of this section, a Part D plan sponsor must ensure both of the following: (i) That the beneficiary continues to have reasonable access to frequently abused drugs, taking into account geographic location, beneficiary preference, the beneficiary's predominant usage of a prescriber or pharmacy or both, impact on cost-sharing, and reasonable travel time; and (ii) reasonable access to frequently abused drugs in the case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services.

Since the statute explicitly allows the beneficiary to submit preferences, we interpret the additional reference to beneficiary preference in the context of reasonable access to mean that a beneficiary allowable preference should prevail over a sponsor's evaluation of geographic location, the beneficiary's predominant usage of a prescriber and/or pharmacy impact on cost-sharing and reasonable travel time. In the absence of a beneficiary preference for pharmacy and/or prescriber, however, a Part D plan sponsor must take into account geographic location, the beneficiary's predominant usage of a prescriber and/or pharmacy, impact on cost-sharing and reasonable time travel in selecting a pharmacy and/or prescriber, as applicable, from which the at-risk beneficiary will have to obtain frequently abused drugs under the plan. Thus, absent a beneficiary's allowable preference, or the beneficiary's selection would contribute to prescription drug abuse or drug diversion, the sponsor must ensure reasonable access by choosing the network pharmacy or prescriber that the beneficiary uses most frequently to obtain frequently abused drugs, unless the plan is a stand-alone

PDP and the selection involves a prescriber(s). In the latter case, the prescriber will not be a network provider, because such plans do not have provider networks. In urgent circumstances, we propose that reasonable access means the sponsor must have reasonable policies and procedures in place to ensure beneficiary access to coverage of frequently abused drugs without a delay that may seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function.

Determining reasonable access may be complicated when an enrollee has multiple addresses or his or her health care necessitates obtaining frequently abused drugs from more than one prescriber and/or more than one pharmacy. Section 1860D-4(c)(5) addresses this issue by requiring the Part D plan sponsor to select more than one prescriber to prescribe frequently abused drugs and more than one pharmacy to dispense them, as applicable, when it reasonably determines it is necessary to do so to provide the at-risk beneficiary with reasonable access.

Given the foregoing, we propose the following at § 423.153(f)(12): Selection of Prescribers and Pharmacies. (i) A Part D plan sponsor must select, as applicable—(A) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network prescriber who is authorized to prescribe frequently abused drugs for the beneficiary, unless the plan is a stand-alone PDP and the selection involves a prescriber(s), in which case, the prescriber need not be a network prescriber; and (B) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network pharmacy that may dispense such drugs to such beneficiary.

We also propose to address chain pharmacies and group practices by adding a paragraph (ii) that states: (ii) (A) For purposes of this subsection (f)(12) of this section, in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy shall collectively be treated as one pharmacy; and (B) For purposes of this subsection (f)(12), in the case of a group practice, all prescribers of the group practice shall be treated as one prescriber.

We would interpret these provisions to mean that a sponsor would be required to select more than one prescriber of frequently abused drugs, if more than one prescriber has asserted

during case management that multiple prescribers of frequently abused drugs are medically necessary for the at-risk beneficiary. We further propose that if no prescribers of frequently abused drugs were responsive during case management, and the beneficiary does not submit preferences, the sponsor would be required to select the pharmacy or prescriber that the beneficiary predominantly uses to obtain frequently abused drugs.

(4) Confirmation of Pharmacy and Prescriber Selection (§ 423.153(f)(13))

Section 1860D–4(c)(5)(D)(v) of the Act requires that, before selecting a prescriber or pharmacy, a Part D plan sponsor must notify the prescriber and/or pharmacy that the at-risk beneficiary has been identified for inclusion in the drug management program which will limit the beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) and/or prescriber(s) and that the prescriber and/or pharmacy has been selected as a designated prescriber and/or pharmacy for the at-risk beneficiary.

We propose that plan sponsors can obtain a network provider's confirmation in advance by including a provision in the network agreement specifying that the provider agrees to serve as at-risk beneficiaries' selected prescriber or pharmacy, as applicable. In these cases, the network provider would agree to forgo providing specific confirmation if selected under a drug management program to serve an at-risk beneficiary. However, the contract between the sponsor and the network provider would need to specify how the sponsor will notify the provider of its selection. Absent a provision in the network contract, however, the sponsor would be required to receive confirmation from the prescriber(s) and/or pharmacy(ies) that the selection is accepted before conveying this information to the at-risk beneficiary. Otherwise, the plan would need to make another selection and seek confirmation.

We propose § 423.153(f)(13) to read: Confirmation of Selections(s). (i) Before selecting a prescriber or pharmacy under this paragraph, a Part D plan sponsor must notify the prescriber or pharmacy, as applicable, that the beneficiary has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber or pharmacy or both is (are) being selected as the beneficiary's designated prescriber or pharmacy or both for frequently abused drugs. (ii) The sponsor must receive confirmation from the prescriber(s) or pharmacy(ies) or both that the selection

is accepted before conveying this information to the at-risk beneficiary, unless the prescriber or pharmacy has agreed in advance in its network agreement with the sponsor to accept all such selections and the agreement specifies how the prescriber or pharmacy will be notified by the sponsor of its selection.

(ix) Drug Management Program Appeals (§§ 423.558, 423.560, 423.562, 423.564, 423.580, 423.582, 423.584, 423.590, 423.602, 423.636, 423.638, 423.1970, 423.2018, 423.2020, 423.2022, 423.2032, 423.2036, 423.2038, 423.2046, 423.2056, 423.2062, 423.2122, and 423.2126)

Section 1860D–4(c)(5)(E) of the Act specifies that the identification of an individual as an at-risk beneficiary for prescription drug abuse under a Part D drug management program, a coverage determination made under such a program, the selection of a prescriber or pharmacy, and information sharing for subsequent plan enrollments shall be subject to reconsideration and appeal under section 1860D–4(h) of the Act. This provision also permits the option of an automatic escalation to external review to the extent provided by the Secretary.

As discussed earlier in this preamble, we are proposing to integrate the lock-in provisions with existing Part D Opioid DUR Policy/OMS. Determinations made in accordance with any of those processes, proposed at § 423.153(f), and discussed previously, are interrelated issues that we collectively refer to as an "at-risk determination" made under a drug management program. The at-risk determination includes prescriber and/or pharmacy selection for lock-in, beneficiary-specific POS claim edits for frequently abused drugs, and information sharing for subsequent plan enrollments. Given the concomitant nature of the at-risk determination and associated aspects of the drug management program applicable to an at-risk beneficiary, we expect that any dispute under a plan's drug management program will be adjudicated as a single case involving a review of all aspects of the drug management program for the at-risk beneficiary. While a beneficiary who is subject to a Part D plan sponsor's drug management program always retains the right to request a coverage determination under existing § 423.566 for any Part D drug that the beneficiary believes may be covered by their plan, we believe that appeals of an at-risk determination made under proposed § 423.153(f) should involve consideration of all relevant elements of

that at-risk determination. For example, if a Part D plan determines that a beneficiary is at-risk, implements a beneficiary-specific claim edit on 2 drugs that beneficiary is taking and locks that beneficiary into a specific pharmacy, the affected beneficiary should not be expected to raise a dispute about the pharmacy selection and about one of the claim edits in distinct appeals.

We note that, while section 1860D–4(c)(5)(B)(ii)(III) of the Act requires the initial written notice to the beneficiary, which identifies him or her as *potentially* being at-risk, to include "notice of, and information about, the right of the beneficiary to appeal such identification under subsection (h)," we interpret "such identification" to refer to any subsequent identification that the beneficiary is actually at-risk. Because CARA, at section 1860D–4(c)(5)(E) of the Act, specifically provides for appeal rights under subsection (h) but does not refer to identification as a potential at-risk beneficiary, we believe this interpretation is consistent with the statutory intent. Furthermore, when a beneficiary is identified as being potentially at-risk, but has not yet been identified as at-risk, the plan is not taking any action to limit such beneficiary's access to frequently abused drugs; therefore, the situation is not ripe for appeal. While an LIS SEP under § 423.38 would be restricted at the time the beneficiary is identified as potentially at-risk under proposed § 423.100, the loss of such SEP is not appealable under section 1860D–4(h) of the Act.

As noted previously, section 1860D–4(c)(5)(E) of the Act specifically refers to the Part D benefit appeals provisions in section 1860D–4(h) of the Act, which require Part D plan sponsors to meet the requirements of paragraphs (4) and (5) of section 1852(g) of the Act for benefits in a manner similar to the manner such requirements apply to MA organizations. Section 1852(g)(4) of the Act specifically provides for independent review of "reconsiderations that *affirm denial of coverage, in whole or in part (emphasis added).*" We believe section 1860D–4(c)(5)(E) of the Act broader reference to "reconsideration and appeal" should be interpreted to mean that individuals have a right to a plan level appeal, consistent with the reconsideration provisions under section 1860D–4(g) of the Act, followed by the right to independent review if the plan level affirms the initial adverse decision. In other words, we believe the reference to "reconsideration" means that a Part D plan sponsor should conduct the initial

level of appeal following an at-risk determination under the plan sponsor's drug management program, consistent with the existing Part D drug benefit appeals process, despite the absence of a specific reference to section 1860D-4(g) of the Act.

Part D enrollees, plan sponsors, and other stakeholders are already familiar with the Part D benefit appeals process. Resolving disputes that arise under a plan sponsor's drug management program within the existing Part D benefit appeals process would allow at-risk beneficiaries to be more familiar with, and more easily access, the appeals process instead of creating a new process specific to appeals related to a drug management program. Also, allowing a plan sponsor the opportunity to review information it used to make an at-risk determination under the drug management program (and any additional relevant information submitted as part of the appeal) would be efficient for both the individual and the Medicare program because it would potentially resolve the issues at a lower level of administrative review. Conversely, permitting review by the independent review entity (IRE) before a plan sponsor has an opportunity to review and resolve any errors or omissions that may have been made during the initial at-risk determination would likely result in an unnecessary increase in costs for plan sponsors as well as CMS' Part D IRE contract costs.

As noted previously, the Secretary has the discretion under CARA to provide for automatic escalation of drug management program appeals to external review. 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 Part D benefit appeals process, cases are auto-forwarded to the IRE only when the plan fails to issue a coverage determination within the applicable timeframe. During the stakeholder call and in subsequent written comments, most commenters opposed automatic escalation to the IRE, citing support for using the existing appeals process for reasons of administrative efficiency and better outcomes for at-risk beneficiaries. The majority of stakeholders supported following the existing Part D appeals process, and some commenters specifically supported permitting the plan to review its lock-in decision prior to the case being subject to IRE review. Stakeholders cited a variety of reasons for their opposition, including increased costs to plans, the IRE, and the Part D

program. Stakeholders cited administrative efficiency in using the existing appeal process that is familiar to enrollees, plans, and the IRE, while other commenters expressed support for automatic escalation to the IRE as a beneficiary protection.

We are proposing that at-risk determinations made under the processes at § 423.153(f) be adjudicated under the existing Part D benefit appeals process and timeframes set forth in Subpart M. However, we are not proposing to revise the existing definition of a coverage determination. The types of decisions made under a drug management program align more closely with the regulatory provisions in Subpart D than with the provisions in Subpart M related to coverage or payment for a drug based on whether the drug is medically necessary for an enrollee. Therefore, we believe it is clearer to set forth the rules for at-risk determinations as part of § 423.153 and cross reference § 423.153(f) in relevant provisions in Subpart M and Subpart U. While a coverage determination made under a drug management program would be subject to the existing rules related to coverage determinations, the other types of initial determinations made under a drug management program (for example, a restriction on the at-risk beneficiary's access to coverage of frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers) would be subject to the processes set forth at proposed § 423.153(f). Consistent with existing rules for redeterminations at § 423.582, an enrollee who wishes to dispute an at-risk determination would have 60 days from the date of the second written notice to make such request, unless the enrollee shows good cause for untimely filing under § 423.582(c). As previously discussed for proposed § 423.153(f)(6), the second written notice is sent to a beneficiary the plan has identified as an at-risk beneficiary and with respect to whom the sponsor limits his or her access to coverage of frequently abused drugs regarding the requirements of the sponsor's drug management programs.

Also consistent with the existing Part D benefit appeals process, we are proposing that at-risk beneficiaries (or an at-risk beneficiary's prescriber, on behalf of the at-risk beneficiary) must affirmatively request IRE review of adverse plan level appeal decisions made under a plan sponsor's drug management program. In other words, under this proposal, an adverse redetermination would not be automatically escalated to the Part D IRE, unless the plan sponsor fails to

meet the redetermination adjudication timeframe. We are also proposing to amend the existing Subpart M rules at § 423.584 and § 423.600 related to obtaining an expedited redetermination and IRE reconsideration, respectively, to apply them to appeals of a determination made under a drug management program. The right to an expedited appeal of such a determination, which must be adjudicated as expeditiously as the at-risk beneficiary's health condition requires, would ensure that the rights of at-risk beneficiaries are protected with respect to access to medically necessary drugs. While we are not proposing to adopt auto-escalation, we believe our proposed approach ensures that an at-risk beneficiary has the right to obtain IRE review and higher levels of appeal (ALJ/attorney adjudicator, Council, and judicial review). Accordingly, we also are proposing to add the reference to an "at-risk determination" to the following regulatory provisions that govern ALJ and Council processes: §§ 423.2018, 423.2020, 423.2022, 423.2032, 423.2036, 423.2038, 423.2046, 423.2056, 423.2062, 423.2122, and 423.2126.

Finally, we are also proposing a change to § 423.1970(b) to address the calculation of the amount in controversy (AIC) for an ALJ hearing in cases involving at-risk determinations made under a drug management program in accordance with proposed § 423.153(f). Specifically, we propose that the projected value of the drugs subject to the drug management program be used to calculate the amount remaining in controversy. For example, if the beneficiary is disputing the lock-in to a specific pharmacy for frequently abused drugs and the beneficiary takes 3 medications that are subject to the plan's drug management program, the projected value of those 3 drugs would be used to calculate the AIC, including the value of any refills prescribed for the drug(s) in dispute during the plan year.

In addition to the proposed changes related to the implementation of drug management program appeals, we are also proposing to make technical changes to § 423.562(a)(1)(ii) to remove the comma after "includes" and replace the reference to "§§ 423.128(b)(7) and (d)(1)(iii)" with a reference to "§§ 423.128(b)(7) and (d)(1)(iv)."

(x) Termination of a Beneficiary's Potential At-Risk or At-Risk Status (§ 423.153(f)(14))

Section 1860D-4(c)(5)(F) of the Act provides that the Secretary shall develop standards for the termination of the identification of an individual as an at-risk beneficiary, which shall be the

earlier of the date the individual demonstrates that he or she is no longer likely to be an at-risk beneficiary in the absence of limitations, or the end of such maximum period as the Secretary may specify.

Most commenters recommended a maximum 12-month period for an at-risk beneficiary to be locked-in. We also note that a 12-month lock-in period is common in Medicaid lock-in programs.²⁰ A few commenters stated that a physician should be able to determine that a beneficiary is no longer an at-risk beneficiary. One commenter was opposed to an arbitrary termination based on a time period.

Given that most commenters recommended a 12-month period and such a period is common in Medicaid “lock-in” program, we propose a maximum 12-month period for both a lock-in period, and also for the duration of a beneficiary-specific POS claim edit for frequently abused drugs through the addition of the following language at § 423.153(f)(14): Termination of Identification as an At-Risk Beneficiary. The identification of an at-risk beneficiary as such shall terminate as of the earlier of the following—

(i) The date the beneficiary demonstrates through a subsequent determination, including but not limited to, a successful appeal, that the beneficiary is no longer likely, in the absence of the limitations under this paragraph, to be an at-risk beneficiary; or

(ii) The end of a 12 calendar month period calculated from the effective date of the limitation, as specified in the notice provided under paragraph (f)(6) of this section.

Thus, we note that if a beneficiary continues to meet the clinical guidelines and, if the sponsor implements an additional, overlapping limitation on the at-risk beneficiary’s access to coverage for frequently abused drugs, the beneficiary may experience a coverage limitation beyond 12-months. The same is true for at-risk beneficiaries who were identified as such in the most recent prescription drug plan in which they were enrolled and the sponsor of his or her subsequent plan immediately implements a limitation on coverage of frequently abused drugs.

Section 1860–D–4(c)(5)(F)(ii) of the Act states that nothing in CARA shall be construed as preventing a plan from identifying an individual as an at-risk beneficiary after such termination on

the basis of additional information on drug use occurring after the date of notice of such termination. Accordingly, we note that our proposed approach to termination of an at-risk determination would not prevent an at-risk beneficiary from being subsequently identified as a potential at-risk beneficiary or at-risk beneficiary on the basis of new information on drug use occurring after the date of such termination that causes the beneficiary to once again meet the clinical guidelines.

(xi) Data Disclosure and Sharing of Information for Subsequent Sponsor Enrollments (§ 423.153(f)(15))

In order for Part D sponsors to conduct the case management/clinical contact/prescriber verification required by proposed § 423.153(f)(2), CMS must identify potential at-risk beneficiaries to sponsors who are in the sponsors’ Part D prescription drug benefit plans. In addition, new sponsors must have information about potential at-risk beneficiaries and at-risk beneficiaries who were so identified by their immediately prior plan and enroll in the new sponsor’s plan and such identification had not terminated before the beneficiary disenrolled from the immediately prior plan. Finally, as discussed earlier, sponsors may identify potential at-risk beneficiaries by their own application of the clinical guidelines on a more frequent basis. It is important that CMS be aware of which Part D beneficiaries sponsors identify on their own, as well as which ones have been subjected to limitations on their access to coverage for frequently abused drugs under sponsors’ drug management programs for Part D program administration and other purposes. This data disclosure process would be consistent with current policy, as described earlier in this preamble.

As we also discussed earlier, under the current policy, CMS provides quarterly reports to sponsors about beneficiaries enrolled in their plans who meet the OMS criteria. In turn, Part D sponsors are expected to provide responses to CMS through the OMS for each case identified within 30 days of receiving a report that reflects the status or outcome of their case management.²¹ At the same time, also within 30 days, sponsors are expected to report additional beneficiaries to OMS that they identify using their own opioid overutilization identification criteria.²²

Regarding data disclosures, section 1860D–4(c)(5)(H) of the Act provides that, in the case of potential at-risk beneficiaries and at-risk beneficiaries, the Secretary shall establish rules and procedures to require the Part D plan sponsor to disclose data, including any necessary individually identifiable health information, in a form and manner specified by the Secretary, about the decision to impose such limitations and the limitations imposed by the sponsor under this part.

Sponsors also report information to CMS’ MARx system about pending, implemented and terminated beneficiary-specific POS claim edit for opioids within 7 business days of the date on the applicable beneficiary notice or of the termination.²³ The MARx system transfers information about pending and implemented claim edits to the gaining sponsor with the beneficiary’s enrollment record if the beneficiary disenrolls and enrolls in the gaining sponsor’s plan. If a gaining sponsor requests case management information from the losing sponsor about the beneficiary, we expect the losing sponsor to transfer the information to the gaining sponsor as soon as possible, but no later than 2 weeks from the date of the gaining sponsor’s request.²⁴

Section 1860–D–4(c)(5)(I) of the Act requires that the Secretary establish procedures under which Part D sponsors must share information when at-risk beneficiaries or potential at-risk beneficiaries enrolled in one prescription drug plan subsequently disenroll and enroll in another prescription drug plan offered by the next sponsor (gaining sponsor). We plan to expand the scope of the reporting to MARx under the current policy to include the ability for sponsors to report similar information to MARx about all pending, implemented and terminated limitations on access to coverage of frequently abused drugs associated with their plans’ drug management programs.

We propose to codify the data disclosure and information sharing process under the current policy, with the expansion just described, by adding the following requirement to § 423.153: (f)(15) Data Disclosure. (i) CMS identifies each potential at-risk beneficiary to the sponsor of the prescription drug plan in which the beneficiary is enrolled. (ii) A Part D sponsor that operates a drug management program must disclose any

²⁰ Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2015 Annual Report: Prescription Drug Fee-For Service Program (December 2016).

²¹ See “Medicare Part D Overutilization Monitoring System,” July 5, 2013.

²² See “Medicare Part D Overutilization Monitoring System, January 17, 2014.

²³ Final Parts C&D 2017 Call Letter, April 4, 2016.

²⁴ See “Beneficiary-Level Point-of-Sale Claim Edits and Other Overutilization Issues,” August 25, 2014.

data and information to CMS and other Part D sponsors that CMS deems necessary to oversee Part D drug management programs at a time, and in a form and manner, specified by CMS. The data and information disclosures must do all of the following: (A) Respond to CMS within 30 days of receiving a report about a potential at-risk beneficiary from CMS; (B) Provide information to CMS about any potential at-risk beneficiary that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries; (C) Provide information to CMS within 7 business days of the date of the initial notice or second notice that the sponsor provided to a beneficiary, or within 7 days of a termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs; and (D) Transfer case management information upon request of a gaining sponsor as soon as possible but no later than 2 weeks from the gaining sponsor's request when: (1) An at-risk beneficiary or potential at-risk beneficiary disenrolls from the sponsor's plan and enrolls in another prescription drug plan offered by the gaining sponsor; and (2) The edit or limitation that the sponsor had implemented for the beneficiary had not terminated before disenrollment.

(xii) Summary

Our proposal is intended to be responsive to stakeholder input that CMS focus on opioids; allow for flexibility to adjust the clinical guidelines and frequently abused drugs in the future; is reflective of the importance of the provider-patient relationship; protects beneficiary's rights and access, and allows for operational manageability and consistency with the current policy to the extent possible. This proposal, if finalized, should result in effective Part D drug management programs within a regulatory framework provided by CMS, and further reduce opioid overutilization in the Part D program.

2. Flexibility in the Medicare Advantage Uniformity Requirements

We have determined that providing access to services (or specific cost sharing for services or items) that is 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 Medicare Advantage (MA) regulations at § 422.100(d). This regulatory requirement is a means to implement

both section 1852(d) of the Act, which requires that benefits under the MA plan be 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. We have determined that these statutory provisions and the regulation at § 422.100(d) mean that we have the authority to permit MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees (that is, all enrollees who meet the identified criteria) are treated the same. For example, reduced cost sharing flexibility would allow an MA plan to offer diabetic enrollees zero cost sharing for endocrinologist visits. Similarly, with this flexibility, a MA plan may offer diabetic enrollees more frequent foot exams as a tailored, supplemental benefit. In addition, with this flexibility, a MA plan may offer diabetic enrollees a lower deductible. Under this example, non-diabetic enrollees would not have access to these diabetic-specific tailored cost-sharing or supplemental benefits; however, any enrollee that develops diabetes would then have access to these benefits.

Such flexibility under our new interpretation of the uniformity requirement is not without limits, however, as section 1852(b)(1)(A) of the Act prohibits an MA plan from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health-status related factors. MA regulations (for example, §§ 422.100(f)(2) and 422.110(a)) reiterate and implement this non-discrimination requirement. In interpreting these obligations to protect against discrimination, we have historically indicated that the purpose of the requirements is to protect high-acuity enrollees from adverse treatment on the basis of their higher cost health conditions (79 FR 29843; 76 FR 21432; and 74 FR 54634). As MA plans consider this new flexibility in meeting the uniformity requirement, they must be mindful of ensuring compliance with non-discrimination responsibilities and obligations.²⁵ MA plans that exercise this flexibility must ensure that the cost

sharing reductions and targeted supplemental benefits are for health care services that are medically related to each disease condition. CMS will be concerned about potential discrimination if an MA plan is targeting cost sharing reductions and additional supplemental benefits for a large number of disease conditions, while excluding other higher-cost conditions. We will 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.

For example, an MA plan could identify enrollees diagnosed with specific diseases, such as diabetes, chronic heart failure, and COPD, as medically vulnerable and in need of certain services, which could be offered to these enrollees in the form of tailored supplemental benefits. In identifying eligible enrollees, the MA plan must use medical criteria that are objective and measurable, and the enrollee must be diagnosed by a plan provider or have their existing diagnosis certified or affirmed by a plan provider to assure equal application of the objective criteria necessary to provide equal treatment of similarly situated individuals.

For contract year 2019, we are considering issuing guidance clarifying the flexibility MA plans have to offer targeted supplemental benefits for their most medically vulnerable enrollees. A benefit package that offers differential access to enhanced services or benefits or reduced cost sharing or different deductibles based on objective criteria, and ensures equal treatment of similarly situated enrollees, for whom such services and benefits are useful, can be priced at a uniform premium consistent with the requirements for availability and accessibility throughout the service area for all enrollees in section 1852(d)(1)(A) of the Act and for uniform bids and premiums in section 1854(c) of the Act. We believe this flexibility will help MA plans better manage health care services for the most vulnerable enrollees. The benefit and cost sharing flexibility we have discussed here applies to Part C benefits but not Part D benefits. We are requesting comments and/or questions from stakeholders about the implementation of this flexibility. We note that CMS is currently testing value based insurance design (VBID) through the use of our demonstration authority under Section 1115A of the Act (42 U.S.C. 1315a, added by Section 3021 of the Affordable Care Act), which will include some of the elements we have discussed

²⁵ Among these responsibilities and obligations are compliance with Title VI of the Civil Rights Act, section 504 of the Rehabilitation Act, the Age Discrimination Act, and section 1557 of the Affordable Care Act.

previously. However, there are also features of the VBID demonstration that are unique to the demonstration test. We expect the VBID demonstration to provide CMS with insights into future VBID innovations for the MA program.

3. Segment Benefits Flexibility

In reviewing section 1854(h) of the Social Security Act and Medicare Advantage (MA) regulations governing plan segments, we have determined that the statute and existing regulations may be interpreted to allow MA plans to vary supplemental benefits, in addition to premium and cost sharing, by segment, as long as the benefits, premium, and cost sharing are uniform within each segment of an MA plan's service area. Plans segments are county-level portions of a plan's overall service area which, under current CMS policy, are permitted to have different premiums and cost sharing amounts as long as these premiums and cost sharing amounts are uniform throughout the segment. We are proposing to revise our interpretation of the existing statute and regulations to allow MA plan segments to vary by benefits in addition to premium and cost sharing, consistent with the MA regulatory requirements defining segments at § 422.262(c)(2).

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

As provided at § 422.100(f)(4) and (5) and § 422.101(d)(2) and (3), all Medicare Advantage (MA) plans (including employer group waiver plans (EGWPs) and special needs plans (SNPs)), must 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. CMS added §§ 422.100(f)(4) and (f)(5), effective for coverage in 2011, under the authority of sections 1852(b)(1)(A), 1856(b)(1), and 1857(e)(1) of the Act 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) (75 FR 19709–11). Section 1858(b)(2) of the Act requires a limit on in-network out-of-pocket expenses for enrollees in Regional MA Plans. In addition, Local Preferred Provider Organization (LPPO) plans, under § 422.100(f)(5), and Regional PPO (RPPO) plans, under section 1858(b)(2) of the Act and § 422.101(d)(3), are required to have a “catastrophic” limit inclusive of both in- and out-of-network cost sharing for all Parts A and B services, the annual limit which is also established by CMS. All cost sharing (that is, deductibles, coinsurance, and copayments) for Parts

A and B services, excluding plan premium, must be included in each plan's Maximum Out-of-Pocket (MOOP) amount subject to these limits.

As discussed in the 2010 rulemaking (75 FR 19709), CMS affords greater flexibility in establishing Parts A and B cost sharing to MA plans that adopt a lower, voluntary MOOP limit 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 CY 2011 to 68.1 percent in CY 2017. This has resulted in the percentage of total enrollees in a voluntary MOOP plan decreasing from 51 percent in CY 2011 to 21 percent in CY 2017.

As stated in the CY 2018 final Call Letter²⁶ and in the 2010 final rule (75 FR 19710), 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) for local and regional MA plans. The mandatory MOOP amount represents approximately the 95th percentile of projected beneficiary out-of-pocket spending. Stated differently, 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 voluntary MOOP amount of \$3,400 represents approximately the 85th percentile of projected Medicare FFS out-of-pocket costs. The Office of the Actuary conducts an annual analysis to help CMS determine the MOOP limits. Since the MOOP requirements for local and regional MA plans were finalized in regulation, a strict application of the 95th and 85th percentile would have resulted in MOOP limits for local and regional MA plans fluctuating from year-to-year. Therefore, CMS has exercised discretion in order to maintain stable MOOP limits from year-to-year, when the beneficiary-level distribution of Parts A and B cost sharing for individuals enrolled in Medicare FFS is approximately equal to the appropriate percentile. This approach avoids enrollee confusion, allows plans to provide stable benefit packages year over year, and does not discourage the adoption of the lower voluntary MOOP amount because of fluctuations in the amount. CMS expects to change MOOP limits if a

consistent pattern of increasing or decreasing costs emerges over time.

As part of the annual Call Letter process, stakeholders have suggested changes to how CMS establishes MOOP limits. Some of the comments suggested CMS use Medicare FFS and MA encounter data to inform its decision-making. Other suggestions received have included increasing the voluntary MOOP limit, increasing the number of service categories that have higher cost sharing in return for a plan offering a lower MOOP limit, and considering three levels of MOOP and service category cost sharing to encourage plan offerings with lower MOOP limits.

CMS's goal is to establish future MOOP limits based on the most relevant and available data, or combination of data, that reflects beneficiary health care costs in the MA program and maintains benefit stability over time. Medicare FFS data currently represents the most relevant and available data at this time. CMS may consider future rulemaking regarding the use of MA encounter cost data to understand program health care costs and compare to Medicare FFS data in establishing cost sharing limits. Under this current proposal to revise the regulations controlling MOOP limits, CMS might change its existing methodology of using the 85th and 95th percentiles of projected beneficiary out-of-pocket Medicare FFS spending in the future. CMS expects to establish future limits by striking the appropriate balance between limiting MOOP costs and potential changes in premium, benefits, and cost sharing with the goal of making sure beneficiaries can access affordable and sustainable benefit packages. While CMS intends to continue using the 85th and 95th percentiles of projected beneficiary out-of-pocket spending for the immediate future to set MA MOOP limits, CMS proposes to amend the regulation text in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (d)(3) to incorporate authority to balance factors discussed previously. The flexibility provided by these proposed changes will permit CMS to annually adjust mandatory and voluntary MOOP limits based on changes in market conditions and to ensure the sustainability of the MA program and benefit options.

The proposed new authority permitting changes in data and methodology related to establishing MOOP limits would be exercised by CMS in advance of each plan year; CMS would use the annual Call Letter and other guidance documents to explain its application of this proposed regulatory standard and the data used to identify MOOP limits in advance of bid

²⁶ The CY 2018 final Call Letter may be accessed at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvgtgSpecRateStats/Announcements-and-Documents.html>.

deadlines. This will provide MA organizations adequate time to comment and prepare for changes. In addition, CMS plans to transition any significant changes under this proposal over time to avoid disruption to benefit designs and minimize potential beneficiary confusion.

CMS proposes to codify specific requirements because of the number of comments received in the past about MOOP changes. CMS proposes to amend §§ 422.100(f)(4) and (f)(5) and 422.101(d)(2) and (d)(3) to clarify that CMS may use Medicare FFS data to establish annual MOOP limits. In addition, CMS would have authority to increase the voluntary MOOP limit to another percentile level of Medicare FFS, increase the number of service categories that have higher cost sharing in return for offering a lower MOOP amount, and implement more than two levels of MOOP and cost sharing limits to encourage plan offerings with lower MOOP limits. This proposal includes authority to increase the number of service categories that have higher cost sharing in return for offering a lower (voluntary) MOOP amount and considering more than two levels of MOOP (with associated cost sharing limits) to encourage plan offerings with lower MOOP limits. Consistent with past practice, CMS will continue to publish annual limits and a description of how the regulation standard was applied (that is, the methodology used) in the annual Call Letter prior to bid submission so that MA plans can submit bids consistent with parameters that CMS has determined to meet the cost sharing limits requirements. CMS seeks comments and suggestions on the topics discussed in this section.

5. Cost Sharing Limits for Medicare Parts A and B Services (§§ 417.454 and 422.100)

As provided at §§ 417.454(e), 422.100(f)(6), and 422.100(j), MA plan cost sharing for Parts A and B services specified by CMS must not exceed certain levels. Section 422.100(f)(6) provides that cost sharing must not be discriminatory and CMS determines annually the level at which certain cost sharing becomes discriminatory. Sections 417.454(e) and 422.100(j), on the other hand, are based on how section 1852(a)(1)(B)(iii) and (iv) of the Act directs that cost sharing for certain services may not exceed cost sharing levels in Medicare Fee-for-Service (FFS); under the statute and the regulations, CMS may add to that list of services. CMS reviews cost sharing set by MA organizations using parameters based on Parts A and B services that are

more likely to have a discriminatory impact on beneficiaries. The review parameters are currently based on Medicare FFS data and reflect a combination of patient utilization scenarios and length of stays or services used by average to sicker patients. CMS uses multiple utilization scenarios for some services (for example, inpatient care) to guard against MA organizations distributing benefit cost sharing amounts in a manner that is discriminatory. Review parameters are also established for frequently used professional services, such as primary and specialty care services.

CMS proposes here to amend § 422.100(f)(6) to clarify that it may use Medicare FFS data to establish appropriate cost sharing limits. In addition, CMS intends to use MA utilization encounter data to inform patient utilization scenarios used to help identify MA plan cost sharing standards and thresholds that are not discriminatory; we solicit comment on whether to codify that use of MA encounter data for this purpose in § 422.100(f)(6). This proposal is not related to a statutory change.

This proposal aims to allow CMS to use the most relevant and appropriate information in determining whether specific cost sharing is discriminatory and to set standards and thresholds above which CMS believes cost sharing is discriminatory. CMS intends to continue the practice of furnishing information to MA organizations about the methodology used to establish cost sharing limits and the thresholds CMS identifies as non-discriminatory through the annual Call Letter process or Health Plan Management System (HPMS) memoranda and solicit comments, as appropriate. This process allows MA organizations to prepare plan bids consistent with parameters that CMS have determined to be non-discriminatory.

As specified in section 1852(a)(1)(B)(iv) of the Act, the cost sharing charged by MA plans for chemotherapy administration services, renal dialysis services, and skilled nursing care may not exceed the cost sharing for those services under Parts A and B. Although CMS has not established a specific service category cost sharing limit for all possible services, CMS has issued guidance that MA plans must pay at least 50 percent of the contracted (or Medicare allowable) rate and that cost sharing for services cannot exceed 50 percent of the total MA plan financial liability for the benefit in order for the cost sharing for such services to be considered non-discriminatory; CMS believes that cost

sharing (service category deductibles, copayments or co-insurance) that fails to cover at least half the cost of a particular service or item acts to discriminate against those for whom those services and items are medically necessary and discourages enrollment by beneficiaries who need those services and items. If a plan uses a copayment method of cost sharing, then the copayment for an in-network Medicare FFS service category cannot exceed 50 percent of the average contracted rate of that service under this guidance (Medicare Managed Care Manual, Chapter 4, Section 50.1). Some service categories may identify specific benefits for which a unique copayment would apply, while others include a variety of services with different levels of cost which may reasonably have a range of copayments based on groups of similar services, such as durable medical equipment or outpatient diagnostic and radiological services.

CMS affords MA plans that adopt a lower, voluntary MOOP limit greater flexibility in establishing Parts A and B cost sharing than is available to plans that adopt the higher, mandatory MOOP limit. As discussed in section III.A.5, CMS intends to continue to establish more than one set of Parts A and B service cost sharing thresholds for plans choosing to offer benefit designs with either a lower, voluntary MOOP limit or the higher, mandatory MOOP limit set under §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3). Medicare FFS data currently represents the most relevant and available data at this time and is used to evaluate cost sharing for specific services as well in applying the standard currently at § 422.100(f)(6) and in considering CMS's authority to add (by regulation) categories of services for which cost sharing may not exceed levels in Medicare FFS.

As noted with regard to setting MOOP limits under §§ 422.100 and 422.101, CMS expects that MA encounter data will be more accurate and complete in the future and may consider future rulemaking regarding the use of MA encounter to understand program health care costs and compare to Medicare FFS data in establishing cost sharing limits. For reasons discussed in section III.A.5, CMS proposes to amend § 422.100(f)(6) to permit use of Medicare FFS to evaluate whether cost sharing for Part A and B services is discriminatory to set the evaluation limits announced each year in the Call Letter; in addition, we propose to use MA utilization encounter data as part of that evaluation process. As with the proposal to authorize use of this data for setting MOOP limits, CMS intends to use the Advance Notice/Call Letter process to communicate its

application of the regulation and to transition any significant changes over time to avoid disruption to benefit designs and minimize potential beneficiary confusion.

This proposal will allow CMS to use the most relevant and appropriate information in determining cost sharing standards and thresholds. For example, analyses of MA utilization encounter data can be used with Medicare FFS data to establish the appropriate utilization scenarios to determine MA plan cost sharing standards and thresholds. CMS seeks comments and suggestions on this proposal, particularly whether additional regulation text is needed to achieve CMS's goal of setting and announcing each year presumptively discriminatory levels of cost sharing.

6. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§ 422.254 and 422.256)

As provided at §§ 422.254(a)(4) and 422.256(b)(4), CMS will only approve a bid submitted by a Medicare Advantage (MA) organization if its plan benefit package is substantially different from those of other plans offered by the organization in the area with respect to key plan characteristics such as premiums, cost sharing, or benefits offered. MA organizations may submit bids for multiple plans in the same area under the same contract only if those plans are substantially different from one another based on CMS's annual meaningful difference evaluation standards. CMS proposes to eliminate this meaningful difference requirement beginning with MA bid submissions for contract year (CY) 2019. Separate meaningful difference rules were concurrently adopted for MA and stand-alone prescription drug plans (PDPs), but this specific proposal is limited to the meaningful difference provision related to the MA program. This proposal is not related to a statutory change.

This proposal aims to improve competition, innovation, available benefit offerings, and provide beneficiaries with affordable plans that are tailored for their unique health care needs and financial situation. CMS will maintain requirements that prohibit plans from misleading beneficiaries in their communication materials, provide CMS the authority to disapprove a bid if a plan's proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals, and allow CMS to non-renew a plan that fails to attract a sufficient number of enrollees over a sustained period of time

(§§ 422.100(f)(2), 422.510(a)(4)(xiv), 422.2264, and 422.2260(e)). CMS expects organizations to continue designing plan benefit packages that, within a service area, are different from one another with respect to key benefit design characteristics, so that any potential beneficiary confusion is minimized when comparing multiple plans offered by the organization. For example, beneficiaries may consider the following factors when they make their health care decisions: plan type, Part D coverage, differences in provider network, Part B and plan premiums, and unique populations served (for example, special needs plans, or SNPs). In addition, CMS intends to continue the practice of furnishing information to MA organizations about their bid evaluation methodology through the annual Call Letter process and/or Health Plan Management System (HPMS) memoranda and solicit comments, as appropriate. This process allows CMS to articulate bid requirements and MA organizations to prepare bids that satisfy CMS requirements and standards prior to bid submission in June each year.

Research studies indicate that consumers, especially elderly consumers, may be challenged by a large number of plan choices that may: (1) Result in not making a choice, (2) create a bias to not change plans, and (3) impact MA enrollment growth.²⁷ Beneficiaries indicate they want to make informed and effective decisions, but do not feel qualified. As a result, they seek help from Medicare Plan Finder (MPF), brokers or plan representatives, providers, and family members. Although challenged by choices, beneficiaries do not want their plan choices to be limited and understand key decision factors such as premiums, out-of-pocket cost sharing, Part D coverage, familiar providers, and company offering the plan.²⁸ CMS continues to explore enhancements to MPF that will improve the customer experience; some examples of recent updates are provided below.

As discussed later in this section, CMS believes that it is challenging to apply the current standardized meaningful difference evaluation (which is applied consistently to all plans) in a manner that accommodates and evaluates important considerations objectively. CMS is concerned that the

current evaluation may create unintended consequences related to innovative benefit designs. In addition, CMS's efforts in implementing more sophisticated approaches to consumer engagement and decision-making should help beneficiaries, caregivers, and family members make informed plan choices. For example, in MPF, plan details have been expanded to include MA and Part D benefits and a new consumer friendly tool for the CY 2018 Medicare open enrollment period which will assist beneficiaries in choosing a plan that meets their unique and financial needs based on a set of 10 quick questions.

Prior to implementing the meaningful difference evaluation for CY 2011 bid submissions, the beneficiary weighted average number of plans per county was about 30 in 2010 compared to 18 in 2017 (these numbers do not include SNPs or employer group plans which have additional criteria for enrollment). Private-fee-for-service (PFFS) plans represented 13 of the 30 plans in 2010 and less than 1 of the 18 plans in 2017. The Medicare Improvements for Patients and Providers Act of 2008 required PFFS plans to establish contracted provider networks by 2011 and many PFFS plans non-renewed. The weighted average number of plans has remained relatively stable since the decline of PFFS options. MA enrollment continued to grow from more than 11 million in July 2010 to 18.7 million in July 2017, fueled by the continued overall acceptance of managed care, the baby boom generation aging into Medicare beginning in 2011, and decreases in average plan premium during the time period.

As stated in the October 22, 2009, proposed rule (74 FR 54670 through 73) and April 15, 2010, final rule (75 FR 19736 through 40), CMS's goal for the meaningful difference evaluation was to ensure a proper balance between affording beneficiaries a wide range of plan choices and avoiding undue beneficiary confusion in making coverage selections. The meaningful difference evaluation was initiated when cost sharing and benefits were relatively consistent within each plan and similar plans within the same contract could be readily compared by measuring estimated out-of-pocket costs and other factors currently integrated in the evaluation's methodology.

The current meaningful difference evaluation uses estimated enrollee out-of-pocket costs based on the CMS Out-of-Pocket Cost (OOPC) model. This model uses a nationally representative cohort of beneficiaries from the Medicare Beneficiary Surveys (MCBS)

²⁷ McWilliams JM, Afendulis CC, McGuire TG, Landon BE. Complex Medicare advantage choices may overwhelm seniors—especially those with impaired decision making. *Health Aff (Millwood)*. 2011;30(9):1786–94.

²⁸ Jacobson, G. Swoope, C., Perry, M. Slosar, M. How are seniors choosing and changing health insurance plans? Kaiser Family Foundation. 2014.

and is intended to be objective and applied in a standardized and consistent manner across plans. MCBS data collected by CMS from beneficiaries are used to create the cohort of beneficiaries whose medical and prescription data are used to estimate out-of-pocket costs. The OOPC model generates estimated out-of-pocket costs based on utilization from the cohort of beneficiaries and each plan's benefit design entered into the Plan Benefit Package submitted to CMS as part of the bidding process. Detailed information about the meaningful difference evaluation is available in the CY 2018 Final Call Letter issued April 3, 2017 (pages 115–118) and information about the CMS OOPC model is available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/OOPCResources.html>. Estimated enrollee cost sharing is determined by the cost sharing amounts for Part A, B, and D services and most mandatory supplemental benefits (for example, dental services). Benefit service categories within a plan may have a range of multiple and varying cost sharing amounts. For example, the outpatient procedures, tests, labs, and radiology services benefit category includes many services that may have a wide range of cost sharing amounts. The OOPC model uses the minimum or lowest cost sharing value placed in the Plan Benefit Package (PBP) for each service category to estimate out-of-pocket costs in these situations. As discussed in the CY 2018 Final Call Letter, the differences between similar plans must have at least a \$20 per member per month estimated beneficiary out-of-pocket cost difference. Differences in plan type (for example, HMO, LPP0), SNP sub-type, and inclusion of Part D coverage are considered meaningful differences which aligns with beneficiary decision-making. Premiums, risk scores, actual plan utilization and enrollment are not included in the evaluation because these factors would introduce risk selection, costs, and margin into the evaluation, resulting in a negation of the evaluation's objectivity.

Based on CMS's efforts to revisit MA standards and the implementation of the governing law to find flexibility for MA beneficiaries and plans, MA organizations are able to: (1) Tier the cost sharing for contracted providers as an incentive to encourage enrollees to seek care from providers the plan identifies based on efficiency and quality data which was communicated in CY 2011 guidance; (2) establish

Provider Specific Plans (PSPs) designed to offer enrollees benefits through a subset of the overall contracted network in a given service area, which are sometimes referred to as narrower networks, and which was collected in the PBP beginning in CY 2011; and (3) beginning in CY 2019, provide different cost sharing and/or additional supplemental benefits for enrollees based on defined health conditions within the same plan (Flexibility in the Medicare Advantage Uniformity Requirements). These flexibilities allow MA organizations to provide beneficiaries with access to health care benefits that are tailored to individual needs, but make it difficult for CMS to objectively measure meaningful differences between plans. Items 1 and 3 provide greater cost sharing flexibility to address individual beneficiary needs, but result in a much broader range of cost sharing values being entered into PBP. As discussed in the previous paragraph, the CMS OOPC model uses the lowest cost sharing value for each service category to estimate out-of-pocket costs which may or may not be a relevant comparison between different plans for purposes of evaluating meaningful difference when variable cost sharing of this type is involved.

CMS remains committed to ensuring transparency in plan offerings so that beneficiaries can make informed decisions about their health care plan choices. It is also important to encourage competition, innovation, and provide access to affordable health care approaches that address individual needs. The current meaningful difference methodology evaluates the entire plan and does not capture differences in benefits that are tied to specific health conditions. As a result, the meaningful difference evaluation would not fully represent benefit and cost sharing differences experienced by enrollees and could lead to MA organizations to focus on CMS standards, rather than beneficiary needs, when designing benefit packages.

In order to capture differences in provider network, more tailored benefit and cost sharing designs, or other innovations, the evaluation process would have to use more varied and complex assumptions to identify plans that are not meaningfully different from one another. CMS believes that such an evaluation could result in more complicated and potentially confusing benefit designs to achieve differences between plans. This process may require greater administrative resources for MA organizations and CMS, while not producing results that are useful to beneficiaries.

The current meaningful difference methodology may force MA organizations to design benefit packages to meet CMS standards rather than beneficiary needs. To satisfy current CMS meaningful difference standards, MA organizations may have to change benefit coverage or cost sharing in certain plans to establish the necessary benefit value difference, even if substantial difference exists based on factors CMS is currently unable to incorporate into the evaluation (such as tiered cost sharing, and unique benefit packages based on enrollee health conditions). Although these changes in benefits coverage may be positive or negative, CMS is concerned the meaningful difference requirement results in organizations potentially reducing the value of benefit offerings. On the basis of bid review activities performed over the past several years, CMS is concerned that benefits may be decreased or cost sharing increased to satisfy the meaningful difference evaluation. These are unintended consequences of the existing meaningful difference evaluation and may restrict innovative benefit designs that address individual beneficiary needs and affordability.

Beneficiaries may also consider plan and Part B premiums when choosing among health plan options. Making changes to the existing meaningful difference evaluation to consider premiums differences as sufficient to distinguish among otherwise similar plans may limit the value of CMS's evaluation by introducing factors that plans can easily leverage, such as risk selection, costs, and margin, to satisfy the evaluation test without resulting in additional benefit value or choice for enrollees.

Stakeholders have expressed concern that without the meaningful difference evaluation the number of bids and plan choices will likely increase and make beneficiary decisions more difficult. The number of plan bids may increase because of a variety of factors, such as payments, bidding and service area strategies, serving unique populations, and in response to other program constraints or flexibilities. CMS expects that eliminating the meaningful difference requirement will improve the plan options available for beneficiaries, but CMS does not believe the number of *similar* plan options offered by the same MA organization in each county will necessarily increase significantly or create confusion in beneficiary decision-making. New flexibilities in benefit design and more sophisticated approaches to consumer engagement and decision-making should help

beneficiaries, caregivers, and family members make informed plan choices among more individualized plan offerings. Based on the previously stated information, CMS does not expect a significant increase in time spent in bid review as a direct result of eliminating meaningful difference nor increased health care provider burden.

In addition, new flexibilities in benefit design may allow MA organizations to address different beneficiary needs within existing plan options and reduce the need for new plan options to navigate existing CMS requirements. In addition, MA organizations may be able to offer a portfolio of plan options with clear differences between benefits, providers, and premiums which would allow beneficiaries to make more effective decisions if the MA organizations are not required to change benefit and cost sharing designs in order to satisfy §§ 422.254 and 422.256. Currently, MA organizations must satisfy CMS meaningful difference standards (and other requirements), rather than solely focusing on beneficiary purchasing needs when establishing a range of plan options.

CMS supports beneficiary decision-making by providing tools and materials that focus on key beneficiary purchasing criteria, such as eligibility to enroll in SNPs, need for Part D coverage, Part D formulary and benefit coverage, plan type preference (for example, HMO vs. PPO), network providers, medical benefit coverage, premiums, and the brand or organization offering the plan options. CMS is also taking steps to improve information available through MPF and 1-800-MEDICARE to help beneficiaries, caregivers, and family members make informed plan choices.

CMS continually evaluates consumer engagement tools and outreach materials (including marketing, educational, and member materials) to ensure information is formatted consistently so beneficiaries can easily compare multiple plans. CMS also provides annual guidance and model materials to MA organizations to assist them in providing resources, such as the plan's Annual Notice of Change and Evidence of Coverage, which contain valuable information for the enrollee to evaluate and select the best plan for their needs. To reinforce informed decision making, CMS invests substantial resources in engagement strategies such as 1-800-MEDICARE, MPF, standard and electronic mail, and social media to continuously communicate with beneficiaries, caregivers, family members, providers,

community resources, and other stakeholders.

CMS will continue to furnish information to MA organizations and solicit comments on bid evaluation methodology through the annual Call Letter process or HPMS memoranda, as appropriate.

In addition, CMS is maintaining requirements around plans not misleading beneficiaries in communication materials, disapproving a bid if CMS finds that a plan's proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals, and non-renewing plans that fail to attract a sufficient number of enrollees over a sustained period of time (§§ 422.100(f)(2), 422.510(a)(4)(xiv), 422.2264, and 422.2260(e)). CMS expects these measures will continue to protect beneficiaries from discriminatory plan benefit packages and health plans that demonstrate a lack of beneficiary interest if the meaningful difference requirement is eliminated. For all these reasons, CMS proposes to remove §§ 422.254(a)(4) and 422.256(b)(4) to eliminate the meaningful difference requirement for MA bid submissions. CMS seeks comments and suggestions on the topics discussed in this section about making sure beneficiaries have access to innovative plans that meet their unique needs.

7. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68)

Section 1851(c)(3)(A)(ii) of the Act provides the Secretary with the authority to implement default enrollment rules for the Medicare Advantage (MA) program in addition to the statutory direction that beneficiaries who do not elect an MA plan are defaulted to original (fee-for-service) Medicare. This provision states that the Secretary may establish procedures whereby an individual currently enrolled in a non-MA health plan offered by an MA organization at the time of his or her Initial Coverage Election Period is deemed to have elected an MA plan offered by the organization if he or she does not elect to receive Medicare coverage in another way.

We initially addressed default enrollment upon conversion to Medicare in rulemaking (70 FR 4606 through 4607) in 2005, indicating that we would retain the flexibility to implement this provision through future instructions and guidance to MA

organizations. Such subregulatory guidance was established later that same year and was applicable to the 2006 contract year. As outlined in Chapter 2 of the Medicare Managed Care Manual, we established an optional enrollment mechanism, whereby MA organizations may develop processes and, with CMS approval, provide seamless continuation of coverage by way of enrollment in an MA plan for newly MA eligible individuals who are currently enrolled in other health plans offered by the MA organization (such as commercial or Medicaid plans) at the time of the individuals' initial eligibility for Medicare. The guidance emphasized that MA organizations not limit seamless continuation of coverage to situations in which an enrollee becomes eligible for Medicare by virtue of age, but includes all newly eligible Medicare beneficiaries, including those whose Medicare eligibility is based on disability. We did not mandate that organizations implement a process for seamless continuation of coverage but, instead, gave organizations the option of implementing such a process for its enrollees who are approaching Medicare eligibility. From its inception, the guidance has required that individuals receive advance notice of the proposed MA enrollment and have the ability to "opt out" of such an enrollment prior to the effective date of coverage. This guidance has been in practice for the past decade for MA organizations that requested to use this voluntary enrollment mechanism, but we have encountered complaints and heard concerns about the practice. We are proposing new regulation text to establish limits and requirements for these types of default enrollments to address these concerns and our administrative experience with seamless continuation of coverage, commonly referred to as seamless conversion.

Based on our experience with the seamless conversion process thus far, we are proposing, to be codified at § 422.66(c)(2), requirements for seamless default enrollments upon conversion to Medicare. As proposed in more detail later in this section, such default enrollments would be into dual eligible special needs plans (D-SNPs) and be subject to five substantive conditions: (1) The individual is enrolled in an affiliated Medicaid managed care plan and is dually eligible for Medicare and Medicaid; (2) the state has approved use of this default enrollment process and provided Medicare eligibility information to the MA organization; (3) the individual does not opt out of the default enrollment; (4) the MA

organization provides a notice that meets CMS requirements to the individual; and (5) CMS has approved the MA organization to use the default enrollment process before any enrollments are processed. We are also proposing that coverage under these types of default enrollments begin on the first of the month that the individual's Part A and Part B eligibility is effective. We are also proposing changes to §§ 422.66(d)(1) and (d)(5) and 422.68 that coordinate with the proposal for § 422.66.

In the Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter, we explained how entities that sponsor Medicaid managed care organizations (MCOs) and affiliated D-SNPs can promote coverage of an integrated Medicare and Medicaid benefit through existing authority for seamless continuation of coverage of Medicaid MCO members as they become eligible for Medicare. We received positive comments from state Medicaid agencies that supported this enrollment mechanism and requested that we clarify the process for approval of seamless continuation of coverage as a mechanism to promote enrollment in integrated D-SNPs that deliver both Medicare and Medicaid benefits. We also received comments from beneficiary advocates asking that additional consumer protections, including requiring written beneficiary confirmation and a special enrollment period for those individuals who transition from non-Medicare products to Medicare Advantage. We believe that our proposal, described later in this section, adequately addresses the concerns on which these requests are based, given that the default enrollment process would be permissible only for individuals enrolled in a Medicaid managed care plan in states that support this process. This means that the Medicare plan into which individuals would be defaulted would be one that is offered by the same parent organization as their existing Medicaid plan, such that much of the information needed by the MA plan would already be in the possession of the MA organization to facilitate the default enrollment process. Also, default enrollment would not be permitted if the state does not actively support this process, ensuring an accurate source of data for use by MA organizations to appropriately identify and notify individuals eligible for default enrollment.

On October 21, 2016,²⁹ in response to inquiries regarding this enrollment mechanism, its use by MA organizations, and the beneficiary protections currently in place, we announced a temporary suspension of acceptance of new proposals for seamless continuation of coverage. Based on our subsequent discussions with beneficiary advocates and MA organizations approved for this enrollment mechanism, it is clear that organizations attempting to conduct seamless continuation of coverage from commercial coverage (that is, private coverage and Marketplace coverage) find it difficult to comply with our current guidance and approval parameters. This is especially true of the requirement to identify commercial members who are approaching Medicare eligibility based on disability. Also challenging for these organizations is the requirement that they have the means to obtain the individual's Medicare number and are able to confirm the individual's entitlement to Part A and enrollment in Part B no fewer than 60 days before the MA plan enrollment effective date.

In addition, the ability for organizations to conduct seamless enrollment of individuals converting to Medicare will be further limited due to the statutory requirement that CMS remove Social Security Numbers (SSNs) from all Medicare cards by April 2019. A new Medicare number will replace the SSN-based Health Insurance Claim Number (HICN) on the new Medicare cards for Medicare transactions. Beginning in April 2018, we'll start mailing the new Medicare cards with the new number to all people with Medicare. Given the random and unique nature of the new Medicare number, we believe MA organizations will be limited in their ability to automatically enroll newly eligible Medicare beneficiaries without having to contact them to obtain their Medicare numbers, as CMS does not share Medicare numbers with organizations for their commercial members who are approaching Medicare eligibility. We note that contacting the individual in order to obtain the information necessary to process the enrollment does not align with the intent of default enrollment, which is designed to process enrollments and have coverage automatically shift into the MA plan without an enrollment action required by the beneficiary.

²⁹ https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnroll/Downloads/HPMS_Memo_Seamless_Moratorium.pdf.

Organizations operating Medicaid managed care plans are better able to meet these requirements when states provide data, including the individual's Medicare number, on those about to become Medicare eligible. As part of coordination between the Medicare and Medicaid programs, CMS shares with states, via the State MMA file, data of individuals with Medicaid who are newly becoming entitled to Medicare; such data includes the Medicare number of newly eligible Medicare beneficiaries. MA organizations with state contracts to offer D-SNPs would be able to obtain (under their agreements with state Medicare agencies) the data necessary to process the MA enrollment submission to CMS. Therefore, we are proposing to revise § 422.66 to permit default enrollment only for Medicaid managed care enrollees who are newly eligible for Medicare and who are enrolled into a D-SNP administered by an MA organization under the same parent organization as the organization that operates the Medicaid managed care plan in which the individual remains enrolled. These requirements would be codified at § 422.66(c)(2)(i) (as a limit on the type of plan into which enrollment is defaulted) and (c)(2)(i)(A) (requiring existing enrollment in the affiliated Medicaid managed care plan as a condition of default MA enrollment). At paragraph (c)(2)(i)(B), we are also proposing to limit these default enrollments to situations where the state has actively facilitated and approved the MA organization's use of this enrollment process and articulates this in the agreement with the MA organization offering the D-SNP, as well as providing necessary identifying information to the MA organization.

The option of default enrollment can be particularly beneficial for Medicaid managed care enrollees who are newly eligible for Medicare, because in the case that the parent organization of the Medicaid managed care plan also offers a D-SNP, default enrollment promotes enrollment in a plan that offers some level of integration of acute care, behavioral health and, for eligible beneficiaries, long-term care services and supports, including institutional care, and home and community-based services (HCBS). This is in line with CMS' support of state efforts to increase enrollment of dually eligible individuals in fully integrated systems of care and the evidence³⁰ that such systems

³⁰ There is a growing evidence that integrated care and financing models can improve beneficiary experience and quality of care, including:

- Health Management Associates, *Value Assessment of the Senior Care Options (SCO)*

improve health outcomes. Further this proposal will provide states with additional flexibility and control. States can decide if they wish to allow their contracted Medicaid managed care plans to use default enrollment of Medicaid enrollees into D-SNPs and can control which D-SNPs receive default enrollments through two means: The contracts that states maintain with D-SNPs (§ 422.107(b)) and by providing the data necessary for MA organizations to successfully implement the process. Under our proposal, MA organizations can process default enrollments only for dual-eligible individuals in states where the contract with the state under § 422.107 approves it and the state identifies eligibility and shares necessary data with the organization.

To ensure that Medicaid beneficiaries considered for default enrollment upon their conversion to Medicare are aware of the default MA enrollment and of the changes to their Medicare and Medicaid coverage, we also propose, at § 422.66(c)(2)(i)(C) and (c)(2)(iv), that the MA organization must issue a notice no fewer than 60 days before the default enrollment effective date to the enrollee. The proposed revised notice³¹ must include clear information on the D-SNP, as well as instructions to the individual on how to opt out (or decline) the default enrollment and how to enroll in Original Medicare or a different MA plan. This notice requirement aims to help ensure a smooth transition of eligible individuals into the D-SNP for those who choose not to opt out. All MA organizations currently approved to conduct seamless conversion enrollment issue at least one notice 60 days prior to the MA enrollment effective date, so our proposal would not result in any additional burden to these MA organizations using this process. Recent discussions with MA organizations

currently conducting seamless conversion enrollment have revealed that several of them already include in their process additional outreach, including reminder notices and outbound telephone calls to aid in the transition. We believe that these additional outreach efforts are helpful and we would encourage their use under our proposal.

We also propose, in paragraph (c)(2)(i)(E) and (2)(ii), that MA organizations must obtain approval from CMS before implementing default enrollment. Under our proposal in paragraph (c)(2)(i)(B), CMS approval would be granted only if the applicable state approves the default enrollment through its agreement with the MA organization. MA organizations would be required to implement default enrollment in a non-discriminatory manner, consistent with their obligations under § 422.110; that is, MA organizations could not select for default enrollment only certain of the members of the affiliated Medicaid plan who were identified as eligible for default enrollment. Lastly, we propose that CMS may suspend or rescind approval at any time if it is determined that the MA organization is not in compliance with the requirements. We request comment whether this authority to rescind approval should be broader; we have considered whether a time limit on the approval (such as 2 to 5 years) would be appropriate so that CMS would have to revisit the processes and procedures used by an MA organization under this proposed regulation in order to assure that the regulation requirements are still being followed. We are particularly interested in comment on this point in conjunction with our alternative (discussed later in this section) proposal to codify the existing parameters for this type of seamless conversion default enrollment such that all MA organizations would be able to use this default enrollment process for newly eligible and newly enrolled Medicare beneficiaries in the MA organization's non-Medicare coverage.

Under our proposal, default enrollment of individuals at the time of their conversion to Medicare would be more limited than the default enrollments Congress authorized the Secretary to permit in section 1851(c)(3)(A)(ii) of the Act. However, we are also proposing some flexibility for MA organizations that wish to offer seamless continuation of coverage to their non-Medicare members, commercial, Medicaid or otherwise, who are gaining Medicare eligibility. As discussed in more detail below,

affirmative elections would be necessary for individuals not enrolled in a Medicaid managed care plan, consistent with § 422.50. However, because individuals enrolled in an organization's commercial plan, for example would already be known to the parent organization offering both the non-Medicare plan and the MA plan and the statute acknowledges that this existing relationship is somewhat relevant to Part C coverage, we propose to amend § 422.66(d)(5) and to establish, through subregulatory guidance, a new and simplified positive (that is, "opt in") election process that would be available to all MA organizations for the MA enrollments of their commercial, Medicaid or other non-Medicare plan members. To reflect our change in policy with regard to a default enrollment process and this proposal to permit a simplified election process for individuals who are electing coverage in an MA plan offered by the same entity as the individual's non-Medicare coverage, we are also proposing to add text in § 422.66(d)(5) authorizing a simplified election for purposes of converting existing non-Medicare coverage, commercial, Medicaid or otherwise, to MA coverage offered by the same organization. This new mechanism would allow for a less burdensome process for MA organizations to offer enrollment in their MA plans to their non-Medicare health plan members who are newly eligible for Medicare. As the MA organization has a significant amount of the information from the member's non-Medicare enrollment, this new simplified election process aims to make enrollment easier for the newly-eligible beneficiary to complete and for the MA organization to process. It would align with the individual's Part A and Part B initial enrollment period (and initial coordinated election period for MA coverage), provided he or she enrolled in both Medicare Parts A and B when first eligible for Medicare. This new election process would provide a longer period of time for MA organizations to accept enrollment requests than the time period in which MA organizations would be required to effectuate default enrollments, as organizations would be able to accept enrollments throughout the individual's Initial Coverage Election Period (ICEP), which for an aged beneficiary is the 7-month period that begins 3 months before the month in which the individual turns 65 and ends 3 months after the month in which the individual turns 65. We would use existing authority to create this new enrollment

Program, July 21, 2015, available at: http://www.mahp.com/unify-files/HMAFinalSCOWhitePaper_2015_07_21.pdf;

• MedPAC chapter "Care coordination programs for dual-eligible beneficiaries," June 2012, available at: <http://www.medpac.gov/docs/default-source/reports/chapter-3-appendixes-care-coordination-programs-for-dual-eligible-beneficiaries-june-2012-report-.pdf?sfvrsn=0>;

• Anderson, Wayne L., Zhanlian Fen, and Sharon K. Long, RTI International and Urban Institute, *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 2016, available at: <https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis>.

³¹ Enrollment requirements and burden are currently approved by OMB under control number 0938-0753 (CMS-R-267). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number.

mechanism which, if implemented, would be available to MA organizations in the 2019 contract year. We solicit comments on the proposed changes to the regulation text as well as the form and manner in which such enrollments may occur.

This optional simplified election process for the enrollment of non-Medicare plan members into MA upon their initial eligibility (or initial entitlement) for Medicare would provide individuals the option to remain with the organization that offers their non-Medicare coverage. A positive election in this circumstance provides an additional beneficiary protection for non-dually eligible individuals, so that they may actively choose a Medicare plan structure similar to that of their commercial, Medicaid or other non-Medicare health plans, as there may be significant differences between an organization's commercial plans, for example, and its MA plans in terms of provider networks, drug formularies, costs and benefit structures. While these differences may result in a more restrictive network, a mandated change in a primary care physician and increased out-of-pocket costs for converting enrollees, default enrollment of a dually eligible individual enrolled in a Medicaid plan into a D-SNP, triggers no premium liability or cost sharing for medical care or prescription drugs above levels that apply under Original Medicare. Further, the individual remains in the Medicaid managed care plan and is gaining additional Medicare coverage, which is not always the case in other contexts. We solicit comment on these coordinated proposals to implement section 1851(c)(3)(A)(ii) in general as discussed below and in two particular ways: (1) To permit default MA enrollments for dually-eligible beneficiaries who are newly eligible for Medicare under certain conditions and (2) to permit simplified elections for seamless continuations of coverage for other newly-eligible beneficiaries who are in non-Medicare health coverage offered by the same parent organization that offers the MA plan. We further invite comments regarding whether the CMS approval of an organization's request to conduct default enrollment should be limited to a specific time frame. In addition, we are proposing amendments to §§ 422.66(d)(1) and 422.68 that are also related to MA enrollment. Currently, as described in the 2005 final rule (70 FR 4606 through 4607), § 422.66(d)(1) requires MA organizations to accept, during the month immediately preceding the

month in which he or she is entitled to both Part A and Part B, enrollment requests from an individual who is enrolled in a non-Medicare health plan offered by the MA organization and who meets MA eligibility requirements. To better reflect section 1851(c)(3)(A)(ii), we are proposing to amend § 422.66(d)(1) to add text clarifying that seamless continuations of coverage are available to an individual who requests enrollment during his or her Initial Coverage Election Period. In light of our proposal to permit a simplified election process for individuals who are electing coverage in an MA plan offered by the same parent organization as the individual's non-Medicare coverage, we are also proposing a revision to § 422.68(a) to ensure that ICEP elections made during or after the month of entitlement to both Part A and Part B are effective the first day of the calendar month following the month in which the election is made. This proposed revision would codify the subregulatory guidance that MA organizations have been following since 2006. This proposal is also consistent with the proposal at § 422.66(c)(2)(iii) regarding the effective date of coverage for default enrollments into D-SNPs. We also solicit comment on these related proposals.

In conclusion, we are proposing to add regulation text at § 422.66(c)(2)(i) through (iv) to set limits and requirements for a default enrollment of the type authorized under section 1851(c)(3)(A)(ii). We are proposing a clarifying amendment to § 422.66(d)(1) regarding when seamless continuation coverage can be elected and revisions to § 422.66(d)(5) to reflect our proposal for a new and simplified positive election process that would be available to all MA organizations. Lastly, we are proposing revisions to § 422.68(a) to ensure that ICEP elections made during or after the month of entitlement to both Part A and Part B are effective the first day of the calendar month following the month in which the election is made.

We invite comments in general on our proposal, as well as on the alternatives presented. We recognize that our proposal narrows the scope of default enrollments compared to what CMS approved under section 1851(c)(3)(A) of the Act in the past. As we contemplated the future of the seamless conversion mechanism, we considered retaining processes similar to how the seamless conversion mechanism is outlined currently in section 40.1.4 of Chapter 2 of the Medicare Managed Care Manual and had been in practice through October 2016. We considered proposing

regulations to codify that guidance as follows—

- Articulating the requirements for an MA organization's proposal to use the seamless conversion mechanism, including identifying eligible individuals in advance of Medicare eligibility;
- Establishing timeframes for processing and the effective date of the enrollment; and
- Requiring notification to individuals at least 60 days prior to the conversion of their right to opt-out or decline the enrollment.

In considering this alternative, we contemplated adding additional beneficiary protections, including the issuance of an additional notice to ensure that individuals understood the implication of taking no action. While this alternative would have led to increased use of the seamless conversion enrollment mechanism than what had been used in the past, the operational challenges, particularly in relation to the new Medicare Beneficiary Identification number may be significant for MA organizations to overcome at this time.

We also considered proposing regulations to limit the use of default enrollment to only the aged population. While this alternative would simplify a MA organization's ability to identify eligible individuals, we have concerns about disparate treatment among newly eligible individuals based on their reason for obtaining Medicare entitlement.

We invite comments on our proposal and the alternate approaches, including the following:

- Codify the existing parameters for this type of seamless conversion default enrollment such that all MA organizations would be able to use this default enrollment process for newly eligible and newly enrolled Medicare beneficiaries in the MA organization's non-Medicare coverage.
- Codify the existing parameters for this type of seamless conversion default enrollment, as described previously, but allow that use of default enrollment be limited to only the aged population.

If commenters recommend one or more alternate approaches, we ask for suggested solutions that address the concerns noted in this discussion, particularly related to the requirement that plans identify commercial members who are approaching Medicare eligibility based on disability, as well as how plans could confirm MA eligibility and process enrollments without access to the individual's Medicare number.

8. Passive Enrollment Flexibilities To Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (§ 422.60(g))

Beneficiaries who are dually eligible for both Medicare and Medicaid typically 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 unnecessary, duplicative, or missed services. One method for overcoming this challenge is through integrated care, which provides dually eligible beneficiaries with the full array of Medicaid and Medicare benefits for which they are eligible through a single delivery system, thereby improving quality of care, beneficiary satisfaction, care coordination, and reducing administrative burden.

Integrated care options are increasingly available for dually eligible beneficiaries, which include a variety of integrated D-SNPs. D-SNPs can provide greater integrated care than enrollees would otherwise receive in other MA plans or Medicare Fee-For-Service (FFS), particularly when an individual is enrolled in both a D-SNP and Medicaid managed care organization offered by the same organization. D-SNPs that meet higher standards of integration, quality, and performance benchmarks—known as highly integrated D-SNPs—are able to offer additional supplemental benefits to support integrated care pursuant to § 422.102(e). D-SNPs that are fully integrated—known as Fully Integrated Dual-Eligible (FIDE) SNPs, as defined at § 422.2 provide for a much greater level of integration and coordination than non-integrated D-SNPs, providing all primary, acute, and long-term care services and supports under a single entity.

While enrollment in integrated care options continues to grow, there are instances in which beneficiaries may face disruptions in coverage in integrated care plans. These disruptions can result from numerous factors, including market forces that impact the availability of integrated D-SNPs and state re-procurements of Medicaid managed care organizations. Such disruptions can result in beneficiaries being enrolled in two separate organizations for their Medicaid and Medicare benefits, thereby losing the benefits of integration achieved when the same entity offers both benefit packages. In an effort to protect the

continuity of integrated care for dually eligible beneficiaries, we are proposing a limited expansion of our regulatory authority to initiate passive enrollment for certain dually eligible beneficiaries in instances where integrated care coverage would otherwise be disrupted.

Section 1851(c)(1) of the Act authorizes us to develop mechanisms for beneficiaries to elect MA enrollment, and we have used this authority to create passive enrollment. The current regulation at § 422.60(g) limits the use of passive enrollment to two scenarios: (1) In instances where there is an immediate termination of an MA contract; or (2) in situations in which we determine that remaining enrolled in a plan poses potential harm to beneficiaries. The passive enrollment defined in § 422.60(g) requires beneficiaries to be provided prior notification and a period of time prior to the effective date to opt out of enrollment from a plan. Current § 422.60(g)(3) provides every passively enrolled beneficiary with a special election period to allow for election of different Medicare coverage: Selecting a different managed care plan or opting out of MA completely and, instead, receiving services through Original Medicare (a FFS delivery system). A beneficiary who is offered a passive enrollment is deemed to have elected enrollment in the designated plan if he or she does not elect to receive Medicare coverage in another way.

Our proposal is a limited expansion of this regulatory authority to promote continued enrollment of dually eligible beneficiaries in integrated care plans to preserve and promote care integration under certain circumstances. The proposal includes use of these existing opt-out procedures and special election period. Therefore, we are proposing to redesignate these requirements from (g)(1) through (3) to (g)(3) through (g)(5) respectively, with minor revisions in proposed paragraph (g)(5) to describe the application of special election period and in proposed paragraph (g)(4) to make minor grammatical changes to the text to improve its readability and clarity.

Our proposal is to add authority to passively enroll full-benefit dually eligible beneficiaries who are currently enrolled in an integrated D-SNP into another integrated D-SNP under certain circumstances. We anticipate that these proposed regulations would permit passive enrollments only when all the following conditions are met:

- When necessary to promote integrated care and continuity of care;

- Where such action is taken in consultation with the state Medicaid agency;

- Where the D-SNP receiving passive enrollment contracts with the state Medicaid agency to provide Medicaid services; and

- Where certain other conditions are met to promote continuity and quality of care.

We expect that these factors would all occur in situations when affected beneficiaries would otherwise be experiencing an involuntary disruption in either their Medicare or Medicaid coverage. We anticipate using this new proposed authority exclusively in such situations.

All individuals would be provided with a special election period (which, as established in subregulatory guidance, lasts for 2 months), as described in § 422.62(b)(4), provided they are not otherwise eligible for another SEP (for example, under proposed § 423.38(c)(4)(ii)).

For illustrative purposes we have outlined two scenarios in which this proposed regulatory authority could be used to promote continued access to integrated care and maintain continuity of care for dually eligible individuals:

- *State Re-Procurement of Medicaid Managed Care Contracts:* In several states, dually eligible beneficiaries receive Medicaid services through managed care plans that the state selects through a competitive procurement process. Some states also require that the sponsors of Medicaid health plans also offer a D-SNP in the same service area to promote opportunities for integrated care. Dually eligible beneficiaries can face disruptions in coverage due to routine state re-procurements of Medicaid managed care contracts. Individuals enrolled in Medicaid managed care plans that are not renewed are typically transitioned to a separate Medicaid managed care plan. In such a scenario, dually eligible beneficiaries enrolled in the non-renewing Medicaid managed care plan's corresponding D-SNP product would now be enrolled in two separate organizations for their Medicaid and Medicare services, resulting in non-integrated coverage. Under this proposed regulation, CMS would have the ability, in consultation with the state Medicaid agency that contracts with integrated D-SNPs, to passively enroll dually eligible beneficiaries facing such a disruption into an integrated D-SNP that corresponds with their new Medicaid managed care plan, thereby promoting continuous enrollment in integrated care.

• *Non-Renewal of D-SNP Contracts:* Beneficiaries enrolled in an integrated D-SNP that non-renews its MA contract at the end of the contract year can face disruptions in integrated care coverage, requiring them to actively select a new MA plan or default into Original Medicare and a standalone prescription drug plan. While states are permitted to passively enroll beneficiaries for Medicaid coverage as defined in § 438.54(c), CMS is not permitted to do so for Medicare coverage when an MA plan non-renews at the end of the contract year, as current authority for passive enrollment is limited to midyear terminations. Rather, beneficiaries in the D-SNP that is non-renewing its contract would need to actively select and enroll in an MA plan that integrates their Medicare and Medicaid coverage in order to continue the same level of integrated care. Permitting CMS the ability to passively enroll D-SNP enrollees into other integrated D-SNP plans in consultation with the state Medicaid agency would support beneficiaries remaining in integrated care.

With a limited expansion of our passive enrollment regulatory authority, we can better promote integrated care and continuity of care for dually eligible beneficiaries. Therefore, we are proposing to redesignate the introductory text in § 422.60(g) as paragraph (g)(1), with a new heading, technical revisions to the existing text that specifies when passive enrollments may be implemented by CMS designated as (g)(1)(i) and (ii), and a new paragraph (iii). This new (g)(1)(iii) would authorize CMS to passively enroll certain dually eligible individuals currently enrolled in an integrated D-SNP into another integrated D-SNP, after consulting with the state Medicaid agency that contracts with the D-SNP or other integrated managed care plan, to promote continuity of care and integrated care.

We also propose to add a new paragraph (g)(2) to include a number of requirements that an MA plan would have to meet in order to qualify to receive passive enrollments under paragraph (g)(1)(iii). We also propose to include in paragraph (g)(1)(iii) a reference to new paragraph (g)(2) to make it clear that a contract with the state is also necessary for a D-SNP to be eligible to receive these passive enrollments. Specifically, we propose that in order to receive passive enrollments under the new authority, MA plans must be highly integrated, thereby restricting passive enrollment to those MA plans that operate as a FIDE SNP or meet the integration standard for

a highly-integrated D-SNP, as defined in § 422.2 and described in § 422.102(e) respectively. In an effort to ensure continuity of care, acquiring MA plans would also be required to have substantially similar provider and facility networks and Medicare- and Medicaid-covered benefits as the integrated MA plan (or plans) from which beneficiaries are passively enrolled. MA plans receiving passive enrollment would also be required to not have any prohibition on new enrollment imposed by CMS and have appropriate limits on premium and cost-sharing for beneficiaries. If our proposed paragraphs (g)(1) and (g)(2) are finalized, we would describe in subregulatory guidance the procedure through which CMS would determine qualification for passive enrollment. We also propose that to receive these passive enrollments, that D-SNP must meet minimum quality standards based on MA Star Ratings; we direct the reader to the proposal at section III.A.12. of this rule regarding the MA Star Rating System. Our proposed regulation text refers to a requirement to have a minimum overall MA Star Rating of at least 3 stars, which represents average or above-average performance. The rating for the year prior to receipt of passive enrollment would be used in order to provide sufficient time for CMS, states, and MAOs to prepare for the passive enrollment process. Low-enrollment contracts or new plans without MA Star Ratings as defined in § 422.252 would also be eligible for passive enrollment under our proposal, as long as the plan meets all other proposed requirements.

Our goal with this proposed requirement is to ensure that the D-SNP plans receiving these passive enrollments provide high-quality care, coverage and administration of benefits. As passive enrollments, in some sense, are a benefit to a plan, by providing an enrollee and associated payments without the plan having successfully marketed to the enrollee, we believe that it is important that these enrollments are limited to plans that have demonstrated commitment to quality. Further, it is important to ensure that when we are making an enrollment decision for a beneficiary who does not make an alternative coverage choice that we are guided by the beneficiary's best interests, which are likely served by a plan that is rated as having average or above-average performance on the MA Stars Rating System. However, we recognize that MA Star Ratings do not capture performance for those services that would be covered under Medicaid,

including community behavioral health treatment and long-term services and supports. We welcome comments on the process for determining qualification for passive enrollment under this proposal and particularly on the minimum quality standards. We request that commenters identify specific measures and minimum ratings that would best serve our goals in this proposal and are specific or especially relevant to coverage for dually eligible beneficiaries.

In addition to the proposed minimum quality standards and other requirements for a D-SNP to receive passive enrollments, we are considering limiting our exercise of this proposed new passive enrollment authority to those circumstances in which such exercise would not raise total cost to the Medicare and Medicaid programs. We seek comment on this potential further limitation on exercise of the proposed passive enrollment regulatory authority to better promote integrated care and continuity of care. In particular, we seek stakeholder feedback how to calculate the projected impact on Medicare and Medicaid costs from exercise of this authority.

The intent of the proposed passive enrollment regulatory authority is to better promote integrated care and continuity of care—including with respect to Medicaid coverage—for dually eligible beneficiaries. As such, we would implement this authority in consultation with the state Medicaid agencies that are contracting with these plan sponsors for provision of Medicaid benefits.

We considered proposing new beneficiary notification requirements for passive enrollments that occur under proposed paragraph (g)(1)(iii). We considered requiring MA organizations receiving the passive enrollment to provide two notifications to all potential enrollees prior to their enrollment effective date. We acknowledge that under the Financial Alignment Initiative demonstrations, states are required to provide two passive enrollment notices. Under the passive enrollment authority proposed here, we would continue to encourage, but not require, a second notice or additional outreach to impacted individuals. Given the existing beneficiary notifications that are currently required under Medicare regulations and concerns regarding the quantity of notifications sent to beneficiaries, we are not proposing to modify the existing notification requirements, so these existing standards would apply for existing passive enrollments and for the newly proposed passive enrollment authority.

However, we solicit comment on alternatives regarding beneficiary notices, including comments about the content and timing of such notices. Our proposal redesignates the notice requirements to paragraph (g)(4) with minor grammatical revisions.

Finally, we propose a technical correction to a citation in § 422.60(g), which discusses situations involving an immediate termination of an MA plan as provided in § 422.510(a)(5). This citation is outdated, as the regulatory language at § 422.510(a)(5) has been moved to § 422.510(b)(2)(i)(B). We propose to replace the current citation with a reference to § 422.510(b)(2)(i)(B).

9. Part D Tiering Exceptions (§§ 423.560, 423.578(a) and (c))

a. Background

Section 1860D–4(g)(2) of the Act specifies that a beneficiary enrolled in a Part D plan offering prescription drug benefits for Part D drugs through the use of a tiered formulary may request an exception to the plan sponsor's tiered cost-sharing structure. The statute requires such plan sponsors to have a process in place for making determinations on such requests, consistent with guidelines established by the Secretary. At the start of the Part D program, we finalized regulations at § 423.578(a) that require plan sponsors to establish and maintain reasonable and complete exceptions procedures. These procedures permit enrollees, under certain circumstances, to obtain a drug in a higher cost-sharing tier at the more favorable cost-sharing applicable to alternative drugs on a lower cost-sharing tier of the plan sponsor's formulary. Such an exception is granted when the plan sponsor determines that the non-preferred drug is medically necessary based on the prescriber's supporting statement. The tiering exceptions regulations establish the general scope of issues that must be addressed under the plan sponsor's tiering exceptions process. Our goal with the exceptions rules codified in the Part D final rule (70 FR 4352) was to allow plan sponsors sufficient flexibility in benefit design to obtain pricing discounts necessary to offer optimal value to beneficiaries, while ensuring that beneficiaries with a medical need for a non-preferred drug are afforded the type of drug access and favorable cost-sharing called for under the law.

At the start of the program, most Part D formularies included no more than four cost-sharing tiers, generally with only one generic tier. For the 2006 and 2007 plan years respectively, about 83 percent and 89 percent of plan benefit

packages (PBP) that offered drug benefits through use of a tiered formulary had 4 or fewer tiers. Since that time, there have been substantial changes in the prescription drug landscape, including increasing costs of some generic drugs, as well as the considerable impact of high-cost drugs on the Part D program. Plan sponsors have responded by modifying their formularies and PBPs, resulting in the increased use of two generic-labeled drug tiers and mixed drug tiers that include brand and generic products on the same tiers. The flexibilities CMS permits in benefit design enable plan sponsors to continue to offer comprehensive prescription drug coverage with reasonable controls on out of pocket costs for enrollees, but increasingly complex PBPs with more variation in type and level of cost-sharing. For the 2017 plan year, about 91 percent of all Part D PBPs offer drug benefits through use of a tiered formulary. Over 98 percent of those tiered PBPs use a formulary containing 5 or 6 tiers; of those, about 98 percent contain two generic-labeled tiers.

These changes and increased complexities, and more than a decade of program experience, lead us to believe that our current regulations are no longer sufficient to ensure that tiering exceptions are understood by beneficiaries and adjudicated by plan sponsors in the manner the statute contemplates. For this reason, we propose to amend §§ 423.560, 423.578(a) and 423.578(c) to revise and clarify requirements for how tiering exceptions are to be adjudicated and effectuated.

While section 1860D–4(g)(2) of the Act uses the terms “preferred” and “non-preferred” drug, rather than “brand” and “generic”, it also gives the Secretary authority to establish guidelines for making a determination with respect to a tiering exception request. The statute further specifies that “a non-preferred drug *could* be covered under the terms applicable for preferred drugs” (emphasis added) if the prescribing physician determines that the preferred drug would not be as effective or would have adverse effects for the individual. The statute therefore contemplates that tiering exceptions must allow for an enrollee with a medical need to obtain favorable cost-sharing for a non-preferred product, but that such access be subject to reasonable limitations. Establishing regulations that allow plans to impose certain limitations on tiering exceptions helps ensure that all enrollees have access to needed drugs at the most favorable cost-sharing terms possible.

b. General Rules

We are proposing to revise § 423.578(a)(2) to read as follows: “Part D plan sponsors must establish criteria that provide for a tiering exception consistent with paragraphs § 423.578(a)(3) through (a)(6) of this section.” We believe that inserting a cross-reference to paragraph (a)(6), which establishes allowable limitations on tiering exceptions, and which we are also proposing to revise, would streamline and clarify the requirements for such exceptions. The proposed revisions would establish rules that more definitively base eligibility for tiering exceptions on the lowest applicable cost sharing for the tier containing the preferred alternative drug(s) for treatment of the enrollee's health condition in relation to the cost sharing of the requested, higher-cost drug, and not based on tier labels.

c. Limitations on Tiering Exceptions

We are also proposing to revise the regulations at § 423.578(a)(6) to specify when a Part D plan sponsor may limit tiering exceptions. We believe the current text, which permits a plan sponsor to exempt any dedicated generic tier from its tiering exceptions procedures, is being applied in a manner that restricts tiering exceptions more stringently than is appropriate. Specifically, Part D sponsors have been considering any tier that is labeled “generic” to be exempt from tiering exceptions even if the tier also contains brand name drugs. This has become even more problematic with the increase in the number of PBPs with more than one tier labeled “generic”. Based on an analysis of 2017 plan data entered into the Health Plan Management System (HPMS), for all Part D plans using a tiered formulary, 62 percent have indicated at least two tiers that contain only generic drugs, and 7 percent have three such tiers. Combined with the allowable exemption of a specialty tier (used by 99.8 percent of tiered Part D plans in 2017), almost two-thirds of all tiered PBPs could exempt 3 of their 5 or 6 tiers from tiering exceptions without any consideration of medical need or placement of preferred alternative drugs. To ensure appropriate enrollee access to tiering exceptions, we are proposing to revise § 423.578(a)(6) to specify that a Part D plan sponsor would not be required to offer a tiering exception for a brand name drug to a preferred cost-sharing level that applies only to generic alternatives. Under this proposal, however, plans would be required to approve tiering exceptions for non-preferred generic drugs when

the plan determines that the enrollee cannot take the preferred generic alternative(s), including when the preferred generic alternative(s) are on tier(s) that include only generic drugs or when the lower tier(s) contain a mix of brand and generic alternatives. In other words, plans would not be permitted to exclude a tier containing alternative drug(s) with more favorable cost-sharing from their tiering exceptions procedures altogether just because that lower-cost tier is dedicated to generic drugs. As described in the following paragraph, we are also proposing at § 423.578(a)(6) to establish specific tiering exceptions policy for biological products.

Proposed § 423.578(a)(6)(iii) would specify that, “If a Part D plan sponsor maintains a specialty tier, as defined in § 423.560, the 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.” We also propose to add the following definition to Subpart M at § 423.560:

Specialty tier means 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. We note that, while the proposed definition of specialty tier does not refer to “unique” drugs as existing § 423.578(a)(7) does, we do not intend to change the criteria for the specialty tier, which has always been based on the drug cost. This proposal would retain the current regulatory provision that permits Part D plan sponsors to disallow tiering exceptions for any drug that is on the plan’s specialty tier. This policy is currently codified at § 423.578(a)(7), which would be revised and redesignated as § 423.578(a)(6)(iii). We believe that retaining the existing policy limiting the availability of tiering exceptions for drugs on the specialty tier is important because of the beneficiary protection that limits cost-sharing for the specialty tier to 25 percent coinsurance (up to 33 percent for plans that have a reduced or \$0 Part D deductible), ensuring that these very high cost drugs remain accessible to enrollees at cost sharing equivalent to the defined standard benefit.

We also clarify that, if the specialty tier has cost sharing more preferable than another tier, then a drug placed on such other non-preferred tier is eligible for a tiering exception down to the cost sharing applicable to the specialty tier if an applicable alternative drug is on the specialty tier and the other requirements of § 423.578(a) are met. In other words, while plans are not required to allow tiering exceptions for drugs on the

specialty tier to a more preferable cost-sharing tier, the specialty tier is not exempt from being considered a preferred tier for purposes of tiering exceptions.

We believe a shift in regulatory policy that establishes a distinction between non-preferred branded drugs, biological products, and non-preferred generic and authorized generic drugs, achieves needed balance between limitations in plans’ exceptions criteria and beneficiary access, and aligns with how many plan sponsors already design their tiering exceptions criteria. Accordingly, we are proposing to revise § 423.578(a)(6) to clarify and establish additional limitations plans would be permitted to place on tiering exception requests. First, we are proposing new paragraphs (i) and (ii), which would permit plans to limit the availability of tiering exceptions for the following drug types to a preferred tier that contains the same type of alternative drug(s) for treating the enrollee’s condition:

- Brand name drugs for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)); and
- Biological products, including follow-on biologics, licensed under section 351 the Public Health Service Act.

With the proposed revisions, that approved tiering exceptions for brand name drugs would generally be assigned to the lowest applicable cost-sharing associated with brand name alternatives, and approved tiering exceptions for biological products would generally be assigned to the lowest applicable cost-sharing associated with biological alternatives. Similarly, tiering exceptions for non-preferred generic drugs would be assigned to the lowest applicable cost-sharing associated with alternatives that are either brand or generic drugs (see further discussion later in this section related to assignment of cost-sharing for approved tiering exceptions to the lowest applicable tier). Given the widespread use of multiple generic tiers on Part D formularies, and the inclusion of generic drugs on mixed, higher-cost tiers, we believe these changes are needed to ensure that tiering exceptions for non-preferred generic drugs are available to enrollees with a demonstrated medical need. Procedures that allow for tiering exceptions for higher-cost generics when medically necessary promote the use of generic

drugs among Part D enrollees and assist them in managing out of pocket costs.

We are also proposing at § 423.578(a)(6)(i) to codify that plans are not required to offer tiering exceptions for brand name drugs or biological products at the cost-sharing level of alternative drug(s) for treating the enrollee’s condition, where the alternatives include only the following drug types:

- Generic drugs for which an application is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), or
- Authorized generic drugs as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)(3)).

As discussed in the Call Letter, CMS collects Part D plan formulary data based on the National Library of Medicare RxNorm concept unique identifier (RxCUI), and not at the manufacturer-specific National Drug Code (NDC) level. This process does not allow us to clearly identify whether a plan sponsor includes coverage of authorized generic NDCs or not. We believe this position is consistent with how plans currently administer their formularies. Under this regulatory proposal, a plan sponsor could not completely exclude a lower tier containing only generic and authorized generic drugs from its tiering exception procedures, but would be permitted to limit the cost sharing for a particular brand drug or biological product to the lowest tier containing the same drug type. Plans would be required to grant a tiering exception for a higher cost generic or authorized generic drug to the cost sharing associated with the lowest tier containing generic and/or authorized generic alternatives when the medical necessity criteria is met.

d. Alternative Drugs for Treatment of the Enrollee’s Condition

In response to the 2018 Call Letter and RFI, we received comments from plan sponsors and PBMs requesting that CMS provide additional guidance on how to determine what constitutes an alternative drug for purposes of tiering exceptions, including establishment of additional limitations on when such exceptions are approvable. The statutory language for tiering and formulary exceptions at sections 1860D–4(g)(2) and 1860D–4(h)(2) of the Act, respectively, specifically refers to a preferred or formulary drug “for treatment of the same condition.” We interpret this language to be referring to the condition as it affects the enrollee—that is, taking into consideration the individual’s overall clinical condition,

including the presence of comorbidities and known relevant characteristics of the enrollee and/or the drug regimen, which can factor into which drugs are appropriate alternative therapies for that enrollee. The Part D statute at § 1860D–4(g)(2) requires that coverage decisions subject to the exceptions process be based on the medical necessity of the requested drug *for the individual* for whom the exception is sought. We believe that requirement reasonably includes consideration of alternative therapies for treatment of the enrollee's condition, based on the facts and circumstances of the case.

e. Approval of Tiering Exception Requests

We are proposing to revise § 423.578(c)(3) by renumbering the provision and adding a new paragraph (ii) to codify our current policy that cost sharing for an approved tiering exception request is assigned at the lowest applicable tier when preferred alternatives sit on multiple lower tiers. Under this proposal, assignment of cost sharing for an approved tiering exception must be at the most favorable cost-sharing tier containing alternative drugs, *unless* such alternative drugs are not applicable pursuant to limitations set forth under proposed § 423.578(a)(6). We are also proposing to delete similar language from existing (c)(3) that proposed new paragraph (c)(3)(ii) would replace.

f. Additional Technical Changes and Corrections

Finally, we are proposing various technical changes and corrections to improve the clarity of the tiering exceptions regulations and consistency with the regulations for formulary exceptions. Specifically, we are proposing the following:

- Revise the introductory text of § 423.578(a) to clarify that a “requested” non-preferred drug for treatment of an enrollee's health condition may be eligible for an exception.

- Revise § 423.578(a)(1) to include “tiering” when referring to the exceptions procedures described in this subparagraph.

- Revise § 423.578(a)(4) by making “conditions” singular and by adding “(s)” to “drug” to account for situations when there are multiple alternative drugs.

- Revise § 423.578(a)(5) by removing the text specifying that the prescriber's supporting statement “demonstrate the medical necessity of the drug” to align with the existing language for formulary exceptions at § 423.578(b)(6). The requirement that the supporting

statement address the enrollee's medical need for the requested drug is already explained in the introductory text of § 423.578(a).

- Redesignate paragraphs § 423.578(c)(3)(i) through (iii) as paragraphs § 423.578(c)(3)(i)(A) through (C), respectively. This proposed change would improve consistency between the regulation text for tiering and formulary exceptions.

We anticipate that the proposed changes to the tiering exceptions regulations will make this process more accessible and transparent for enrollees and less cumbersome for plan sponsors to administer. We also believe that, by helping plan sponsors ensure their tiering exceptions processes comply with CMS requirements, IRE overturn rates for tiering exception requests will remain low.

10. Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries (§ 423.38)

As discussed in section III.A.2 of this proposed rule, the MMA added section 1860D–1(b)(3)(D) to the Act to establish a special election period (SEP) for full-benefit dual eligible (FBDE) beneficiaries under Part D. This SEP, codified at § 423.38(c)(4), was later extended to all other subsidy-eligible beneficiaries by regulation (75 FR 19720). The SEP allows eligible beneficiaries to make Part D enrollment changes (that is, enroll in, disenroll from, or change Part D plans, including Medicare Advantage Prescription Drug (MA–PD) plans) throughout the year, unlike other Part D enrollees who generally may switch plans only during the annual enrollment period (AEP) each fall.

The MMA sought to strike a balance of promoting beneficiary plan choice, but also ensuring that FBDE beneficiaries who did not make an active election would still have Part D coverage. The statute directed the Secretary to enroll FBDE beneficiaries into a PDP if they did not enroll in a Part D plan on their own. (As noted previously, CMS extended the SEP through rulemaking to make it available to all other subsidy-eligible beneficiaries.) When the automatic enrollment of subsidy-eligible beneficiaries was originally proposed in rulemaking, we noted that beneficiaries would have the option to use the SEP if they determined there was a better plan option for them, and codified a continuous SEP (that is, that was available monthly).

At the time, we did not know on what factors FBDE beneficiaries would rely to make their plan choice. Now, with over

10 years of programmatic experience, we have observed certain enrollment trends in terms of FBDE and other LIS beneficiaries:

- Most LIS beneficiaries do not make an active choice to join a PDP. For plan year 2015, over 71 percent of LIS individuals in PDPs were placed into that plan by CMS.

- Once in a plan, whether it was a CMS-initiated enrollment or a choice they made on their own, most LIS beneficiaries do not make changes during the year. Of all LIS beneficiaries who were eligible for the SEP in 2016, less than 10 percent utilized it. Overall, we have seen slight growth of SEP usage over the past 5 years (for example, less than 8 percent in 2012, approximately 9 percent in 2014).

- A small subset (0.8 percent) of LIS beneficiaries use the SEP to actively enroll in a plan of their choice and then disenroll within 2 months.

While we know that the majority of LIS-eligible beneficiaries do not take advantage of the SEP, we have seen the Medicare and Medicaid environment evolve in such a way that it may be disadvantageous to beneficiaries if they changed plans during the year, let alone if they made multiple changes. States and plans have noted that they are best able to provide or coordinate care if there is continuity of enrollment, particularly if the beneficiary is enrolled in an integrated product (as discussed later in this section). We now know that in addition to choice, there are other critical issues that must be considered in determining when and how often beneficiaries should be able to change their Medicare coverage during the year, such as coordination of Medicare-Medicaid benefits, beneficiary care management, and public health concerns such as the national opioid epidemic (and the drug management programs discussed in section II.A.1). In addition, there are different care models available now such as dual eligible special needs plans (D–SNPs), Fully Integrated Dual Eligible (FIDE) SNPs, and Medicare-Medicaid Plans (MMPs) that are discussed later in this section and specifically designed to meet the needs of high risk, high needs beneficiaries.

Current enrollment trends demonstrate that while a majority of subsidy-eligible beneficiaries still receive their Part D coverage through standalone PDPs, an increasing percentage of beneficiaries are enrolled in MA–PDs and other capitated managed care products, including over one in three dually eligible beneficiaries. A smaller but rapidly growing subset are enrolled in capitated

Medicare managed care products that also integrate Medicaid services. For example:

- The MMA established D-SNPs to provide coordinated care to dually eligible beneficiaries. Between 2007 and 2016, growth in D-SNPs has increased by almost 150 percent.

- FIDE SNPs are a type of SNP created by the Affordable Care Act (ACA) in 2010 designed to promote full integration and coordination of Medicare and Medicare benefits for dually eligible beneficiaries by a single managed care organization. In 2017, there are 39 FIDE SNPs providing coverage to approximately 155,000 beneficiaries.

- MMPs, which operate as part of a model test under Section 1115(A) of the Act, are fully-capitated health plans that serve dually eligible beneficiaries though demonstrations under the Financial Alignment Initiative. The demonstrations are designed to promote full access to seamless, high quality integrated health care across both Medicare and Medicaid. In 2017, there are 58 MMPs providing coverage to nearly 400,000 beneficiaries.

The current SEP, especially in the context of these products that integrate Medicare and Medicaid, highlights differences in Medicare and Medicaid managed care enrollment policies. Bringing Medicare and Medicaid enrollment policies into greater alignment, even partially, is a mechanism to reduce complexity in the health care system and better partner with states. Both are important priorities for CMS.

In addition, the application of the continuous SEP carries different service delivery implications for enrollees of MA-PD plans and related products than for standalone enrollees of PDPs. At the outset of the Part D program, when drug coverage for dually eligible beneficiaries was transitioned from Medicaid to Medicare, there were concerns about how CMS would effectively identify, educate, and enroll dually eligible beneficiaries. While processes (for example, auto-enrollment, reassignment) were established to facilitate coverage, the continuous SEP served as a fail-safe to ensure that the beneficiary was always in a position to make a choice that best served their healthcare needs. Unintended consequences have resulted from this flexibility, including, as noted by the Medicare Payment Advisory

Commission (MedPAC³²), opportunities for marketing abuses.

Among the key obstacles the SEP (and resulting plan movement) can present are—

- Interfering with the coordination of care among the providers, health plans, and states;

- Hindering the ability for beneficiaries to benefit from case management and disease management;

- Wasting the effort and resources needed to conduct enrollee needs assessments and developing plans of care for services covered by Medicare and Medicaid;

- Limiting a plan's opportunity for continuous treatment of chronic conditions; and

- Diminishing incentives for plans to innovate and invest in serving potentially high-cost members.

While we still support in the underlying principle that LIS beneficiaries should have the ability to make an active choice, we find that plan sponsors are better able to administer benefits to beneficiaries, including coordination of Medicare and Medicaid benefits, and maximize care management and positive health outcomes, if dual and other LIS-eligible beneficiaries are held to the similar election period requirements as all other Part D-eligible beneficiaries. Therefore, we are proposing to amend § 423.38(c)(4) to make the SEP for FBDE and other subsidy-eligible individuals available only in certain circumstances. These circumstances would be considered separate and unique from one another, so there could be situations where a beneficiary could still use the SEP multiple times if he or she meets more than one of the conditions proposed as follows. Specifically, we are proposing to revise to § 423.38(c) to specify that the SEP is available only as follows:

- In new paragraph (c)(4)(i), eligible beneficiaries (that is, those who are dual or other LIS-eligible and meet the definition of at-risk beneficiary or potential at-risk beneficiary under proposed § 423.100) would be able to use the SEP once per calendar year.

- In new paragraph (c)(4)(iii), eligible beneficiaries who have been assigned to a plan by CMS or a State would be able to use the SEP before that election becomes effective (that is, opt out and enroll in a different plan) or within 2 months of their enrollment in that plan.

- In new paragraph (c)(9), dual and other LIS-eligible beneficiaries who

have a change in their Medicaid or LIS-eligible status would have an SEP to make an election within 2 months of the change, or of being notified of such change, whichever is later. This SEP would be available to beneficiaries who experience a change in Medicaid or LIS status regardless of whether they have been identified as potential at-risk beneficiaries or at-risk beneficiaries under proposed § 423.100. In addition, we are also proposing to remove the phrase "at any time" in the introductory language of § 423.38(c) for the sake of clarity.

The onetime annual SEP opportunity would be able to be used at any time of the year to enroll in a new plan or disenroll from the current plan, provided that their eligibility for the SEP has not been limited consistent with section 1860D-1(b)(3)(D) of the Act, as amended by CARA (as discussed in section III.A.2. of this proposed rule). We believe that the onetime annual SEP would still provide dually eligible beneficiaries adequate opportunity to change their coverage during the year if desired, but is also responsive to consistent feedback we have received from States and plans that have noted that the current SEP, which allows month-to-month movement, can disrupt continuity of care, especially in integrated care plans. They specifically noted that effective care management can best be achieved through continuous enrollment.

Beneficiaries who have been enrolled in a plan by CMS or a state (that is, through processes such as auto enrollment, facilitated enrollment, passive enrollment, default enrollment (seamless conversion), or reassignment), would be allowed a separate, additional use of the SEP, provided that their eligibility for the SEP has not been limited consistent with section 1860D-1(b)(3)(D) of the Act, as amended by CARA. These beneficiaries would still have a period of time before the election takes effect to opt out and choose their own plan or they would be able to use the SEP to make an election within 2 months of the assignment effective date. Once a beneficiary has made an election (either prior to or after the effective date) it would be considered "used" and no longer would be available. If a beneficiary wants to change plans after 2 months, he or she would have to use the onetime annual election opportunity discussed previously, provided that it has not been used yet. If that election has been used, the beneficiary would have to wait until they are eligible for another election period to make a change.

³² Medicare Payment Advisory Commission, "Report to Congress: Medicare Payment Policy," March 2008.

Under a new proposed SEP, individuals who have a change in their Medicaid or LIS-eligible status would have an election opportunity that is separate from, and in addition to, the two scenarios discussed previously. (As discussed in section III.A.2. of this rule, and unlike the other two conditions discussed previously, individuals identified as “at risk” would be able to use this SEP.) This would apply to individuals who gain, lose, or change Medicaid or LIS eligibility. We believe that in these instances, it would be appropriate to give these beneficiaries an opportunity to re-evaluate their Part D coverage in light of their changing circumstances. Beneficiaries eligible for this SEP would need to use it within 2 months of the change or of being notified of the change, whichever is later.

We considered multiple alternatives related to the SEP proposal. We describe two such alternatives in the following discussion:

Limit of two or three uses of the SEP per year. In 2016, 1.2 million beneficiaries used the SEP for FBDE or other subsidy-eligible individuals, including over 27,000 who used the SEP three or more times, and over 1,700 who used the SEP five or more times during the year. These SEP changes are in addition to changes made during the AEP and any other election periods for which a beneficiary may qualify. We believe that any overuse of the SEP creates significant inefficiencies and impedes meaningful continuity of care and care coordination. As such, we considered applying a simple numerical limit to the number of times the LIS SEP could be used by any beneficiary within each calendar year. We specifically considered limits of either two or three uses of the SEP per year.

Compared to our proposal to limit the use of the SEP to one time per calendar year, this alternative would permit more opportunities for midyear changes. However, it could still allow for a high level of membership churning. Relative to our proposal, it would also be less effective in limiting the opportunities for aggressive marketing to LIS beneficiaries outside of the AEP. We welcome comments on this alternative.

Limits on midyear MA–PD plan switching. We also considered a more complex option, drawing heavily on earlier MedPAC recommendations.³³ Under this alternative we would:

- Modify the SEP to prohibit its use to elect a non-integrated MA–PD plan.

As such, the SEP would not be used for switching between MA–PD plans, movement from integrated products to a non-integrated MA–PD plan, or movement from Medicare FFS to an MA–PD plan. Beneficiaries would still be able to select non-integrated MA–PD plans during other enrollment periods, such as the AEP, the open enrollment period (OEP) outlined in section III.C.2. of this proposed rule, and any other SEP for which they may be eligible; and

- Allow continuous use of the dual SEP to allow eligible beneficiaries to enroll into FIDE SNPs or comparably integrated products for dually eligible beneficiaries through model tests under section 1115(A) of the Act.

This alternative would still permit continuous election of Medicare FFS with a standalone PDP throughout the year and a continuous option to change between standalone PDPs.

We believe this alternative would create greater stability among plans and limit the opportunities for misleading and aggressive marketing to dually-eligible individuals. It would also maintain the opportunity for continuous enrollment into integrated products to reflect our ongoing partnership with states to promote integrated care. However, this alternative would be more complex to administer and explain to beneficiaries, and it encourages enrollment into a limited set of MA plans compared to all the plans available to the beneficiary under the MA program. We welcome comments on this alternative.

We believe that our proposed approach to narrowing of the scope of the SEP preserves a dual or other LIS-eligible beneficiary’s ability to make an active choice. As noted previously, less than 10 percent of the LIS population used the dual SEP in 2016. We acknowledge that even though this is a small percentage of the population, given the number of beneficiaries who receive Extra Help, this equates to over a million elections. We note, though, that of this group, the majority (74.5 percent) used the SEP one time. Under our proposal, this population would still be able to make an election, thus, we believe that the majority of beneficiaries would not be negatively impacted by these changes. We opted for our proposed approach, as opposed to the alternatives, because we believe it encourages continuity of enrollment and care, without overcomplicating both beneficiary understanding of how the SEP is available to them, as well as plan sponsor operational responsibilities.

If the proposal is finalized, we would revise our messaging and beneficiary education materials as necessary to

ensure that dual and other LIS-eligible beneficiaries understand that the SEP is no longer an unlimited opportunity. We would also need to ensure that beneficiaries who are assigned to a plan by CMS or the State understand that they must use the SEP within 2 months after the new coverage begins if they wish to change from the plan to which they were assigned.

We note that other election periods, including the AEP, the new OEP, or other SEPs (for example, when moving to a new service area), would still be available to individuals. In addition, the proposed limitations would also apply to the Part C SEP established in sub-regulatory guidance for dual-eligible individuals or individuals who lose their dual-eligibility.

We welcome public comment on this proposal and the considered alternatives. Specifically, we seek input on the following areas:

- Are there other limited circumstances where the dual SEP should be available?
- Are there special considerations CMS should keep in mind if we finalize this policy?
- Are there other alternative approaches we should consider in lieu of narrowing the scope of the SEP?
- In addition to CMS outreach materials, what are the best ways to educate the affected population and other stakeholders of the new proposed SEP parameters?

11. Medicare Advantage and Part D Prescription Drug Program Quality Rating System

a. Introduction

We are committed to transforming the health care delivery system—and the Medicare program—by putting a strong focus on person-centered care, in accordance with the CMS Quality Strategy, so each provider can direct their time and resources to each beneficiary and improve their outcomes. As part of this commitment, one of our most important strategic goals is to improve the quality of care for Medicare beneficiaries. The Part C and D Star Ratings support the efforts of CMS to improve the level of accountability for the care provided by health and drug plans, physicians, hospitals, and other Medicare providers. We currently publicly report the quality and performance of health and drug plans on the Medicare Plan Finder tool on www.medicare.gov in the form of summary and overall ratings for the contracts under which each MA plan (including MA–PD plans) and Part D plan is offered, with drill downs to

³³ Medicare Payment Advisory Commission, “Report to Congress: Medicare Payment Policy,” March 2008.

ratings for domains, ratings for individual measures, and underlying performance data. We also post additional measures on the display page³⁴ at www.cms.gov for informational purposes. The goals of the Star Ratings are to display quality information on Medicare Plan Finder for public accountability and to help beneficiaries, families, and caregivers make informed choices by being able to consider a plan's quality, cost, and coverage; to incentivize quality improvement; to provide information to oversee and monitor quality; and to accurately measure and calculate scores and stars to reflect true performance. In addition, CMS has started to incorporate efforts to recognize the challenges of serving high risk, high needs populations while continuing the focus on improving health care for these important groups.

In this rule as part of the Administration's efforts to improve transparency, we propose to codify the existing Star Ratings System for the MA and Part D programs with some changes. As noted later in this section in more detail, the proposed changes include more clearly delineating the rules for adding, updating, and removing measures and modifying how we calculate Star Ratings for contracts that consolidate. Although the rulemaking process will create a longer lead time for changes, codifying the Star Ratings methodology will provide plans with more stability to plan multi-year initiatives, because they will know the measures several years in advance. We have received comments for the past several years from MA organizations and other stakeholders asking that CMS use **Federal Register** rulemaking for the Star Ratings System; we discuss in section III.12.c. (regarding plans for the transition period before the codified rules are used) how section 1832(b) authorizes CMS to establish and annually modify the Star Ratings System using the Advance Notice and Rate Announcement process because the system is an integral part of the policies governing Part C payment. We think this is an appropriate time to codify the methodology, because the rating system has been used for several years now and is relatively mature so there is less need for extensive changes every year; the smaller degree of flexibility in having codified regulations rather than using the process for adopting payment methodology changes may be appropriate. Further, by adopting and codifying the rules that

govern the Star Ratings System, we are demonstrating a commitment to transparency and predictability for the rules in the system so as to foster investment.

b. Background

We originally acted upon our authority to disseminate information to beneficiaries as the basis for developing and publicly posting the 5-star ratings system (sections 1851(d) and 1852(e) of the Act). The MA statute explicitly requires that information about plan quality and performance indicators be provided to beneficiaries in an easy to understand language to help them make informed plan choices. These data are to include disenrollment rates, enrollee satisfaction, health outcomes, and plan compliance with requirements.

The Part D statute (at section 1860D–1(c)) imposes a parallel information dissemination requirement with respect to Part D plans, and refers specifically to comparative information on consumer satisfaction survey results as well as quality and plan performance indicators. Part D plans are also required by regulation (§ 423.156) to make Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey data available to CMS and are required to submit pricing and prescription drug event data under statutes and regulations specific to those data. Regulations require plans to report on quality improvement and quality assurance and to provide data which CMS can use to help beneficiaries compare plans (§§ 422.152 and 423.153). In addition we may require plans to report statistics and other information in specific categories (§§ 422.516 and 423.514).

Currently, for similar reasons of providing information to beneficiaries to assist them in plan enrollment decisions, we also review and rate section 1876 cost plans on many of the same measures and publish the results. We also propose to continue to include 1876 cost contracts in the MA and Part D Star Rating system to provide comparative information to Medicare beneficiaries making plan choices. We propose specific text, to be codified at § 417.472(k), noting that 1876 cost contracts must agree to be rated under the quality rating system specified at subpart D of part 422. Cost contracts are also required by regulation (§ 17.472(j)) to make CAHPS survey data available to CMS. As is the case today, no quality bonus payments (QBP) would be associated with the ratings for 1876 cost contracts.

In line with §§ 422.152 and 423.153, CMS uses the Healthcare Effectiveness

Data and Information Set (HEDIS), Health Outcomes Survey (HOS), CAHPS data, Part C and D Reporting requirements and administrative data, and data from CMS contractors and oversight activities to measure quality and performance of contracts. We have been displaying plan quality information based on that and other data since 1998.

Since 2007, we have published annual performance ratings for stand-alone Medicare PDPs. In 2008, we introduced and displayed the Star Ratings for Medicare Advantage Organizations (MAOs) for both Part C only contracts (MA-only contracts) and Part C and D contracts (MA-PDs). Each year since 2008, we have released the MA Star Ratings. An overall rating combining health and drug plan measures was added in 2011, and differential weighting of measures (for example, outcomes being weighted 3 times the value of process measures) began in 2012. The measurement of year to year improvement began in 2013, and an adjustment (Categorical Adjustment Index) was introduced in 2017 to address the within-contract disparity in performance revealed in our research among beneficiaries that are dual eligible, receive a low income subsidy, and/or are disabled.

The MA and Part D Star Ratings measure the quality of care and experiences of beneficiaries enrolled in MA and Part D contracts, with 5 stars as the highest rating and 1 star as the lowest rating. The Star Ratings provide ratings at various levels of a hierarchical structure based on contract type, and all ratings are determined using the measure-level Star Ratings. Contingent on the contract type, ratings may be provided and include overall, summary (Part C and D), and domain Star Ratings. Information about the measures, the hierarchical structure of the ratings, and the methodology to generate the Star Ratings is detailed in the annually updated Medicare Part C and D Star Ratings Technical Notes, referred to as Technical Notes, available at <http://go.cms.gov/partcanddstarratings>.

The MA and Part D Star Ratings System is designed to provide information to the beneficiary that is a true reflection of the plan's quality and encompasses multiple dimensions of high quality care. The information included in the ratings is selected based on its relevance and importance such that it can meet the data needs of beneficiaries using it to inform plan choice. While encouraging improved health outcomes of beneficiaries in an efficient, person centered, equitable, and high quality manner is one of the

³⁴ <http://go.cms.gov/partcanddstarratings> (under the downloads).

primary goals of the ratings, they also provide feedback on specific aspects of care that directly impact outcomes, such as process measures and the beneficiary's perspective. The ratings focus on aspects of care that are within the control of the health plan and can spur quality improvement. The data used in the ratings must be complete, accurate, reliable, and valid. A delicate balance exists between measuring numerous aspects of quality and the need for a small data set that minimizes reporting burden for the industry. Also, the beneficiary or his or her representative must have enough information to make an informed decision without feeling overwhelmed by the volume of data.

The Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Healthcare and Education Reconciliation Act (Pub. L. 111–152), provides for quality ratings, based on a 5-star rating system and the information collected under section 1852(e) of the Act, to be used in calculating payment to MA organizations beginning in 2012. Specifically, sections 1853(o) and 1854(b)(1)(C) of the Act provide, respectively, for an increase in the benchmark against which MA organizations bid and in the portion of the savings between the bid and benchmark available to the MA organization to use as a rebate. Under the Act, Part D plan sponsors are not eligible for quality based payments or rebates. We finalized a rule on April 15, 2011 to implement these provisions and to use the existing Star Ratings System that had been in place since 2007 and 2008. (76 FR 21485–21490).³⁵ In addition, the Star Ratings measures are tied in many ways to responsibilities and obligations of MA organizations and Part D sponsors under their contracts with CMS. We believe that continued poor performance on the measures and overall and summary ratings indicates systemic and wide-spread problems in an MA plan or Part D plan. In April 2012, we finalized a regulation to use consistently low summary Star Ratings—meaning 3 years of summary Star Ratings below 3 stars—as the basis for a contract termination for Part C and Part D plans. (§§ 422.510(a)(14) and 423.509(a)(13)). Those regulations further reflect the role the Star Ratings have had in CMS' oversight, evaluation, and monitoring of MA and Part D plans to ensure compliance with the

respective program requirements and the provision of quality care and health coverage to Medicare beneficiaries.

The true potential of the use of the MA and Part D Star Ratings System to reach our goals and to serve as a catalyst for change can only be realized by working in tandem with our many stakeholders including beneficiaries, industry, and advocates. The following guiding principles have been used historically in making enhancements to the MA and Part D Star Ratings:

- Ratings align with the current CMS Quality Strategy.
- Measures developed by consensus-based organizations are used as much as possible.
- Ratings are a true reflection of plan quality and enrollee experience; the methodology minimizes risk of misclassification.
- Ratings are stable over time.
- Ratings treat contracts fairly and equally.
- Measures are selected to reflect the prevalence of conditions and the importance of health outcomes in the Medicare population.
- Data are complete, accurate, and reliable.
- Improvement on measures is under the control of the health or drug plan.
- Utility of ratings is considered for a wide range of purposes and goals.
 - ++ Accountability to the public.
 - ++ Enrollment choice for beneficiaries.
 - ++ Driving quality improvement for plans and providers.
- Ratings minimize unintended consequences.
- Process of developing methodology is transparent and allows for multi-stakeholder input.

We are using these goals to guide our proposal and how we interpret and apply the proposed regulations once finalized. For each provision we are proposing, we solicit comment on whether our specific proposed regulation text best serves these guiding principles. We also solicit comment on whether additional or other principles are better suited for these roles in measuring and communicating quality in the MA and Part D programs in a comparative manner.

As we continue to consider making changes to the MA and Part D programs in order to increase plan participation and improve benefit offerings to enrollees, we would also like to solicit feedback from stakeholders on how well the existing stars measures create meaningful quality improvement incentives and differentiate plans based on quality. We welcome all comments on those topics, and will consider them

for changes through this or future rulemaking or in connection with interpreting our regulations (once finalized) on the Star Rating system measures. However, we are particularly interested in receiving stakeholder feedback on the following topics:

- Additional opportunities to improve measures so that they further reflect the quality of health outcomes under the rated plans.
- Whether CMS' current process for establishing the cut points for Star Rating can be simplified, and if the relative performance as reflected by the existing cut points accurately reflects plan quality.
- How CMS should measure overall improvement across the Star Ratings measures. We are requesting input on additional improvement adjustments that could be implemented, and the effect that these adjustments could have on new entrants (that is, new MA organizations and/or new plans offered by existing MA organizations).
- Additional adjustments to the Star Ratings measures or methodology that could further account for unique geographic and provider market characteristics that affect performance (for example, rural geographies or monopolistic provider geographies), and the operational difficulties that plans could experience if such adjustments were adopted.
- In order to further encourage plan participation and new market entrants, whether CMS should consider implementing a demonstration to test alternative approaches for putting new entrants (that is, new MA organizations) on a level playing field with renewing plans from a Star Ratings perspective for a pre-determined period of time.
- Adding measures that evaluate quality from the perspective of adopting new technology (for example, the percent of beneficiaries enrolled through online brokers or the use of telemedicine) or improving the ease, simplicity, and satisfaction of the beneficiary experience in a plan.
- Including survey measures of physicians' experiences. (Currently, we measure beneficiaries' experiences with their health and drug plans through the CAHPS survey.) Physicians also interact with health and drug plans on a daily basis on behalf of their patients. We are considering developing a survey tool for collecting standardized information on physicians' experiences with health and drug plans and their services, and we would welcome comments.

³⁵ The ratings were first used as part of the Quality Bonus Payment Demonstration for 2012 through 2014 and then used for payment purposes as specified in sections 1853(o) and 1854(b)(1)(C) and the regulation at 42 CFR 422.258(d)(7).

c. Basis, Purpose and Applicability of the Quality Star Ratings System

We propose to codify regulation text, at §§ 422.160 and 423.180, that identifies the statutory authority, purpose, and applicability of the Star Ratings System regulations we are proposing to add to part 422 subpart D and part 423 subpart D. Under our proposal, the existing purposes of the quality rating system—to provide comparative information to Medicare beneficiaries pursuant to sections 1851(d) and 1860D–1(c) of the Act, to identify and apply the payment consequences for MA plans under sections 1853(o) and 1854(b)(1)(C) of the Act, and to evaluate and oversee overall and specific performance by plans—would continue. To reflect how the Part D ratings are used for MA–PD plan QBP status and rebate retention allowances, we also propose specific text, to be codified at § 423.180(b)(2), noting that the Part D Star Rating will be used for those purposes.

We are proposing here, broadly stated, to codify the current quality Star Ratings System uses, methodology, measures, and data collection beginning with the measurement periods in calendar year 2019. We are proposing some changes, such as how we handle consolidations from the current Star Ratings program, but overall the proposal is to continue the Star Ratings System as it has been developed and has stabilized. Data will be collected and performance will be measured using these proposed rules and regulations for the 2019 measurement period; the associated quality Star Ratings will be used to assign QBP ratings for the 2022 payment year and released prior to the annual coordinated election period held in late 2020 for the 2021 contract year. Application of the final regulations resulting from this proposal will determine whether the measures proposed in section III.A.12.i. of the proposed rule (Table 2) are updated, transitioned to or from the display page, and otherwise used in conjunction with the 2019 performance period.

Under our proposal, the current quality Star Ratings System and the procedures for revising it will remain in place for the 2019 and 2020 quality Star Ratings. Section 1853(b) of the Act authorizes an advance notice and rate announcement to announce and seek comment for proposed changes to the MA payment methodology, which includes the Part C and D Star Ratings program. The statute identifies specific notice and comment timeframes, but that process does not require publication in the **Federal Register**. We

have used the draft and final Call Letter, which are attachments to the Advance Notice and final Rate Announcement respectively,³⁶ to propose for comment and finalize changes to the quality Star Ratings System since the ratings became a component of the payment methodology for MA and MA–PD plans. (76 FR 214878 through 89). Because the Star Ratings System has been integrated into the payment methodology since the 2012 contract year (as a mechanism used to determine how much a plan is paid, and not the mechanism by which (or a rule about when) a plan is paid), the Star Ratings are part of the process for setting benchmarks and capitation rates under section 1853, and the process for announcing changes to the Star Ratings System falls within the scope of section 1853(b). Although not expressly required by section 1853(b), CMS has historically solicited comment on significant changes to the ratings system using a Request for Comment process before the Advance Notice and draft Call Letter are released; this Request for Comment³⁷ provides MAOs, Part D sponsors, and other stakeholders an opportunity to request changes to and raise concerns about the Star Ratings methodology and measures before CMS finalizes its proposal for the Advance Notice. We intend to continue the current process at least until the 2019 measurement period that we are proposing as the first measurement period under these new regulations, but we may discontinue that process at a later date as the rulemaking process may provide sufficient opportunity for public input. In addition, CMS issues annually the Technical Notes³⁸ that describe in detail how the methodology is applied from the changes in policy adopted through the Advance Notice and Rate Announcement process. We intend to continue the practice of publishing the Technical Notes during the preview periods. Under our proposal, we would also continue to use the draft and final Call Letters as a means to provide subregulatory application), interpretation, and guidance of the final version of these proposed regulations where necessary. Our proposed regulation text does not detail these plans for continued use of the current process and future for

³⁶ Advance Notices and Rate Announcements are posted each year on the CMS Web site at: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>.

³⁷ Requests for Comment are posted at <http://go.cms.gov/partcanddstarratings> under the downloads.

³⁸ <http://go.cms.gov/partcanddstarratings> (under the downloads) for the Technical Notes.

subregulatory guidance because we believe such regulation text would be unnecessary. We propose to codify the first performance period (2019) and first payment year (2022) to which our proposed regulations would apply at § 422.160(c) and § 423.180(c).

d. Definitions

There are a number of technical and other terms relevant to our proposed regulations. Therefore, we propose the following definitions for the respective subparts in part 422 and part 423 in paragraph (a) of §§ 422.162 and 423.182 respectively. Some proposed definitions are discussed in more detail later in this preamble in connection with other proposed regulation text related to the definition.

- *CAHPS* refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.

- *Case-mix adjustment* means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.

- *Categorical Adjustment Index (CAI)* means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy or have disability status in that contract (or plan as applicable).

- *Clustering* refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as possible to observations in any other group. Clustering of the measure-specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify

the four cut points resulting in the creation of five levels (one for each Star Rating), such that the scores in the same Star Rating level are as similar as possible and the scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.

- *Consolidation* means when an MA organization/Part D sponsor that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.
- *Consumed contract* means a contract that will no longer exist after a contract year's end as a result of a consolidation.
- *Display page* means the CMS Web site on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.
- *Domain rating* means the rating that groups measures together by dimensions of care.
- *Dual Eligible (DE)* means a beneficiary who is enrolled in both Medicare and Medicaid.
- *HEDIS* is the Healthcare Effectiveness Data and Information Set which is a widely used set of performance measures in the managed care industry, developed and maintained by the National Committee for Quality Assurance (NCQA). HEDIS data include clinical measures assessing the effectiveness of care, access/availability measures, and service use measures.
- *Highest rating* means the overall rating for MA-PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.
- *Highly-rated contract* means a contract that has 4 or more stars for their highest rating when calculated without the improvement measures and with all applicable adjustments (CAI and the reward factor).
- *HOS* means the Medicare Health Outcomes Survey which is the first

patient reported outcomes measure that was used in Medicare managed care. The goal of the Medicare HOS program is to gather valid, reliable, and clinically meaningful health status data in the Medicare Advantage (MA) program for use in quality improvement activities, pay for performance, program oversight, public reporting, and improving health. All managed care organizations with MA contracts must participate.

- *Low Income Subsidy (LIS)* means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see § 423.34 for definition of a low-income subsidy eligible individual).
- *Measurement period* means the period for which data are collected for a measure or the performance period that a measure covers.
- *Measure score* means the numeric value of the measure or an assigned 'missing data' message.
- *Measure star* means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1–5 star scale.
- *Overall Rating* means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.
- *Part C Summary Rating* means a global rating that summarizes the health plan quality and performance on Part C measures.
- *Part D Summary Rating* means a global rating of the prescription drug plan quality and performance on Part D measures.
- *Plan Benefit Package (PBP)* means a set of benefits for a defined MA or PDP service area. The PBP is submitted by PDP sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.
- *Reliability* means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality ("signal") rather than random variation ("noise"); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).
- *Reward factor* means a rating-specific factor added to the contract's summary or overall (or both) rating if a contract has both high and stable relative performance.
- *Statistical significance* assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same. Although not part of the proposed

regulatory definition, we clarify that CMS uses statistical tests (for example, t-test) to determine if a contract's measure value is statistically different (greater than or less than depending on the test) from the national mean for that measure, or whether conversely, the observed differences from the national mean could have arisen by chance.

- *Surviving contract* means the contract that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.
- *Traditional rounding rules* mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3 or 4, then the value should be rounded down by deleting the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place deleted.

e. Contract Ratings

Star Ratings and data reporting are at the contract level for most measures. Currently, data for measures are collected at the contract level including data from all PBPs under the contract, except for the following Special Needs Plan (SNP)-specific measures which are collected at the PBP level: Care for Older Adults—Medication Review, Care for Older Adults—Functional Status Assessment, and Care for Older Adults—Pain Assessment. The SNP-specific measures are rolled up to the contract level by using an enrollment-weighted mean of the SNP PBP scores. Subject to the discussion later in this section about the feasibility and burden of collecting data at the PBP (plan) level and the reliability of ratings at the plan level, we propose to continue the practice of calculating the Star Ratings at the contract level and all PBPs under the contract would have the same overall and/or summary ratings.

However, beneficiaries select a plan, rather than a contract, so we have considered whether data should be collected and measures scored at the plan level. We have explored the feasibility of separately reporting quality data for individual D-SNP PBPs, instead of the current reporting level. For example, in order for CAHPS measures to be reliably scored, the number of respondents must be at least 11 people and reliability must be at least 0.60. Our current analyses show that, at the PBP level, CAHPS measures could be reliably reported for only about one-third of D-SNP PBPs due to sample size

issues, and HEDIS measures could be reliably reported for only about one-quarter of D-SNP PBP. If reporting were done at the plan level, a significant number of D-SNP plans would not be rated and in lieu of a Star Rating, Medicare Plan Finder would display that the plan is “too small to be rated.” However, when enough data are available, plan level quality reporting would better reflect the quality of care provided to enrollees in that plan. Plan-level quality reporting would also give states that contract with D-SNPs plan-specific information on their performance and provide the public with data specific to the quality of care for dual eligible (DE) beneficiaries enrolled in these plans. For all plans as well as D-SNPs, reporting at the plan level would significantly increase plan burden for data reporting and would have to be balanced against the availability of additional clinical information available at the plan level. Plan-level ratings would also potentially increase the ratings of higher-performing plans when they are in contracts that have a mix of high and low performing plans. Similarly, plan-level ratings would also potentially decrease the ratings of lower-performing plans that are currently in contracts with a mix of high and low performing plans. Measurement reliability issues due to small sample sizes would also decrease our ability to measure true performance at the plan level and add complexities to the rating system. We are soliciting comments on balancing the improved precision associated with plan level reporting (relative to contract level reporting) with the negative consequences associated with an increase in the number of plans without adequate sample sizes for at least some measures; we ask for comments about this for D-SNPs and for all plans as we continue to consider whether rating at the plan level is feasible or appropriate. In particular, we are interested in feedback on the best balance and whether changing the level at which ratings are calculated and reported better serves beneficiaries and our goals for the Star Ratings System.

We are also exploring whether some measure data could be reported at a higher level (parent organization versus contract) to ease and simplify reporting and still remain useful (for example, call center measures as we anticipate that parent organizations use a consolidated call center to serve all contracts and plans) to incorporate into the Star Ratings. Further, we are exploring if contract market area reporting is feasible when a contract covers a large

geographic area. For example, when HEDIS reporting began in 1997, there were contract-specific market areas that evolved into reporting by market area for five states with large Medicare populations.³⁹ We are planning to continue work in this area to determine the best reporting level for each measure that most accurately reflects performance and minimizes to the extent possible plan reporting burden. As we consider alternative reporting units, we welcome comments and suggestions about requiring reporting at different levels (for example, parent organization, contract, plan, or geographic area) by measure.

We propose to continue at this time calculating the same overall and/or summary Star Ratings for all PBPs offered under an MA-only, MA-PD, or PDP contract. We propose to codify this policy in regulation text at §§ 422.162(b) and 423.182(b). We also propose a cost plan regulation at § 417.472(k) to require cost contracts to be subject to the part 422 and part 423 Medicare Advantage and Part D Prescription Drug Program Quality Rating System as they are measured and rated like an MA plan. Specifically, we propose, at paragraph (b)(1) that CMS will calculate overall and summary ratings at the contract level and propose regulation text that cross-references other proposed regulations regarding the calculation of measure scoring and rating, and domain, summary and overall ratings. Further, we propose to codify, at (b)(2) of each section, that data from all PBPs offered under a contract will continue to be used to calculate the ratings for the contract. For SNP specific measures collected at the PBP level, we propose that the contract level score would be an enrollment-weighted mean of the PBP scores using enrollment in each PBP as reported as part of the measure specification, which is consistent with current practice. The proposed text is explicit that domain and measure ratings, other than the SNP-specific measures, are based on data from all PBPs under the contract.

f. Contract Consolidations

We are proposing a change in how contract-level Star Ratings are assigned in the case of contract consolidations. We have historically permitted MAOs and Part D sponsors to consolidate contracts when a contract novation occurs or to better align business practices. As noted in MedPAC's March 2016 Report to Congress (<https://aspe.hhs.gov/pdf-report/report>

³⁹ The following states were divided into multiple market areas: CA, FL, NY, OH, and TX.

congress-social-risk-factors-and-performance-under-medicare-value-based-purchasing-programs), there has been a continued increase in the number of enrollees being moved from lower Star Rating contracts that do not receive a QBP to higher Star Rating contracts that do receive a QBP as part of contract consolidations, which increases the size of the QBPs that are made to MAOs due to the large enrollment increase in the higher rated, surviving contract. We are worried that this practice results in masking low quality plans under higher rated surviving contracts. This does not provide beneficiaries with accurate and reliable information for enrollment decisions, and it does not truly reward higher quality contracts. We propose here to modify from the current policy the calculation of Star Ratings for surviving contracts that have consolidated. Instead of assigning the surviving contract the Star Rating that the contract would have earned without regard to whether a consolidation took place, we propose to assign and display on Medicare Plan Finder Star Ratings based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) so that the ratings reflect the performance of all contracts (surviving and consumed) involved in the consolidation. Under this proposal, the calculation of the measure, domain, summary, and overall ratings would be based on these enrollment-weighted mean scores. The number of contracts this would impact is small relative to all contracts that qualify for QBPs. During the period from 1/1/2015 through 1/1/2017 annual consolidations for MA contracts ranged from a low of 7 in 2015 to a high of 19 in 2016 out of approximately 500 MA contracts. As proposed in §§ 422.162(b)(3)(i)-(iii) and 423.182(b)(3)(i)-(iii), CMS will use enrollment-weighted means of the measure scores of the consumed and surviving contracts to calculate ratings for the first and second plan years following the contract consolidations. We believe that use of enrollment-weighted means will provide a more accurate snapshot of the performance of the underlying plans in the new consolidated contract, such that both information to beneficiaries and QBPs are not somehow inaccurate or misleading. We also propose, however, that the process of weighting the enrollment of each contract and applying this general rule would vary depending on the specific types of measures involved in order to take into account the measurement period and

data collection processes of certain measures. Our proposal would also treat ratings for determining quality bonus payment (QBP) status for MA contracts differently than displayed Star Ratings for the first year following the consolidation for consolidations that involve the same parent organization and plans of the same plan type.

We propose to codify our new policy at §§ 422.162(b)(3) and 423.182(b)(3). First, we propose generally, at paragraph (b)(3)(i) of each regulation, that CMS will assign Star Ratings for consolidated contracts using the provisions of paragraph (b)(3). We are proposing in § 422.162(b)(3) both a specific rule to address the QBP rating following the first year after the consolidation and a rule for subsequent years. As Part D plan sponsors are not eligible for QBPs, the Part D regulation text is proposed without the QBP aspect. We propose in § 422.162(b)(3)(iv) and § 423.182(b)(3)(ii) the process for assigning Star Ratings for posting on the Medicare Plan Finder for the first 2 years following the consolidation.

For the first contract year following a consolidation, as proposed at paragraphs § 422.162(b)(3)(iv) and § 423.182(b)(3)(ii), we propose to use the enrollment-weighted means as calculated below to set Star Ratings for publication (and, in § 422.162(b)(3)(iii), use of certain enrollment-weighted means for establishing QBP status:

- The Star Ratings measure scores for the consolidated entity's first plan year would be based on enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except the survey-based and call center measures.

- The survey-based measures (that is, CAHPS, HOS, and HEDIS measures collected through CAHPS or HOS) would use enrollment of the surviving and consumed contracts at the time the sample is pulled for the rating year. For example, for a contract consolidation that is effective January 1, 2021 the CAHPS sample for the 2021 Star Ratings would be pulled in January 2020 so enrollment in January 2020 would be used. The call center measures would use mean enrollment during the study period. We believe that these proposals for survey-based measures are more nuanced and account for how the data underlying those measures are gathered. By using the enrollment-weighted means we are reflecting the true underlying performance of both the surviving and consumed contracts.

For the second year following the consolidation, for all MA and Part D

Sponsors, the Star Ratings would be calculated as follows:

- The enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts would be used for all measures except HEDIS, CAHPS, and HOS.

- The current reporting requirements for HEDIS and HOS already combine data from the surviving and consumed contract(s) following the consolidation, so we are not proposing any modification or averaging of these measure scores. For example, for HEDIS if an organization consolidates one or more contracts during the change over from measurement to reporting year, then only the surviving contract is required to report audited summary contract-level data but it must include data on all members from all contracts involved. For this reason, we are proposing regulation text that HEDIS and HOS measure data will be used as reported in the second year after consolidation.

- The CAHPS survey sample that would be selected following the consolidation would be modified to include enrollees in the sample universe from which the sample is drawn from both the surviving and consumed contracts. If there are two contracts (that is, Contract A is the surviving contract and Contract B is the consumed contract) that consolidate, and Contract A has 5,000 enrollees eligible for the survey and Contract B has 1,000 eligible for the survey, the universe from which the sample would be selected would be 6,000.

After applying these rules for calculating the measure scores in the first and second year after consolidation, CMS would use the other rules proposed in §§ 422.166 and 423.186 to calculate the measure, domain, summary, and overall Star Ratings for the consolidated contract. In the third year after consolidation and subsequent years, the performance period for all the measures would be after the consolidation, so our proposal is limited to the Star Ratings issued the first 2 years after consolidation.

When consolidations involve two or more contracts for health and/or drug services of the same plan type under the same parent organization combining into a single contract at the start of a contract year, we propose to calculate the QBP rating for that first year following the consolidation using the enrollment-weighted mean, using traditional rounding rules, of what would have been the QBP ratings of the surviving and consumed contracts using the contract enrollment in November of

the year the Star Ratings were released. In November of each year following the release of the ratings on Medicare Plan Finder, the preliminary QBP ratings are displayed in the Health Plan Management System (HPMS) for the year following the Star Ratings year. For example, the first year the consolidated entity is in operation is plan year 2020; the 2020 QBP rating displayed in HPMS in November 2018 would be based on the 2019 Star Ratings (which are released in October 2018) and calculated using the weighted mean of the November 2018 enrollment of the surviving and consumed contracts. Because the same parent organization is involved in these situations, we believe that many administrative processes and procedures are identical in the Medicare health plans offered by the sponsoring organization, and using a weighted mean of what would have been their QBP ratings accurately reflects their performance for payment purposes. In subsequent years after the first year following the consolidation, QBPs status would be determined based on the consolidated entity's Star Rating posted on Medicare Plan Finder. Under our proposal, the measure, domain, summary, and in the case of MA-PD plans the overall Star Ratings posted on Medicare Plan Finder for the second year following consolidation would be based on the enrollment-weighted measure scores so would include data from all contracts involved. Consequently, the ratings used for QBP status determinations would reflect the care provided by both the surviving and consumed contracts.

In conclusion, we are proposing a new set of rules regarding the calculation of Star Ratings for consolidated contracts to be codified at paragraphs (b)(3)(i) through (iv) of §§ 422.162 and 423.182. In most cases, we propose that the Star Ratings for the first and second year following the consolidation to be an enrollment-weighted mean of the scores at the measure level for the consumed and surviving contracts. For the QBP rating for the first year following the consolidation, we propose to use the enrollment-weighted mean of the QBP rating of the surviving and consumed contracts (which would be the overall or summary rating depending on the plan type) rather than averaging measure scores. We solicit comment on this proposal and whether our separate treatment of different measure types during the first and second year adequately addresses the differences in how data are collected (and submitted) for those measures during the different

periods. We would also like to know whether sponsoring organizations believe that the special rule for consolidations involving the same parent organization and same plan types adequately addresses how those situations are different from cases where an MA organization buys or sells a plan or contract from or to a different entity and whether these rules should be extended to situations where there are different parent organizations involved. For commenters that support the latter, we also request comment on how CMS should determine that the same administrative processes are used and whether attestations from sponsoring organizations or evidence from prior audits should be required to support such determinations.

g. Data Sources

Under 1852(e) of the Act, MA organizations are required to collect, analyze, and report data that permit measurement of health outcomes and other indices of quality. The Star Ratings System is based on information collected consistent with section 1852(e) of the Act. Section 1852(e)(3)(B) of the Act prohibits the collection of data on quality, outcomes, and beneficiary satisfaction other than the types of data that were collected by the Secretary as of November 1, 2003; there is a limited exception for SNPs to collect, analyze, and report data that permit the measurement of health outcomes and other indicia of quality. The statute does not require that only the same data be collected, but that we do not change or expand the type of data collected until after submission of a Report to Congress (prepared in consultation with MA organizations and accrediting bodies) that explains the reason for the change(s). We clarify here that the types of data included under the Star Ratings System are consistent with the types of data collected as of November 1, 2003. Since 1997, Medicare managed care organizations have been required to annually report quality of care performance measures through HEDIS. We have also been conducting the CAHPS survey since 1997 to measure beneficiaries' experiences with their health plans, and since 2007 we have been measuring experiences with drug plans with CAHPS. HOS began in 1998 to capture changes in the physical and mental health of MA enrollees. To some extent, these surveys have been revised and updated over time, but the same types of data—clinical measures, beneficiary experiences, and changes in physical and mental health, respectively—have remained the focus of these surveys. In

addition, there are several measures in the Stars Ratings System that are based on performance that address telephone customer service, members' complaints, disenrollment rates, and appeals; however these additional measures are not collected directly from the sponsoring organizations for the primary purpose of quality measurement. These additional measures are calculated from information that CMS has gathered as part of the administration of the Medicare program, such as information on appeals forwarded to the Independent Review Entity under subparts M, enrollment, and compliance and enforcement actions.

The Part D program was implemented in 2006, and while there is no parallel provision regarding applicable Part D sources of data, we have used similar datasets, for example CAHPS survey data, for beneficiaries' experiences with prescription drug plans. Section 1860D–4(d) of the Act specifically directs the administration and collection of data from consumer surveys in a manner similar to those conducted in the MA program. All of these measures reflect structure, process, and outcome indices of quality that form the measurement set under Star Ratings. Since 2007, we have publicly reported a number of measures related to the drug benefit as part of the Star Ratings. For MA organizations that offer prescription drug coverage, we have developed a series of measures focusing on administration of the drug benefit. Similar to MA measures of quality relative to health services, the Part D measures focus on customer service and beneficiary experiences, effectiveness, and access to care relative to the drug benefit. We believe that the Part D Star Ratings are consistent with the limitation expressed in section 1852(e) of the Act even though the limitation does not apply to our collection of Part D quality data from Part D sponsors.

We intend to continue to base the types of information collected in the Part C Star Ratings on section 1852(e) of the Act, and we propose at § 422.162(c)(1) that the type of data used for Star Ratings will be data consistent with the section 1852(e) limits and data gathered from CMS administration of the MA program. In addition, we propose in § 422.162(c)(1) and in § 423.182(c)(1) to include measures that reflect structure, process, and outcome indices of quality, including Part C measures that reflect the clinical care provided, beneficiary experience, changes in physical and mental health, and benefit administration, and Part D measures that reflect beneficiary

experiences and benefit administration. The measures encompass data submitted directly by MA organizations (MAOs) and Part D sponsors to CMS, surveys of MA and Part D enrollees, data collected by CMS contractors, and CMS administrative data. We also propose, primarily so that the regulation text is complete on this point, a regulatory provision at §§ 422.162(c)(2) and 423.182(c)(2) that requires MA organizations and Part D plan sponsors to submit unbiased, accurate, and complete quality data as described in paragraph(c)(1) of each section. Our authority to collect quality data is clear under the statute and existing regulations, such as section 1852(e)(3)(A) and 1860D–4(d) and §§ 422.12(b)(2) and 423.156. We propose the paragraph (c)(2) regulation text to ensure that the quality ratings system regulations include a regulation on this point for readers and to avoid confusion in the future about the authority to collect this data. In addition, it is important that the data underlying the ratings are unbiased, accurate, and complete so that the ratings themselves are reliable. This proposed regulation text would clearly establish the sponsoring organization's responsibility to submit data that can be reliably used to calculate ratings and measure plan performance.

h. Adding, Updating, and Removing Measures

We are committed to continuing to improve the Part C and D Star Ratings System by focusing on improving clinical and other outcomes. We anticipate that new measures will be developed and that existing measures will be updated over time. NCQA and the Pharmacy Quality Alliance (PQA) continually work to update measures as clinical guidelines change and develop new measures focused on health and drug plans. To address these anticipated changes, we propose in §§ 422.164 and 423.184 specific rules to govern the addition, update, and removal of measures. We also propose to apply these rules to the measure set proposed in this rulemaking, to the extent that there are changes between the final rule and the Star Ratings based on the performance periods beginning on or after January 2019.

As discussed in more detail in the following paragraphs, we propose the following general rules to govern adding, updating, and removing measures:

- For data quality issues identified during the calculation of the Star Ratings for a given year, we propose to continue our current practice of

removing the measure from the Star Ratings.

- That new measures and substantive updates to existing measures would be added to the Star Ratings System based on future rulemaking but that prior to such a rulemaking, CMS would announce new measures and substantive updates to existing measures and solicit feedback using the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act (that is the Call Letter attachment to the Advance Notice and Rate Announcement).

- That existing measures (currently existing or existing after a future rulemaking) used for Star Ratings would be updated with regular updates from the measure stewards through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act when the changes are not substantive.

- That existing measures (currently existing or existing after a future rulemaking) used for Star Ratings would be removed from use in the Star Ratings when there has been a change in clinical guidelines associated with the measure or reliability issues identified in advance of the measurement period; CMS would announce the removal using the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Removal might be permanent or temporary, depending on the basis for the removal.

We are proposing specific rules for updating and removal that would be implemented through subregulatory action, so that rulemaking will not be necessary for certain updates or removals. Under this proposal, CMS would announce application of the regulation standards in the Call Letter attachment to the Advance Notice and Rate Announcement process under section 1853(b) of the Act.

First, we propose to codify, at §§ 422.164(a) and 423.184(a), regulation text stating the general rule that CMS would add, update, and remove measures used to calculate Star Ratings as provided in §§ 422.164 and 423.184. In each paragraph regarding addition, updating, and removal of measures and the use of improvement measures, we also propose rules to identify when these types of changes would not involve rulemaking based on application of the standards and authority in the regulation text. Under our proposal, CMS would solicit feedback of its application of the rules

using the draft and final Call Letter each year.

Second, we propose, in paragraph (b) of these sections, that CMS would review the quality of the data on which performance, scoring, and rating of measures is done each year. We propose to continue our current practice of reviewing data quality across all measures, variation among organizations and sponsors, and measures' accuracy, reliability, and validity before making a final determination about inclusion of measures in the Star Ratings. The intent is to ensure that Star Ratings measures accurately measure true plan performance. If a systemic data quality issue is identified during the calculation of the Star Ratings, we would remove the measure from that year's rating under proposed paragraph (b).

Third, we propose to address the addition of new measures in paragraph (c).

In identifying whether to add a measure, we will be guided by the principles we listed in section III.A.12.b. of the proposed rule. Measures should be aligned with best practices among payers and the needs of the end users, including beneficiaries. Our strategy is to continue to adopt measures when they are available, nationally endorsed, and in alignment with the private sector, as we do today through the use of measures developed by NCQA and the PQA, and the use of measures that are endorsed by the National Quality Forum (NQF). We propose to codify this standard for adopting new measures at §§ 422.164(c)(1) and 423.184(c)(1). We do not intend this standard to require that a measure be adopted by an independent measure steward or endorsed by NQF in order for us to propose its use for the Star Ratings, but that these are considerations that will guide us as we develop such proposals. We also propose that CMS may develop its own measures as well when appropriate to measure and reflect performance in the Medicare program.

For the 2021 Star Ratings, we propose (at section III.A.12.) of the proposed rule to have measures that encompass outcome, intermediate outcome, patient/consumer experience, access, process, and improvement measures. It is important to have a mix of different types of measures in the Star Ratings program to understand how all of the different facets of the provision of health and drug services interact. For example, process measures are evidence-based best practices that lead to clinical outcomes of interest. Process measures are generally easier to collect,

while outcome measures are sometimes more challenging requiring in some cases medical record review and more sophisticated risk-adjustment methodologies.

Over time new measures will be added and measures will be removed from the Star Ratings program to meet our policy goals. As new measures are added, our general guidelines for deciding whether to propose new measures through future rulemaking will use the following criteria:

- **Importance:** The extent to which the measure is important to making significant gains in health care processes and experiences, access to services and prescription medications, and improving health outcomes for MA and Part D enrollees.

- **Performance Gap:** The extent to which the measure demonstrates opportunities for performance improvement based on variation in current health and drug plan performance.

- **Reliability and Validity:** The extent to which the measure produces consistent (reliable) and credible (valid) results.

- **Feasibility:** The extent to which the data related to the measure are readily available or could be captured without undue burden and could be implemented by the majority of MA and Part D contracts.

- **Alignment:** The extent to which the measure or measure concept is included in one or more existing federal, State, and/or private sector quality reporting programs.

We would balance these criteria as part of our decision making process so that each new measure proposed for addition to the Star Ratings meets each criteria in some fashion or to some extent. We intend to apply these criteria to identify and adopt new measures for the Star Ratings, which will be done through future rulemaking that includes explanations for how and why we propose to add new measures. When we identify a measure that meets these criteria, we propose to follow the process in our proposed paragraphs (c)(2) through (4) of §§ 422.164 and 423.184. We would initially solicit feedback on any potential new measures through the Call Letter.

As new performance measures are developed and adopted, we propose, at §§ 422.164(c)(3) and (4) and 423.184(c)(3) and (4), that they would initially be incorporated into the display page for at least 2 years but that we would keep a new measure on the display page for a longer period if CMS finds there are reliability or validity issues with the measure. As noted in the

Introduction, the rulemaking process will create a longer lead time for changes, in particular to add a new measure to the Star Ratings or to make substantive changes to measures as discussed later in this section. Here is an example timeline for adding a new measure to the Star Ratings. In this scenario, the new measure has already been developed by the NCQA and the PQA, and endorsed by the NQF. Otherwise, that process may add an extra 3 to 5 years to the timeline.

- January 2019: Solicit feedback on whether to add the new measure in the draft 2020 Call Letter.
- April 2019: Summarize feedback on adding the new measure in the 2020 Call Letter.
- 2020/2021: Propose adding the new measure to the 2024 Star Ratings (2022 measurement period) in a proposed rule; finalize through rulemaking (for 1/1/2022 effective date).
- 2020: Performance period and collection of data for the new measure and collection of data for posting on the 2022 display page.
- 2021: Performance period and collection of data for the new measure and collection of data for posting on the 2023 display page.
- Fall 2021: Publish new measure on the 2022 display page (2020 measurement period).
- January 1, 2022: Applicability date of new measure for Star Ratings.
- 2022: Performance period and collection of data for the new measure and collection of data for inclusion in the 2024 Star Ratings.
- Fall 2022: Publish new measure on the 2023 display page (2021 measurement period).
- Fall 2023: Publish new measure in the 2024 Star Ratings (2022 measurement period).
- 2025: QBP status and rebate retention allowances are determined for the 2025 payment year.

Fourth, at §§ 422.164(d) and 423.184(d) we propose to address updates to measures based on whether an update is substantive or non-substantive. Since quality measures are routinely updated (for example, when clinical codes are updated), we propose to adopt rules for the incorporation of non-substantive updates to measures that are part of the Star Ratings System without going through new rulemaking. As proposed in paragraphs (d)(1) of §§ 422.164 and 423.184, we would only incorporate updates without rulemaking for measure specification changes that do not substantively change the nature of the measure.

Substantive changes (for example, major changes to methodology) to

existing measures would be proposed and finalized through rulemaking. In paragraphs (d)(2) of §§ 422.164 and 423.184, we propose to initially solicit feedback on whether to make the substantive measure update through the Call Letter prior to the measurement period for which the update would be initially applicable. For example, if the change announced significantly expands the denominator or population covered by the measure (for example, the age group included in the measures is expanded), the measure would be moved to the display page for at least 2 years and proposed through rulemaking for inclusion in Star Ratings. We intend this process for substantive updates to be similar to the process we would use for adopting new measures under proposed paragraph (c). As appropriate, the legacy measure may remain in the Star Ratings while the updated measure is on the display page if, for example, the updated measure expands the population covered in the measure and the legacy measure would still be relevant and measuring a critical topic to continue including in the Star Ratings while the updated measure is on display. Adding the updated measure to the Star Ratings would be proposed through rulemaking.

We propose to adopt rules to incorporate specification updates that are non-substantive in paragraph (d)(1). Non-substantive updates that occur (or are announced by the measure steward) during or in advance of the measurement period will be incorporated into the measure and announced using the Call Letter. We propose to use such updated measures to calculate and assign Star Ratings without the updated measure being placed on the display page. This is consistent with current practice.

In paragraph (d)(1)(i-v) of §§ 422.164 and paragraph (d)(1)(i-v) of 423.184, we propose to codify a non-exhaustive list for identifying non-substantive updates announced during or prior to the measurement period and how we would treat them under our proposal. The list includes updates in the following circumstances:

- If the change narrows the denominator or population covered by the measure with no other changes, the updated measure would be used in the Star Ratings program without interruption. For example, if an additional exclusion—such as excluding nursing home residents from the denominator—is added, the change would be considered non-substantive and would be incorporated automatically. In our view, changes to narrow the denominator generally

benefit Star Ratings of sponsoring organizations and should be treated as non-substantive for that reason.

- If the change does not meaningfully impact the numerator or denominator of the measure, the measure would continue to be included in the Star Ratings. For example, if additional codes are added that increase the number of numerator hits for a measure during or before the measurement period, such a change would not be considered substantive because the sponsoring organization would generally benefit from that change. This type of administrative (billing) change has no impact on the current clinical practices of the plan or its providers, and thus would not necessitate exclusion from the Star Ratings System of any measures updated in this way.

- The clinical codes for quality measures (such as HEDIS measures) are routinely revised as the code sets are updated. For updates to address revisions to the clinical codes without change in the intent of the measure and the target population, the measure would remain in the Star Ratings program and would not move to the display page. Examples of clinical codes that might be updated or revised without substantively changing the measure include:

- ++ ICD-10-CM (“ICD-10”) code sets. Annually, there are new ICD 10 coding updates, which are effective from October 1 through September 30th of any given year.

- ++ Current Procedural Terminology (CPT) codes. These codes are published and maintained by the American Medical Association (AMA) to describe tests, surgeries, evaluations, and any other medical procedure performed by a healthcare provider on a patient.

- ++ Healthcare Common Procedure Coding System (HCPCS) codes. These codes cover items, supplies, and non-physician services not covered by CPT codes.

- ++ National Drug Code (NDC). The PQA updates NDC lists biannually, usually in January and July.

- If the measure specification change is providing additional clarifications such as the following, the measure would also not move to the display page since this does not change the intent of the measure but provides more information about how to meet the measure specifications:

- ++ Adding additional tests that would meet the numerator requirements.

- ++ Clarifying documentation requirements (for example, medical record documentation).

++ Adding additional instructions to identify services or procedures that meet (or do not meet) the specifications of the measure.

- If the measure specification change is adding additional data sources, the measure would also not move to the display page because we believe such changes are merely to add alternative ways to collect the data to meet the measure specifications without changing the intent of the measure.

We solicit comment on our proposal to add non-substantive updates to measures and using the updated measure (replacing the legacy measure) to calculate Star Ratings. In particular, we are interested in stakeholders' views whether only non-substantive updates that have been adopted by a measure steward after a consensus-based or notice and comment process should be added to the Star Ratings under this proposed authority. Further, we solicit comment on whether there are other examples or situations involving non-substantive updates that should be explicitly addressed in the regulation text or if our proposal is sufficiently extensive.

In addition to updates and additions of measures, we are proposing rules to address the removal of measures from the Star Ratings to be codified in §§ 422.164(e) and 423.184(e). In paragraph (e)(1) of each section, we propose the two circumstances under which a measure would be removed entirely from the calculation of the Star Ratings. The first circumstance would be changes in clinical guidelines that mean that the measure specifications are no longer believed to align with or promote positive health outcomes. As clinical guidelines change, we would need the flexibility to remove measures from the Star Ratings that are not

consistent with current guidelines. We are proposing to announce such subregulatory removals through the Call Letter so that removals for this reason are accomplished quickly and as soon as the disconnect with positive clinical outcomes is definitively identified. We note that this proposal is consistent with our current practice. For example, previously we retired the Glaucoma Screening measure for HEDIS 2015 after the U.S. Preventive Services Task Force concluded that the clinical evidence is insufficient to assess the balance of benefits and harms of screening for glaucoma in adults.

In addition to removal of measures because of changes in clinical guidelines, we currently review measures continually to ensure that the measure remains sufficiently reliable such that it is appropriate to continue use of the measure in the Star Ratings. We propose, at paragraph (e)(1)(ii), that we would also have authority to subregulatorily remove measures that show low statistical reliability so as to move swiftly to ensure the validity and reliability of the Star Ratings, even at the measure level. We will continue to analyze measures to determine if measure scores are "topped out" (that is, showing high performance across all contracts decreasing the variability across contracts and making the measure unreliable) so as to inform our approach to the measure, or if measures have low reliability. Although some measures may show uniform high performance across contracts and little variation between them, we seek evidence of the stability of such high performance, and we want to balance how critical the measures are to improving care, the importance of not creating incentives for a decline in performance after the measures

transition out of the Star Ratings, and the availability of alternative related measures. If, for example, performance in a given measure has just improved across all contracts, or if no other measures capture a key focus in Star Ratings, a "topped out" measure which would have lower reliability may be retained in Star Ratings. Under our proposal to be codified at paragraph (e)(2), we would announce application of this rule through the Call Letter in advance of the measurement period.

We request comment on these proposals regarding the processes to add, update, and remove Star Ratings measures.

i. Measure Set for Performance Periods Beginning on or After January 1, 2019

We are proposing the measures included in Table 2 to be collected for performance periods beginning on or after January 1, 2019 for the 2021 Part C and D Star Ratings. The CAHPS measure specification, including case-mix adjustment, is described in the Technical Notes and at *mapdpcahps.org*. The HOS measure specification, including case-mix adjustment, is described at (http://hosonline.org/globalassets/hos-online/survey-results/hos_casemix_coefficient_tables_c17.pdf). These specifications are part of our proposal.

We are not proposing to codify this list of measures and specifications in regulation text in light of the regular updates and revisions contemplated by our proposals at §§ 422.164 and 423.184. We intend, as proposed in paragraph (a) of these sections, that the Technical Notes for each year's Star Ratings would include the applicable full list of measures.

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TABLE 2: PROPOSED INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2019

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, the 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.

1. 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 January 1, 2018 to December 31, 2018 period.
2. For CAHPS, HOS, and HEDIS/HOS measures, the measurement period is listed as 'most recent data submitted for the survey of enrollees.' See measure stewards' technical manuals, as referenced in Data Source column, for the specific measurement periods of the most recent data submitted.
- 3.

TABLE 2A: PART C MEASURES

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Breast Cancer Screening (BCS)	Percent of female plan members aged 52-74 who had a mammogram during the past 2 years.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0031	Clustering	MA-PD and MA-only
Colorectal Cancer Screening (COL)	Percent of plan members aged 50 to 75 who had appropriate screenings for colorectal cancer.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0034	Clustering	MA-PD and MA-only
Annual Flu Vaccine	Percent of plan members who received an influenza vaccination prior to flu season.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	CAHPS**	Most recent data submitted for the survey of enrollees	#0040	Relative Distribution and Significance Testing	MA-PD and MA-only

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Improving or Maintaining Physical Health	Percent of plan members aged 65 or older whose physical health status was the same or better than expected after 2 years.	Staying Healthy: Screenings, Tests and Vaccines	Outcome Measure Weight of 3	HOS***	Most recent data submitted for the survey of enrollees	Not Applicable	Clustering	MA-PD and MA-only
Improving or Maintaining Mental Health	Percent of plan members aged 65 or older whose mental health was the same or better than expected after 2 years.	Staying Healthy: Screenings, Tests and Vaccines	Outcome Measure Weight of 3	HOS***	Most recent data submitted for the survey of enrollees	Not Applicable	Clustering	MA-PD and MA-only
Monitoring Physical Activity (PAO)	Percent of plan members aged 65 or older who had a doctor's visit in the past 12 months and who received advice to start, increase or maintain their level exercise or physical activity.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	HEDIS / HOS***	Most recent data submitted for the survey of enrollees	#0029	Clustering	MA-PD and MA-only
Adult BMI Assessment (ABA)	Percent of plan members 18-74 years of age who had an outpatient visit and whose body mass index (BMI) was documented.	Staying Healthy: Screenings, Tests and Vaccines	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0421	Clustering	MA-PD and MA-only
Special Needs Plan (SNP) Care Management	Percent of eligible Special Needs Plan (SNP) enrollees who received a health risk assessment (HRA).	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	Part C Plan Reporting	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	Special Needs Plans
Care for Older Adults (COA) – Medication Review	Percent of Special Needs Plan enrollees 66 years and older who received at least one medication review conducted by a prescribing practitioner or clinical pharmacist and the presence of a medication list in the medical record.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0553	Clustering	Special Needs Plans
Care for Older Adults (COA) – Functional Status Assessment	Percent of Special Needs Plan enrollees 66 years and older who received at least one functional status assessment.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	Special Needs Plans
Care for Older Adults (COA)– Pain Assessment	Percent of Special Needs Plan enrollees 66 years and older who received at least one pain assessment.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	Special Needs Plans

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Osteoporosis Management in Women who had a Fracture (OMW)	Percent of female plan enrollees 67 - 85 who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat osteoporosis in the 6 months after the fracture.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0053	Clustering	MA-PD and MA-only
Diabetes Care (CDC) – Eye Exam	Percent of diabetic enrollees 18-75 with diabetes (type 1 and type 2) who received an eye exam (retinal).	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0055	Clustering	MA-PD and MA-only
Diabetes Care (CDC) – Kidney Disease Monitoring	Percent of diabetic enrollees 18-75 with diabetes (type 1 and type 2) who had medical attention for nephropathy.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0062	Clustering	MA-PD and MA-only
Diabetes Care (CDC) – Blood Sugar Controlled	Percent of diabetic enrollees 18-75 whose most recent HbA1c level is greater than 9%, or who were not tested.	Managing Chronic (Long Term) Conditions	Intermediate Outcome Measure Weight of 3	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0059	Clustering	MA-PD and MA-only
Controlling Blood Pressure (CBP)	Percent of plan members 18–85 years of age who had a diagnosis of hypertension (HTN) and whose blood pressure was adequately controlled (<140/90) for members 18-59 years of age and 60-85 years of age with diagnosis of diabetes or (150/90) for members 60-85 without a diagnosis of diabetes.	Managing Chronic (Long Term) Conditions	Intermediate Outcome Measure Weight of 3	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0018	Clustering	MA-PD and MA-only
Rheumatoid Arthritis Management (ART)	Percent of plan members who were diagnosed with rheumatoid arthritis and who were dispensed at least one ambulatory prescription for a disease modifying anti-rheumatic drug (DMARD).	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0054	Clustering	MA-PD and MA-only
Reducing the Risk of Falling (FRM)	Percent of plan members 65 years of age or older who had a fall or had problems with balance or walking in the past 12 months, who were seen by a practitioner in the past 12 months and received fall risk intervention from their current practitioner.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS / HOS***	Most recent data submitted for the survey of enrollees	#0035	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 Rating	Reporting Requirements (Contract Type)
Improving Bladder Control (MUI)	Percent of plan members 65 years of age or older who reported having a urine leakage problem in the past 6 months and who received treatment for their current urine leakage problem.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS / HOS***	Most recent data submitted for the survey of enrollees	#0030	Clustering	MA-PD and MA-only
Medication Reconciliation Post-Discharge (MRP)	Percent of plan members 18 years of age and older for whom medications were reconciled the date of discharge through 30 days after discharge (31 total days).	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#0554	Clustering	MA-PD and MA-only
Plan All-Cause Readmissions (PCR)	Percent of acute inpatient stays that were followed by an unplanned acute readmission for any diagnosis within 30 days, for members 65 years of age and older. Rates of readmission are risk-adjusted.	Managing Chronic (Long Term) Conditions	Outcome Measure Weight of 3	HEDIS*	The calendar year 2 years prior to the Star Ratings year	#1768	Clustering	MA-PD and MA-only, except for 1876 Cost Plans
Getting Needed Care	Percent of the best possible score the plan earned on how easy it is for members to get needed care, including care from specialists.	Member Experience with Health Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	#0006	Relative Distribution and Significance Testing	MA-PD and MA-only
Getting Appointments and Care Quickly	Percent of the best possible score the plan earned on how quickly members get appointments and care.	Member Experience with Health Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	#0006	Relative Distribution and Significance Testing	MA-PD and MA-only
Customer Service	Percent of the best possible score the plan earned on how easy it is for members to get information and help from the plan when needed.	Member Experience with Health Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	#0006	Relative Distribution and Significance Testing	MA-PD and MA-only
Rating of Health Care Quality	Percent of the best possible score the plan earned from members who rated the quality of the health care they received.	Member Experience with Health Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	#0006	Relative Distribution and Significance Testing	MA-PD and MA-only
Rating of Health Plan	Percent of the best possible score the plan earned from members who rated the health plan.	Member Experience with Health Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	#0006	Relative Distribution and Significance Testing	MA-PD and MA-only

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Care Coordination	Percent of the best possible score the plan earned on how well the plan coordinates members' care. (This includes whether doctors had the records and information they needed about members' care and how quickly members got their test results.)	Member Experience with Health Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	Not Applicable	Relative Distribution and Significance Testing	MA-PD and MA-only
Complaints about the Health Plan	Rate of complaints, logged into the Complaint Tracking Module (CTM), about the health plan per 1,000 members.	Member Complaints and Changes in the Health Plan's Performance	Patients' Experience and Complaints Measure Weight of 1.5	Complaints Tracking Module (CTM)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only
Members Choosing to Leave the Plan	Percent of plan members who chose to leave the plan.	Member Complaints and Changes in the Health Plan's Performance	Patients' Experience and Complaints Measure Weight of 1.5	Medicare Beneficiary Database Suite of Systems (MBDSS)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only
Health Plan Quality Improvement	Measure of a health plan's performance, whether improved or declined from 1 year to the next (§ 422.164(f)).	Member Complaints and Changes in the Health Plan's Performance	Improvement Measure Weight of 5	Star Ratings	The current and prior Star Ratings years	Not Applicable	Clustering	MA-PD and MA-only
Plan Makes Timely Decisions about Appeals	Percent of plan members who got a timely response when they made an appeal request to the health plan about a decision to refuse payment or coverage, including cases dismissed by the IRE because the plan has subsequently approved coverage/payment.	Health Plan Customer Service	Measures Capturing Access Weight of 1.5	Independent Review Entity (IRE)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only
Reviewing Appeals Decisions	Percent of appeals where a plan's decision was "upheld" by the Independent Review Entity (IRE) of all the plan's appeals (upheld, overturned, and partially overturned appeals only) that the IRE reviewed.	Health Plan Customer Service	Measures Capturing Access Weight of 1.5	Independent Review Entity (IRE)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	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 Rating	Reporting Requirements (Contract Type)
Call Center – Foreign Language Interpreter and TTY Availability	Percent of time that TTY services and foreign language interpretation were available when needed by prospective members who called the health plan’s prospective enrollee customer service phone number.	Health Plan Customer Service	Measures Capturing Access Weight of 1.5	Call Center	Data collected first half of the year prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only, except for 1876 Cost Plans
Statin Therapy for Patients with Cardiovascular Disease (SPC)	Percent of plan members (males 21–75 years of age and females 40–75 years of age) who were identified as having clinical atherosclerotic cardiovascular disease (ASCVD) and were dispensed at least one high or moderate-intensity statin medication.	Managing Chronic (Long Term) Conditions	Process Measure Weight of 1	HEDIS*	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and MA-only

* NCQA HEDIS Technical Specifications, Volume 2

** Medicare Advantage and Prescription Drug Plan CAHPS Survey Quality Assurance Protocols & Technical Specifications Manual (<http://ma-pdcahps.org/en/quality-assurance/>)

*** NCQA HEDIS Specifications for the Medicare Health Outcomes Survey, Volume 6

TABLE 2B: PART D MEASURES

Measure	Metric	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements by Contract Type
Call Center – Foreign Language Interpreter and TTY Availability	Percent of time that TTY services and foreign language interpretation were available when needed by prospective members who called the health plan’s prospective enrollee customer service phone number.	Drug Plan Customer Service	Measures Capturing Access Weight of 1.5	Call Center	Data collected first half of the year prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP, except 1876 Cost Plans

Measure	Metric	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements by Contract Type
Appeals Auto-Forward	Rate of cases auto-forwarded to the Independent Review Entity (IRE) because the plan exceeded decision timeframes for coverage determinations or redeterminations.	Drug Plan Customer Service	Measures Capturing Access Weight of 1.5	Independent Review Entity (IRE)	The calendar year two years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
Appeals Upheld	Percent of appeals where a plan's decision was "upheld" by the Independent Review Entity (IRE) of all the plan's appeals (upheld, overturned, and partially overturned appeals only) that the IRE reviewed.	Drug Plan Customer Service	Measures Capturing Access Weight of 1.5	Independent Review Entity (IRE)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
Complaints about the Drug Plan	Rate of complaints about the drug plan per 1,000 members.	Member Complaints and Changes in the Drug Plan's Performance	Patients' Experience and Complaints Measure Weight of 1.5	Complaints Tracking Module (CTM)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
Members Choosing to Leave the Plan	Percent of plan members who chose to leave the plan.	Member Complaints and Changes in the Drug Plan's Performance experience and outcomes	Patients' Experience and Complaints Measure Weight of 1.5	Medicare Beneficiary Database Suite of Systems (MBDSS)	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
Drug Plan Quality Improvement	Measure of a drug plan's performance, whether improved or declined from 1 year to the next (§ 422.184(f)).	Member Complaints and Changes in the Drug Plan's Performance	Improvement Measure Weight of 5	Star Ratings	The current and prior Star Ratings years	Not Applicable	Clustering	MA-PD and PDP
Rating of Drug Plan	Percent of the best possible score the plan earned from members who rated the prescription drug plan.	Member Experience with the Drug Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	Not Applicable	Relative Distribution and Significance Testing	MA-PD and PDP
Getting Needed Prescription Drugs	Percent of the best possible score the plan earned on how easy it is for members to get the prescription drugs they need using the plan.	Member Experience with the Drug Plan	Patients' Experience and Complaints Measure Weight of 1.5	CAHPS**	Most recent data submitted for the survey of enrollees	Not Applicable	Relative Distribution and Significance Testing	MA-PD and PDP

Measure	Metric	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements by Contract Type
MPF Price Accuracy	A score comparing the prices members actually pay for their drugs to the drug prices the plan provided for the Medicare Plan Finder website.	Drug Safety and Accuracy of Drug Pricing	Process Measure Weight of 1	PDE data, MPF Pricing Files	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
Medication Adherence for Diabetes Medications	Percent of plan members with a prescription for diabetes medication who fill their prescription often enough to cover 80% or more of the time they are supposed to be taking the medication.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE) data	The calendar year 2 years prior to the Star Ratings year	#0541	Clustering	MA-PD and PDP
Medication Adherence for Hypertension (RAS antagonists)	Percent of plan members with a prescription for a blood pressure medication who fill their prescription often enough to cover 80% or more of the time they are supposed to be taking the medication.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE) data	The calendar year 2 years prior to the Star Ratings year	#0541	Clustering	MA-PD and PDP
Medication Adherence for Cholesterol (Statins)	Percent of plan members with a prescription for a cholesterol medication (a <i>statin drug</i>) who fill their prescription often enough to cover 80% or more of the time they are supposed to be taking the medication.	Drug Safety and Accuracy of Drug Pricing	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE) data	The calendar year 2 years prior to the Star Ratings year	#0541	Clustering	MA-PD and PDP
MTM Program Completion Rate for CMR	Percent of Medication Therapy Management (MTM) program enrollees who received a Comprehensive Medication Review (CMR).	Drug Safety and Accuracy of Drug Pricing	Process Measure Weight of 1	Part D Plan Reporting	The calendar year 2 years prior to the Star Ratings year	Not Applicable	Clustering	MA-PD and PDP
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	Intermediate Outcome Measure Weight of 3	Prescription Drug Event (PDE) data	The calendar year 2 years prior to the Star Ratings year	#2712	Clustering	MA-PD and PDP

* NCQA HEDIS Technical Specifications, Volume 2.

** Medicare Advantage and Prescription Drug Plan CAHPS Survey Quality Assurance Protocols & Technical Specifications Manual (<http://ma-pdpcahps.org/en/quality-assurance/>).

*** NCQA HEDIS Specifications for the Medicare Health Outcomes Survey (http://www.hosonline.org/globalassets/hos-online/publications/hos_hedis_volume6_2017.pdf).

j. Improvement Measures

In the 2013 Part C and D Star Ratings, we implemented the Part C and D improvement measures (CY2013 Rate Announcement, <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2013.pdf>). The improvement measures address the overall improvement or decline in individual measure scores from the prior to the current year. We propose to continue the current methodology detailed in the Technical Notes for calculating the improvement measures and to codify it at §§ 422.164(f) and 423.184(f). For a measure to be included in the improvement calculation, the measure must have numeric value scores in both the current and prior year and not have had a substantive specification change during those years. In addition, the improvement measure will not include any data on measures that are already focused on improvement (for example, HOS measures focused on improving or maintaining physical or mental health). The Part C improvement measure includes only Part C measure scores, and the Part D improvement measure includes only Part D measure scores. All measures meeting these criteria would be included in the improvement measures under our proposal at paragraph (f)(1)(i) through (iv) of §§ 422.164 and 423.184.

Annually, the subset of measures to be included in the improvement measures following these criteria would be announced through the Call Letter, similar to our proposal for regular updates and removal of measures. Under our proposal, once the measures to be used for the improvement measures are identified, CMS would determine which contracts have sufficient data for purposes of applying and scoring the improvement measure(s). Following current practices, the improvement measure score would be calculated only for contracts that have numeric measure scores for both years for at least half of the measures identified for use in the improvement measure. We propose this standard for determining contracts eligible for an improvement measure at paragraph (f)(2).

We propose at part §§ 422.164(f)(3) and (4) and 423.184(f)(3) and (4) the process for calculating the improvement measure score(s) and a special rule for any identified improvement measure for a contract that received a measure-level Star Rating of 5 in each of the 2 years examined, but whose associated measure score indicates a statistically

significant decline in the time period. The improvement measure would be calculated in a series of distinct steps:

- The improvement change score (the difference in the measure scores in the 2-year period) would be determined for each measure that has been identified as part of an improvement measure and for which a contract has a numeric score for each of the 2 years examined.
- Each contract's improvement change score would be categorized as a significant change or not by employing a two tailed t-test with a level of significance of 0.05.
- The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.
- The improvement measure score would then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.
- The improvement measure score would be converted to a measure-level Star Rating using the hierarchical clustering algorithm.

The improvement measure score cut points would be determined using two separate clustering algorithms. Improvement measure scores of zero and above would use the clustering algorithm to determine the cut points for the Star Rating levels of 3 and above. Improvement measure scores below zero would be clustered to determine the cut points for 1 and 2 stars. The Part D improvement measure thresholds for MA-PDs and PDPs would be reported separately.

We propose a special rule in paragraph (f)(3) to hold harmless sponsoring organizations that have 5-star ratings for both years on a measure used for the improvement measure calculation. This hold harmless provision was added in 2014 to avoid the unintended consequence for contracts that score 5 stars on a subset of measures in each of the 2 years. For any identified improvement measure for which a contract received a rating of 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change. The measure will be included in the count of measures used to determine

eligibility for the improvement measure and in the denominator of the improvement measure score. The intent of the hold harmless provision for a contract that receives a measure rating of 5 stars for each year is to prevent the measure from lowering a contract's improvement measure when the contract still demonstrates high performance. We propose in section III.A.12. of this proposed rule another hold harmless provision to be codified at §§ 422.166(g)(1) and 423.186(g)(1).

We request comment on the methodology for the improvement measures, including rules for determining which measures are included, the conversion to a Star Rating, and the hold harmless provision for individual measures that are used for the determination of the improvement measure score.

k. Data Integrity

The data underlying a measure score and rating must be complete, accurate, and unbiased for it to be useful for the purposes we have proposed at §§ 422.160(b) and 423.180(b). As part of the current Star Ratings methodology, all measures and the associated data have multiple levels of quality assurance checks. Our longstanding policy has been to reduce a contract's measure rating if we determine that a contract's measure data are incomplete, inaccurate, or biased. Data validation is a shared responsibility among CMS, CMS data providers, contractors, and Part C and D sponsors. When applicable (for example, data from the IRE, PDE, call center), CMS expects sponsoring organizations to routinely monitor their data and immediately alert CMS if errors or anomalies are identified so CMS can address these errors.

We propose to codify at §§ 422.164(g) and 423.184(g) specific rules for the reduction of measure ratings when CMS identifies incomplete, inaccurate, or biased data that have an impact on the accuracy, impartiality, or completeness of data used for the impacted measures. Data may be determined to be incomplete, inaccurate, or biased based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that impacted specific measure(s). One example of such situations that give rise to such determinations includes a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements. Our modifications to measure-specific ratings due to data integrity issues are separate from any CMS compliance or enforcement actions related to a sponsor's deficiencies. This policy and

these rating reductions are necessary to avoid falsely assigning a high star to a contract, especially when deficiencies have been identified that show we cannot objectively evaluate a sponsor's performance in an area.

As a standard practice, we check for flags that indicate bias or non-reporting, check for completeness, check for outliers, and compare measures to the previous year to identify significant changes which could be indicative of data issues. CMS has developed and implemented Part C and Part D Reporting Requirements Data Validation standards to assure that data reported by sponsoring organizations pursuant to §§ 422.516 and 423.514 satisfy the regulatory obligation. Sponsor organizations should refer to specific guidance and technical instructions related to requirements in each of these areas. For example, information about HEDIS measures and technical specifications is posted on: <http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures.aspx>. Information about Data Validation of Reporting Requirements data is posted on: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartCDDDataValidation.html> and https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html.

We propose, in paragraphs (g)(1)(i) through (iii), rules for specific circumstances where we believe a specific response is appropriate. First, we propose a continuation of a current policy: To reduce HEDIS measures to 1 star when audited data are submitted to NCQA with an audit designation of "biased rate" or BR based on an auditor's review of the data if a plan chooses to report; this proposal would also apply when a plan chooses not to submit and has an audit designation of "non-report" or NR. Second, we propose to continue to reduce Part C and D Reporting Requirements data, that is, data required pursuant to §§ 422.514 and 423.516, to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with data validation standards/sub-standards for data directly used to calculate the associated measure. In our view, data that do not reach at least 95 percent on the data validation standards are not sufficiently accurate, impartial, and complete for use in the Star Ratings. As the sponsoring organization is responsible for these data and submits

them to CMS, we believe that a negative inference is appropriate to conclude that performance is likely poor. Third, we propose a new specific rule to authorize scaled reductions in Star Ratings for appeal measures in both Part C and Part D.

The data downgrade policy was adopted to address instances when the data that would be used for specific measures are not reliable for measuring performance due to their incompleteness or biased/erroneous nature. For instances where the integrity of the data is compromised because of the action or inaction of the sponsoring organization (or its subcontractors or agents), this policy reflects the underlying fault of the sponsoring organization for the lack of data for the applicable measure. Without some policy for reduction in the rating for these measures, sponsoring organizations could "game" the Star Ratings and merely fail to submit data that illustrate poor performance. We believe that removal of the measure from the ratings calculation would unintentionally reward poor data compilation and submission activities such that our only recourse is to reduce the rating to 1 star for affected measures.

For verification and validation of the Part C and D appeals measures, we propose to use statistical criteria to determine if a contract's appeals measure-level Star Ratings would be reduced for missing IRE data. The criteria would allow us to use scaled reductions for the appeals measures to account for the degree to which the data are missing. The completeness of the IRE data is critical to allow fair and accurate measurement of the appeals measures. All plans are responsible and held accountable for ensuring high quality and complete data to maintain the validity and reliability of the appeals measures.

In response to stakeholder concerns about CMS' prior practice of reducing measure ratings to one star based on any finding of data inaccuracy, incompleteness, or bias, CMS initiated the Timeliness Monitoring Project (TMP) in CY 2017.⁴⁰ The first submission for the TMP was for the measurement year 2016 related to Part C organization determinations and reconsiderations and Part D coverage

⁴⁰ This project was discussed in the November 28, 2016 HPMS memo, "Industry-wide Appeals Timeliness Monitoring," <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Timeliness-Monitoring.pdf>, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Industry-wide-Appeals-Timeliness-Monitoring-Memo-November-28-2016.pdf>.

determinations and redeterminations. The timeframe for the submitted data was dependent on the enrollment of the contract with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a two-month period, and larger contracts submitting data from a one-month period.⁴¹

We propose to use multiple data sources whenever possible, such as the TMP data or information from audits to determine whether the data at the Independent Review Entity (IRE) are complete. Given the financial and marketing incentives associated with higher performance in Star Ratings, safeguards are needed to protect the Star Ratings from actions that inflate performance or mask deficiencies.

CMS is proposing to reduce a contract's Part C or Part D appeal measures Star Ratings for IRE data that are not complete or otherwise lack integrity based on the TMP or audit information. The reduction would be applied to the measure-level Star Ratings for the applicable appeals measures. There are varying degrees of data issues and as such, we are proposing a methodology for reductions that reflects the degree of the data accuracy issue for a contract instead of a one-size fits all approach. The methodology would employ scaled reductions, ranging from a 1-star reduction to a 4-star reduction; the most severe reduction for the degree of missing IRE data would be a 4-star reduction which would result in a measure-level Star Rating of 1 star for the associated appeals measures (Part C or Part D). The data source for the scaled reduction is the TMP or audit data, however the specific data used for the determination of a Part C IRE data completeness reduction are independent of the data used for the Part D IRE data completeness reduction. If a contract receives a reduction due to missing Part C IRE data, the reduction would be applied to both of the contract's Part C appeals measures. Likewise, if a contract receives a reduction due to missing Part D IRE data, the reduction would be applied to both of the contract's Part D appeals measures. We solicit comment on this proposal and its scope; we are looking in particular for comments related to how to use the process we are proposing

⁴¹ Contracts with a mean annual enrollment of less than 50,000 are required to submit data for a three-month time period. Contracts with a mean enrollment of at least 50,000 but at most 250,000 are required to submit data for a two-month time period. Contracts with a mean enrollment greater than 250,000 are required to submit data for a one-month period.

in this proposal to account for data integrity issues discovered through means other than the TMP and audits of sponsoring organizations.

CMS' proposed scaled reduction methodology is a three-stage process using the TMP or audit information to determine: First, whether a contract may be subject to a potential reduction for the Part C or Part D appeals measures; second, the basis for the estimate of the error rate; and finally, whether the estimated error rate is significantly greater than the cut points for the scaled reductions of 1, 2, 3, or 4 stars.

Once the scaled reduction for a contract is determined using this methodology, the reduction would be applied to the contract's associated appeals measure-level Star Ratings. The minimum measure-level Star Rating is 1 star. If the difference between the associated appeals measure-level Star

Rating (before the application of the reduction) and the identified scaled reduction is less than one, the contract would receive a measure-level Star Rating of 1 star for the appeals measure.

The error rate for the Part C and Part D appeals measures using the TMP or audit data and the projected number of cases not forwarded to the IRE for a 3-month period would be used to identify contracts that may be subject to an appeals-related IRE data completeness reduction. A minimum error rate is proposed to establish a threshold for the identification of contracts that may be subject to a reduction. The establishment of the threshold allows the focus of the possible reductions on contracts with error rates that have the greatest potential to distort the signal of the appeals measures. Since the timeframe for the TMP data is dependent on the enrollment of the

contract, with smaller contracts submitting data from a three-month period, medium-sized contracts submitting data from a 2-month period, and larger contracts submitting data from a one-month period, the use of a projected number of cases allows a consistent time period for the application of the criteria proposed.

The calculated error rate formula (Equation 1) for the Part C measures is proposed to be determined by the quotient of the number of cases not forwarded to the IRE and the total number of cases that should have been forwarded to the IRE. The number of cases that should have been forwarded to the IRE is the sum of the number of cases in the IRE during TMP or audit data collection period and the number of cases not forwarded to the IRE during the same period.

$$\text{Part C Calculated Error Rate} = \frac{\text{Number of cases not forwarded to the IRE}}{\text{Total number of cases that should have been forwarded to IRE}} \quad \text{Equation (1)}$$

The calculated error rate formula (Equation 2) for the Part D measures is

proposed to be determined by the quotient of the number of untimely

cases not auto-forwarded to the IRE and the total number of untimely cases.

$$\text{Part D Calculated Error Rate} = \frac{\text{Number of untimely cases not auto-forwarded to the IRE}}{\text{Total number of untimely cases}} \quad \text{Equation (2)}$$

The projected number of cases not forwarded to the IRE in a 3-month period would be calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or audit data by a constant determined by the TMP time period. Contracts with mean annual enrollments greater than 250,000 that submitted data from 1-month period would have their number of cases found not to be forwarded to the IRE based on the TMP data multiplied by the constant 3.0. Contracts with mean enrollments of 50,000 but at most 250,000 that submitted data from a 2-month period would have their number of cases found

not to be forwarded to the IRE based on the TMP data multiplied by the constant 1.5. Small contracts with mean enrollments less than 50,000 that submitted data for a 3-month period would have their number of cases found not to be forwarded to the IRE based on the TMP data multiplied by the constant 1.0.

Under this proposal, contract ratings would be subject to a possible reduction due to lack of IRE data completeness if both following conditions are met:

- The calculated error rate is 20 percent or more.

- The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.

The requirement for a minimum number of cases is needed to address statistical concerns with precision and small numbers. If a contract meets only one of the conditions, the contract would not be subject to reductions for IRE data completeness issues.

If a contract is subject to a possible reduction based on the aforementioned conditions, a confidence interval estimate for the true error rate for the contract would be calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent.

The midpoint of the score interval would be determined using Equation 3.

$$\text{Midpoint} = \text{Calculated Error Rate} \times \left(\frac{\text{Total Number of Cases}}{\text{Total Number of Cases} + z^2} \right) + \frac{1}{2} \left(\frac{z^2}{\text{Total Number of Cases} + z^2} \right) \quad \text{Equation (3)}$$

The z score that corresponds to a level of statistical significance of 0.05, commonly denoted as $z_{\alpha/2}$ but for ease of presentation represented here as z. (The z value that will be used for the purpose of the calculation of the interval is 1.959964.).

For the Part C appeals measures, the midpoint of the confidence interval would be calculated using Equation 3 along with the calculated error rate from the TMP, which is determined by Equation 1. The total number of cases in Equation 3 is the number of cases that

should have been in the IRE for the Part C TMP data.

For the Part D appeals measures, the midpoint of the confidence interval would be calculated using Equation 3 along with the calculated error rate from the TMP, which is determined by Equation 2. The total number of cases in

Equation 3 is the total number of untimely cases for the Part D appeals measures.

Letting the calculated error rate be represented by and the total number of

cases represented as n, Equation 3 can be streamlined as Equation 4:

$$Midpoint = \hat{p} \left(\frac{n}{n+z^2} \right) + \frac{1}{2} \left(\frac{z^2}{n+z^2} \right) \tag{Equation (4)}$$

The lower bound of the confidence interval estimate for the error rate is calculated using Equation 5 below:

$$Lower\ Bound = Midpoint - z \times \sqrt{\frac{1}{n+z^2} \left[\hat{p}(1 - \hat{p}) \left(\frac{n}{n+z^2} \right) + \frac{1}{4} \left(\frac{z^2}{n+z^2} \right) \right]} \tag{Equation (5)}$$

For each contract subject to a possible reduction, the lower bound of the interval estimate of the error rate would be compared to each of the thresholds in Table 3. If the contract's calculated lower bound is higher than the threshold, the contract would receive the reduction that corresponds to the highest threshold that is less than the lower bound. In other words, the contract's lower bound is being employed to determine whether the contract's error rate is significantly greater than the thresholds of 20 percent, 40 percent, 60 percent, and 80 percent. The proposed scaled reductions are in Table 3, and would be codified in narrative form at paragraph (g)(1)(iii)(D) of both regulations.

The reductions due to IRE data completeness issues would be applied after the calculation of the measure-level Star Rating for the appeals measures. The reduction would be applied to the Part C appeals measures and/or the Part D appeals measures.

It is important to note that a contract's lower bound could be statistically significantly greater than more than one threshold. The reduction would be determined by the highest threshold that the contract's lower bound exceeds. For example, if the lower bound for a contract is 64.560000 percent, the contract's estimated value is significantly greater than the thresholds of 20 percent, 40 percent, and 60 percent because the lower bound value 64.560000 percent is greater than each of these thresholds. The lower bound for the contract's confidence interval is not greater than 80 percent. The contract would be subject to the reduction that corresponds to the 60 percent threshold, which is three stars.

TABLE 3—APPEALS MEASURE STAR RATINGS REDUCTIONS BY THE INCOMPLETE DATA ERROR RATE

Proposed thresholds using the lower bound of confidence interval estimate of the error rate (%)	Reduction for incomplete IRE data (stars)
20	1
40	2
60	3
80	4

We propose regulation text at § 422.164(g)(1)(iii)(A) through (N) and § 423.184(g)(1)(iii)(A) through (K) to codify these parameters and formulas for the scaled reductions. We note that the proposed text for the Part C regulation includes specific paragraphs related to MA and MA-PD plans that are not included in the proposed text for the Part D regulation but that the two are otherwise identical.

In addition, we propose in §§ 422.164(g)(2) and 423.184(g)(2) to authorize reductions in a Star Rating for a measure when there are other data accuracy concerns (that is, those not specified in paragraph (g)(1)). We propose an example in paragraph (g)(2) of another circumstance where CMS would be authorized to reduce ratings based on a determination that performance data are incomplete, inaccurate, or biased. We also propose this other situation would result in a reduction of the measure rating to 1 star.

We have taken several steps in past years to protect the integrity of the data we use to calculate Star Ratings. However, we welcome comments about alternative methods for identifying inaccurate or biased data and comments on the proposed policies for reducing stars for data accuracy and completeness issues. Further, we welcome comments on the proposed methodology for scaled reductions for the Part C and Part D appeals measures

to address the degree of missing IRE data.

1. Measure-Level Star Ratings

We propose in §§ 422.166(a) and 423.186(a) the methods for calculating Star Ratings at the measure level. As part of the Part C and D Star Ratings System, Star Ratings are currently calculated at the measure level. To separate a distribution of scores into distinct groups or star categories, a set of values must be identified to separate one group from another group. The set of values that break the distribution of the scores into non-overlapping groups is a set of cut points. We propose to continue to determine cut points by applying either clustering or a relative distribution and significance testing methodology; we propose to codify this policy in paragraphs (a)(1) of each section. We propose in paragraphs (a)(2) and (a)(3) of each section that for non-CAHPS measures, we would use a clustering methodology and that for CAHPS measures, we would use relative distribution and significance testing. Measure scores would be converted to a 5-star scale ranging from 1 to 5, with whole star increments for the cut points. A rating of 5 stars would indicate the highest Star Rating possible, while a rating of 1 star would be the lowest rating on the scale. Consistent with current policy, we propose to use the two methodologies described as follows to convert measure scores to measure-level Star Ratings.

The clustering method would be applied to all Star Ratings measures, except for the CAHPS measures. For each individual measure, we would determine the measure cut points using all measure scores for all contracts required to report that do not have missing, flagged as biased, or erroneous data. For the Part D measures, we propose to determine MA-PD and PDP cut points separately. The scores would

be grouped such that scores within the same rating (that is 1 star, 2 stars, etc.) are as similar as possible, and scores in different ratings are as different as possible. The hierarchical clustering algorithm and the associated tree and cluster assignments using SAS (a statistical software package) are currently used to determine the cut points for the assignment of the measure-level Star Ratings. We intend to continue use of this software under this proposal, but improvements in statistical analysis will not result in rulemaking or changes in these proposed rules. Rather, we believe that the software used to apply the clustering methodology is generally irrelevant.

Conceptually, the clustering algorithm identifies natural gaps within the distribution of the scores and creates groups (clusters) that are then used to identify the cut points that result in the creation of a pre-specified number of categories. The Euclidean distance between each pair of contracts' measure scores serves as the input for the clustering algorithm. The hierarchical clustering algorithm begins with each contract's measure score being assigned to its own cluster. Ward's minimum variance method is used to separate the variance of the measure scores into within-cluster and between-cluster sum of squares components in order to determine which pairs of clusters to merge. For the majority of measures, the final step in the algorithm is done a single time with five categories specified for the assignment of individual scores to cluster labels. The cluster labels are then ordered to create the 1 to 5-star scale. The range of the values for each cluster (identified by cluster labels) is examined and would be used to determine the set of cut points for the Star Ratings. The measure score that corresponds to the lower bound for the measure-level ratings of 2 through 5 would be included in the star-specific rating category for a measure for which a higher score corresponds to better performance. For a measure for which a lower score is better, the process would be the same except that the upper bound within each cluster label would determine the set of cut

points. The measure score that corresponds to the cut point for the ratings of 2 through 5 would be included in the star-specific rating category. In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters. Under our proposal to use clustering to set cut points, we would not require the same number of observations (contracts) within each rating and instead would use a data-driven approach.

As proposed in paragraphs (a)(2)(ii) of each section the improvement measures for Part C and Part D would require the clustering algorithm to be done twice for the identification of the cut points that would allow the conversion of the improvement measure scores to the star scale. The Part D improvement measure score clustering for MA-PDs and PDPs would be reported separately. Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating, while improvement scores less than zero would be assigned either 1 or 2 stars. The clustering would be conducted separately for improvement measure scores greater than or equal to zero and those with improvement measure scores less than zero. For contracts with improvement scores greater than or equal to zero, the clustering process would result in three clusters with measure-level Star Ratings of 3, 4, or 5 with the lower bound of each cluster serving as the cut point for the associated Star Rating. For those contracts with improvement scores less than zero, the clustering algorithm would result in two clusters with measure-level Star Ratings of 1 or 2.

We propose in paragraphs (a)(3) of each section to use percentile standing relative to the distribution of scores for other contracts, measurement reliability standards, and statistical significance testing to determine star assignments for the CAHPS measures. This method would combine evaluating the relative percentile distribution of scores with significance testing and measurement reliability standards in order to maximize the accuracy of star assignments based on scores produced

from the CAHPS survey. For CAHPS measures, contracts are first classified into base groups by comparisons to percentile cut points defined by the current-year distribution of case-mix adjusted contract means. Percentile cut points would then be rounded to the nearest integer on the 0–100 reporting scale, and each base group would include those contracts whose rounded mean score is at or above the lower limit and below the upper limit. Then, the number of stars assigned would be determined by the base group assignment, the statistical significance and direction of the difference of the contract mean from the national mean, an indicator of the statistical reliability of the contract score on a given measure (based on the ratio of sampling variation for each contract mean to between-contract variation), and the standard error of the mean score. Table 4, which we propose to codify at §§ 422.166(a)(3) and 423.186(a)(3), details the CAHPS star assignment rules for each rating. All statistical tests, including comparisons involving standard error, would be computed using unrounded scores.

We propose that if the reliability of a CAHPS measure score is very low for a given contract, less than 0.60, the contract would not receive a Star Rating for that measure. For purposes of applying the criterion for 1 star on Table 3, at item (c), low reliability scores would be defined as those with at least 11 respondents and reliability greater than or equal to 0.60 but less than 0.75 and also in the lowest 12 percent of contracts ordered by reliability. The standard error would be considered when the measure score is below the 15th percentile (in base group 1), significantly below average, and has low reliability: In this case, 1 star would be assigned if and only if the measure score is at least 1 standard error below the unrounded cut point between base groups 1 and 2. Similarly, when the measure score is at or above the 80th percentile (in base group 5), significantly above average, and has low reliability, 5 stars would be assigned if and only if the measure score is at least 1 standard error above the unrounded cut point between base groups 4 and 5.

TABLE 4—CAHPS STAR ASSIGNMENT RULES

Star	Criteria for assigning star ratings
1	A contract is assigned one star if both criteria (a) and (b) are met plus at least one of criteria (c) and (d): (a) Its average CAHPS measure score is lower than the 15th percentile; AND (b) its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score; (c) the reliability is not low; OR (d) its average CAHPS measure score is more than one standard error (SE) below the 15th percentile.

TABLE 4—CAHPS STAR ASSIGNMENT RULES—Continued

Star	Criteria for assigning star ratings
2	A contract is assigned two stars if it does not meet the one-star criteria and meets at least one of these three criteria: (a) Its average CAHPS measure score is lower than the 30th percentile and the measure does not have low reliability; OR (b) its average CAHPS measure score is lower than the 15th percentile and the measure has low reliability; OR (c) its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score and below the 60th percentile.
3	A contract is assigned three stars if it meets at least one of these three criteria: (a) Its average CAHPS measure score is at or above the 30th percentile and lower than the 60th percentile, AND it is not statistically significantly different from the national average CAHPS measure score; OR (b) its average CAHPS measure score is at or above the 15th percentile and lower than the 30th percentile, AND the reliability is low, AND the score is not statistically significantly lower than the national average CAHPS measure score; OR (c) its average CAHPS measure score is at or above the 60th percentile and lower than the 80th percentile, AND the reliability is low, AND the score is not statistically significantly higher than the national average CAHPS measure score.
4	A contract is assigned four stars if it does not meet the 5-star criteria and meets at least one of these three criteria: (a) Its average CAHPS measure score is at or above the 60th percentile and the measure does not have low reliability; OR (b) its average CAHPS measure score is at or above the 80th percentile and the measure has low reliability; OR (c) its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score and above the 30th percentile.
5	A contract is assigned five stars if both criteria (a) and (b) are met plus at least one of criteria (c) and (d): (a) Its average CAHPS measure score is at or above the 80th percentile; AND (b) its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score; (c) the reliability is not low; OR (d) its average CAHPS measure score is more than one SE above the 80th percentile.

We request comments on our proposed methods to determine cut points. For certain measures, we previously published pre-determined 4-star thresholds. If commenters recommend pre-determined 4-star thresholds, we request suggestions on how to minimize generating Star Ratings that do not reflect a contract’s “true” performance, otherwise referred to as the risk of “misclassifying” a contract’s performance (for example, scoring a “true” 4-star contract as a 3-star contract, or vice versa, or creating “cliffs” in Star Ratings and therefore, potential benefits between plans with nearly identical Star Ratings on different sides of a fixed threshold), and how to continue to create incentives for quality improvement. We also welcome comments on alternative recommendations for revising the cut point methodology. For example, we are considering methodologies that would minimize year-to-year changes in the cut points by setting the cut points so they are a moving average of the cut points from the two or three most recent years or setting caps on the degree to which a measure cut point could change from one year to the next. We welcome comments on these particular methodologies and recommendations for other ways to provide stability for cut points from year to year.

m. Hierarchical Structure of the Ratings

We propose to continue our existing policy to use a hierarchical structure for the Star Ratings. The basic building block of the MA Star Ratings System is,

and under our proposal would continue to be, the measure. Because the MA Star Ratings System consists of a large collection of measures across numerous quality dimensions, the measures would be organized in a hierarchical structure that provides ratings at the measure, domain, Part C summary, Part D summary, and overall levels. The regulation text at §§ 422.166 and 423.186 is built on this structure and provides for calculating ratings at each “level” of the system. The organization of the measures into larger groups increases both the utility and efficiency of the rating system. At each aggregated level, ratings are based on the measure-level stars. Ratings at the higher level are based on the measure-level Star Ratings, with whole star increments for domains and half-star increments for summary and overall ratings; a rating of 5 stars would indicate the highest Star Rating possible, while a rating of 1 star would be the lowest rating on the scale. Half-star increments are used in the summary and overall ratings to allow for more variation at the higher hierarchical levels of the ratings system. We believe this greater variation and the broader range of ratings provide more useful information to beneficiaries in making enrollment decisions while remaining consistent with the statutory direction in sections 1853(o) and 1854(b) of the Act to use a 5-star system. These policies for the assignment of stars would be codified with other rules for the ratings at the domain, summary, and overall level. Domain ratings employ an unweighted mean of the measure-level

stars, while the Part C and D summary and overall ratings employ a weighted mean of the measure-level stars and up to two adjustments. We propose to codify these policies at paragraphs (b)(2), (c)(1) and (d)(1) of §§ 422.166 and 423.186.

n. Domain Star Ratings

Groups of measures that together represent a unique and important aspect of quality and performance are organized to form a domain. Domain ratings summarize a plan’s performance on a specific dimension of care. Currently the domains are used purely for purposes of displaying data on Medicare Plan Finder to organize the measures and help consumers interpret the data. We propose to continue this policy at §§ 422.166(b)(1)(i) and 423.186(b)(1)(i).

At present, there are nine domains—five for Part C measures for MA-only and MA-PDs plans and four for Part D measures for MA-PDs. We propose to continue to group measures for purposes of display on Medicare Plan Finder and to continue use of the same domains as in current practice in §§ 422.166(b)(1)(i) and 423.196(b)(1)(i). The current domains are listed in Tables 5 and 6.

TABLE 5—PART C DOMAINS

Domain
Staying Healthy: Screenings, Tests and Vaccines.
Managing Chronic (Long Term) Conditions. Member Experience with Health Plan.

TABLE 5—PART C DOMAINS—
Continued

Domain
Member Complaints and Changes in the Health Plan's Performance. Health Plan Customer Service.

TABLE 6—PART D DOMAINS

Domain
Drug Plan Customer Service. Member Complaints and Changes in the Drug Plan's Performance. Member Experience with the Drug Plan. Drug Safety and Accuracy of Drug Pricing.

Currently, Star Ratings for domains are calculated using the unweighted mean of the Star Ratings of the included measures. They are displayed to the nearest whole star, using a 1–5 star scale. We propose to continue this policy at paragraph (b)(2)(ii). We also propose that a contract must have stars for at least 50 percent of the measures required to be reported for that domain for that contract type to have that domain rating calculated in order to have enough data to reflect the contract's performance on the specific dimension. For example, if a contract is rated only on one measure in Staying Healthy: Screenings, Tests and Vaccines, that one measure would not necessarily be representative of how the contract performs across the whole domain so we do not believe it is appropriate to calculate and display a domain rating. We propose to continue this policy by providing, at paragraph (b)(2)(i), that a minimum number of measures must be reported for a domain rating to be calculated.

o. Part C and D Summary Ratings

In the current rating system the Part C summary rating provides a rating of the health plan quality and the Part D summary rating provides a rating of the prescription drug plan quality. We are proposing, at §§ 422.166(c) and 423.186(c), to codify regulation text governing the adoption of Part C summary ratings and Part D summary ratings. An MA-only plan and a Part D standalone plan would receive a summary rating only for, respectively, Part C measures and Part D measures.

First, in paragraphs (c)(1) of each section, we propose the overall formula for calculating the summary ratings for Part C and Part D. Under current policy, the summary rating for an MA-only contract is calculated using a weighted mean of the Part C measure-level Star Ratings with up to two adjustments: The

reward factor (if applicable) and the categorical adjustment index (CAI); similarly, the current summary rating for a PDP contract is calculated using a weighted mean of the Part D measure-level Star Ratings with up to two adjustments: The reward factor (if applicable) and the CAI. We propose in §§ 422.166(c)(1) and 423.186(c)(1) that the Part C and Part D summary ratings would be calculated as the weighted mean of the measure-level Star Ratings with an adjustment to reward consistently high performance (reward factor) and the application of the CAI, pursuant to paragraph (f) (where we propose the specifics for these adjustments) for Parts C and D, respectively.

Second, and also consistent with current policy, we propose an MA-only contract and PDP would have a summary rating calculated only if the contract meets the minimum number of rated measures required for its respective summary rating: A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have the summary rating calculated. The proposed regulation text would be codified as paragraph (c)(2)(i) of §§ 422.166 and 423.186. The same rules would be applied to both the Part C and Part D summary ratings for the minimum number of rated measures and flags for display. We would apply this regulation to require a MA–PD to have a Part C and a Part D summary rating if the minimum requirement of rated measures for each summary rating type is met. The improvement measures are based on identified measures that are each counted towards meeting the proposed requirement for the calculation of a summary rating. We propose (at paragraph (c)(2)(ii)) that the improvement measures themselves are not included in the count of minimum number of measures for the Part C or Part D summary ratings.

Third, we propose a paragraph (c)(3) in both §§ 422.166 and 423.186 to provide that the summary ratings are on a 1 to 5 star scale in half-star increments. Traditional rounding rules would be employed to round the summary rating to the nearest half-star. The summary rating would be displayed in HPMS and Medicare Plan Finder to the nearest half-star. As proposed in §§ 422.166(h) and 423.186(h), if a contract has not met the measure requirement for calculating a summary rating, the display in HPMS (and on Medicare Plan Finder) for the applicable summary rating would be the flag “Not enough data available” or if the measurement period is less than 1 year

past the contract's effective date the flag would be “Plan too new to be measured”.

We welcome comments on the calculations for the Part C and D summary ratings.

p. Overall Rating

The overall Star Rating is a global rating that summarizes the plan's quality and performance for the types of services offered by the plans under the rated contract. We propose at §§ 422.166(d) and 423.186(d) to codify the standards for calculating and assigning overall Star Ratings for MA–PD contracts. The overall rating for an MA–PD contract is proposed to be calculated using a weighted mean of the Part C and Part D measure level Star Ratings, respectively, with an adjustment to reward consistently high performance described in paragraph (f)(1) and the application of the CAI, pursuant to described in paragraph (f)(2).

Consistent with current policy, we propose at paragraph (d)(2) that an MA–PD would have an overall rating calculated only if the contract receives both a Part C and Part D summary rating, and scores for at least 50% of the measures are required to be reported for the contract type to have the overall rating calculated. As with the Part C and D summary ratings, the Part C and D improvement measures would not be included in the count for the minimum number of measures for the overall rating. Any measure that shares the same data and is included in both the Part C and Part D summary ratings would be included only once in the calculation for the overall rating; for example, Members Choosing to Leave the Plan and Complaints about the Plan. As with summary ratings, we propose that overall MA–PD ratings would use a 1 to 5 star scale in half-star increments; traditional rounding rules would be employed to round the overall rating to the nearest half-star. These policies are proposed as paragraphs (d)(2)(i) through (iv).

In accordance with our general proposed policy at §§ 422.166(h) and 423.186(h), the overall rating would be posted on HPMS and Medicare Plan Finder, with specific messages for lack of ratings for certain reasons. Applying that rule, if an MA–PD contract has only one of the two required summary ratings, the overall rating would not be calculated and the display in HPMS would be the flag “Not enough data available.”

For QBP purposes, low enrollment contracts and new MA plans are defined in § 422.252. Low enrollment contract

means a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcomes Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan; new MA plan means a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years. Low enrollment contracts and new plans do not receive an overall or summary rating because of the lack of necessary data. However, they are treated as qualifying plans for the purposes of QBPs. Section 1853(o)(3)(A)(ii)(II) of the Act, as implemented at § 422.258(d)(7), provides that for 2013 and subsequent years, CMS shall develop a method for determining whether an MA plan with low enrollment is a qualifying plan for purposes of receiving an increase in payment under section 1853(o). This determination is applied at the contract level and thus determines whether a contract (meaning all plans under that contract) is a qualifying contract. The statute, at section 1853(o)(3)(A)(iii) of the Act, provides for treatment of new MA plans as qualifying plans eligible for a specific QBP. We therefore propose, at §§ 422.166(d)(3) and 423.186(d)(3), that low enrollment contracts (as defined in § 422.252 of this chapter) and new MA plans (as defined in § 422.252 of this chapter) do not receive an overall and/or summary rating; they would be treated as qualifying plans for the purposes of QBPs as described in § 422.258(d)(7) of this chapter and announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. This proposal would merely codify existing policy and practice.

q. Measure Weights

Prior to the 2012 Part C and D Plan Ratings (now known as Star Ratings), all individual measures included in the

program were weighted equally, suggesting equal importance. Based on feedback from stakeholders, including health and drug plans and beneficiary advocacy groups, we moved to provide greater weight to clinical outcomes and lesser weight to process measures. Patient experience and access measures were also given greater weight than process measures, but not as high as outcome measures. The differential weighting was implemented to help create further incentives to drive improvement in clinical outcomes, patient experience, and access. These differential weights for measures were implemented for the 2012 Ratings following a May 2011 Request for Comments and adopted in the CY2013 Rate Announcement and Final Call Letter.

In the Contract Year 2012 Final Rule for Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs rule (79 FR 21486), we stated that scoring methodologies should also consider improvement as an independent goal. To this end, we implemented in the CY 2013 Rate Announcement the Part C and D improvement measures that measure the overall improvement or decline in individual measure scores from the prior to the current year. Given the importance of recognizing quality improvement as an independent goal, for the 2015 Star Ratings, we proposed and subsequently finalized through the 2015 Rate Announcement and final Call Letter an increase in the weight of the improvement measure from 3 times to 5 times that of a process measure. This weight aligns the Part C and D Star Ratings program with value-based purchasing programs in Medicare fee-for-service which heavily weight improvement.

We are proposing in §§ 422.166(e) and 423.186(e) to continue the current weighting of measures in the Part C and D Star Ratings program by assigning the highest weight (5) to improvement

measures, followed by outcome and intermediate outcome measures (weight of 3), then by patient experience/complaints and access measures (weight of 1.5), and finally process measures (weight of 1). We are considering increasing the weight of the patient experience/complaints and access measures and are interested in stakeholder feedback on this potential change in order to reflect better the importance of these issues in plan performance. If we were to increase the weight, we are considering increasing it from a weight of 1.0 to between 1.5 and 3 similar to outcome measures. This increased weight would reflect CMS' commitment to serve Medicare beneficiaries by putting the patients first, including their assessments of the care received by plans. We solicit comment on this point, particularly the potential change in the weight of the patient experience/complaints and access measures.

Table 7 includes the proposed measure categories, the definitions of the measure categories, and the weights. In calculating the summary and overall ratings, a measure given a weight of 3 counts three times as much as a measure given a weight of 1. In section III.A.12. of this proposed rule, we propose (as Table 2) the measure set and include the category and weight for each measure; those weight assignments are consistent with this proposal. We propose that as new measures are added to the Part C and D Star Ratings, we would assign the measure category based on these categories and the regulation text proposed at §§ 422.166(e) and 423.186(e), subject to two exceptions. We propose in paragraphs (e)(2) of each section as the first exception, to assign new measures to the Star Ratings program a weight of 1 for their first year in the Star Ratings. In subsequent years the weight associated with the measure weighting category would be used. This is consistent with current policy.

TABLE 7—MEASURE CATEGORIES, DEFINITIONS AND WEIGHTS

Measure category	Definition	Weight
Improvement	Part C and Part D improvement measures are derived through comparisons of a contract's current and prior year measure scores.	5
Outcome and Intermediate Outcome.	Outcome measures reflect improvements in a beneficiary's health and are central to assessing quality of care. Intermediate outcome measures reflect actions taken which can assist in improving a beneficiary's health status. Controlling Blood Pressure is an example of an intermediate outcome measure where the related outcome of interest would be better health status for beneficiaries with hypertension.	3
Patient Experience/Complaints.	Patient experience measures reflect beneficiaries' perspectives of the care and services they received.	1.5
Access	Access measures reflect processes and issues that could create barriers to receiving needed care. Plan Makes Timely Decisions about Appeals is an example of an access measure.	1.5

TABLE 7—MEASURE CATEGORIES, DEFINITIONS AND WEIGHTS—Continued

Measure category	Definition	Weight
Process	Process measures capture the health care services provided to beneficiaries which can assist in maintaining, monitoring, or improving their health status.	1

In addition, we propose (at §§ 422.166(e)(3) and 423.186(e)(3)) a second exception to the general weighting rule for MA and Part D contracts that have service areas that are wholly located in Puerto Rico. We recognize the additional challenge unique to Puerto Rico related to the medication adherence measures used in the Star Ratings Program due to the lack of Low Income Subsidy (LIS). For the 2017 Star Ratings, we implemented a different weighting scheme for the Part D medication adherence measures in the calculation of the overall and summary Star Ratings for contracts that solely serve the population of beneficiaries in Puerto Rico. We propose, at §§ 422.166(e)(3) and 423.186(e)(3), to continue to reduce the weights for the adherence measures to 0 for the summary and overall rating calculations and maintain the weight of 3 for the adherence measures for the improvement measure calculations for contracts that solely serve the population of beneficiaries in Puerto Rico. We request comment on our proposed weighting strategy for Measure Weights generally and for Puerto Rico, including the weighting values themselves.

r. Application of the Improvement Measure Scores

Consistent with current policy, we propose at §§ 422.166(g) and 423.186(g) a hold harmless provision for the inclusion or exclusion of the improvement measure(s) for highly-rated contracts' highest ratings. We are proposing, in paragraphs (g)(1)(i) through (iii), a series of rules that specify when the improvement measure is included in calculating overall and summary ratings.

MA-PDs would have the hold harmless provisions for highly-rated contracts applied for the overall rating. For an MA-PD that receives an overall rating of 4 stars or more without the use of the improvement measures and with all applicable adjustments (CAI and the reward factor), a comparison of the rounded overall rating with and without the improvement measures is done. The overall rating with the improvement measures used in the comparison would include up to two adjustments, the reward factor (if applicable) and the CAI. The overall rating without the

improvement measures used in the comparison would include up to two adjustments, the reward factor (if applicable) and the CAI. The higher overall rating would be used for the overall rating. For an MA-PD that has an overall rating of 2 stars or less without the use of the improvement measure and with all applicable adjustments (CAI and the reward factor), the overall rating would exclude the improvement measure. For all others, the overall rating would include the improvement measure.

MA-only and PDPs would have the hold harmless provisions for highly-rated contracts applied for the Part C and D summary ratings, respectively. For an MA-only or PDP that receives a summary rating of 4 stars or more without the use of the improvement measure and with all applicable adjustments (CAI and the reward factor), a comparison of the rounded summary rating with and without the improvement measure and up to two adjustments, the reward factor (if applicable) and CAI, is done. The higher summary rating would be used for the summary rating for the contract's highest rating. For MA-only and PDPs with a summary rating of 2 stars or less without the use of the improvement measure and with all applicable adjustments (CAI and the reward factor), the summary rating would exclude the improvement measure. For all others, the summary rating would include the improvement measure. MA-PDs would have their summary ratings calculated with the use of the improvement measure regardless of the value of the summary rating.

In addition, at paragraph (g)(2), we also propose text to clarify that summary ratings use only the improvement measure associated with the applicable Part C or D performance.

We welcome comments on the hold harmless improvement provision we propose to continue to use, particularly any clarifications in how and when it should be applied.

s. Reward Factor (Formerly Referred to as Integration Factor)

In 2011, the integration factor was added to the Star Ratings methodology to reward contracts that have consistently high performance. The integration factor was later renamed the

reward factor. (The reference to either reward or integration factor refers to the same aspect of the Star Ratings.) This factor is calculated separately for the Part C summary rating, Part D summary rating for MA-PDs, Part D summary rating for PDPs, and the overall rating for MA-PDs. It is currently added to the summary (Part C or D) and overall rating of contracts that have both high and stable relative performance for the associated summary or overall rating. The contract's performance will be assessed using its weighted mean relative to all rated contracts without adjustments.

The contract's stability of performance will be assessed using its weighted variance relative to all rated contracts at the same rating level (overall, summary Part C, and summary Part D). The Part D summary thresholds for MA-PDs are determined independently of the thresholds for PDPs. We propose to codify the calculation and use of the reward factor in §§ 422.166(f)(1) and 423.186(f)(1).

Annually, we propose to update the performance and variance thresholds for the reward factor based upon the data for the Star Ratings year, consistent with current policy. A multistep process would be used to determine the values that correspond to the thresholds for the reward factors for the summary and/or overall Star Ratings for a contract. The determination of the reward factors would rely on the contract's ranking of its weighted variance and weighted mean of the measure-level stars to the summary or overall rating relative to the distribution of all contracts' weighted variance and weighted mean to the summary and/or overall rating. A contract's weighted variance would be calculated using the quotient of the following two values: (1) The product of the number of applicable measures based on rating-type and the sum of the products of the weight of each applicable measure and its squared deviation⁴² and (2) the product of one less than the number of applicable measures and the sum of the weights of the applicable measures. A contract's weighted mean performance would be

⁴² A deviation is the difference between the performance measure's Star Rating and the weighted mean of all applicable measures for the contract.

found by calculating the quotient of the following two values: (1) The sum of the products of the weight of a measure and its associated measure-level Star Ratings of the applicable measures for the rating-type and (2) the sum of the weights of the applicable measures for the rating type. The thresholds for the categorization of the weighted variance and weighted mean for contracts would be based upon the distribution of the calculated values of all rated contracts of the same type. Because highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean is calculated both with and without the improvement measures.

A contract's weighted variance is categorized into one of three mutually exclusive categories, identified in Table 8A, based upon the weighted variance of its measure-level Star Ratings and its ranking relative to all other contracts'

weighted variance for the rating type (Part C summary for MA-PDs and MA-only, overall for MA-PDs, Part D summary for MA-PDs, and Part D summary for PDPs), and the manner in which the highest rating for the contract was determined—with or without the improvement measure(s). For an MA-PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance for the rating type (Part C summary, Part D summary) with the improvement measure. Similarly, a contract's weighted mean is categorized into one of three mutually exclusive categories, identified in Table 8B, based on its weighted mean of all measure-level Star Ratings and its ranking relative to all other contracts' weighted means for the rating type (Part C summary for MA-PDs and MA-only, overall, Part D summary for MA-PDs, and Part D summary for PDPs) and the manner in which the highest rating for the contract was determined—with or without the improvement measure(s).

For an MA-PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted means for the rating type (Part C summary, Part D summary) with the improvement measure. Further, the same threshold criterion is employed per category regardless of whether the improvement measure was included or excluded in the calculation of the rating. The values that correspond to the thresholds are based on the distribution of all rated contracts and are determined with and without the improvement measure(s) and exclusive of any adjustments. Table 8A details the criteria for the categorization of a contract's weighted variance for the summary and overall ratings. Table 8B details the criteria for the categorization of a contract's weighted mean (performance) for the overall and summary ratings. The values that correspond to the cutoffs are provided each year during the plan preview and are published in the Technical Notes.

TABLE 8A—CATEGORIZATION OF A CONTRACT BASED ON ITS WEIGHTED VARIANCE RANKING

Variance category	Ranking
Low	Below the 30th percentile.
Medium	At or above the 30th percentile to less than the 70th percentile.
High	At or above the 70th percentile.

TABLE 8B—CATEGORIZATION OF A CONTRACT BASED ON WEIGHTED MEAN (PERFORMANCE) RANKING

Weighted mean (performance) category	Ranking
High	At or above the 85th percentile.
Relatively High	At or above the 65th percentile to less than the 85th percentile.
Other	Below the 65th percentile.

These definitions of high, medium, and low weighted variance ranking and high, relatively high, and other weighted mean ranking would be codified in narrative form in paragraph (f)(1)(ii).

A contract's categorization for both weighted mean and weighted variance determines the value of the reward factor. Table 9 shows the values of the reward factor based on the weighted variance and weighted mean

categorization; these values would be codified, as a chart, in paragraph (f)(i)(iii). The weighted variance and weighted mean thresholds for the reward factor are available in the Technical Notes and updated annually.

TABLE 9—CATEGORIZATION OF A CONTRACT FOR THE REWARD FACTOR

Weighted variance	Weighted mean (performance)	Reward factor
Low	High	0.4
Medium	High	0.3
Low	Relatively High	0.2
Medium	Relatively high	0.1
High	Other	0.0

We propose to continue the use of a reward factor to reward contracts with consistently high and stable performance over time. Further, we propose to continue to employ the

methodology described in this subsection to categorize and determine the reward factor for contracts. As proposed in paragraphs (c)(1) and (d)(1), these reward factor adjustments would

be applied at the summary and overall rating level.

t. Categorical Adjustment Index

A growing body of evidence links the prevalence of beneficiary-level social risk factors with performance on measures included in Medicare value-based purchasing programs, including MA and Part D Star Ratings. With support from our contractors, we undertook research to provide scientific evidence as to whether MA organizations or Part D sponsors that enroll a disproportionate number of vulnerable beneficiaries are systematically disadvantaged by the current Star Ratings. In 2014, we issued a Request for Information to gather information directly from organizations to supplement the data that CMS collects, as we believe that plans and sponsors are uniquely positioned to provide both qualitative and quantitative information that is not available from other sources. In February and September 2015, we released details on the findings of our research.⁴³ We have also reviewed reports about the impact of socioeconomic status (SES) on quality ratings, such as the report published by the NQF posted at www.qualityforum.org/risk_adjustment_ses.aspx and the Medicare Payment Advisory Commission's (MedPAC) *Report to the Congress: Medicare Payment Policy* posted at <http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf?sfvrsn=0>. We have more recently been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE⁴⁴) and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs, and we have been considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare

beneficiaries on quality measures and measures of resource use in nine Medicare value-based purchasing programs. The report also included considerations for strategies to account for social risk factors in these programs. A January 10, 2017 report released by the National Academies of Sciences, Engineering, and Medicine provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.⁴⁵

We have also engaged NCQA and the PQA to examine their measure specifications used in the Star Ratings program to determine if re-specification is warranted. The majority of measures used for the Star Ratings program are consensus-based. Measure specifications can be changed only by the measure steward (the owner and developer of the measure). Thus, measure scores cannot be adjusted for differences in enrollee case mix unless required by the measure steward. Measure re-specification is a multiyear process. For example, NCQA has a standard process for reviewing any measure and determining whether a measure requires re-specification. NCQA's re-evaluation process is designed to ensure any resulting measure updates have desirable attributes of relevance, scientific soundness, and feasibility:

- Relevance describes the extent to which the measure captures information important to different groups, for example, consumers, purchasers, policymakers. To determine relevance, NCQA assesses issues such as health importance, financial importance, and potential for improvement among entities being measured.
- Scientific soundness captures the extent to which the measure adheres to clinical evidence and whether the measure is valid, reliable, and precise.
- Feasibility captures the extent to which a measure can be collected at reasonable cost and without undue burden. To determine feasibility, NCQA also assesses whether a measure is precisely specified and can be audited. The overall process for assessing the value of re-specification emphasizes multi-stakeholder input, use of evidence-based guidelines and data, and wide public input.

Beginning with 2017 Star Ratings, we implemented the CAI that adjusts for the average within-contract disparity in performance associated with the

percentages of beneficiaries who receive a low income subsidy and/or are dual eligible (LIS/DE) and/or have disability status. We developed the CAI as an interim analytical adjustment while we developed a long-term solution. The adjustment factor varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and beneficiaries with disabilities. By design, the CAI values are monotonic in at least one dimension (LIS/DE or disability status) and thus, contracts with larger LIS/DE and/or disability percentages realize larger positive adjustments. MA-PD contracts can have up to three rating-specific CAI adjustments—one for the overall Star Rating and one for each of the summary ratings (Part C and Part D). MA-only contracts can have one adjustment for the Part C summary rating. PDPs can have one adjustment for the Part D summary rating. We propose to codify the calculation and use of the reward factor and the CAI in §§ 422.166(f)(2) and 423.186(f)(2), while we consider other alternatives for the future.

As is currently done today, the adjusted measure scores of a subset of the Star Ratings measures would serve as the foundation for the determination of the index values. Measures would be excluded as candidates for adjustment if the measures are already case-mix adjusted for SES (for example, CAHPS and HOS outcome measures), if the focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue (for example, appeals, call center, Part D price accuracy measures), if the measure is scheduled to be retired or revised during the Star Rating year in which the CAI is being applied, or if the measure is applicable to only Special Needs Plans (SNPs) (for example, SNP Care Management, Care for Older Adults measures). We propose to codify these paragraphs for determining the measures for CAI values at paragraph (f)(2)(ii). The categorization of a beneficiary as LIS/DE for the CAI would rely on the monthly indicators in the enrollment file. For the determination of the CAI values, the measurement period would correspond to the previous Star Ratings year's measurement period. For the identification of a contract's final adjustment category for its application of the CAI in the current year's Star Ratings Program, the measurement period would align with the Star Ratings year. If a beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period, the

⁴³ The February release can be found at <https://www.cms.gov/medicareprescription-drug-coverage/prescriptiondrugcovgenin/performance.html>.

The September release can be found at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Research-on-the-Impact-of-Socioeconomic-Status-on-Star-Ratingsv1-09082015.pdf>.

⁴⁴ <https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs>.

⁴⁵ National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press—<https://www.nap.edu/catalog/21858/accounting-for-social-risk-factors-in-medicare-payment-identifying-social>.

beneficiary would be categorized as LIS/DE. For the categorization of a beneficiary as disabled, we would employ the information from the Social Security Administration (SSA) and Railroad Retirement Board (RRB) record systems. Disability status would be determined using the variable original reason for entitlement (OREC) for Medicare. The percentages of LIS/DE and disability per contract would rely on the Medicare enrollment data from the applicable measurement year. The counts of beneficiaries for enrollment and categorization of LIS/DE and disability would be restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year. Further, a beneficiary would be assigned to the contract based on the December file of the applicable measurement period. We propose to codify these paragraphs for determining the enrollment counts at paragraph (f)(2)(i)(B).

Using the subset of the measures that meet the basic inclusion requirements, we propose to select the measure set for adjustment based on the analysis of the dispersion of the LIS/DE within-contract differences using all reportable numeric scores for contracts receiving a rating in the previous rating year. For the selection of the Part D measures, MA-PDs and PDPs would be independently analyzed. For each contract, the proportion of beneficiaries receiving the measured clinical process or outcome for LIS/DE and non-LIS/DE beneficiaries would be estimated separately, and the difference between the LIS/DE and non-LIS/DE performance rates per contract would be calculated. CMS would use a logistic mixed effects model for estimation purposes that includes LIS/DE as a predictor, random effects for contract and an interaction term of contract and LIS/DE.

Using the analysis of the dispersion of the within-contract disparity of all contracts included in the modelling, the measures for adjustment would be identified employing the following decision criteria: (1) A median absolute difference between LIS/DE and non-LIS/DE beneficiaries for all contracts analyzed is 5 percentage points or more or ⁴⁶ (2) the LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts. We propose to codify these paragraphs for the selection criteria for the adjusted measures for the CAI at paragraph (f)(2)(iii).

The Part D measures for PDPs would be analyzed separately. In order to apply

consistent adjustments across MA-PDs and PDPs, the Part D measures would be selected by applying the selection criteria to MA-PDs and PDPs independently and, then, selecting measures that met the criteria for either delivery system. The measure set for adjustment of Part D measures for MA-PDs and PDPs would be the same after applying the selection criteria and pooling the Part D measures for MA-PDs and PDPs. We propose to codify these paragraphs for the selection of the adjusted measure set for the CAI for MA-PDs and PDPs at (f)(2)(iii)(C). We also seek comment on the proposed methodology and criteria for the selection of the measures for adjustment. Further, we seek comment on alternative methods or rules to select the measures for adjustment for future rulemaking.

Annually, while the CAI is being developed using the rules we are proposing here, we would release on *CMS.gov* an updated analysis of the subset of the Star Ratings measures identified for adjustment using this rule as ultimately finalized. Basic descriptive statistics would include the minimum, median, and maximum values for the within-contract variation for the LIS/DE differences. The set of measures for adjustment for the determination of the CAI would be announced in the draft Call Letter.

We propose, at paragraph (f)(2)(iv) of each regulation, to determine the adjusted measure scores for LIS/DE and disability status from regression models of beneficiary-level measure scores that adjust for the average within-contract difference in measure scores for MA or PDP contracts. The approach employed to determine the adjusted measure scores approximates case-mix adjustment using a beneficiary-level, logistic regression model with contract fixed effects and beneficiary-level indicators of LIS/DE and disability status, similar to the approach currently used to adjust CAHPS patient experience measures. However, unlike CAHPS case-mix adjustment, the only adjusters would be LIS/DE and disability status.

The sole purpose of the adjusted measure scores is for the determination of the CAI values. The adjusted measure scores would be converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.

All contracts would have their adjusted summary rating(s) and for MA-PDs, an adjusted overall rating, calculated employing the standard

methodology proposed at §§ 422.166 and 423.186 (which would also be outlined in the Technical Notes each year), using the subset of adjusted measure-level Star Ratings and all other unadjusted measure-level Star Ratings. In addition, all contracts would have their summary rating(s) and for MA-PDs, an overall rating, calculated using the traditional methodology and all unadjusted measure-level Star Ratings.

For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled using the enrollment data that parallels the previous Star Ratings year's data would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled). The initial categories would be created using all groups formed by the initial LIS/DE and disabled groups. The total number of initial categories would be the product of the number of initial groups for LIS/DE and the number of initial groups for the disabled dimension.

The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled). The mean difference within each final adjustment category by rating-type (Part C, Part D for MA-PD, Part D for PDPs, or overall) would be the CAI values for the next Star Ratings year.

The percentage of LIS/DE is a critical element in the categorization of contracts into the final adjustment category to identify a contract's CAI. Starting with the 2017 Star Ratings, we applied an additional adjustment for contracts that solely serve the population of beneficiaries in Puerto Rico to address the lack of LIS in Puerto Rico. The adjustment results in a modified percentage of LIS/DE beneficiaries that is subsequently used to categorize contracts into the final adjustment category for the CAI.

We propose to continue this adjustment and to calculate the contract-level modified LIS/DE percentage for Puerto Rico using the following sources of information: The most recent data available at the time of the development of the model of both the 1-year American Community Survey (ACS) estimates for the percentage of people living below the Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL, and

⁴⁶ The use of the word 'or' in the decision criteria implies that if one condition or both conditions are met, the measure would be selected for adjustment.

the Medicare enrollment data from the same measurement period used for the Star Ratings year.

The data to develop the model would be limited to the 10 states, drawn from the 50 states plus the District of Columbia, with the highest proportion of people living below the FPL as identified by the 1-year ACS estimates. Further, the Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries with mailing addresses in the 10 highest poverty states. A linear regression model would be developed using the known LIS/DE percentage and the corresponding DE percentage from the subset of MA contracts.

The estimated slope from the linear regression approximates the expected relationship between LIS/DE for each contract in Puerto Rico and its DE percentage. The intercept term is adjusted for use with Puerto Rico contracts by assuming that the Puerto Rico model will pass through the point (x, y) where x is the observed average DE percentage in the Puerto Rico contracts based on the enrollment data, and y is the expected average percentage of LIS/DE in Puerto Rico. The expected average percentage of LIS/DE in Puerto Rico (the y value) is not observable, but is estimated by multiplying the observed average percentage of LIS/DE in the 10 highest poverty states by the ratio based on the most recent 5-year ACS estimates of the percentage living below 150 percent of the FPL in Puerto Rico compared to the corresponding percentage in the set of 10 states with the highest poverty level. (Further details of the methodology can be found in the CAI Methodology Supplement available at <http://go.cms.gov/partcanddstarratings>.)

Using the model developed from this process, the estimated modified LIS/DE percentage for contracts operating solely in Puerto Rico would be calculated. The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent. All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.

We propose to continue to employ the LIS/DE indicator for contracts operating solely in Puerto Rico while the CAI is being used as an interim analytical adjustment. Further, we propose that the modeling results would continue to be detailed in the appendix of the Technical Notes and the modified LIS/DE percentages would be available for contracts to review during the plan previews.

We propose to continue the use of the CAI while the measure stewards continue their examination of the measure specifications and ASPE completes their studies mandated by the IMPACT Act and formalizes final recommendations. Contracts would be categorized based on their percentages of LIS/DE and disability using the data as outlined previously. The CAI value would be the same for all contracts within each final adjustment category. The CAI values would be determined using data from all contracts that meet reporting requirements from the prior year's Star Rating data. The CAI calculation for the PDPs would be performed separately and use the PDP specific cut points. Under our proposal, CMS would include the CAI values in the draft and final Call Letter attachment of the Advance Notice and Rate Announcement each year while the interim solution is applied. The values for the CAI value would be displayed to 6 decimal places. Rounding would take place after the application of the CAI value and if applicable, the reward factor; standard rounding rules would be employed. (All summary and overall Star Ratings are displayed to the nearest half-star.)

While we consider the recommendations from the ASPE report, findings from measure developers, and work by NQF on risk adjustment for quality measures, we are continuing to collaborate with stakeholders. We are seeking to balance accurate measurement of genuine plan performance, effective identification of disparities, and maintenance of incentives to improve the outcomes for disadvantaged populations. Keeping this in mind, we continue to seek public comment on whether and how we should account for low SES and other social risk factors in the Part C and D Star Ratings.

We look forward to continuing to work with stakeholders as we consider the issue of accounting for LIS/DE, disability and other social risk factors and reducing health disparities in CMS programs. As we have stated previously, we are continuing to consider options to how to measure and account for social risk factors in our Star Ratings program. What we discovered through our research to date is, although a sponsoring organization's administrative costs may increase as a result of enrolling significant numbers of beneficiaries with LIS/DE status or disabilities, the impacts of SES on the quality ratings are quite modest, affect only a small subset of measures, and do not always negatively impact the measures. However, CMS would like to

better understand whether, how, and to what extent a sponsoring organization's administrative costs differ for caring for low-income beneficiaries and we welcome comment on that topic. Administrative costs may include non-medical costs such as transportation costs, coordination costs, marketing, customer service, quality assurance and costs associated with administering the benefit. We continue our commitment toward ensuring that all beneficiaries have access to and receive excellent care, and that the quality of care furnished by plans is assessed fairly in CMS programs.

u. High and Low Performing Icons

Consistent with our current practice, we are proposing regulation text to govern assignment of high and low performing icons at §§ 422.166(i) and 423.186(i). We propose to continue current policy that a contract would receive a high performing icon as a result of its performance on the Part C and D measures. The high performing icon would be assigned to an MA-only contract for achieving a 5-star Part C summary rating, a PDP contract for a 5-star Part D summary rating, and an MA-PD contract for a 5-star overall rating.

We propose that a contract would receive a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon would be calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years (for example, the 2016, 2017, and 2018 Star Ratings). If the contract had any combination of Part C and Part D summary ratings of 2.5 or lower in all 3 years of data, it would be marked with a low performing icon. A contract must have a summary rating in either Part C or Part D for all 3 years to be considered for this icon. These rules would be codified at §§ 422.166(i)(2)(i) and 423.186(i)(2)(i).

We also propose, at paragraph (i)(2)(ii), to continue our policy of disabling the Medicare Plan Finder online enrollment function for Medicare health and prescription drug plans with the low-performing icon to ensure that beneficiaries are fully aware that they are enrolling in a plan with low quality and performance ratings; we believe this is an important beneficiary protection to ensure that the decision to enroll in a low rated and low performing plan has been thoughtfully considered. Beneficiaries who still want to enroll in a low-performing plan or who may need to in order to get the benefits and services they require (for example, in geographical areas with limited plans) will be warned, via explanatory

messaging of the plan's poorly rated performance and directed to contact the plan directly to enroll.

v. Plan Preview of Star Ratings

We propose in §§ 422.166(i)(3) and 423.186(i)(3) that CMS have plan preview periods before each Star Ratings release, consistent with current practice. Part C and D sponsors can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder. During the first plan preview, we expect Part C and D sponsors to closely review the methodology and their posted numeric data for each measure. The second plan preview would include any revisions made as a result of the first plan preview. In addition, our preliminary Star Ratings for each measure, domain, summary score, and overall score would be displayed. During the second plan preview, we expect Part C and D sponsors to again closely review the methodology and their posted data for each measure, as well as their preliminary Star Rating assignments. As part of this regulation, we are proposing that CMS continue to offer plan preview periods, but are not codifying the details of each period because over time the process has evolved to provide more data to sponsors to help validate their data. We envision it to continue to evolve in the future and do not believe that codifying specific display content is necessary.

It is important that Part C and D sponsors regularly review their underlying measure data that are the basis for the Part C and D Star Ratings. For measures that are based on data reported directly from sponsors, any issues or problems should be raised well in advance of CMS' plan preview periods. A draft version of the Technical Notes would be available during the first plan preview. The draft is then updated for the second plan preview and finalized when the ratings data have been posted to Medicare Plan Finder.

We welcome comments on the proposed plan preview process.

w. Technical Changes

We also propose a number of technical changes to other existing regulations that refer to the quality ratings of MA and Part D plans; we propose to make technical changes to refer to the proposed new regulation text that provides for the calculation and assignment of Star Ratings. Specifically, we propose:

- In § 422.258(d)(7), to revise paragraph (d)(7) to read: *Increases to the applicable percentage for quality.* Beginning with 2012, the blended

benchmark under paragraphs (a) and (b) of this section will reflect the level of quality rating at the plan or contract level, as determined by the Secretary. The quality rating for a plan is determined by the Secretary according to the 5-star rating system (based on the data collected under section 1852(e) of the Act) specified in subpart D of this part 422. Specifically, the applicable percentage under paragraph (d)(5) of this section must be increased according to criteria in paragraphs (d)(7)(i) through (v) of this section if the plan or contract is determined to be a qualifying plan or a qualifying plan in a qualifying county for the year.

- In § 422.260(a), to revise the paragraph to read: *Scope.* The provisions of this section pertain to the administrative review process to appeal quality bonus payment status determinations based on section 1853(o) of the Act. Such determinations are made based on the overall rating for MA-PDs and Part C summary rating for MA-only contracts for the contract assigned pursuant to subpart 166 of this part 422.

- In § 422.260(b), to revise the definition of "quality bonus payment (QBP) determination methodology" to read: *Quality bonus payment (QBP) determination methodology* means the quality ratings system specified in subpart 166 of this part 422 for assigning quality ratings to provide comparative information about MA plans and evaluating whether MA organizations qualify for a QBP.

- In § 422.504(a)(18), to revise paragraph (a)(18) to read: To maintain a Part C summary plan rating score of at least 3 stars pursuant to the 5-star rating system specified in subpart 166 of this part 422. A Part C summary plan rating is calculated as provided in § 422.166.

- In § 423.505(b)(26), to revise paragraph (b)(26) to read: Maintain a Part D summary plan rating score of at least 3 stars pursuant to the 5-star rating system specified in subpart 186 of this part 423. A Part D summary plan rating is calculated as provided in § 423.186.

We welcome comment on these technical changes and whether there are additional changes that should be made to account for our proposal to codify the Star Ratings methodology and measures in regulation text.

12. Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505)

Section 1860D-4(b)(1)(A) of the Act and § 423.120(a)(8)(i) require a Part D plan sponsor to contract with any pharmacy that meets the Part D plan sponsor's standard terms and conditions

for network participation. Section 423.505(b)(18) requires Part D plan sponsors to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.

In the preamble to final rule published on January 28, 2005 (January 2005 final rule) (70 FR 4194) which implemented § 423.120(a)(8)(i) and § 423.505(b)(18), we indicated that standard terms and conditions, particularly for payment terms, could vary to accommodate geographic areas or types of pharmacies, so long as all similarly situated pharmacies were offered the same terms and conditions. We also stated that we viewed these standard terms and conditions as a "floor" of minimum requirements that all similarly situated pharmacies must abide by, but that Part D plans could modify some standard terms and conditions to encourage participation by particular pharmacies. We believe this approach strikes an appropriate balance between the any willing pharmacy requirement at section 1860D-4(b)(1)(A) of the Act and the provisions of section 1860D-4(b)(1)(B) of the Act, which permits Part D plan sponsors to offer reduced cost sharing at preferred pharmacies.

The balancing of these goals has led to the development of preferred pharmacy networks in which certain pharmacies agree to additional or different terms from the standard terms and conditions. This has resulted in the development of "standard" terms and conditions that in some cases has had the effect, in our view, of circumventing the any willing pharmacy requirements and inappropriately excluding pharmacies from network participation. This section is intended to clarify or modify our interpretation of the existing regulations to ensure that plan sponsors can continue to develop and maintain preferred networks while fully complying with the any willing pharmacy requirement.

First, we intend to clarify that the any willing pharmacy requirement applies to all pharmacies, regardless of how they have organized one or more lines of pharmacy business. Second, we propose to revise the definition of retail pharmacy and define mail-order pharmacy. Third, we propose to clarify our regulatory requirements for what constitutes "reasonable and relevant" standard contract terms and conditions. Finally, we propose to codify our existing guidance with respect to when a pharmacy must be provided with a

Part D plan sponsor's standard terms and conditions.

a. Any Willing Pharmacy Required for All Pharmacy Business Models

With the pharmaceutical distribution and pharmacy practice landscape evolving rapidly, and because pharmacies now frequently have multiple lines of business, many pharmacies no longer fit squarely into traditional pharmacy type classifications. For example, compounding pharmacies and specialty pharmacies, including but not limited to manufacturer-limited-access pharmacies, and those that may specialize in certain drugs, disease states, or both, are increasingly common, and Part D enrollees increasingly need access to their services. As noted previously, in implementing the any willing pharmacy provision, we indicated that standard terms and conditions could vary to accommodate different types of pharmacies so long as all similarly situated pharmacies were offered the same terms and conditions. In the original rule to implement Part D (70 FR 4194, January 28, 2005), we defined certain types of pharmacies (that is, retail, mail order, Long Term Care (LTC)/institutional, and I/T/U [Indian Health Service, Indian tribe or tribal organization, or urban Indian organization]) at § 423.100 to operationalize various statutory provisions that specifically mention these types of pharmacies (for example, section 1860D–4(b)(1)(C)(iv) of the Act). However, these definitions were never intended to limit the scope of the any willing pharmacy requirement. Nevertheless, we have anecdotal evidence that some Part D plan sponsors have declined to permit willing pharmacies to participate in their networks on the grounds that they do not meet the Part D plan sponsor's definition of a pharmacy type for which it has developed standard terms and conditions.

Section 1860D–4(b)(1)(A) of the Act requires Part D plan sponsors to permit the participation of “any pharmacy” that meets the standard terms and conditions. Accordingly, it is not appropriate for Part D plan sponsors to offer standard terms and conditions for network participation that are specific to only one particular type of pharmacy, and then decline to permit a willing pharmacy to participate on the grounds that it does not squarely fit into that pharmacy type. Therefore, we are clarifying in this preamble that although Part D sponsors may continue to tailor their standard terms and conditions to

various types of pharmacies, Part D plan sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network on the basis of not fitting in the correct pharmacy type classification. In particular, we consider “similarly situated” pharmacies to include any pharmacy that has the capability of complying with standard terms and conditions for a pharmacy type, even if the pharmacy does not operate exclusively as that type of pharmacy.

Thus, Part D plan sponsors must not exclude pharmacies from their retail pharmacy networks solely on the basis that they, for example, maintain a traditional retail business while also specializing in certain drugs or diseases or providing home delivery service by mail to surrounding areas. Or as another example, a Part D plan sponsor must not preclude a pharmacy from network participation as a retail pharmacy because that pharmacy also operates a home infusion book of business, or vice versa. Later in this section we are proposing to codify our requirements for when a Part D sponsor must provide a pharmacy with a copy of its standard terms and conditions. These requirements, if finalized, would apply to all pharmacies, regardless of whether they fit into traditional pharmacy classifications or have unique or innovative business or care delivery models.

b. Revise the Definition of Retail Pharmacy and Add a Definition of Mail-Order Pharmacy

Since the inception of the Part D program, Part D statute, regulations, and sub-regulatory guidance have referred to “mail-order” pharmacy and services without defining the term “mail order”. Unclear references to the term “mail order” have generated confusion in the marketplace over what constitutes “mail-order” pharmacy or services. This confusion has contributed to complaints from pharmacies and beneficiaries regarding how Part D plan sponsors classify pharmacies for network participation, the Plan Finder, and Part D enrollee cost-sharing expectations. Additionally, pharmacies that are not mail-order pharmacies, but that may offer home delivery services by mail (relative to that pharmacy's overall operation), have complained because Part D plan sponsors classified them as mail-order pharmacies for network participation and required them to be licensed in all United States, territories, and the District of Columbia, as would be required for traditional mail-order

pharmacies providing a mail-order benefit.

In creating the Part D program, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) added the convenient access provision of section 1860D–4(b)(1)(C) of the Act and the level playing field provision of section 1860D–4(b)(1)(D) of the Act. The convenient access provisions, as codified at § 423.120(a)(1)–(7), require Part D plan sponsors to secure the participation in their networks a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary) and includes special provisions for standards with respect to Long Term Care (LTC) and I/T/U pharmacies (as defined at § 423.100). The level playing field provision, as codified at § 423.120(a)(10), requires Part D plan sponsors to permit enrollees to receive the same benefits, including extended days' supplies, through a pharmacy (other than a mail-order pharmacy) (that is, a retail pharmacy), although the Part D plan sponsor may require the enrollee to pay a higher level of cost-sharing to do so.

We currently define “retail pharmacy” at § 423.100 to mean “any licensed pharmacy that is *not a mail-order pharmacy* from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.” Although we did not define “non-retail pharmacy,” § 423.120(a)(3) provides that “a Part D plan's contracted pharmacy network may be supplemented by non-retail pharmacies, “including pharmacies offering home delivery *via mail-order* and institutional pharmacies,” provided the convenient access requirements are met (emphasis added). In the preamble to our January 2005 final rule, we also stated, “examples of non-retail pharmacies include I/T/U, FQHC, Rural Health Center (RHC) and hospital and other provider-based pharmacies, as well as Part D [plan]-owned and operated pharmacies that serve only plan members” (see 70 FR 4249). We also stated “home infusion pharmacies will not count toward Part D plans' pharmacy access requirements (at § 423.120(a)(1)) because they are not retail pharmacies” (see 70 FR 4250).

Since 2005, our regulation at § 423.120(a) has included access requirements for retail, home infusion, LTC, and I/T/U pharmacies. While mail-order pharmacies could be considered

one of several subsets of non-retail pharmacies, we never defined the term mail-order pharmacy in regulation, nor have we specified access or service-level requirements at § 423.120(a) for mail-order pharmacies.

As discussed previously, our classifications of certain types of pharmacies were never intended to limit or exclude participation of pharmacies, such as pharmacies with multiple lines of business, that do not fit into one of these classifications. Additionally, we have recognized since our January 2005 final rule that pharmacies may have multiple lines of business, including retail pharmacies that may offer home delivery services (see 70 FR 4235 and 4255).

Nonetheless, despite this guidance and specific access requirements for LTC and HI pharmacies at § 423.120(a), some Part D plan sponsors interpreted “including pharmacies offering home delivery via mail-order and institutional pharmacies” at § 423.120(a)(3) to mean that any pharmacies, even retail pharmacies, that may offer home delivery services by mail are mail-order pharmacies. Although § 423.120(a)(3) specifically allows for access to non-retail pharmacies, and we intended “including pharmacies offering home delivery via mail-order and institutional pharmacies” to mean home infusion pharmacies, mail-order pharmacies, long-term care pharmacies, or other non-retail pharmacies that offer home delivery services by mail, some Part D plan sponsors began to require any interested pharmacies, even retail pharmacies, that may offer home delivery services by mail to contract as mail-order pharmacies in order to participate in the plan’s contracted pharmacy network. Because Part D plan sponsors frequently require contracted mail-order pharmacies to be licensed in all United States, territories, and the District of Columbia, the classification of any pharmacies that may offer home delivery services by mail as mail-order pharmacies for purposes of contracting with Part D plan sponsors as a network pharmacy, including licensure requirements, led to complaints from beneficiaries and pharmacies, including retail, specialty, and other pharmacies.

Although the language at § 423.120(a)(3) is specific to non-retail pharmacies, there is a great deal of confusion regarding mail-order pharmacy in the Part D marketplace. We believe it is inappropriate to classify pharmacies as “mail-order pharmacies” solely on the basis that they offer home delivery by mail. Because the statute at section 1860D–4(b)(1)(D) of the Act discusses cost sharing in terms of mail

order versus other non-retail pharmacies, mail-order cost sharing is unique to mail-order pharmacies, as we have proposed to define the term. For example, while a non-retail home infusion pharmacy may provide services by mail, cost-sharing is commensurate with retail cost-sharing. Therefore, to clarify what a mail-order pharmacy is, we propose to define mail-order pharmacy at § 423.100 as a licensed pharmacy that dispenses and delivers extended days’ supplies of covered Part D drugs via common carrier at mail-order cost sharing.

Although we propose to add the definition of mail-order pharmacy, we also believe that our existing definition of retail pharmacy has contributed, in part, to the confusion in the Part D marketplace. As discussed previously, the existing definition of “retail pharmacy” at § 423.100 means “any licensed pharmacy that is not a mail-order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.” This definition, given the rapidly evolving pharmacy practice landscape, may be a source of some confusion given that it expressly excludes mail-order pharmacies, but not other non-retail pharmacies such as home infusion or specialty pharmacies.

We note that Medicaid recently adopted a definition of “retail community pharmacy.” Pursuant to section 1927(k)(10) of the Act, as amended by section 2503 of the Affordable Care Act (ACA), for purposes of Medicaid prescription drug coverage, CMS defines “retail community pharmacy” at § 447.504(a) as “an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the state and that dispenses medications to the walk-in general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.” Although this definition adds greater clarity about the locations or practice settings where retail pharmacies may be found, we were concerned that, for the purposes of the Part D program, the mention of additional types of pharmacies in our regulation could contribute to more confusion instead of less.

However, two aspects of this definition are similar to Part D statutory language in section 1860D–4(b)(1)(C) and (D) of the Act. The first is the concept that a retail pharmacy is open to dispense prescription medications to the walk-in general public, which echoes the requirement at section 1860D–4(b)(1)(C) of the Act that Part D plan sponsors secure the participation in their networks a sufficient number of pharmacies that dispense (other than mail order) drugs directly to patients. The second is the concept that prescriptions are dispensed at retail prices, or for the Part D program, retail cost-sharing, which echoes the requirement at section 1860D–4(b)(1)(D) of the Act that Part D plan sponsors permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail-order pharmacy), with any differential in charge paid by such enrollees. Because these concepts are consistent with the Part D statute, we believe their inclusion in our definition of retail pharmacy at § 423.100 would be appropriate.

Therefore, to clarify what a retail pharmacy is, we propose to revise the definition of retail pharmacy at § 423.100. First, we note that the existing definition of “retail pharmacy” is not in alphabetical order, and we propose a technical change to move it such that it would appear in alphabetical order. Second, we propose to incorporate the concepts of being open to the walk-in general public and retail cost-sharing such that the definition of retail pharmacy would mean “any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy.”

Although we were originally unsure whether Part D enrollees would need routine access to specialty drugs and specialty pharmacies beyond our out-of-network requirements (see 70 FR 4250), as the Part D program has evolved, the use of specialty drugs in the Part D program has grown exponentially and will likely continue to do so. The June 2016 MedPAC report (available at <http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf>) notes growth in the use of specialty drugs in the Part D program is currently outpacing other drugs and health spending, generally. Such drugs are often high-cost and complex, for

diseases including, but not limited to, cancer, Hepatitis C, HIV/AIDS, multiple sclerosis, and rheumatoid arthritis. The report also highlights that each year since 2009, more than half of the United States Food and Drug Administration (FDA) approvals have been for specialty drugs. Because many specialty drugs can be self-administered on an outpatient basis, even in the patient's home, and for chronic or long-term use, increasing numbers of Part D enrollees need routine access to specialty drugs and specialty pharmacies. Nonetheless, because the pharmacy landscape is changing so rapidly, we believe any attempt by us to define specialty pharmacy could prematurely and inappropriately interfere with the marketplace, and we decline to propose a definition of specialty pharmacy at this time.

Similar to specialty pharmacy, we also decline to further define non-retail pharmacy. The pharmacy types that we define and propose to modify and define in regulation describe functional lines of business that an individual pharmacy may have, solely, or in combination. However, unlike mail order, home infusion, I/T/U, FQHC, LTC, hospital, other institutional, other provider-based, and "members-only" Part D plan-owned and operated pharmacy types or lines of business that comprise "non-retail", the term "non-retail" does not, itself, define a unique pharmacy functional line of business, and does not lend itself to a clear definition. Consistent with statutory any willing pharmacy and preferred pharmacy provisions, mail-order pharmacies may be preferred or non-preferred. Part D plan sponsors may establish unique non-preferred mail-order cost-sharing, or may establish such non-preferred mail-order cost sharing commensurate with those for retail pharmacies.

We solicit comment on our proposed definition of mail-order pharmacy and our proposed modification to the definition of retail pharmacy. Specifically, we solicit comment regarding whether stakeholders believe these definitions strike the right balance to resolve confusion in the marketplace, afford Part D plan sponsor flexibility, and incorporate recent innovations in pharmacy business and care delivery models.

c. Treatment of Accreditation and Other Similar Any Willing Pharmacy Requirements in Standard Terms and Conditions

As noted previously, since the beginning of the Part D program, we have considered standard terms and

conditions for network participation to set a "floor" of minimum requirements by which all similarly situated pharmacies must abide. We further believe it is reasonable for a Part D plan sponsor to require additional terms and conditions beyond those required in the standard contract for network participation for pharmacies to have preferred status. Therefore, we implemented the requirements of section 1860D-4(b)(1)(A) of the Act by requiring that standard terms and conditions be "reasonable and relevant," but declined to further define "reasonable and relevant" in order to provide Part D plans with maximum flexibility to structure their standard terms and conditions.

We note that a pharmacy's ability to participate in a preferred or specially labeled subset of the Part D plan sponsor's larger contracted pharmacy network or to offer preferred cost sharing assumes that, at a minimum, the pharmacy is able to participate in the network. Where there are barriers to a pharmacy's ability to participate in the network at all, it raises the question of whether the standard (that is, entry-level) terms and conditions are reasonable and relevant.

It has been our longstanding policy that Part D plans cannot restrict access to certain Part D drugs to specialty pharmacies within their Part D network in such a manner that contravenes the convenient access protections of section 1860D-4(b)(1)(C) of the Act and § 423.120(a) of our regulations. (See Q&A at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/QASpecialtyAccess_051706.pdf). In 2006, we informed sponsors they cannot restrict access to drugs on the "specialty/high cost" tier to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements (for example, Risk Evaluation and Mitigation Strategies (REMS) processes) or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy (that is, a contracted network pharmacy that does not belong to the restricted subset). Since 2006, it has been our general policy that these types of special requirements for Part D plan sponsors to limit dispensing of specialty drugs be directly linked to patient safety or regulatory reasons.

As the specialty drug distribution market has grown, so has the number of organizations competing to distribute or

dispense specialty drugs, such as pharmacy benefit managers (PBMs), health plans, wholesalers, health systems, physician practices, retail pharmacy chains, and small, independent pharmacies (see the URAC White Paper, "Competing in the Specialty Pharmacy Market: Achieving Success in Value-Based Healthcare," available at <http://info.urac.org/specialtypharmacyreport>). CMS is concerned that Part D plan sponsors might use their standard pharmacy network contracts in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies. In fact, we have received complaints from pharmacies that Part D plan sponsors have begun to require accreditation of pharmacies, including accreditation by multiple accrediting organizations, or additional Part D plan-/PBM-specific credentialing criteria, for network participation. We agree that there is a role in the Part D program for pharmacy accreditation, to the extent pharmacy accreditation requirements in network agreements promote quality assurance. In particular, we support Part D plan sponsors that want to negotiate an accreditation requirement in exchange for, for example, designating a pharmacy as a specialty or preferred pharmacy in the Part D plan sponsor's contracted pharmacy network. However, we do not support the use of Part D plan sponsor- or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations, apart from drug-specific limited dispensing criteria such as FDA-mandated REMS or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy (as discussed previously). Moreover, we are especially concerned about anecdotal reports that allege such standard terms and conditions for network participation are waived, for example, when a Part D plan sponsor needs a particular pharmacy in its network in order to meet convenient access requirements, or even for certain pharmacies that received preferred pharmacy status.

If the premise of accreditation or Part D plan sponsor- or PBM-specific credentialing requirements is to ensure more stringent quality standards, then there is no reasonable explanation for why a quality-related standard term or condition could be waived for situations when the Part D plan sponsor needs a particular pharmacy in its contracted

pharmacy network in order to meet the convenient access standards or to designate a particular pharmacy with preferred pharmacy status. A term or condition which can be dropped in such situations is by definition not "standard" according to the plain meaning of the word. Waivers or inconsistent application of such standard terms and conditions is an explicit acknowledgement that such terms and conditions are not necessary for the ability of a pharmacy to perform its core functions, and are thus neither reasonable nor relevant for any willing pharmacy standard terms and conditions.

It has been our longstanding policy to leave the establishment of pharmacy practice standards to the states, and we do not intend to change that now. We continue to believe pharmacy practice standards established by the states provide applicable minimum standards for all pharmacy practice standards, and § 423.153(c)(1) requires representation that network providers are required to comply with minimum standards for pharmacy practice as established by the states.

Additionally, because a pharmacy's ability to dispense certain medications is not dependent on it having the ability to dispense other medications, it is not relevant for sponsors to require pharmacies to dispense a particular roster of certain drugs or drugs for certain disease states in order to receive standard terms and conditions for network participation as a contracted network pharmacy for that Part D plan sponsor. Consequently, consistent with our longstanding policy, discussed previously, we would not expect Part D plan sponsors to limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements (for example, Risk Evaluation and Mitigation Strategies (REMS) processes) or except as required by applicable state law(s) if the contracted network pharmacy is capable of and appropriately licensed under applicable state law(s) for doing so. We solicit comment on this topic.

d. Timing of Contracting Requirements

CMS has received complaints over the years from pharmacies that have sought to participate in a Part D plan sponsor's contracted network but have been told by the Part D plan sponsor that its standard terms are not available until the sponsor has completed all other network contracting. In other instances, pharmacies have told us that Part D plan sponsors delay sending them the

requested terms and conditions for weeks or months or require pharmacies to complete extensive paperwork demonstrating their eligibility to participate in the sponsor's network before the sponsor will provide a document containing the standard terms and conditions. CMS believes such actions have the effect of frustrating the intent of the any willing pharmacy requirement, and as a result, we believe it is necessary to codify specific procedural requirements for the delivery of pharmacy network standard terms and conditions.

To this end, we propose to establish deadlines by which Part D plan sponsors must furnish their standard terms and conditions to requesting pharmacies. The first deadline we propose to establish is the date by which Part D plan sponsors must have standard terms and conditions available for pharmacies that request them. By mid-September of each year, Part D plan sponsors have signed a contract with CMS committing them to delivering the Part D benefit through an accessible pharmacy network during the upcoming year and have provided information about that network to CMS for posting on the Medicare Plan Finder Web site. At that point, Part D plan sponsors should have had ample opportunity to develop standard contract terms and conditions for the upcoming plan year. Therefore, we propose to require at § 423.505(b)(18)(i) that Part D plan sponsors have standard terms and conditions readily available for requesting pharmacies no later than September 15 of each year for the succeeding benefit year.

The second deadline we propose concerns the promptness of Part D plan sponsors' responses to pharmacy requests for standard terms and conditions. As discussed previously, we propose to require all Part D plan sponsors to have standard terms and conditions developed and ready for distribution by September 15. Therefore, we propose to require at § 423.505(b)(18)(ii) that, after that date and throughout the following plan year, Part D plan sponsors must provide the applicable standard terms and conditions document to a requesting pharmacy within two business days of receipt of the request. Part D plan sponsors would be required to clearly identify for interested pharmacies the avenue (for example, phone number, email address, Web site) through which they can make this request. In instances where the Part D plan sponsor requires a pharmacy to execute a confidentiality agreement with respect to the terms and conditions, the Part D plan sponsor

would be required to provide the confidentiality agreement within two business days after receipt of the pharmacy's request and then provide the standard terms and conditions within 2 business days after receipt of the signed confidentiality agreement. While Part D plan sponsors may ask pharmacies to demonstrate that they are qualified to meet the Part D plan sponsors' standard terms and conditions before executing the contract, Part D plan sponsors would be required to provide the pharmacy with a copy of the contract terms for its review within the two-day timeframe. If finalized, this proposed requirement would permit pharmacies to do their due diligence with respect to whether a Part D plan sponsor's standard terms and conditions are acceptable at the same time Part D plan sponsors are conducting their own review of the qualifications of the requesting pharmacy. We specifically seek comment on whether these timeframes are the right length to address our goal but are operationally realistic. We also request examples of situations where a longer timeframe might be needed.

13. Changes to the Days' Supply Required by the Part D Transition Process

We promulgated regulations under the authority of section 1860D-11(d)(2)(B) of the Act to require Part D sponsors to provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on the prescription drug plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules). These regulations are codified at § 423.120(b)(3). Specifically, these regulations require that a Part D sponsor ensure certain enrollees access to a temporary supply of drugs within the first 90 days under a new plan (including drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) by ensuring a temporary fill when an enrollee requests a fill of a non-formulary drug during this time period. In the outpatient setting, the supply must be for at least 30 days of medication, unless the prescription is written for less. In the LTC setting, this supply must be for up to at least 91 days and may be up to 98 days, consistent with the dispensing increment, unless a less amount is prescribed.

We propose to make two changes to these regulations. First, we propose to shorten the required transition days'

supply in the long-term care (LTC) setting to the same supply currently required in the outpatient setting. Second, we propose a technical change to the current required days' transition supply in the outpatient setting to be a month's supply.

We provided our rationale for the transition fill days' supply requirement in the LTC setting in CMS final rule CMS-4085-F published on April 15, 2010 (75 FR 19678). In that final rule, we stated that for a new enrollee in a LTC facility, the temporary supply may be for up to 31 days (unless the prescription is written for less than 31 days), consistent with the dispensing practices in the LTC industry. We further stated that, due to the often complex needs of LTC residents that often involve multiple drugs and necessitate longer periods in order to successfully transition to new drug regimens, we will require sponsors to honor multiple fills of non-formulary Part D drugs, as necessary during the entire length of the 90-day transition period. Thus, we required a Part D sponsor to provide a LTC resident enrolled in its Part D plan with at least a 31 day supply of a prescription with refills provided, if needed, up to a 93 days' supply (unless the prescription is written for less) (75 FR 19721). In a subsequent final rule published on April 15, 2011, we changed the 93 days' supply to 91 to 98 days' supply, as noted previously, to acknowledge variations in days' supplies that could result from the short-cycle dispensing of brand drugs in the LTC setting (76 FR 21460 and 21526).

We received and responded to a comment in the April 2010 final rule about transition and a longer timeframe in the LTC setting. We stated that a number of commenters supported our proposal of requiring an extended transition supply for enrollees residing in LTC facilities but that commenters requested that we provide the same protections to individuals requiring LTC in community-based settings. In our response to the comment, we indicated that residents of LTC institutions were more limited in access to prescribing physicians hired by LTC facilities due to a limited visitation schedule and more likely to require extended transition timeframes in order for the physician to work with the facility and LTC pharmacies on transitioning residents to formulary drugs. We further stated that we believed that community-based enrollees, in contrast, were less limited in their access to prescribing physicians and did not require an extended transition period to work with their physicians to successfully transition to

a formulary drug. (75 FR 19721). Thus, the requirement to provide longer transition fill days' supply in the LTC setting was a result of our concerns that a longer timeframe would be needed in the LTC setting.

After more than 10 years of experience with Part D in LTC facilities, we have not seen the concerns that we expressed in the 2010 final rule materialize. We are not aware of any evidence that transition for a Part D beneficiary in the LTC setting necessarily takes any longer than it does for a beneficiary in the outpatient setting. We understand that it is common for Part D beneficiaries in the LTC setting to be cared for by on-staff or consultant physicians and other health professionals with prescriptive authority who are under contract with the LTC facility. Additionally, we also understand that Part D beneficiaries in the LTC setting are typically served by an on-site pharmacy or one under contract to service the LTC facility. Given this structure of the LTC setting, we understand that the LTC prescribers and pharmacies are readily available to address transition for Part D beneficiaries in the LTC setting. In addition, LTC facilities now have many years' experience with the Medicare Part D program generally and transition specifically.

While our concerns about the needed timeframe for transition in the LTC setting do not seem to have materialized, we have continuing concerns about drug waste and the costs associated with such waste in the LTC setting. Some of these concerns have been addressed by our rule requiring the short-cycle dispensing of brand drugs to Part D beneficiaries in LTC facilities in the April 2011 final rule. That rule, codified at 42 CFR 423.154, requires that all Part D sponsors require all network pharmacies servicing LTC facilities to dispense certain solid oral doses of covered Part D brand-name drugs to enrollees in such facilities in no greater than 14-day increments at a time to reduce drug waste. However, we now believe that CMS could eliminate additional drug waste and cost by no longer requiring a longer transition days' supply in the LTC setting. Therefore, we are proposing that the transition days' supply in the LTC setting be the same as it is in the outpatient setting.

Our second proposed change involves the current required 30 days' transition supply in the outpatient setting, which is codified at § 423.120(b)(3)(iii)(A). We have received a number of inquiries from Part D sponsors regarding scenarios involving medications that do

not easily add up to a 30 days' supply when dispensed (for example, drugs that typically are dispensed in 28-day packages). Historically, our response to those inquiries has been that the regulation requires plans to provide at least 30 days of medication, which requires plans to dispense more than one package to comply with the text of the regulation. However, the intent of the regulation was for the transition fill in the outpatient setting to be for at least a month's supply. For this reason, we are proposing a change to the regulation from "30 days" to "a month's supply." If finalized, this change would mean that the regulation would require that a transition fill in the outpatient setting be for a supply of at least a month of medication, unless the prescription is written by the prescriber for less. Therefore, the supply would have to be for at least the days' supply that the applicable Part D prescription drug plans has approved as its retail month's supply in its Plan Benefit Package submitted to CMS for the relevant plan year, again, unless the prescription is written by the prescriber for less.

Together, our two proposals—if finalized—would mean that § 423.120(b)(3)(iii)(A) would be consolidated into § 423.120(b)(3)(iii) to read that the transition process must "[e]nsure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (b)(3)(ii) of this section (including Part D drugs that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules) by providing a one-time, temporary supply of at least a month's supply of medication, unless the prescription is written by a prescriber for less than a month's supply and requires the Part D sponsor to allow multiple fills to provide up to a total of a month's supply of medication." Section 423.120(b)(3)(iii)(B) would be eliminated.

Please note that we also are proposing in II.A.15. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes to revise § 423.120(b)(3)(i)(B) to state that the transition process is not applicable in cases in which a Part D sponsor substitutes a generic drug for a brand name drug as specified under paragraph § 423.120(b)(3)(iv) or § 423.120(b)(6) of this section.

14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

Section 1860D–4(b)(3)(E) of the Act requires Part D sponsors to provide “appropriate notice” to the Secretary, affected enrollees, authorized prescribers, pharmacists, and pharmacies regarding any decision to either: (1) Remove a drug from its formulary, or (2) make any change in the preferred or tiered cost-sharing status of a drug. Section 423.120(b)(5) implements that requirement by defining appropriate notice as that given at least 60 days prior to such change taking effect during a given contract year. We have recognized that both current and prospective enrollees of a prescription drug plan need to have the most current formulary information by the time of the annual election period described in § 423.38(b) in order to enroll in the Part D plan that best suits their particular needs. To this end, § 423.120(b)(6) prohibits Part D sponsors and MA organizations from removing a covered Part D drug from a formulary or changing the preferred or tiered cost-sharing status of a covered Part D drug between the beginning of the annual election period described in § 423.38(b)(2) and 60 days subsequent to the beginning of the contract year associated with that annual election period. Our concern has been to prevent situations in which Part D sponsors change their formularies early in the contract year without providing appropriate notice as described in § 423.120(b)(5) to new enrollees. Thus, § 423.120(b)(6) has required that all materials distributed during the annual election period reflect the formulary the Part D sponsor will offer at the beginning of the contract year for which it is enrolling Part D eligible individuals. Lastly, under § 423.128(d)(2)(iii), Part D sponsors must also provide current and prospective Part D enrollees with at least 60 days’ notice regarding the removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan’s formulary. The general notice requirements and burden are currently approved by OMB under control number 0938–0964 (CMS–10141).

MedPAC observed that the continuity of a plan’s formulary is very important to all beneficiaries in order to maintain access to the medications that were offered by the plan at the time the beneficiaries enrolled. While we agree with MedPAC’s assertion, we acknowledge the need to balance

formulary continuity with requests from Part D sponsors to provide greater flexibility to make midyear changes to formularies. Indeed, MedPAC made its observation in a report that suggested that CMS’s rules regarding formulary changes warranted examination. There MedPAC pointed out, among other things, that CMS could provide Part D sponsors with greater flexibility to make changes such as adding a generic drug and removing its brand name version without first receiving agency approval. (MedPAC, Report to the Congress: Medicare and the Health Care Delivery System, June 2016, page 192.)

This proposed rule would implement MedPAC’s recommendation by permitting generic substitutions without advance approval as specified later in this section. We have also taken this opportunity to examine our regulations to determine how to otherwise facilitate the use of certain generics. Currently, Part D sponsors can add drugs to their formularies at any time; however, there is no guarantee that enrollees will switch from their brand name drugs to newly added generics. Therefore, Part D sponsors seeking to better manage the Part D benefit may choose to remove a brand name drug, or change its preferred or tiered cost-sharing, and substitute or add its therapeutic equivalent. But even this takes some time: Under current regulations, Part D sponsors must submit formulary change requests to CMS and provide specified notice before removing drugs or changing their cost-sharing (except for unsafe drugs or those withdrawn from the market). As noted earlier, the general notice requirements and burden are currently approved by OMB under control number 0938–0964 (CMS–10141). Also, as detailed previously, § 423.120(b)(5)(i) requires 60 days’ notice to specified entities prior to the effective date of changes and 60 days’ direct notice to affected enrollees or a 60 day refill. The ability of Part D sponsors to make generic substitutions as approved by CMS is further limited by the fact that as detailed previously, under § 423.120(b)(6), Part D sponsors generally cannot remove drugs or make cost-sharing changes from the start of the annual election period (AEP) until 2 months after the plan year begins.

We propose to provide Part D sponsors with more flexibility to implement generic substitutions as follows: The proposed provisions would permit Part D sponsors meeting all requirements to immediately remove brand name drugs (or to make changes in their preferred or tiered cost-sharing status), when those Part D sponsors replace the brand name drugs with (or

add to their formularies) therapeutically equivalent newly approved generics—rather than having to wait until the direct notice and formulary change request requirements have been met. The proposed provisions would also allow sponsors to make those specified generic substitutions at any time of the year rather than waiting for them to take effect 2 months after the start of the plan year. Related proposals would require advance general and retrospective direct notice to enrollees and notice to entities; clarify online notice requirements; except specified generic substitutions from our transition policy; and conform our definition of “affected enrollees.” Lastly, to address stakeholder requests for greater flexibility to make midyear formulary changes in general, we are also proposing to decrease the days of enrollee notice and refill required when (aside from generic substitution and drugs deemed unsafe or withdrawn from the market) drug removal or changes in cost-sharing will affect enrollees.

Specifically, we propose to add a new paragraph (b)(5)(iv) to § 423.120 to permit Part D sponsors to immediately remove, or change the preferred or tiered cost-sharing of, brand name drugs and substitute or add therapeutically equivalent generic drugs provided specified requirements are met. The generic drug would need to be offered at the same or a lower cost-sharing and with the same or less restrictive utilization management criteria originally applied to the brand name drug. The Part D sponsor could not have as a matter of timing been able to previously request CMS approval of the change because the generic drug had not yet been released to the market. Also, the Part D sponsor must have previously provided prospective and current enrollees general notice that certain generic substitutions could occur without additional advance notice. As proposed, we would permit Part D sponsors to substitute a generic drug for a brand name drug immediately rather than make that change effective, for instance, at the start of the next month. However, we solicit comment as to whether there would be a reason to require such a delay, especially given the fact that we are proposing not to require advance direct notice (rather, only advance general notice) or CMS approval. The proposed regulation would also require that, when generic drug substitutions occur, Part D sponsors must provide direct notice to affected enrollees and other specified notice to CMS and other entities. We also propose to specify in a revision to

§ 423.120(b)(3)(i)(B) that the transition process is not applicable in cases in which a Part D sponsor substitutes a generic drug for a brand name drug under paragraph (b)(6) of this section.

A proposed exception to § 423.120(b)(6) would permit Part D sponsors to make the above specified changes (removing covered Part D drugs from their formularies, or changing their cost-sharing, when substituting or adding their generic equivalents) during any time of the year. That section generally provides—with a current exception only for unsafe drugs and drugs removed from the market—that Part D sponsors generally cannot remove drugs or make cost-sharing changes between the beginning of the AEP and 60 days after the plan year begins. We believe that revising this provision would assist Part D sponsors by permitting substitutions to take place effect during a longer time period than is currently permitted. Given that the previous exception would permit generic substitutions prior to the start of the calendar year, we also propose to conform the definition of “affected enrollees” to clarify that applicable changes must affect their access to drugs during the current plan year.

We are aware that some may be concerned about not requiring advance CMS approval or advance direct notice to enrollees prior to making the permitted generic substitutions, or requiring a transition fill. But we would only permit immediate substitution when the generics are deemed therapeutically equivalent to the brand name drug being removed by the Federal Drug and Food Administration (FDA) and meet other requirements specified later in this section. This would not apply to follow-on biological products under current FDA guidance. The FDA has, in fact noted that, “A generic drug is a medication created to be the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics.” (“Generic Drug Facts,” see FDA Web site, <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm>, accessed September 19, 2017, hereafter FDA, “Abbreviated New Drug Application (ANDA): Generics”). Additionally, immediate generic substitution has long been an established bedrock of commercial insurance, and we are not aware of any harm to the insured resulting from such policies.

Also, we do not believe a transition policy would be appropriate for these

situations: The purpose of the transition process is to make sure that the medical needs of enrollees are safely accommodated in that they do not go without their medications or face an abrupt change in treatment. If the proposal to permit Part D sponsors to immediately substitute generics for brand name drugs upon market release were finalized, most enrollees in this situation would not have had an opportunity to try the drug prior to the drug substitution to see how it worked for them. In other words, an enrollee could not be certain that a generic substitution would not work, would constitute an abrupt change in treatment, or that the enrollee would be better served by taking no medication rather than the generic unless he or she had previously tried the generic drug.

Moreover, we have built beneficiary protections into the proposed provisions. First, proposed § 423.120(b)(5)(iv)(A) addresses safety concerns by permitting Part D sponsors to add only therapeutically equivalent generic drugs. This means the FDA must have approved the generic drug in an abbreviated new drug application pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), and it must be listed with the innovator drug in the publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the Orange Book) in which the FDA identifies drug products approved on the basis of safety and effectiveness by the FDA, and be considered by the FDA to be therapeutically equivalent to the brand name drug.

Second, we share the concern that prospective enrollees could be misled by Part D sponsors that deliberately offer brand name drugs during open enrollment periods only to remove them or change their cost-sharing as quickly as possible during the plan year. We believe that our proposed provision would address such problems: Under proposed § 423.120(b)(5)(iv)(B), a Part D sponsor cannot substitute a generic for a brand name drug unless it could not have previously requested formulary approval for use of that drug. As a matter of operations, CMS permits Part D sponsors to submit formularies, and their respective change requests, only during certain windows. Under proposed § 423.120(b)(5)(iv)(B), a Part D sponsor could not remove a brand name drug or change its preferred or tiered cost-sharing if that Part D sponsor could have included its generic equivalent with its initial formulary submission or during a later update window.

However, to be certain, that we have not missed practical or other complications that would hinder the ability of Part D sponsors to timely seek approval within the CMS timeframes, we solicit comment as to whether we should consider immediate substitution, potentially in limited circumstances, of specified generics for which Part D sponsors could have previously requested formulary approval. At the same time, we remain mindful of beneficiary protections and are hesitant to simply permit substitution of any generics regardless of how long they have been on the market. Accordingly, we welcome suggestions of any other practical cut-offs, as well as information on possible effects on beneficiaries that could result if we were to permit Part D sponsors to substitute specified generics that have been on the market for longer time periods.

Third, we believe the two-pronged approach of the proposed provision would provide appropriate notice for this type of formulary change. The general notice requirement of proposed § 423.120(b)(iv)(C) would require that, before making any generic substitutions, a Part D sponsor provide all prospective and current enrollees with notice in the formulary and other applicable beneficiary communication materials stating that the Part D sponsor can remove, or change the preferred or tiered cost-sharing of, any brand name drug immediately without additional advance notice (beyond the general advance notice) when a new equivalent generic is added. This would, for instance, include the Evidence of Coverage (EOC). Proposed § 423.120(b)(iv)(C) would also require that this general notice advise prospective and current enrollees that they will get direct notice about any specific drug substitutions made that would affect them and that the direct notice would advise them of the steps they could take to request coverage determinations and exceptions. Therefore, the general notice would advise enrollees about what might take place before any changes occur.

When the Part D sponsor substitutes a generic for a brand name drug, the proposed direct notice provision, § 423.120(b)(5)(iv)(E), would require the Part D sponsor to provide affected enrollees with direct notice consistent with § 423.120(b)(5)(ii). We currently require Part D sponsors to provide this information 60 days before such changes are made. Under the proposed changes, enrollees would receive the same information they receive under the current regulation—the only difference being that the notice could be provided

after the effective date of the generic substitution. As discussed earlier, under the proposed provision Part D sponsors seeking to make immediate substitutions would be newly required to have previously provided general notice in beneficiary communication materials such as formularies and EOCs that certain generic substitutions could take place without additional advance notice.

We understand there may be concerns that the direct notice identifying the specific drug substitution would arrive after the formulary change has already taken place. As explained previously, we believe generic substitutions pose no threat to enrollee safety. Also, as noted earlier, we are proposing to revise § 423.120(b)(6) to permit generic substitutions to take place throughout the entire year. This means that, under the proposed provision, a Part D sponsor meeting all the requirements would be able to substitute a generic drug for a brand name drug well before the actual start of the plan year (for instance, if a generic drug became available on the market days after the summer update). There is nothing in our regulation that would prohibit advance notice and, in fact, we would encourage Part D sponsors to provide direct notice as early as possible to any beneficiaries who have reenrolled in the same plan and are currently taking a brand name drug that will be replaced with a generic drug with the start of the next plan year. We would also anticipate that Part D sponsors will be promptly updating the formularies posted online and provided to potential beneficiaries to reflect any permitted generic substitutions—and at a minimum meeting any current timing requirements provided in applicable guidance. At this time we are not proposing to set a regulatory deadline by which Part D sponsors must update their formularies before the start of the new plan year. However, if we were to finalize this provision and thereafter find that Part D sponsors were not timely updating their formularies, we would reexamine this policy. And we would note, as regards timing, that § 423.128(d)(2)(iii) requires that the current formulary posted online be updated at least monthly.

In cases in which the Part D sponsor would necessarily have to send notice after the fact, for example instances in which a drug is not released to the market until after the beginning of the plan year and the Part D sponsor then immediately makes a generic substitution, the proposed general notice would have already advised enrollees that they would receive information about any specific drug

generic substitutions that affected them and that they would still be able to request coverage determinations and exceptions. While the timing would most likely mean most enrollees would only be able to make such requests after receiving a generic drug fill, in the vast majority of cases, an enrollee could not be certain that a generic substitution would not work unless he or she actually tried the generic drug. Additionally, we are strongly encouraging Part D sponsors to provide the retrospective direct notices of these generic substitutions (including direct notice to affected enrollees and notice to entities including CMS) no later than by the end of the month after which the change becomes effective. While sponsors are required to report this information to both enrollees and entities including CMS, we currently are not proposing to codify the end of month timing requirement; however, if we were to finalize this provision and thereafter find that Part D sponsors were not timely providing retrospective notice, we would reexamine this policy.

Fourth, enrollees would be protected from higher cost-sharing under proposed paragraph (b)(5)(iv)(A), which would require Part D sponsors to offer the generic with the same or lower cost-sharing and the same or less restrictive utilization management criteria as the brand name drug.

We also believe requirements and guidance regarding beneficiary communications will continue to provide beneficiary protections. Section 423.128(e)(5) currently requires Part D sponsors to furnish directly to enrollees an explanation of benefits (EOB) that includes any applicable formulary changes for which Part D plans are required to provide notice as described in § 423.120(b)(5). As noted previously, § 423.128(d)(2)(iii) currently requires Part D sponsors to post at least 60 days' notice of removals and cost-sharing changes online for current and prospective Part D enrollees. In light of our proposal for generic substitutions described previously, we propose to modify § 423.128(d)(2)(iii) to require Part D sponsors to provide "timely" notice under 423.120(b)(5). This would mean that, under the proposed provision, a Part D sponsor would need to provide at least 30 days' online notice to affected enrollees before removing drugs or making cost-sharing changes except when adding a therapeutically equivalent generic as specified, and as has currently been the requirement, removing unsafe or withdrawn drugs. Part D sponsors could provide online notice after the effective date of changes only in those limited instances.

As regards content, § 423.128(d)(2)(iii) requires—and would continue to do so under the proposed revisions—that Part D sponsors post online notice regarding any removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary. Posting information online related to removing a specific drug or changing its cost-sharing solely to meet the content requirements of § 423.128(d)(2)(iii) cannot replace general notice under proposed § 423.120(b)(5)(iv)(C); direct notice to affected enrollees under § 423.120(b)(5)(ii); or notice to CMS when required under § 423.120(b)(5). For instance, as noted in the January, 28, 2005 final rule (70 FR 4265), we view online notification under § 423.128(d)(2)(iii) on its own as an inadequate means of providing specific information to the enrollees who most need it, and we consider it an additional way that Part D sponsors provide notice of formulary changes to affected enrollees.

However, we do not mean to restrict or otherwise affect other rules governing the provisions of materials online. For instance, if Part D sponsors were able to fulfill CMS marketing and beneficiary communications requirements by posting a specific document online rather than providing it in paper, the fact the document was posted online would not preclude it from providing general notice required under our proposed provisions. In other words, if otherwise valid, provision of general notice in a document posted online could suffice as notice as regards that specified document under proposed § 423.120(b)(5)(iv)(C). In contrast, we do not wish to suggest that posting one type of notice online would necessarily suffice to meet distinct notice requirements. For instance, providing the general advance notice that would be required under § 423.120(b)(5)(iv)(C) in a document posted online could not meet the online content requirements of § 423.128(d)(2)(iii) related to providing information about removing drugs or changing their cost-sharing. Nor, as noted previously, could the opposite apply: Posting the content required under § 423.128(d)(2)(iii) online could not fulfill the advance general notice requirements that would be required under proposed § 423.120(b)(5)(iv)(C) (or suffice to provide direct notice to affected enrollees under § 423.120(b)(5)(ii) or notice to CMS under § 423.120(b)(5)).

In addition to requiring the direct notice to affected enrollees discussed previously, proposed § 423.120(b)(iv)(D) would also require Part D sponsors to provide the following entities with

notice of the generic substitutions consistent with § 423.120(b)(5)(ii): CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists. (To avoid repetition, we propose to revise the provision to refer to all of these entities as “CMS and other specified entities” for the purposes of § 423.120(b).) Even though, as proposed, a Part D sponsor that met all of the requirements would be able to make the generic substitution immediately without submitting any formulary change requests to CMS, the Part D sponsor must include the generic substitution in the next available formulary submission to CMS. We note that Part D plans can determine the most effective means to communicate formulary change information to State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists and that, under our proposed provision, we would consider online posting sufficient for those purposes.

Lastly as part of our reexamination of the need to generally provide Part D sponsors greater flexibility in formulary changes, we plan to decrease the amount of direct notice required in cases where the removal of a drug or change in cost-sharing status will affect enrollees currently taking the drug. (This would contrast proposed notice requirements that would apply to immediate substitution of specified generics. There we would also require advance general notice that such changes can occur, and direct notice of the specific changes could be provided after their effective date.) Section 423.120(b)(5)(i) currently requires at least 60 days’ notice to all entities prior to the effective date of changes and at least 60 days’ direct notice to affected enrollees or a 60 day refill upon the request of an affected enrollee. We propose to reduce the notice requirement in both instances to at least 30 days and the refill requirement to a month. Beneficiaries would be affected, and therefore receive the 30 days’ notice or a month refill, in cases in which, for instance, Part D sponsors planned to add prior authorization requirements as a result of new safety-related information or clinical guidelines. This proposal would permit Part D sponsors to institute formulary changes in half the time.

We are, again, aware that some may be concerned that we are reducing the number of days advance notice afforded

to enrollees in these instances. But again, we believe current CMS requirements provide the necessary beneficiary protections, and that 30 (rather than 60) days’ notice still will afford enrollees sufficient time to either change to a covered alternative drug or to obtain needed prior authorization or an exception for the drug affected by the formulary change. Existing CMS regulations establish robust beneficiary protections in the coverage and appeals process, including expedited adjudication timeframes for exigent circumstances (maximum timeframe of 24 hours for coverage determinations and 72 hours for level 1 and 2 appeals), and a requirement that Part D plan sponsors automatically forward all untimely coverage determinations and redeterminations to the IRE for independent review. Further, while 60 days’ notice is currently required, we have no evidence to suggest that beneficiaries are currently utilizing the full 60 days. The reduction to 30 days would align these requirements with the timeframes for transition fills. And, with over 11 years of program experience, we have no evidence to suggest that 30 days has been an insufficient temporary days supply for transition fills.

(Note we are also proposing to amend the refill amount to months (namely a month) rather than days (it was 60 days previously) to conform to a proposed revision to the transition policy regulations at § 423.120(b)(3).) For further discussion, see section III.A.15 of this proposed rule, Changes to the Transition.)

Summary: The following provides a high level summary of notice changes proposed in § 423.120(b). Details on these requirements appear in the preamble and proposed provisions. This summary does not address other proposed changes (for instance, changes to transition requirements); notice provisions we do not propose to change (for instance, notice for safety edits); or other rules that may also apply (for instance, marketing and beneficiary communications rules regarding formulary updates).

- Notice required for expedited substitutions of certain generics: Part D sponsors that would otherwise be permitted to make certain generic substitutions as specified under proposed § 423.120(b)(5)(iv) would be required to provide the following types of notice:

- ++ Advance general notice in the formulary and EOC and other applicable beneficiary communications stating that such changes may occur without notice.

- ++ Notice that identifies the specific drug substitution made—which may be

provided after the effective date of the change—as follows:

- Direct notice to affected enrollees.
- Notice posted online for current and prospective enrollees.
- Notice to CMS.
- Notice to other entities.

- Notice and refill required for certain other midyear formulary changes: Part D sponsors that would be otherwise permitted to remove or change the preferred or tiered cost-sharing status of drugs would be required to provide the below types of notice and refills under proposed § 423.120(b)(5)(i) and (ii). However, these notice requirements do not apply when removing drugs deemed unsafe by the FDA or removed from the market by manufacturers (for applicable requirements see § 423.120(b)(5)(iii).)

- For affected enrollees—
 - ++ Advance direct written notice at least 30 days prior to the effective date; or
 - ++ Written notice of the change and a month supply of the brand name drug under the same terms as provided before the change; and

- For entities and other enrollees:
 - ++ Advance notice identifying the specific drug changes to be made at least 30 days prior to the effective date of the change as follows:

- Notice posted online for current and prospective enrollees;
- Notice to CMS; and
- Notice to other entities.

15. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

Similar to the introduction of an abbreviated approval pathway for generic drugs provided by the Hatch-Waxman Act in 1984 to spur more competition through quicker approvals and introduction of lower cost therapeutic alternatives in the marketplace, Congress enacted the “Biologics Price Competition and Innovation Act of 2009” to balance innovation and consumer interests. Specifically, section 7002 of the ACA amended section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), adding a subsection (k) to create an abbreviated licensure pathway for follow-on biological products that are demonstrated to be either “biosimilar” to or “interchangeable” with a United States Food and Drug Administration (FDA) licensed reference biological product. According to the FDA, “a biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has

no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.” However, “an interchangeable biological product is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.” (See <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/>) Biosimilar biological products are, by definition, not interchangeable, and are not substitutable without a new prescription. Follow-on biological products are listed in the FDA’s *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm>. Part D plan sponsors are also encouraged to monitor the FDA’s Web site for new biologic (BLA) approvals at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.ReportsMenu>.

Sections 1860D–2(b)(4) and 1860D–14(a)(1)(D)(ii–iii) of the Act specify lower Part D maximum copayments for low-income subsidy (LIS) eligible individuals for generic drugs and preferred drugs that are multiple source drugs (as defined in section 1927(k)(7)(A)(i) of the Act) than are available for all other Part D drugs. Currently the statutory cost sharing levels are set at the maximums. CMS does not interpret the statutory language to mean that each plan can establish lower LIS cost sharing on drugs, but rather, that CMS, through rulemaking, could establish lower cost sharing than the maximum amount, and it would therefore be the same for all Part D plans.

For the Part D program, CMS defines a “generic drug” at § 423.4 as a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is approved. Biosimilar and interchangeable biological products do not meet the section 1927(k)(7) definition of a multiple source drug or

the CMS definition of a generic drug at § 423.4. Consequently, follow-on biological products are subject to the higher Part D maximum copayments for LIS eligible individuals and non-LIS Part D enrollees in the catastrophic portion of the benefit applicable to all other Part D drugs. While the statutory maximum LIS copayment amounts apply to all phases of the Part D benefit, the statute only specifies non-LIS maximum copayments for the catastrophic phase. CMS clarified the applicable LIS and non-LIS catastrophic cost sharing in a March 30, 2015 Health Plan Management System (HPMS) memorandum. We advised that additional guidance may be issued for interchangeable biological products at a later date.

Nonetheless, treatment of follow-on biological products, which are generally high-cost, specialty drugs, as brands for the purposes of non-LIS catastrophic and LIS cost sharing generated a great deal of confusion and concern for plans and advocates alike, and CMS received numerous requests to redefine generic drug at § 423.4. Advocates expressed concerns that LIS enrollees were required to pay the higher brand copayment for biosimilar biological products. Stakeholders who contacted us asserted treatment of biosimilar biological products as brands for purposes of LIS cost-sharing creates a disincentive for LIS enrollees to choose lower cost alternatives. Some of these stakeholders also expressed similar concerns for non-LIS enrollees in the catastrophic portion of the benefit.

We agree and propose to revise the definition of generic drug at § 423.4 to include follow-on biological products approved under section 351(k) of the PHS Act (42 U.S.C. 262(k)) solely for purposes of cost-sharing under sections 1860D–2(b)(4) and 1860D–14(a)(1)(D)(ii–iii) of the Act. Lower cost sharing for lower cost alternatives will improve enrollee incentives to choose follow-on biological products over more expensive reference biological products, and will reduce costs to both Part D enrollees and the Part D program.

While CMS generally seeks to encourage the utilization of lower cost follow-on biological products, we propose to limit inclusion of follow-on biological products in the definition of generic drug to purposes of non-LIS catastrophic cost sharing and LIS cost sharing only because we want to avoid causing any confusion or misunderstanding that CMS treats follow-on biological products as generic drugs in all situations. We do not believe that would be appropriate because the same FDA requirements for

generic drug approval (for example, therapeutic equivalence) do not apply to biosimilar biological products, currently the only available follow-on biological products. Accordingly, CMS currently considers biosimilar biological products more like brand name drugs for purposes of transition or midyear formulary changes because they are not interchangeable. In these contexts, treating biosimilar biological products the same as generic drugs would incorrectly signal that CMS has deemed biosimilar biological products (as differentiated from interchangeable biological products) to be therapeutically equivalent. This could jeopardize Part D enrollee safety and may generate confusion in the marketplace through conflation with other provisions due to the many places in the Part D statute and regulation where generic drugs are mentioned. Therefore, we believe the proposed change to treat follow-on biological products as generics should be limited to purposes of non-LIS catastrophic and LIS cost sharing only.

We propose to modify the definition of generic drug at § 423.4 as follows:

- We propose to redesignate the existing definition as paragraph (i).
- We propose to add a new paragraph (ii) to state “for purposes of cost sharing under sections 1860D–2(b)(4) and 1860D–14(a)(1)(D) of the Act only, a biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved.”

We solicit comment on this proposed change to the definition of generic drug at § 423.4.

16. Eliminating the Requirement To Provide PDP Enhanced Alternative (EA) to EA Plan Offerings With Meaningful Differences (§ 423.265)

CMS has the authority under section 1857(e)(1) of the Act, incorporated for Part D by section 1860D–12(b)(3)(D) of the Act, to establish additional contract terms that CMS finds “necessary and appropriate,” as well as authority under section 1860D–11(d)(2)(B) of the Act to propose regulations imposing “reasonable minimum standards” for Part D sponsors. Using this authority we previously issued regulations to ensure that multiple plan offerings by Part D sponsors represent meaningful differences to beneficiaries with respect to benefit packages and plan cost structures. At that time, separate meaningful difference rules were concurrently adopted for MA and stand-alone PDPs. This section addresses proposed changes to our regulations pertaining strictly to meaningful

differences in PDP plan offerings. One of the underlying principles in the establishment of the Medicare Part D prescription drug benefit is that both market competition and the flexibility provided to Part D sponsors in the statute would result in the offering of a broad array of cost effective prescription drug coverage options for Medicare beneficiaries. We continue to support the concept of offering a variety of prescription drug coverage choices for Medicare beneficiaries consistent with our commitment to afford beneficiaries access to the prescription drugs they need.

PDP sponsors must offer throughout a PDP region a basic plan that consists of: Standard deductible and cost sharing amounts (or actuarial equivalents); an initial coverage limit based on a set dollar amount of claims paid on the beneficiary's behalf during the plan year; a coverage gap phase; and finally, catastrophic coverage that applies once a beneficiary's out-of-pocket expenditures for the year have reached a certain threshold. Prior to our adopting regulations requiring meaningful differences between each PDP sponsor's plan offerings in a PDP Region, our guidance allowed sponsors that offered a basic plan to offer additional basic plans in the same region, as long as they were actuarially equivalent to the basic plan structure described in the statute. These sponsors could also offer enhanced alternative plans that provide additional value to beneficiaries in the form of reduced deductibles, reduced copays, coverage of some or all drugs while the beneficiary is in the gap portion 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. As we have gained experience with the Part D program, we have made consistent efforts to ensure that the number and type of plan benefit packages PDP sponsors may market to beneficiaries are no more numerous than necessary to afford beneficiaries choices from among meaningfully different plan options. To that end, CMS sets differential out-of-pocket cost (OOPC) targets each year, using an analysis performed on the previous year's bid submissions, to ensure contracting organizations submit bids that clearly offer differences in value to beneficiaries. Published annually in the Call Letter, the threshold differentials are defined for a basic and enhanced plan, as well as for two enhanced plans, when offered by a parent organization in the same region.

For example, in CY 2018, a basic and enhanced plan are required at minimum to provide for a \$20 out-of-pocket difference, while two enhanced plans are required to have at least a \$30 differential. Over the years, the thresholds have ranged from \$18 to \$23 between basic and enhanced plans, and from \$12 to \$34 between two enhanced plans. We issued regulations in 2010, at § 423.265(b)(2), that established our authority to deny bids that are not meaningfully different from other bids submitted by the same organization in the same service area. Our application of this authority has eliminated PDP sponsors' ability to offer more than one basic plan in a PDP region since all basic plan benefit packages must be actuarially equivalent to the standard benefit structure discussed in the statute, and in guidance we have also limited to two the number of enhanced alternative plans that we approve for a single PDP sponsor in a PDP region. As part of the same 2010 rulemaking, we also established at § 423.507(b)(1)(iii) our authority to terminate existing plan benefit packages that do not attract a number of enrollees sufficient to demonstrate their value in the Medicare marketplace. Both of these authorities have been effective tools in encouraging the development of a variety of plan offerings that provide meaningful choices to beneficiaries.

We continue to be committed to maintaining benefit flexibility and efficiency throughout both the MA and Part D programs. We wish to continue the trend of using transparency, flexibility, program simplification, and innovation to transform the MA and Part D programs for Medicare enrollees to have options that fit their individual health needs. In our April 2017 Request for Information (RFI), we offered stakeholders the opportunity to submit their ideas on how to better accomplish these goals. In response to the RFI, we received two comments specific to the meaningful difference requirement for PDPs. One commenter urged us to eliminate meaningful difference requirements to allow market competition to determine the appropriate number and type of plan offerings. Alternatively, it was suggested that if the meaningful difference standard is retained, we should revise it to allow plans to be treated as meaningfully different based on differences in plan characteristics not previously considered by CMS. The commenter contends that the meaningful difference requirement, as currently applied, unfairly limits the number of plan offerings and

beneficiary choices. Specifically, it was argued that the meaningful difference test does not recognize premiums as elements constituting meaningful differences, despite this being an extremely important factor for beneficiaries in making enrollment decisions. Another commenter recommended that we lower the OOPC differentials between basic and enhanced PDP offerings but at a minimum, we should lower the OOPC differential between enhanced PDP offerings.

While we received relatively few comments related to meaningful difference in response to the RFI, we did receive a number of comments both in support of and opposing the proposed increase in the meaningful difference threshold between enhanced PDP offerings we announced in the Draft CY 2018 Call Letter. Those in favor of our proposal believe that the increase would help to ensure that sponsors are offering meaningfully different plans and would minimize beneficiary confusion. Commenters opposed to the proposal argued that the increase would lead to more expensive plans and would effectively limit plan choice. They argued that expanding OOPC differentials would ultimately create more beneficiary disruption as sponsors would have to consolidate plans that do not meet the new threshold. This result would directly contradict our request that plan sponsors consider options to minimize beneficiary disruption. Commenters suggested that we should utilize OOPC estimates as they were originally intended, to ensure that beneficiaries receive a minimum additional value from enhanced plans. They added that steady and reasonable OOPC thresholds will give beneficiaries more consistent benefits and lower premiums.

We appreciate the importance of ensuring adequate plan choice for beneficiaries and the value of multiple plan offerings with a diversity of benefits, now and in the future. We agree with the argument that two enhanced plans offered by a plan sponsor could vary with respect to their plan characteristics and benefit design, such that they might appeal to different subsets of Medicare enrollees, but in the end have similar out-of-pocket beneficiary costs. We continue to believe however that a meaningful difference, that takes into account out-of-pocket costs, be maintained between basic and enhanced plans to ensure that there is a meaningful value for beneficiaries given the supplemental Part D premium associated with the enhanced plans. Therefore, effective for

Contract Year (CY) 2019, we propose to revise the Part D regulations at § 423.265 (b)(2) to eliminate the PDP EA to EA meaningful difference requirement, while maintaining the requirement that enhanced plans be meaningfully different from the basic plan offered by a plan sponsor in a service area. We believe these proposed revisions will help us accomplish the balance we wish to strike with respect to encouraging competition and plan flexibilities while still providing PDP choices to beneficiaries that represent meaningful choices in benefit packages. Anticipated impacts to this change include: (1) A modest increase in the number of plans that would be offered by PDP sponsors (if the EA to EA meaningful difference requirement was the sole barrier to a PDP sponsor offering a second EA plan in a region) and (2) a potential decrease in the average supplemental Part D premium.

We also announce our future intent to reexamine, with the benefit of additional information, how we define the meaningful difference requirement between basic and enhanced plans offered by a PDP sponsor within a service area. We recognize that the current OOPC methodology is only one method for evaluating whether the differences between plan offerings are meaningful, and will investigate whether the current OOPC model or an alternative methodology should be used to evaluate meaningful differences between PDP offerings. While we intend to conduct our own analyses, we also seek stakeholder input on how to define meaningful difference as it applies to basic and enhanced Part D plans. CMS will continue to provide guidance for basic and enhanced plan offering requirements in the annual Call Letter.

Beneficiaries can continue to rely on the many resources CMS makes available, such as the Medicare Plan Finder (MPF), 1-800-MEDICARE and the Medicare and You Handbook, to assist them and their caregivers in making the best plan choices that meet their individual health needs. To the extent that CMS finds its elimination results in potential beneficiary confusion or harm, CMS will consider reinstating the meaningful difference requirement through future rule making or consider taking other action.

17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

a. Introduction

Part D sponsors and their contracted PBMs have been increasingly successful

in recent years at negotiating price concessions from pharmaceutical manufacturers, network pharmacies, and other such entities. Between 2010 and 2015, the amount of all forms of price concessions received by Part D sponsors and their PBMs increased nearly 24 percent per year, about twice as fast as total Part D gross drug costs, according to the cost and price concession data Part D sponsors submitted to CMS for payment purposes.

The data Part D sponsors submit to CMS as part of the annual required reporting of direct or indirect remuneration (DIR) show that manufacturer rebates, which comprise the largest share of all price concessions received, have accounted for much of this growth.⁴⁷ The data also show that manufacturer rebates have grown dramatically relative to total Part D gross drug costs each year since 2010. Rebate amounts are negotiated between manufacturers and sponsors or their PBMs, independent of CMS, and are often tied to the sponsor driving utilization toward a manufacturer's product through, for instance, favorable formulary tier placement and cost-sharing requirements.

The DIR data show similar trends for pharmacy price concessions. Pharmacy price concessions, net of all pharmacy incentive payments, have grown faster than any other category of DIR received by sponsors and PBMs and now buy down a larger share of total Part D gross drug costs than ever before. Such price concessions are negotiated between pharmacies and sponsors or their PBMs, again independent of CMS, and are often tied to the pharmacy's performance on various measures defined by the sponsor or its PBM.

When manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug. Moreover, given the increase in manufacturer rebates and pharmacy price concessions in recent years, the point-of-sale price of a drug that a Part D sponsor reports on a PDE record as the negotiated price is rendered less transparent at the individual prescription level and less

representative of the actual cost of the drug for the sponsor when it does not include such discounts. Finally, variation in the treatment of rebates and price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program, as explained later in this section.

At the time the Part D program was established, we believed, as discussed in the Part D final rule that appeared in the January 28, 2005 **Federal Register** (70 FR 4244), that market competition would encourage Part D sponsors to pass through to beneficiaries at the point of sale a high percentage of the manufacturer rebates and other price concessions they received, and that establishing a minimum threshold for the rebates to be applied at the point of sale would only serve to undercut these market forces. However, actual Part D program experience has not matched expectations in this regard. In recent years, only a handful of plans have passed through a small share of price concessions to beneficiaries at the point of sale. Instead, because of the advantages that accrue to sponsors in terms of premiums (also an advantage for beneficiaries), the shifting of costs, and plan revenues, from the way rebates and other price concessions applied as DIR at the end of the coverage year are treated under the Part D payment methodology, sponsors may have distorted incentives as compared to what we intended in 2005.

Therefore, in this request for information we discuss considerations related to and solicit comment on requiring sponsors to include at least a minimum percentage of manufacturer rebates and all pharmacy price concessions received for a covered Part D drug in the drug's negotiated price at the point of sale. Feedback received will be used for consideration in future rulemaking on this topic.

b. Background

Section 1860D-2(d)(1) of the Act requires that a Part D sponsor provide beneficiaries with access to negotiated prices for covered Part D drugs. Under our current regulations at § 423.100, the negotiated price is the price paid to the network pharmacy or other network dispensing provider for a covered Part D drug dispensed to a plan enrollee that is reported to CMS at the point of sale by the Part D sponsor. This point of sale price is used to calculate beneficiary cost-sharing. More broadly, the negotiated price is the primary basis by which the Part D benefit is adjudicated, and is used to determine plan, beneficiary, manufacturer (in the

⁴⁷ Sponsors report all DIR to CMS annually by category at the plan level. DIR categories include: Manufacturer rebates, administrative fees above fair market value, price concessions for administrative services, legal settlements affecting Part D drug costs, pharmacy price concessions, drug cost-related risk-sharing settlements, etc.

coverage gap), and government liability during the course of the payment year, subject to final reconciliation following the end of the coverage year.

Under current law, when not explicitly *required* to do so for certain types of pharmacy price concessions, Part D sponsors can *choose* whether to reflect various price concessions, including manufacturer rebates, they or their intermediaries receive in the negotiated price. Specifically, section 1860D-2(d)(1)(B) of the Act merely requires that negotiated prices “shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs” In other words, Part D sponsors are allowed, but generally not currently required, to apply rebates and other price concessions at the point of sale to lower the price upon which beneficiary cost-sharing is calculated. To date, sponsors have elected to include rebates and other price concessions in the negotiated price at the point-of-sale only very rarely. All rebates and other price concessions that are not included in the negotiated price must be reported to CMS as DIR at the end of the coverage year and are used in our calculation of final plan payments, which, under the statute, are required to be based on costs actually incurred by Part D sponsors, net of all applicable DIR.

(1) Premiums and Plan Revenues

The main benefit to a Part D beneficiary of price concessions applied as DIR at the end of the coverage year (and not to the negotiated price at the point of sale) comes in the form of a lower plan premium. A sponsor must factor into its plan bid an estimate of the DIR expected to be generated—that is, it must lower its estimate of plan liability by a share of the projected DIR—which has the effect of reducing the price of coverage under the plan. Under the current Part D benefit design, price concessions that are applied post-point-of-sale, as DIR, reduce plan liability, and thus premiums, more than price concessions applied at the point of sale. When price concessions are applied to reduce the negotiated price at the point of sale, some of the concession amount is apportioned to reduce beneficiary cost-sharing, as explained in this section, instead of plan and government liability; this is not the case when price concessions are applied post-point-of-sale, where the majority of the concession amount accrues to the plan, and the remainder accrues to the government. Therefore, to the extent that plan bids reflect accurate DIR

estimates, the rebates and other price concessions that Part D sponsors and their PBMs negotiate, but do not include in the negotiated price at the point of sale, put downward pressure on plan premiums, as well as the government’s subsidies of those premiums. The average Part D basic beneficiary premium has grown at an average rate of only about 1 percent per year between 2010 and 2015, and is projected to decline in 2018, due in part to sponsors’ projecting DIR growth to outpace the growth in projected gross drug costs each year. The average Medicare direct subsidy paid by the government to cover a share of the cost of coverage under a Part D plan has also declined, by an average of 8.1 percent per year between 2010 and 2015, partly for the same reason.

However, any DIR received that is above the projected amount factored into a plan’s bid contributes primarily to plan profits, not lower premiums. The risk-sharing construct established under Part D by statute allows sponsors to retain as plan profit the majority of all DIR that is above the bid-projected amount.⁴⁸ Our analysis of Part D plan payment and cost data indicates that in recent years, DIR amounts Part D sponsors and their PBMs actually received have consistently exceeded bid-projected amounts.

To capture the relative premium and other advantages that price concessions applied as DIR offer sponsors over lower point-of-sale prices, sponsors sometimes opt for higher negotiated prices in exchange for higher DIR and, in some cases, even prefer a higher net cost drug over a cheaper alternative. This may put upward pressure on Part D program costs and, as explained below, shift costs from the Part D sponsor to beneficiaries who utilize drugs in the form of higher cost-sharing and to the government through higher reinsurance and low-income cost-sharing subsidies.

(2) Cost-Shifting

When manufacturer rebates and other price concessions are not reflected in the negotiated price at the point of sale (that is, applied instead as DIR at the end of the coverage year), beneficiary cost-sharing, which is generally calculated as a percentage of the negotiated price, becomes larger, covering a larger share of the actual cost of a drug. Although this is especially true when a Part D drug is subject to coinsurance, it is also true when a drug

is subject to a copay because Part D rules require that the copay amount be at least actuarially equivalent to the coinsurance required under the defined standard benefit design. For many Part D beneficiaries who utilize drugs and thus incur cost-sharing expenses, this means, on average, higher overall out-of-pocket costs, even after accounting for the premium savings tied to higher DIR. For the millions of low-income beneficiaries whose out-of-pocket costs are subsidized by Medicare through the low income cost-sharing subsidy, those higher costs are borne by the government. This potential for cost-shifting grows increasingly pronounced as manufacturer rebates and pharmacy price concessions increase as a percentage of gross drug costs and continue to be applied outside of the negotiated price. Numerous research studies further suggest that the higher cost-sharing that results can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare.^{49 50 51} These effects of higher beneficiary cost-sharing under the current policies regarding the determination of negotiated prices must be weighed against the impact on beneficiary access to affordable drugs of the lower premiums that are currently charged for Part D coverage.

Moreover, beneficiaries progress through the four phases of the Part D benefit as their total gross drug costs and cost-sharing obligations increase. Because both of these values are calculated based on the negotiated prices reported at the point of sale, when manufacturer rebates and pharmacy price concessions are not applied at the point of sale, the higher negotiated prices that result move Part D beneficiaries more quickly through the Part D benefit. This, in turn, shifts more of the total drug spend into the catastrophic phase, where Medicare liability is highest (80 percent, paid as reinsurance) and plan liability, after the closing of the coverage gap, is lowest (15 percent). Part D program experience further suggests that sponsors are able to offset their already limited liability in the catastrophic phase by capturing additional rebates from manufacturers,

⁴⁹ Michele Heisler et al., “The Health Effects of Restricting Prescription Medication Use Because of Cost,” *Medical Care*, 626–634 (2004).

⁵⁰ Peter Bach, “Limits on Medicare’s Ability to Control Rising Spending on Cancer Drugs,” *The New England Journal of Medicine*, 360, 626–633 (2009).

⁵¹ Sonya Blesser Streeter et al., “Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions,” *Journal of Oncology Practice*, 7, no. 3S, 46S–51S (2011).

⁴⁸ Medicare shares risk with Part D sponsors on the drug costs for which they are liable using symmetrical risk corridors and through the payment of 80 percent reinsurance in the catastrophic phase of the benefit.

the largest share of which, under current Part D rules, as explained previously, are allocated to reduce plan liability. Consistent with this benefit, we note that sponsors have negotiated more high price-high rebate arrangements, especially in recent years, which has caused the proportion of costs for which the plan sponsor is at risk to shrink when those higher rebates are not passed on at the point of sale. Under current rules, therefore, Part D sponsors may have weak incentives, and, in some cases even, no incentive, to lower prices at the point of sale or to choose lower net cost alternatives to high cost-highly rebated drugs when available.

(3) Transparency and Differential Treatment

Given the significant growth in manufacturer rebates and pharmacy price concessions in recent years, when such amounts are not reflected in the negotiated price, at least to some degree, the true price of a drug to the plan is not available to consumers at the point of sale, nor is it reflected on the Medicare Prescription Drug Plan Finder (Plan Finder) tool. Consequently, consumers cannot efficiently minimize both their costs and costs to the taxpayers by seeking and finding the lowest-cost drug or the lowest-cost drug and pharmacy combination.

The quality of information available to consumers is even less conducive to producing efficient choices when rebates and other price concessions are treated differently by different Part D sponsors; that is, when they are applied to the point-of-sale price to differing degrees and/or estimated and factored into plan bids with varying degrees of accuracy. First, when some sponsors include price concessions in negotiated prices while others treat them as DIR, negotiated prices no longer have a consistent meaning across the Part D program, undermining meaningful price comparisons and efficient choices by consumers. Second, if a sponsor's bid is based on an estimate of net plan liability that is understated because the sponsor has been applying price concessions as DIR at the end of the coverage year rather than using them to reduce the negotiated price at the point of sale, it follows that the sponsor may be able to submit a lower bid than a competitor that applies price concessions at the point of sale or opts for lower net cost alternatives to high cost-highly rebated drugs when available. This lower bid results in a lower plan premium that must be paid by enrollees in the plan, which could allow the sponsor to capture additional market share. The resulting competitive advantage

accruing to one sponsor over another in this scenario stems only from a technical difference in how plan costs are reported to CMS. Therefore, the opportunity for differential treatment of rebates and price concessions could result in bids that are not comparable and in premiums that are not valid indicators of relative plan efficiency.

c. Manufacturer Rebates to the Point of Sale

We are soliciting comment from stakeholders on how we might most effectively design a policy requiring Part D sponsors to pass through at the point of sale a share of the manufacturer rebates they receive, in order to mitigate the effects of the DIR construct⁵² on costs to both beneficiaries and Medicare, competition, and efficiency under Part D. In this section, we put forth for consideration potential parameters for such a policy and seek detailed comments on their merits, as well as the merits of any alternatives that might better serve our goals of reducing beneficiary costs and better aligning incentives for Part D sponsors with the interests of beneficiaries and taxpayers. We specifically seek comment on how this issue could be addressed without increasing government costs and without reducing manufacturer payments under the coverage gap discount program. We encourage all commenters to provide quantitative analytical support for their ideas wherever possible.

Specifically, we are considering requiring, through future rulemaking, Part D sponsors to include in the negotiated price reported to CMS for a covered Part D drug a specified minimum percentage of the cost-weighted average of rebates provided by drug manufacturers for covered Part D drugs in the same therapeutic category or class. We will refer to the rebate amount that we would require be included in the negotiated price for a covered Part D drug as the "point-of-sale rebate." Under such a policy, sponsors could apply as DIR at the end of the coverage year only those manufacturer rebates received in excess of the total point-of-sale rebates. In the unlikely event that total manufacturer rebate dollars received for a drug are less than the total point-of-sale rebates, the difference would be reported at the end of the coverage year as negative DIR.

⁵² We use the term "DIR construct" to refer to how DIR is treated under current Part D payment rules and the advantages that accrue to Part D sponsors when they apply rebates and other price concessions as DIR at the end of the coverage year.

(1) Specified Minimum Percentage

We are considering setting the minimum percentage of manufacturer rebates that must be passed through at the point of sale at a point less than 100 percent of the applicable average rebate amount for drugs in the same drug category or class. For operational ease, we are considering setting the same minimum percentage, which we would specify in regulation, for all rebated drugs in all years—that is, the minimum percentage would not change by drug category or class or by year.

It is important to note that we are not considering requiring that 100 percent of rebates be applied at the point of sale. As explained earlier, the statutory definition of negotiated price in section 1860D-2(d)(1)(B) of the Act requires that "negotiated prices shall *take into account* negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . ." (emphasis added). We believe this language, particularly when read in the context of the requirement in section 1860D-2(d)(2) of the Act that Part D sponsors report the aggregate price concessions made available "by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers," contemplates that Part D sponsors have some flexibility in determining how to apply manufacturer rebates in order to reduce costs under the plan.

Furthermore, we are cognizant of the fact that while requiring that a higher share of rebates be included in the negotiated price would more meaningfully address the concerns highlighted earlier and lead to larger cost-sharing savings for *many* beneficiaries, doing so would also result in larger premium increases for *all* beneficiaries, as discussed in greater detail later in this section, and lower flexibility for Part D sponsors in regards to the treatment of manufacturer rebates, and thus, for some sponsors, weaker incentives to participate in the Part D program. We aim to set the minimum percentage of rebates that must be applied at the point of sale at a point that allows an appropriate balance between these outcomes and thus achieves the greatest possible increase in beneficiary access to affordable drugs.

We are soliciting comment on the minimum percentage of manufacturer rebates that should be reflected in the negotiated price in order to achieve this balance. We are also seeking comment on how and how often, if at all, that

minimum percentage should be updated by CMS, and what factors should be considered in making any such change. We request that commenters provide analytical justification for their ideas wherever possible. We also are seeking comment on the effect that specifying a minimum percentage of rebates that must be reflected in the negotiated price would have on the competition for rebates under Part D and the total rebate dollars received by Part D sponsors and PBMs.

(2) Applicable Average Rebate Amount

We are also particularly interested in stakeholder feedback regarding the following methodology to calculate the applicable average rebate amount, a specified minimum percentage of which would be required to be applied at the point of sale:

- *Rebate Year:* We are considering requiring that point-of-sale rebate amounts be based on average manufacturer rebates expected to be received for each drug category or class under the manufacturer rebate agreements for the current payment year, not historical rebate experience. To the extent that rebate agreements are structured with contingencies that would be unclear at the point of sale, sponsors would be required to base the point-of-sale rebate amount on a good faith estimate of the rebates expected to be received. We solicit comments on whether this approach would ensure that the price available to beneficiaries at the point of sale reflects the actual price of a drug at that time, or if an alternative approach would do so more effectively.

- *Rebated Drugs:* We are considering requiring that the average rebate amount be calculated using only drugs for which manufacturers provide rebates. We believe including non-rebated drugs in this calculation would serve only to drive down the average manufacturer rebates, which would dampen the intended effects of any change.

Additionally, we would likely consider each drug product with a unique 11-digit national drug code (NDC) separately for purposes of calculating the average rebate amount. PDE and rebate data submitted to CMS show that gross drug costs and rebate rates under a plan can vary even for the same drugs produced by the same manufacturer that are packaged differently and thus have different NDC-11 identifiers. Therefore, we believe that the average rebate amounts are more likely to be accurate when calculated based on the gross drug cost and rebate data at the 11-digit NDC level. We solicit comment on whether

specifying such a requirement would also serve to ensure consistency in how average rebates are calculated across sponsors, which would make prices more comparable across Part D plans and enforcement easier.

- *Plan-Level Average:* We are considering requiring that average rebate amounts be calculated separately for each plan (that is, calculated at the plan-benefit-package level). In other words, the same average rebate amount would not apply to the point-of-sale price for a covered drug across all plans under one contract, nor across all contracts under one sponsor. We believe this approach would result in the calculation of more accurate average rebates because the PDE and rebate data that are submitted by sponsors demonstrate that gross drug costs and rebate levels are not the same across all plans under one contract, nor across all contracts under one sponsor. This approach would also largely be consistent with how sponsors develop cost estimates for their Part D bids because benefit designs, including formulary structure, and assumptions about enrollee characteristics and utilization vary by plan, even for multiple plans under one contract. Similarly, final payments are calculated by CMS at the plan level, based on the data submitted by the sponsor. We solicit comment on whether the most appropriate approach for calculating the average rebate amount for point-of-sale application would be to do so at the plan level, using plan-specific information, given that moving a portion of manufacturer rebates to the point of sale would impact plan liability and payments, or if another approach would be more appropriate.

- *Drug Category or Class:* We are considering requiring that the manufacturer rebate amount applied to the point-of-sale price for a covered drug be based on the plan's average rebate amount calculated for the rebated drugs in the same category or class. We are considering requiring sponsors to determine the average rebate amount at the therapeutic category or class level, rather than a drug-specific rebate amount, in order to maintain the confidentiality of any manufacturer-sponsor/PBM pricing relationship with respect to an individual drug. Given that rebate rates are typically negotiated at the individual drug level, we believe that the drug category/class-average approach we are considering would help maintain fair competition among drug manufacturers, as well as Part D sponsors, by preventing competitors from reverse engineering the particulars of any proprietary pricing arrangement.

This approach would also increase price transparency over the status quo, especially at the drug category or class level, and improve market competition and efficiency under Part D as a result. In addition to feedback on this general approach and our rationale for it, we are seeking comment, in particular, on the drug classification system that Part D sponsors should be required to use to calculate their drug category/class-level average rebate amounts and why that system would be most appropriate for use in such a point-of-sale rebate policy. We also are seeking comment on the effect of calculating average rebates at the drug category/class level on competition and, in turn, on the total rebate dollars received.

We are also particularly interested in comments on how an average rebate amount should be calculated for a drug that is the only rebated drug in its drug category or class. An alternative approach would be necessary in this case because the average rebate amount calculated under the general approach we have described above would equal the drug-specific rebate amount, which, if included in the negotiated price, could result in the release of proprietary pricing information. We ask that commenters explain how any alternative they suggest for the only rebated drug scenario would address this concern and comment on the level of price transparency that would be achieved under the suggested alternative.

- *Weighting:* We are considering requiring that when calculating the applicable average rebate amount for a particular drug category, the manufacturer rebate amount for each individual drug in that category be weighted by the total gross drug costs incurred for that drug, under the plan, over the most recent month, quarter, year, or another time period to be specified in future rulemaking for which cost data is available. We believe a weighted average is more accurate than a simple average because sponsors do not receive the same level of rebates for all drugs in a particular drug category or class, and thus, contrary to the assumption underlying a simple average, not all drugs contribute equally to the final average rebate percentage for a drug category or class received by the sponsor under a plan at the end of a payment year. A gross drug cost-weighted average ensures that drugs with higher utilization, higher costs, or both will be more important to the final average rebate rate realized for the drug category or class than lower utilization, lower cost, or lower cost-lower utilization drugs in the category or class.

In the case of a drug with less time on the market than the time period for which cost data would be required under this weighting approach or of a plan that has not been active in the Part D program for the time period required under the weighting approach, we are considering requiring that the drug's rebate amount be weighted by a sponsor's projection of total gross drug costs for the plan that takes into account any plan-specific cost experience already available. If no plan-specific cost experience is available when calculating average rebate amounts, such as at the beginning of a payment year for a new plan, are considering requiring sponsors to use the same drug cost projections on which they base their Part D bids. Further, for operational ease, it appears the manufacturer rebates used in the calculation of the average rebate amount would need to include all manufacturer rebates received for the drug, including all point-of-sale rebates. Then, in order not to double count the point-of-sale rebates, the total gross drug costs used to weight the average under this methodology would have to be based on the drug's price at the point of sale before it is lowered by any manufacturer rebates or other price concessions applied at the point of sale. We are interested in stakeholder feedback on these considerations.

For an illustration of how the weighted-average rebate amount for a particular drug category or class would be calculated, see the point-of-sale rebate example later in this section.

- *Timing:* We are considering requiring Part D sponsors to recalculate the applicable average rebate amount every month, quarter, year, or another time period to be specified in future rulemaking, in order to ensure that the average reflects current cost experience and manufacturer rebate information. We believe that a requirement to recalculate the average rebate amount should balance the need to sustain a level of price transparency throughout the entire year with the additional burden on sponsors associated with more frequent updates. We are seeking comment on how often the applicable cost-weighted drug category/class-average rebate amount, and thus the point-of-sale rebate for any drug, should be recalculated.

(3) Point-of-Sale Rebate Drugs

We are considering limiting the application of any point-of-sale rebate requirement to only rebated drugs. Under this approach, the calculated average rebate amount would only be required to be applied to the point-of-

sale prices for drugs that are rebated, with each drug identified by its unique NDC-11 identifier. The alternative would result in a manufacturer that provides no rebates for a particular drug benefiting from a direct competitor's rebate, as the competitor's rebate would be used to lower the negotiated price and thereby potentially increasing sales of the non-rebated drug. However, to be clear, under this potential approach, sponsors would maintain their flexibility to include in the negotiated price for any drug, including a non-rebated drug, manufacturer rebates and other price concessions above those required to be included in the negotiated price for rebated drugs under a point-of-sale rebate policy such as the one we describe here.

Moreover, in order to limit the impact on premiums for all beneficiaries of adopting a requirement that sponsors include a portion of manufacturer rebates in the negotiated price at the point of sale, we are also seeking comment on the merits or limitations of, a more targeted version of the policy approach that would require sponsors to pass through a minimum percentage of rebates at the point of sale only for specific drugs or drug categories or classes. Under this alternative approach, the point-of-sale rebate policy would apply only for drugs or drug categories or classes that most directly contribute to increasing Part D drug costs in the catastrophic phase of coverage or drugs with high price-high rebate arrangements; such drugs or drug categories or classes are likely to have the most significant impact on beneficiary costs and serve to increase program costs overall, as discussed previously. We are interested in stakeholder feedback on whether targeting the rebate requirement in such a way would effectively address the misaligned sponsor incentives and market inefficiencies that exist under Part D today as a result of the DIR construct. In addition to general comments on the alternative, more targeted policy approach, we are particularly interested in recommendations for the criteria that we might use to determine which drugs or drug categories or classes to target under such an alternative approach.

(4) Point-of-Sale Rebate Example

To illustrate how the weighted-average rebate amount for a particular drug class would be calculated under a point-of-sale rebate requirement that includes the features described earlier, we provide the following example: suppose drugs A, B, and C are the only three rebated drugs on the plan's

formulary in a particular drug class. The negotiated prices, before application of the point-of-sale rebates, for the three drugs in the current time period are \$200, \$100, and \$75, respectively. The manufacturer rebates expected by the plan in this payment year, given the information available in the current period, for drugs A, B, and C equal 20, 10, and 5 percent, respectively, of the drugs' pre-rebate negotiated prices. Over the previous time period, total gross drug costs incurred under the plan for drug A equaled \$2 million, for drug B equaled \$750,000, and for drug C equaled \$150,000. Therefore, the gross drug cost-weighted average rebate rate for this drug class in the current time period is calculated as the following: $[(\$2 \text{ million} \times 20 \text{ percent}) + (\$750,000 \times 10 \text{ percent}) + (\$150,000 \times 5 \text{ percent})] / (\$2 \text{ million} + \$750,000 + \$150,000)$, or 16.64 percent. If we were to require that a minimum 50 percent of the average rebate be applied at the point of sale for all rebated drugs in this drug class (and the plan only applies the minimum required percentage), the final negotiated prices for drugs A, B, and C, now equal to \$183.36, \$91.68, and \$68.76, respectively, would be 8.32 percent (50 percent of 16.64 percent) lower than the pre-rebated prices.

For each of the three drugs in this example, beneficiary out-of-pocket costs would be lower under the approach we are considering than under the status quo. Assuming, for instance, these drugs are subject to a 25 percent coinsurance, the enrollee's costs for the three drugs under this approach would be \$45.84 (25 percent of \$183.36) for drug A, \$22.92 (25 percent of \$91.68) for drug B, and \$17.19 (25 percent of \$68.76) for drug C. Under the status quo, the enrollee's costs would be \$50 for drug A (\$4.16 higher), \$25 for drug B (\$2.08 higher), and \$18.75 for drug C (\$1.56 higher).

Any difference between the rebates applied at the point of sale and those actually received would be captured as DIR through reporting at the end of the coverage year. Assume, for instance, that total gross drug costs for drugs A, B, and C equal \$1.5 million, \$1 million, and \$200,000, respectively, in this period. The actual manufacturer rebates received, therefore, will equal \$300,000, \$100,000, and \$10,000, respectively, for drugs A, B, and C in this period, based on the plan's expected rebate rates of 20, 10, and 5 percent, respectively, for the three drugs in this payment year. Based on the point-of-sale rebate rate calculated above for the applicable drug class and the total gross drug cost assumptions provided for the three drugs, we calculate the total point-of-

sale rebates in this period to be \$124,786.48 (8.32 percent of \$1.5 million) for drug A, \$83,189.66 (8.32 percent of \$1 million) for drug B, and \$16,637.93 (8.32 percent of \$200,000) for drug C. Therefore, the manufacturer rebates applied by the plan as DIR at the end of the coverage year for the three drugs, respectively, would be \$175,215.52, \$16,810.34, and -\$6,637.93 and total \$185,387.93 across the drug class.

(5) Additional Considerations

Under the policy approach that we are considering here for moving manufacturer rebates to the point of sale, the responsibility for calculating the appropriate point-of-sale rebate amount over the course of the year would fall on Part D sponsors given their role in administering the Medicare drug benefit. We would leverage existing reporting mechanisms to review the sponsors' calculations, as we do with other cost data required to be reported. Specifically, we would likely use the estimated rebates at point-of-sale field on the PDE record to collect point-of-sale rebate information, and the manufacturer rebates fields on the Summary and Detailed DIR Reports to collect final manufacturer rebate information at the plan and NDC levels. Differences between the manufacturer rebate amounts applied at the point of sale and rebates actually received would become apparent when comparing the data collected through those means at the end of the coverage year.

Additionally, we note that in accordance with § 423.505(k) of the Part D regulations, a Part D sponsor is required to certify the accuracy, completeness, and truthfulness of all data related to payment, including the PDE data and information on allowable costs that it submits for purposes of risk corridor and reinsurance payment. A Part D sponsor certifies its Part D cost data by signing and submitting attestations to CMS. By signing the attestations, the Part D sponsor certifies (based on best knowledge, information, and belief) that the PDE data, DIR data, and any other information provided for the purposes of determining payment to the plan for the applicable contract year are accurate, complete, and truthful. If we were to move forward with a point-of-sale rebate policy, we would also consider amending § 423.505(k) to add a new requirement that the CEO, CFO, or COO attest (based on best knowledge, information, and belief) to the accuracy, completeness, and truthfulness of the average rebate amount included in the negotiated price and reported on the PDE. The submission of accurate,

complete, and truthful data regarding the average rebate amount included in the negotiated price would be necessary to ensure accurate reinsurance and risk corridor payments.

Under the approach we are considering, if a Part D sponsor discovers errors after the certification has been made (that is, after the attestation has been signed), the Part D sponsor would submit corrected PDE data, and, under most circumstances, CMS would reconcile the error through the reopening process described at § 423.346. All reopenings are at the discretion of CMS. CMS performs a global reopening approximately 4 years after the initial reconciliation for that contract year. A Part D sponsor's reopening request resulting from errors in PDE data discovered after the global reopening for the contract year in which the error occurred would be evaluated by CMS on a case by case basis. Any errors in the calculation of the average rebate amount that result in overpayments would be required to be reported and returned consistent with § 423.360 and the applicable subregulatory guidance on overpayments.

We note that prior to the submission of the attestation, and more specifically, prior to the PDE submission deadline for the initial reconciliation for a contract year, if a Part D sponsor discovers an issue with the average rebate amount included in the negotiated price and reported on the PDE, all affected PDEs would need to be adjusted or deleted in accordance with applicable CMS guidance. As of the publication of this request for information, the applicable guidance is October 6, 2011 CMS memorandum, *Revision to Previous Guidance Titled "Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs."*

We encourage stakeholders to comment on what other enforcement and oversight mechanisms should be instituted to ensure compliance with any potential point-of-sale rebate requirement. We are particularly interested in stakeholder feedback on how we might ensure accurate rebate amounts are applied at the point of sale when rebate agreements are structured with contingencies that would be unclear at the point of sale.

We also seek stakeholder comment on what, if any, special considerations should be taken into account in the design of a point-of-sale rebate policy, for Part D employer group waiver plans (EGWPs). We are also interested in feedback on what particular effects requiring Part D sponsors to apply some

manufacturer rebates at the point of sale would have on the EGWP market, as well as on how such a requirement might impact the retiree drug subsidy program.

Finally, we note that the negotiated price is also the basis by which manufacturer liability for discounts in the coverage gap is determined. Under section 1860D-14A(g)(6) of the Act, the negotiated price used for coverage gap discounts is based on the definition of negotiated price in the version of § 423.100 that was in effect as of the passage of the Patient Protection and Affordable Care Act (PPACA). Under this definition, the negotiated price is "reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor *has elected to pass through* to Part D enrollees at the point of sale" (emphasis added). Because this definition of negotiated price only references the price concessions that the Part D sponsor has elected to pass through at the point of sale, we are uncertain as to whether we would have the authority to require sponsors include in the negotiated price the weighted-average rebate amounts that would be required to be passed through under any potential point-of-sale rebate policy, for purposes of determining manufacturer coverage gap discounts. We intend to consider this issue further and will address it in any future rulemaking regarding the requirements for determining the negotiated price that is available at the point of sale.

(6) Impacts of Applying Manufacturer Rebates at the Point of Sale

Under a point-of-sale rebate policy designed as we have described in this comment solicitation, beneficiaries would see lower prices at the pharmacy point-of-sale, and on Plan Finder, beginning immediately in the year the policy takes effect. Lower point-of-sale prices would result directly in lower cost-sharing costs for non-low income beneficiaries, especially for those who use drugs in highly competitive, highly-rebated categories or classes. For low income beneficiaries whose out-of-pocket costs are subsidized through Medicare's low-income cost-sharing subsidy, cost-sharing savings resulting from lower point-of-sale prices would accrue to the government. Plan premiums would likely increase as a result of such a point-of-sale rebate policy—if some rebates are required to be passed through to beneficiaries at the point of sale, fewer such concessions could be apportioned to reduce plan liability, which would have the effect of

increasing the cost of coverage under the plan. At the same time, the reduction in cost-sharing obligations for the average beneficiary would likely be large enough to lower their overall out-of-pocket costs. The increasing cost of coverage under Part D plans as a result of rebates being applied at the point of sale likely would have a more significant impact on government costs, which would increase overall due to the significant growth in Medicare's direct subsidies of plan premiums and low income premium subsidies.

Partially offsetting the increase in direct subsidy and low income premium subsidy costs for the government would be decreases in Medicare's reinsurance and low income cost-sharing subsidies. Decreases in Medicare's reinsurance subsidy result when lower negotiated prices slow down the progression of beneficiaries through the Part D benefit and into the catastrophic phase, and when the government's 80 percent reinsurance payments for allowable drug costs incurred in the catastrophic phase are based on lower negotiated prices. Similarly, low income cost-

sharing subsidies would decrease if beneficiary cost-sharing obligations decline due to the reduction in prices at the point of sale. Finally, the slower progression of beneficiaries through the Part D benefit would also have the effect of reducing manufacturer gap discount payments as fewer beneficiaries would enter the coverage gap phase or progress entirely through it.

The following tables summarize the 10-year impacts we have modeled for when 33, 66, 90, and 100 percent of all manufacturer rebates are applied at the point of sale:⁵³

TABLE 10A—TOTAL IMPACTS FOR 2019 THROUGH 2028

[In \$billions]

	33%	66%	90%	100%
Beneficiary Costs	-\$19.6	-\$39.1	-\$53.2	-\$56.9
Cost-Sharing	-28.8	-57.8	-78.9	-85.2
Premium	9.2	18.7	25.7	28.3
Government Costs	27.3	55.1	75.5	82.1
Direct Subsidy	62.8	128.1	177.4	200.0
Reinsurance	-21.7	-44.7	-62.2	-73.1
LI Cost-Sharing Subsidy	-16.6	-34.2	-47.7	-53.7
LI Premium Subsidy	2.9	5.9	8.1	8.9
Manufacturer Gap Discount	-9.7	-19.4	-26.4	-29.4

TABLE 10B—2019–2028 PER MEMBER-PER MONTH IMPACTS

	33%	66%	90%	100%
Beneficiary Costs	-\$30.33	-\$60.58	-\$82.42	-\$88.13
Cost-Sharing	-44.61	-89.50	-122.26	-131.97
Premium	14.29	28.92	39.83	43.84
Government Costs	42.38	85.40	117.01	127.22
Direct Subsidy	97.45	198.93	275.43	310.58
Reinsurance	-33.76	-69.57	-96.84	-113.75
LI Cost-Sharing Subsidy	-25.80	-53.06	-74.11	-83.42
LI Premium Subsidy	4.49	9.10	12.53	13.81
Manufacturer Gap Discount	-15.01	-30.02	-40.93	-45.48

TABLE 10C—2019–2028 IMPACTS—PERCENT CHANGE

	33%	66%	90%	100%
Beneficiary Costs	-3	-5	-7	-8
Cost-Sharing	-6	-12	-16	-17
Premium	4	7	10	11
Government Costs	2	4	5	6
Direct Subsidy	24	49	67	76
Reinsurance	-3	-7	-9	-11
LI Cost-Sharing Subsidy	-4	-9	-12	-14
LI Premium Subsidy	4	8	11	12
Manufacturer Gap Discount	-7	-13	-18	-20

While we did not account for behavioral changes when modeling these impacts, requiring rebates to be applied at the point of sale might induce changes in sponsor behavior related to

drug pricing that would further reduce the cost of the Part D program for beneficiaries and taxpayers. Specifically, requiring that at least a minimum percentage of manufacturer

rebates be used to lower the price at the point of sale could limit the potential for sponsors to leverage the benefits that accrue to them when price concessions are applied as DIR at the end of the

⁵³ Assumptions: (1) For purposes of calculating impacts only, we assume that total rebates will equal about 20 percent of allowable Part D drug costs projected for each year modeled, and that

rebates are perfectly substituted with the point-of-sale discount in all phases of the Part D benefit, including the coverage gap phase.

(2) Used 2016 distribution of costs by benefit phase to form assumptions.

(3) Assumed no other behavioral changes by sponsors, beneficiaries, or others.

coverage year rather than as discounts at the point of sale, and thus potentially better align sponsors' incentives with those of beneficiaries and taxpayers. For example, we believe such an approach could reduce the incentive for sponsors to favor high cost-highly rebated drugs to lower net cost alternatives, when such alternatives are available, and also potentially increase the incentive for sponsors and PBMs to negotiate lower prices at the point of sale instead of higher DIR. We seek comment on the extent to which a point-of-sale rebate policy might be expected to further align the incentives for beneficiaries, sponsors, and taxpayers.

Finally, we believe requiring that some manufacturer rebates be applied at the point of sale as we are considering doing would improve price transparency and limit the opportunity for differential reporting of costs and price concessions, which may have a positive effect on market competition and efficiency. We solicit comment on whether basing the rebate applied at the point of sale on average rebates at the drug category/class level, as described previously, would meaningfully increase price transparency over the status quo by ensuring a consistent percentage of the rebates received are reflected in the price at the point of sale, while also protecting the details of any manufacturer-sponsor pricing relationship.

d. Pharmacy Price Concessions to Point of Sale

In recent years, a growing proportion of Part D sponsors and their contracted PBMs have entered into payment arrangements with Part D network pharmacies in which a pharmacy's reimbursement for a covered Part D drug is adjusted after the point of sale based on the pharmacy's performance on various measures defined by the sponsor or its PBM. Furthermore, we understand that the share of pharmacies' reimbursements that is contingent upon their performance under such arrangements has also grown steadily each year. As a result, sponsors and PBMs have been recouping increasing sums from network pharmacies after the point of sale (*pharmacy price concessions*) for "poor performance" relative to standards defined by the sponsor or PBM. These sums are far greater than those paid to network pharmacies after the point of sale (*pharmacy incentive payments*) for "high performance." We refer to pharmacy price concessions and incentive payments collectively as *pharmacy payment adjustments*. These findings are largely based on the

aggregate pharmacy payment adjustment data submitted to CMS by Part D sponsors as part of the annual required reporting of DIR, which show that performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased most dramatically after 2012.

In order to address the effects of the DIR construct, as it relates to pharmacy payment adjustments, on cost, competition, and efficiency under Part D, in the Part C and Part D final rule that appeared in the May 23, 2014 **Federal Register** (79 FR 29844), we amended the definition of "negotiated prices" at § 423.100 to require Part D sponsors to include in the negotiated price at the point of sale all pharmacy price concessions and incentive payments to pharmacies, with an exception, which was intended to be narrow, allowed for contingent pharmacy payment adjustments that cannot reasonably be determined at the point of sale (the *reasonably determined exception*). However, when we formulated these requirements in 2014, the most recent year for which DIR data was available was 2012 and we did not anticipate the growth of performance-based pharmacy payment arrangements that we have observed in subsequent years. We now understand that the reasonably determined exception we currently allow applies more broadly than we had initially envisioned because of the shift by Part D sponsors and their PBMs towards these types of contingent pharmacy payment arrangements, and, as a result, this exception prevents the current policy from having the intended effect on price transparency, consistency, and beneficiary costs.

Specifically, we have heard from several stakeholders that have suggested that the reasonably determined exception applies to all performance-based pharmacy payment adjustments. The amount of these adjustments, by definition, is contingent upon performance measured over a period that extends beyond the point of sale and, thus, cannot be known *in full* at the point of sale. Therefore, performance-based pharmacy payment adjustments cannot "reasonably be determined" at the point of sale as they cannot be known in full at the point of sale. We initially proposed, in a September 29, 2014 memorandum entitled *Direct and Indirect Remuneration (DIR) and Pharmacy Price Concessions*, that if the amount of the post-point of sale pharmacy payment adjustment could be reasonably approximated at the point of sale, the adjustment should be reflected in the negotiated price, even if the actual amount of the payment

adjustment was subject to later reconciliation and thus not known in full at the point of sale. However, we did not finalize that interpretation because we determined that it was inconsistent with the existing regulation given that it would have effectively eliminated the reasonably determined exception from inclusion in the negotiated price for all pharmacy price concessions, as we stated in our follow-up memorandum of the same name released on November 5, 2014.

Given the predominance of performance-contingent pharmacy payment arrangements, we do not believe that the existing requirement that pharmacy price concessions be included in the negotiated price can be implemented in a manner that achieves meaningful price transparency, ensures that all pharmacy payment adjustments are taken into account consistently by all Part D sponsors, and prevents the shifting of costs onto beneficiaries and taxpayers. Therefore, we are soliciting comment from stakeholders on how we might update the requirements governing the determination of negotiated prices, to better reflect current pharmacy payment arrangements, so as to ensure that the reported price at the point of sale includes all pharmacy price concessions. In this section, we put forth for consideration one potential approach for doing so and seek comments on its merits, as well as the merits of any alternatives that might better serve our goals of reducing beneficiary costs and better aligning incentives for Part D sponsors with the interests of beneficiaries and taxpayers. We encourage all commenters to provide quantitative analytical support for their ideas wherever possible.

(1) All Pharmacy Price Concessions

We are considering revising the definition of negotiated price at § 423.100 to remove the *reasonably determined* exception and to require that all price concessions from pharmacies be reflected in the negotiated price that is made available at the point of sale and reported to CMS on a PDE record, even when such concessions are contingent upon performance by the pharmacy. We believe we have the discretion to require that all pharmacy price concessions be applied at the point of sale, and not just a share of the amounts as we discussed earlier for manufacturer rebates. Such a requirement would preserve the flexibilities provided under section 1860D-2(d)(1)(B) of the Act with respect to the treatment of manufacturer rebates, while also allowing for greater

transparency and consistency in the reporting of pharmacy price concessions. First, section 1860D–2(d)(2) of the Act, which provides the context critical to our interpretation that sponsors are granted flexibility in how to apply manufacturer rebates, does not contemplate price concessions from sources other than manufacturers, such as pharmacies, being passed through in various ways. Second, even when all price concessions from pharmacies are required to be applied at the point of sale, sponsors would retain the flexibility to determine how to apply manufacturer rebates and other price concessions received from sources other than pharmacies in order to reduce costs under the plan. Finally, we believe that requiring that all pharmacy price concessions be applied at the point of sale would ensure that negotiated prices “take into account” at least some price concessions and, therefore, would be consistent with the plain language of section 1860D–2(d)(1)(B) of the Act. We are considering requiring all, and not only a share of, pharmacy price concessions be included in the negotiated price in order to maximize the level of price transparency and consistency in the determination of negotiated prices and bids and meaningfully reduce the shifting of costs from sponsors to beneficiaries and taxpayers.

(2) Lowest Possible Reimbursement

In order to effectively capture all pharmacy price concessions at the point of sale consistently across sponsors, we are considering requiring the negotiated price to reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug. Under this approach, the price reported at the point of sale would need to include all price concessions that could potentially flow *from* network pharmacies, as well as any dispensing fees, but exclude any additional contingent amounts that could flow *to* network pharmacies and increase prices over the lowest reimbursement level, such as incentive fees. That is, if a performance-based payment arrangement exists between a sponsor and a network pharmacy, the point-of-sale price of a drug reported to CMS would need to equal the final reimbursement that the network pharmacy would receive for that prescription under the arrangement if the pharmacy’s performance score were the lowest possible. If a pharmacy is ultimately paid an amount above the lowest possible contingent incentive reimbursement (such as in situations

where a pharmacy’s performance under a performance-based arrangement triggers a bonus payment or a smaller penalty than that assessed for the lowest level of performance), the difference between the negotiated price reported to CMS on the PDE record and the final payment to the pharmacy would need to be reported as negative DIR. For an illustration of how negotiated prices would be reported under such an approach, see the example provided later in this section.

We are interested in public comment on whether requiring the negotiated price at the point of sale to reflect the lowest possible pharmacy reimbursement would effectively address recent developments in industry practices, that is, the growing prevalence of performance-based pharmacy payment arrangements, and ensure that all pharmacy price concessions are included in the negotiated price, and thus shared with beneficiaries, in a consistent manner by all Part D sponsors. By requiring that sponsors assume the lowest possible pharmacy performance when reporting the negotiated price, we would be prescribing a standardized way for Part D sponsors to treat the unknown (final pharmacy performance) at the point of sale under a performance-based payment arrangement, which many Part D sponsors and PBMs have identified as the most substantial operational barrier to including such concessions at the point of sale. We are also interested in public comment on whether requiring the negotiated price to be the lowest possible pharmacy reimbursement would serve to maximize the cost-sharing savings accruing to beneficiaries by passing through all potential pharmacy price concessions at the point of sale.

Further, we are interested in public comment on whether this approach would be clearer for Part D sponsors to follow than the requirements in place today, which require Part D sponsors to assess which types of pharmacy payment adjustments fall under the reasonably determined exception. We are interested in public comment on whether providing such additional clarity and thus limiting the need for interpretation of the requirements by Part D sponsors would improve consistency in the application of the requirements regarding pharmacy price concessions across sponsors, as well as reducing sponsor burden in terms of the resources necessary to ensure compliance in the absence of clear guidance. In addition, we welcome feedback on whether the change we describe here would improve the quality

of pricing information available across Part D plans and thus improve market competition and cost-efficiency under Part D.

Requiring the negotiated price to reflect the lowest possible pharmacy reimbursement, would move the negotiated price closer to the final reimbursement for most network pharmacies under current pharmacy payment arrangements and thus closer to the actual cost of the drug for the Part D sponsor. We are interested in public comment on whether such an outcome would help us to achieve meaningful price transparency. We have learned from the DIR data reported to CMS and feedback from numerous stakeholders that pharmacies rarely receive an incentive payment above the original reimbursement rate for a covered claim. We gather that performance under most arrangements dictates only the magnitude of the amount by which the original reimbursement is reduced, and most pharmacies do not achieve performance scores high enough to qualify for a substantial, if any, reduction in penalties. Therefore, we seek comment on whether a requirement that the negotiated price reflect the lowest possible reimbursement to a network pharmacy, including all potential pharmacy price concessions, is likely to capture the actual price of the drug at a network pharmacy, or at least move closer to it.

Finally, we are considering requiring that all contingent incentive payments be excluded from the negotiated price because including the actual amount of any contingent incentive payments to pharmacies in the negotiated price would make drug prices appear higher at a “high performing” pharmacy, which receives an incentive payment, than at a “poor performing” pharmacy, which is assessed a penalty. This pricing differential could potentially create a perverse incentive for beneficiaries to choose a lower performing pharmacy for the advantage of a lower price. We seek comment on whether such an approach would prevent this unintended consequence and thus avoid reducing the competitiveness of high performing pharmacies by increasing the negotiated price charged to the beneficiary at those pharmacies.

(3) Lowest Possible Reimbursement Example

To illustrate how Part D sponsors and their intermediaries would report costs under the approach we are considering, we provide the following example: Suppose that under a performance-based payment arrangement between a

Part D sponsor and its network pharmacy, the sponsor will: (1) Recoup 5 percent of its total Part D-related payments to the pharmacy at the end of the contract year for the pharmacy's failure to meet performance standards; (2) recoup no payments for average performance; or (3) provide a bonus equal to 1 percent of total payments to the pharmacy for high performance. For a drug that the sponsor has agreed to pay the pharmacy \$100 at the point of sale, the pharmacy's final reimbursement under this arrangement would be: (1) \$95 for poor performance; (2) \$100 for average performance; or (3) \$101 for high performance. However, under all performance scenarios, the negotiated price reported to CMS on the PDE at the point of sale for this drug would be \$95, or the lowest reimbursement possible under the arrangement. Thus, if a plan enrollee were required to pay 25 percent coinsurance for this drug, then the enrollee's costs under all scenarios would be 25 percent of \$95, or \$23.75, which is less than the \$25 the enrollee would pay today (when the negotiated price is likely to be reported as \$100). Any difference between the reported negotiated price and the pharmacy's final reimbursement for this drug would be reported as DIR at the end of the coverage year. The sponsor would report \$0 as DIR under the poor performance scenario (\$95 minus \$95), – \$5 as DIR under the average

performance scenario (\$95 minus \$100), and – \$6 as DIR under the high performance scenario (\$95 minus \$101), for every covered claim for this drug purchased at this pharmacy.

(4) Additional Considerations

As with the policy approach that we described previously for moving manufacturer rebates to the point of sale, we would leverage existing reporting mechanisms to confirm that sponsors are appropriately applying pharmacy price concessions at the point of sale, as we do with other cost data required to be reported. Specifically, we would likely use the estimated rebates at point-of-sale field on the PDE record to also collect point-of-sale pharmacy price concessions information, and fields on the Summary and Detailed DIR Reports to collect final pharmacy price concession information at the plan and NDC levels. Differences between the amounts applied at the point of sale and amounts actually received, therefore, would become apparent when comparing the data collected through those means at the end of the coverage year.

Finally, as noted previously, the negotiated price is also the basis by which manufacturer liability for discounts in the coverage gap determined. Under section 1860D–14A(g)(6) of the Act, the definition of negotiated price used for coverage gap discounts is based on the regulatory definition of the negotiated price in the

version of § 423.100 that was in effect as of the passage of the PPACA. As discussed previously, this definition of negotiated price only references the price concessions that the Part D sponsor has elected to pass through at the point of sale. As such, we are uncertain as to whether we would have the authority to require sponsors include pharmacy price concessions in the negotiated price for purposes of determining manufacturer coverage gap discounts. We intend to consider this issue further and will address it in any future rulemaking regarding the requirements for determining the negotiated price that is available at the point of sale.

(5) Impacts for Applying Pharmacy Price Concessions at the Point of Sale

Requiring that all pharmacy price concessions that sponsors and PBMs receive be used to lower the price at the point of sale, as we described earlier, would affect beneficiary, government, and manufacturer costs largely in the same manner as discussed previously in regards to moving manufacturer rebates to the point of sale. The difference is in the magnitude of the impacts given that sponsors and PBMs receive significantly higher sums of manufacturer rebates than of pharmacy price concessions. The following table summarizes the 10-year impacts we have modeled for moving all pharmacy price concessions to the point of sale:⁵⁴

TABLE 11—2019–2028 POINT-OF-SALE PHARMACY PRICE CONCESSIONS IMPACTS

	Total (billions)	Per member-per month	Percent change
Beneficiary Costs	–\$10.4	–\$16.09	–1
Cost-Sharing	–16.1	–24.89	–3
Premium	5.7	8.79	2
Government Costs	16.6	25.65	1
Direct Subsidy	33.5	51.89	13
Reinsurance	–8.8	–13.74	–1
LI Cost-Sharing Subsidy	–9.9	–15.23	–3
LI Premium Subsidy	1.8	2.73	2
Manufacturer Gap Discount	–5.0	–7.69	–3

Moreover, while not accounted for when modeling these impacts, we seek comment on whether requiring that all pharmacy price concessions be included in the negotiated price, as we have described, would also lead to prices and Part D bids and premiums being more accurately comparable and reflective of relative plan efficiencies, with no unfair

competitive advantage accruing to one sponsor over another based on a technical difference in how costs are reported. We are further interested in comments on whether this outcome could make the Part D market more competitive and efficient.

B. Improving the CMS Customer Experience

1. Restoration of the Medicare Advantage Open Enrollment Period (§§ 422.60, 422.62, 422.68, 423.38 and 423.40)

Section 4001 of the Balanced Budget Act of 1997 (BBA), added section

⁵⁴ Assumptions: (1) For purposes of calculating impacts only, we assume that pharmacy price concession will equal about 3 percent of allowable Part D costs projected for each year modeled, and

that the concession amounts are perfectly substituted with the point-of-sale discount in all phases of the Part D benefit, including the coverage gap phase.

(2) Used 2016 distribution of costs by benefit phase to form assumptions.

(3) Assumed no other behavioral changes by sponsors, beneficiaries, or others.

1851(e) of the Act establishing specific parameters in which elections can be made and/or changed during open enrollment and disenrollment periods under the Medicare Advantage (MA) program. In addition, section 1851(e)(6) of the Act permits MA organizations, at their discretion, to choose not to accept enrollment requests during the open enrollment period (that is, choose to be closed to accept enrollments for all or a portion of the enrollment period). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1851(e)(2) of the Act to further establish open enrollment periods during which MA-eligible individuals were limited to a single election to (that is, enroll, disenroll, or change MA plans) during such period.

From 2007 to 2010, the Act outlined an Open Enrollment Period (OEP)—referred to hereafter as the “old OEP”—which provided MA-eligible individuals one opportunity to make an enrollment change between January 1 and March 31. It permitted new enrollment into an MA plan from Original Medicare, switches between MA plans, and disenrollment from a MA plan to Original Medicare. During this old OEP, individuals were not allowed to make changes to their Part D coverage. Hence, an individual who had Part D coverage through a Medicare Advantage Prescription Drug plan (MA-PD plan) could only use the old OEP to switch to (1) another MA-PD plan; or (2) Original Medicare with a Prescription Drug Plan (PDP). This old OEP did not permit someone enrolled in either an MA-only plan or Original Medicare without a PDP to enroll in Part D coverage through this enrollment opportunity. The old OEP was codified at § 422.62(a)(5) in 2005 (see 70 FR 4587).

In 2010, section 3204 of the Patient Protection and Affordable Care Act modified section 1851(e)(2)(C) of the Act to no longer offer the old OEP and instead provide a different enrollment period for MA enrollees to leave the MA program and return to Original Medicare in the first 45 days of the calendar year. The statute further permitted individuals who utilized this disenrollment opportunity to enroll in a Part D plan upon their return to Original Medicare. On April 15, 2011, we amended § 422.62(a)(5) and codified §§ 422.62(a)(7) and 423.38(d) to conform with this statutory change and to establish the current Medicare Advantage Disenrollment Period (MADP) with its coordinating Part D enrollment period. These changes were effective for the 2011 plan year (76 FR 21442 and 43).

Section 17005 of the 21st Century Cures Act (the Cures Act) modified section 1851(e)(2) of the Act to eliminate the MADP and to establish, beginning in 2019, a new OEP—hereafter referred to as the “new OEP”—to be held from January 1 to March 31 each year. Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), this new OEP allows individuals enrolled in an MA plan to make a one-time election during the first 3 months of the calendar year to switch MA plans or to disenroll from an MA plan and obtain coverage through Original Medicare. In addition, this provision affords newly MA-eligible individuals (those with Part A and Part B) who enroll in a MA plan, the opportunity to also make a one-time election to change MA plans or drop MA coverage and obtain Original Medicare. Newly eligible MA individuals can only use this new OEP during the first 3 months in which they have both Part A and Part B. Similar to the old OEP, enrollments made using the new OEP are effective the first of the month following the month in which the enrollment is made, as outlined in § 422.68(c). In addition, an MA organization has the option under section 1851(e)(6) of the Act to voluntarily close one or more of its MA plans to OEP enrollment requests. If an MA plan is closed for OEP enrollments, then it is closed to all individuals in the entire plan service area who are making OEP enrollment requests. All MA plans must accept OEP disenrollment requests, regardless of whether or not it is open for enrollment.

There are a few key differences between the old OEP and the new OEP as authorized by the Cures Act. Unlike the old OEP, this new OEP permits changes to Part D coverage for individuals who, prior to the change in election during the new OEP, were enrolled in an MA plan. As eligibility to use the new OEP is available only for MA enrollees, the ability to make changes to Part D coverage is limited to any individual who uses the OEP; however, the new OEP does not provide enrollment rights to any individual who is not enrolled in an MA plan during the applicable 3-month period. Individuals who use the new OEP to make changes to their MA coverage may also enroll in or disenroll from Part D coverage. For example, an individual enrolled in an MA-PD plan may use the new OEP to switch to: (1) Another MA-PD plan; (2) an MA-only plan; or (3) Original Medicare with or without a PDP. The new OEP would also allow an individual enrolled in an MA-only plan

to switch to—(1) another MA-only plan; (2) an MA-PD plan; or (3) Original Medicare with or without a PDP. However, this enrollment period does not allow for Part D changes for individuals enrolled in Original Medicare, including those with enrollment in stand-alone PDPs.

In addition, individuals with enrollment in Original Medicare or other Medicare health plan types, such as cost plans, are not able use the new OEP to enroll in an MA plan, regardless of whether or not they have Part D. We note that the inability for an individual enrolled in Original Medicare to use the new OEP is a significant difference from the old OEP. Furthermore, and significantly different from the old OEP, unsolicited marketing is prohibited by statute during this period.

To implement the changes required by the Cures Act, we propose the following revisions:

- Amend current § 422.62(a)(5) and add §§ 423.38(e) and 423.40(e) to establish the new OEP starting 2019 and the corresponding limited Part D enrollment period.
- Amend §§ 422.62(a)(7), 422.68(f), 423.38(d) and 423.40(d) to end the MADP at the end of 2018.
- Remove current regulations in § 422.62(a)(3) and (a)(4) that outline historical OEPs which have not been in existence for more than a decade. As these past enrollment periods are no longer relevant to the current enrollment periods available to MA-eligible individuals, we are proposing to delete these paragraphs and renumber the enrollment periods which follow them. As such, we propose that § 422.62(a)(5) become § 422.62(a)(3), and both §§ 422.62(a)(6) and (a)(7) be renumbered as §§ 422.62(a)(4) and (a)(5), respectively.
- Amend new redesignated paragraph (a)(4) (proposed to be redesignated from (a)(6)) to make two technical changes to replace the phrase “as defined by CMS” with “as defined in § 422.2” and to capitalize “original Medicare.”
- As noted previously, and discussed in section III.C.7, §§ 422.2268 and 423.2268 would be revised to prohibit marketing to MA enrollees during the OEP.
- Conforming technical edits to update cross references in §§ 422.60(a)(2), 422.62(a)(5)(iii), and 422.68(c).

2. Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503 and 423.504)

Sections 1857(e) and 1860D–12(b)(3)(D) of the Act specify that contracts with MA organizations and

Part D sponsors shall contain other terms and conditions that the Secretary may find necessary and appropriate. We have previously established that all Part C and Part D contracting organizations must have the necessary administrative and management arrangements to have an effective compliance program, as reflected in § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi). Effective compliance programs are those designed and implemented to prevent, detect and correct Medicare non-compliance, fraud waste and abuse and address improper conduct in a timely and well-documented manner. Medicare non-compliance may include inaccurate and untimely payment or delivery of items or medical services, complaints from providers and enrollees, illegal activities and unethical behavior. While there is no “one-size fits all” program for every contracting organization, there are seven core elements that must exist to have an effective compliance program that is tailored to the organization’s unique operations, compliance risks, resources and circumstances. These 7 core elements are codified in current regulations at §§ 422.503(b)(4)(vi)(A) through (G) and 423.504(b)(4)(vi)(A) through (G). One of the 7 core elements is training and education. Compliance programs for Part C and Part D organizations must include training and education between the compliance officer and the sponsoring organization’s employees, senior administrators, governing body members as well as their first-tier, downstream and related entities (FDRs).

FDRs have long complained of the burden of having to complete multiple sponsoring organizations’ compliance trainings and the amount of time it can take away from providing care to beneficiaries. We attempted to resolve this burden by developing our own web-based standardized compliance program training modules and establishing, in a May 23, 2014 final rule (79 FR 29853 and 29855), which was effective January 1, 2016, that FDRs were required to complete the CMS training to satisfy the compliance training requirement. The mandatory use of the CMS training by FDRs was a means to ensure that FDRs would only have to complete the compliance training once on an annual basis. The FDRs could then provide the certificate of completion to all Part C and Part D contracting organizations they served, hence, eliminating the prior duplication of effort that so many FDRs stated was creating a huge burden on their operation.

However, CMS continues to receive hundreds of inquiries and concerns from sponsors and FDRs regarding their

difficulties with adopting CMS’ compliance training to satisfy the compliance program training requirement. While CMS’ previous market research indicated that this provision would mitigate the problems raised by FDRs who held contracts with multiple sponsors and who completed repetitive trainings for each sponsor with which they contract, in practice, we learned that the problems persisted. Many sponsors are unwilling to accept completion of the CMS training as fulfillment of the training requirement and identify which critical positions within the FDR are subject to the training requirement. As a result, FDRs are still being subjected to multiple sponsors’ specific training programs. FDRs have the additional burden of taking CMS training and reporting completion back to the sponsor or sponsors with which they contract. Furthermore, the industry has indicated that the requirement has increased the burden for various Part C and Part D program stakeholders, including hospitals, suppliers, health care providers, pharmacists and physicians, all of which may be considered FDRs. Since the implementation of the mandatory CMS-developed training has not achieved the intended efficiencies in the administration of the Part C and Part D programs, we propose to delete the provisions from the Part C and Part D regulations that require use of the CMS-developed training. Additionally we propose to restructure § 422.503(b)(4)(vi)(C)(1) (with the proposed revisions) into two paragraphs (that is, paragraph (C)(1) and (C)(2)) to separate the scope of the compliance training from the frequency with which the training must occur, as these are two distinct requirements. With this proposed revision, the organization of § 422.503(b)(4)(vi)(C) will mirror that of § 423.504(b)(4)(vi)(C). Further, we propose to revise the text in § 423.504(b)(4)(vi)(C)(2) to track the phrasing in § 422.503(b)(4)(vi)(C)(2), as reorganized. The technical changes in the text eliminate any potential ambiguity created by different phrasing in what we intend to be identical requirements as to the timing requirements for the training. We believe these technical changes make the requirements easier to understand.

Furthermore, we believe that the broader requirement that plan sponsors provide compliance training to their FDRs no longer promotes the effective and efficient administration of the Medicare Advantage and Prescription Drug programs. Part C and Part D sponsoring organizations have evolved

greatly and their compliance program operations and systems are well established. Many of these organizations have developed effective training and learning models to communicate compliance expectations and ensure that employees and FDRs are aware of the Medicare program requirements. Also, the attention focused on compliance program effectiveness by CMS’ Part C and Part D program audits has further encouraged sponsors to continually improve their compliance operations.

CMS does not generally interfere in private contractual matters between sponsoring organizations and their FDRs. Our contract is with the sponsoring organization, and sponsoring organizations are ultimately responsible for compliance with all applicable statutes, regulations and sub-regulatory guidance, regardless who is performing the work. Additionally, delegated entities range in size, structure, risks, staffing, functions, and contractual arrangements which necessitates the sponsoring organization have discretion in its method of oversight to ensure compliance with program requirements. This may be accomplished through routine monitoring and implementing corrective action, which may include training or retraining as appropriate, when non-compliance or misconduct is identified.

We will continue to hold MA organizations and Part D sponsors accountable for the failures of their FDRs to comply with Medicare program requirements, even with these proposed changes. Existing regulations at § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi) require that every sponsor’s contract must specify that FDRs must comply with all applicable federal laws, regulations and CMS instructions. Additionally, we audit sponsors’ compliance programs when we conduct routine program audits, and our audit process includes evaluations of sponsoring organizations’ monitoring and auditing of their FDRs as well as FDR oversight. Our audits also evaluate formulary administration and processing of coverage and appeal requests in the Part C and Part D programs. FDRs often perform some or all of these functions for sponsors, so if they are non-compliant, it will come to light during the program audit and the sponsoring organization is ultimately held responsible for the FDRs’ failure to comply with program requirements.

Given that compliance programs are very well established and have grown more sophisticated since their inception, coupled with the industry’s desire to perform well on audit, the

CMS training requirement is not the driver of performance improvement or FDR compliance with key CMS requirements. Given this accumulated program experience and the growing sophistication of the industry's compliance operations, as well as our continuing requirements on sponsors for oversight and monitoring of FDRs, we are proposing to delete not just the regulatory provision requiring acceptance of CMS' training as meeting the compliance training requirements, but also the reference to FDRs in the compliance training requirements codified at §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C). Specifically, we propose to remove the phrases in paragraphs (C)(1) and (C)(2) that refer to first tier, downstream and related entities and remove the paragraphs specific to FDR training at §§ 422.503(b)(4)(vi)(C)(2) and (3) and 423.504(b)(4)(vi)(C)(3) and (4); we are also proposing technical revisions to restructure § 422.503(b)(4)(vi)(C)(1) into two paragraphs and ensure that the remaining text is grammatically correct and consistent with Office of the Federal Register style. Compliance training would still be required of MA and Part D sponsors, their employees, chief executives or senior administrators, managers, and governing body members. This change will allow sponsoring organizations, and the FDRs with which they contract, the maximum flexibility in developing and meeting training requirements associated with effective compliance programs. We invite comments concerning this proposal and suggestions on other options we can implement to accomplish the desired outcome.

3. Medicare Advantage Plan Minimum Enrollment Waiver (§ 422.514(b))

Under section 1857(b) of the Act, CMS may not enter into a contract with a MA organization unless the organization complies with the minimum enrollment requirement. Under the basic rule at § 422.514(a), to provide health care benefits under the MA program, MA organizations must demonstrate that they have the capability to enroll at least 5,000 individuals, and provider sponsored organizations (PSOs) must demonstrate that they have the capability to enroll at least 1,500 individuals. If an MA organization intends to offer health care benefits outside urbanized areas as defined in § 422.62(f), then the minimum enrollment level is reduced to 1,500 for MA organizations and to 500 for PSOs. The statute permits CMS to waive this requirement in the first 3 years of the contract for an MA contract

applicant. We have codified this authority at § 422.514(b) and limited it to circumstances where the MA contract applicant is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract. We are proposing to revise § 422.514 regarding the minimum enrollment requirements to improve program efficiencies.

Currently, MA organizations, including PSOs, with an approved minimum enrollment waiver for their first contract year have the option to resubmit the waiver request for CMS in the second and third year of the contract. In conjunction with the waiver request, the MA organization must continue to demonstrate the organization's ability to operate and demonstrate that it has and uses an effective marketing and enrollment system, despite continued failure to meet the minimum enrollment requirement. In addition, the current regulation limits our authority to grant the waiver in the third year to situations where the MA organization has at least attained a projected number of enrollees in the second year. Since 2012, we have not received any waiver to the minimum enrollment requirement during the second and third year of the contract. Rather, we only received minimum enrollment waiver requests through the initial application process.

We believe the current requirement to resubmit the waiver in the second and third year of the contract is unnecessary. The statute does not require a reevaluation of the minimum enrollment standard each year and plainly authorizes a waiver "during the first 3 contract years with respect to an organization." The current minimum enrollment waiver review in the initial MA contract application provides CMS the confidence to determine whether an MA organization may operate for the first 3 years of the contract without meeting the minimum enrollment requirement. CMS currently monitors low enrollment at the plan benefit package (PBP) level. We note that a similar provision in current § 422.506(b)(1)(iv) permits CMS to terminate an MA contract (or terminate a specific plan benefit package) if the MA plan fails to maintain a sufficient number of enrollees to establish that it is a viable independent plan option for existing or new enrollees. In addition, compliance with § 422.514 is required under § 422.503(a)(13). If an organization's PBP does not achieve and maintain enrollment levels in accordance with the applicable low and minimum enrollment policies in existing regulations, CMS may move to

terminate the PBP absent an approved waiver from CMS during the first 3 years of the contract pursuant to § 422.510(a).

Under our proposal, we would only review and approve waivers through the MA application process as opposed to the current practice of reviewing annual requests and, potentially, requests from existing MA organizations that fail to maintain enrollment in the second or third year of operation.

We are proposing to revise the text in § 422.514(b) to provide that the waiver of the minimum enrollment requirement may be in effect for the first 3 years of the contract. Further, we are proposing to delete all references to "MA organizations" in paragraph (b) to reflect our proposal that we would only review and approve waiver requests during the contract application process. We also propose to delete current paragraphs (b)(2) and (b)(3) in their entirety to remove the requirement for MA organizations to submit an additional minimum enrollment waiver annually for the second and third years of the contract. Finally, the proposed text also includes technical changes to redesignate paragraphs (b)(1)(i) through (iii) as (b)(1) through (3), consistent with regulation style requirements of the Office of the Federal Register.

4. Revisions to Timing and Method of Disclosure Requirements (§§ 422.111 and 423.128)

As provided in sections 1852(c)(1) and 1860D-4(a)(1)(A) of the Act, Medicare Advantage (MA) organizations and Part D sponsors must disclose detailed information about the plans they offer to their enrollees "at the time of enrollment and at least annually thereafter." This detailed information is specified in section 1852(c)(1) of the Act, with additional information specific to the Part D benefit also required under section 1860D-4(a)(1)(B) of the Act. Under § 422.111(a)(3), CMS requires MA plans to disclose this information to each enrollee "at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period." A similar rule for Part D sponsors is found at § 423.128(a)(3). Additionally, § 417.427 directs 1876 cost plans to follow the disclosure requirements in § 422.111 and § 423.128. In making the changes proposed here, we will also affect 1876 cost plans, though it is not necessary to change the regulatory text at § 417.427.

Sections 422.111(b) and 423.128(b) of the Part C and Part D program regulations, respectively, describe the information plans must disclose. The content listed in § 422.111(b) is found in

an MA plan's Evidence of Coverage (EOC) and provider directory. The content listed in § 423.128(b) is found in a Part D Sponsor's EOC, formulary, and pharmacy directory. Section 422.111(h)(2)(i) requires that plans must maintain an internet Web site that contains the information listed in § 422.111(b) and also states that posting the EOC, Summary of Benefits, and provider network information on the plan's Web site "does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees."

We propose two changes to the disclosure requirements. First, we propose to revise §§ 422.111(a)(3) and 423.128(a)(3) to require MA plans and Part D Sponsors to provide the information in paragraph (b) of the respective regulations by the first day of the annual enrollment period, rather than 15 days before. In addition, we propose to modify the sentence in § 422.111(h)(2)(ii) which states that posting the EOC, Summary of Benefits, and provider network information on the plan's Web site does not relieve the plan of responsibility to provide hard copies to enrollees. We propose to revise the sentence slightly and add "upon request" to the existing regulatory language to make it clear when any document that is required to be delivered under paragraph (a) in a manner that includes provision of a hard copy upon request, posting the document on the Web site (whether that document is the EOC, SB, directory information or other materials) does not relieve the MA organizations of a responsibility to deliver hard copies upon request. We intend these proposals to provide CMS with the flexibility to permit delivery other than through mailing hard copies (which is the requirement today for all materials and information covered by § 422.111(a)), including through electronic delivery or posting on the Web site in conjunction with delivery of a hard copy notice describing how the information and materials are available. We believe this proposal will ultimately provide additional flexibility to plans to take advantage of technological developments and reduce the amount of mail enrollees receive from plans.

Prior to the 2009 contract year, §§ 422.111(a) and 423.128(a) required the provision of the materials in their respective paragraphs (b) at the time of enrollment and at least annually thereafter, but did not specify a deadline. In the September 18, 2008, final rule, CMS required MA organizations to send this material to current enrollees 15 days before the

annual coordinated election period (AEP) (73 FR 54216). The rationale for this requirement was to provide beneficiaries with comprehensive information prior to the AEP so that they could make informed enrollment decisions.

However, we have found through consumer testing that the large size of these mailings overwhelmed enrollees. In particular, the EOC is a long document that enrollees found difficult to navigate. Enrollees were more likely to review the Annual Notice of Change (ANOC), a shorter document summarizing any changes to plan benefits beginning on January 1 of the upcoming year, if it was separate from the EOC. Sections 422.111(d) and 423.128(g)(2) require MA organizations and Part D sponsors to provide the ANOC to all enrollees at least 15 days before the AEP.

The ANOC is intended to convey all of the information essential to an enrollee's decision to remain enrolled in the same plan for the following year or choose another plan during the AEP. CMS's research and experience have indicated that the ANOC is particularly useful to and used by enrollees. Therefore, we are not proposing to change the §§ 422.111(d) and 423.128(g) requirements that the ANOC be received 15 days prior to AEP.

Unlike the ANOC, the EOC is a document akin to a contract that provides enrollees with exhaustive information about their medical coverage and rights and responsibilities as members of a plan. The provider directory, pharmacy directory, and formulary also contain information necessary to access care and benefits. As such, CMS requires MA organizations and Part D sponsors to make these documents available at the start of the AEP, so CMS proposes to amend §§ 422.111(a)(3) and 423.128(a)(3) to remove the current deadline and insert "by the first day of the annual coordinated election period." To the extent that enrollees find the EOC, provider directory, pharmacy directory, and formulary useful in making informed enrollment decisions, CMS believes that receipt of these documents by the first day of the AEP is sufficient. Any changes in the plan rules reflected in these documents for the next year should be adequately described in the ANOC, which will be provided earlier.

This change would also provide an additional 2 weeks for MA organizations and Part D plan sponsors to prepare, review, and ensure the accuracy of the EOC, provider directory, pharmacy directory, and formulary documents. CMS considers the additional time for

the EOC important due to the high number errors plans self-identify in the document through errata sheets they submit to CMS and mail to beneficiaries. In 2017, plans submitted 166 ANOC/EOC errata, which identified 221 ANOC errors and 553 EOC errors. Additional time to produce the EOC will give plans more time to conduct quality assurance and improve accuracy and result in fewer errata sheets in the future.

In addition to the proposed changes in §§ 422.111(a)(3) and 423.128(a)(3), we also propose to give plans more flexibility to provide the materials specified in § 422.111(b) electronically. The language in § 422.111(h)(2)(ii) requiring hard copies of the specified documents first appeared in the January 28, 2005, final rule (70 FR 4587) in § 422.111(f)(12). At that time, MA plans were not required to maintain a Web site, but if they chose to they were required to include the EOC, Summary of Benefits, and provider network information on the Web site. However, plans were prohibited from posting these documents online as a substitute for providing hard copies to enrollees. A subsequent final rule, published April 15, 2011, established that MA plans are required to maintain an internet Web site at § 422.111(h)(2) and moved the requirement that posting documents on the plan Web site did not substitute for hard copies from § 422.111(f)(12) to § 422.111(h)(2)(ii) (76 FR 21502).

There is no parallel to § 422.111(h)(2)(ii) in § 423.128. Instead, § 423.128(a) states that Part D sponsors must disclose the information in paragraph (b) in the manner specified by CMS. Section 423.128(d)(2)(i) requires Part D sponsors to maintain an internet Web site that includes information listed in § 423.128(b). CMS sub-regulatory guidance has instructed plans to provide the EOC in hard copy, but we believe that the regulatory text would permit delivery by notifying enrollees of the internet posting of the documents, subject to the right to request hard copies.⁵⁵ As explained previously regarding the changes to § 422.111, we intend for plans to have the flexibility to provide documents such as the Summary of Benefits, the EOC, and the provider network information in electronic format. We intend to change the relevant sub-regulatory guidance to coincide with this as well.

In the preamble to the 2005 final rule, we noted that the prohibition on

⁵⁵ Medicare Marketing Guidelines, section 60.6, issued July 20, 2017, https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY-2018-Medicare-Marketing-Guidelines_Final072017.pdf.

substituting electronic posting on the MA plan's internet site for delivery of hardcopy documents was in response to comments recommending this change (70 FR 4623). At the time, we did not think enough Medicare beneficiaries used the internet to permit posting the documents online in place of mailing them.

In the 12 years since the rule was finalized, research indicates that internet use has increased significantly among Medicare beneficiaries. Drawing on nationally representative surveys, the Pew Research Center found that 67 percent of American adults age 65 and older use the internet. Half of seniors have broadband available at home. Internet use increases even more among seniors age 65–69, of which 82 percent use the internet and 66 percent have broadband at home.⁵⁶ Electronic documents include advantages such as word search tools, the ability to magnify text, screen reader capabilities, and bookmarks or embedded links, all of which make documents easier to navigate. Given that the younger range of Medicare beneficiaries have a higher rate of internet access, we believe the number of beneficiaries who “use the internet” will only continue to grow with time. Posted electronic documents can also be accessed from anywhere the internet is available.

As mentioned previously, the EOC sometimes contains errors. To correct these, MA and Part D plans currently have to mail errata sheets and post an updated version online. The hardcopy version of the EOC is then out-of-date. Beneficiaries either have to refer to errata sheets in addition to the hardcopy EOC or go online to access a corrected EOC. Increasing beneficiary use of the electronic EOC ensures that beneficiaries are using the most accurate information. Under this proposal to permit flexibility for us to approve non-hard-copy delivery in some cases, we intend to continue requiring hardcopy mailings of any ANOC or EOC errata.

Plans have also continued to request CMS give plans the flexibility to provide the EOC electronically. They have frequently cited the expense of printing and mailing large documents. Medicaid managed care plans already have the flexibility to provide directories, formularies, and member handbooks (similar to the EOC) electronically, per §§ 438.10(h)(1), 438.10(h)(4)(i), and 438.10(g)(3) respectively.

To begin addressing this, in the Medicare Marketing Guidelines released July 2, 2015, CMS notified plans that they could mail either a hardcopy provider and/or pharmacy directory or a hardcopy notice to enrollees instructing them where to find the directories online and how to request a hard copy. That guidance has been moved to Chapter 4, section 110.2.3, of the Medicare Managed Care Manual. If plans choose to mail a notice with the location of the online directory rather than a hard copy, the notice must include: A direct link to the online directory, the customer service number to call and request a hard copy, and if available the email address to request a hard copy. The notice must be distinct, separate, and mailed with the ANOC/EOC.⁵⁷ Section 60.4 of the Medicare Marketing Guidelines released July 20, 2017, extends the same flexibility to formularies, with the same required content in the notice identifying the location of the online formulary. As CMS has received few complaints from any source about this new process, allowing plans the option to use a similar strategy for additional materials is appropriate.

Upon finalizing this rule, we would issue sub-regulatory guidance to identify permissible manners of disclosure; we expect that guidance would be similar to the current guidance for the provider directory, pharmacy directory, and formulary regarding dissemination of the EOC. Importantly, this provision does not eliminate the requirement for plans to provide accessible formats of required documents. As recipients of federal funding, plans are obligated to provide materials in accessible formats upon request, at no cost to the individual, to individuals with disabilities, under Section 504 of the Rehabilitation Act of 1973 and to take reasonable steps to provide meaningful access, including translation services, to individuals who have limited English proficiency under Title VI of the Civil Rights Act of 1964.

To create this flexibility, CMS proposes modifying the sentence, “Such posting does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees,” to include “upon request” in § 422.111(h)(2)(ii) and to revise § 422.111(a) by inserting “in the manner specified by CMS.” These changes will align §§ 422.111(a) and 423.128(a) to authorize CMS to provide flexibility to

MA plans and Part D sponsors to use technology to provide beneficiaries with information. CMS intends to use this flexibility to provide sponsoring organizations with the ability to electronically deliver plan documents (for example, the Summary of Benefits) to enrollees while maintaining the protection of a hard copy for any enrollee who requests such hard copy. As the current version of § 422.111(a) and (h)(2) require hard copies, we believe this proposal will ultimately result in reducing burden and providing more flexibility for sponsoring organizations.

5. Revisions to §§ 422 and 423 Subpart V, Communication/Marketing Materials and Activities

Section 1851(h) of the Act prohibits Medicare Advantage (MA) organizations from distributing marketing materials and application forms to (or for the use of) MA eligible individuals unless the document has been submitted to the Secretary at least 45 days (10 days for certain materials) prior to use and the document has not been disapproved. Further, in section 1851(j), the Secretary is authorized to adopt standards regarding marketing activities, and the statute identifies certain prohibited activities. While the Act requires the submission and review of the marketing materials and applications, it does not provide a definition of what materials fall under the umbrella term “marketing.” Sections 1806D–1(d)(3)(B)(iv) and 1860D–4(l) of the Act provide similar restrictions on use of marketing and enrollment materials and activities to promote enrollment in Part D plans.

Section 1876(c)(3)(C) of the Act states that no brochures, application forms, or other promotional or informational material may be distributed by cost plan to (or for the use of) individuals eligible to enroll with the organization under this section unless (i) at least 45 days before its distribution, the organization has submitted the material to the Secretary for review, and (ii) the Secretary has not disapproved the distribution of the material. As delegated this authority by the Secretary, CMS reviews all such material submitted and disapproves such material upon determination that the material is materially inaccurate or misleading or otherwise makes a material misrepresentation. Similar to 1851(h) of the Act, section 1876(c)(3)(C) of the Act focuses more on the review and approval of materials as opposed to providing an exhaustive list of materials that would qualify as marketing or promotional information and materials.

⁵⁶ Pew Research Center, May 2017, “Tech Adoption Climbs Among Older Adults”, <http://www.pewinternet.org/2017/05/17/tech-adoption-climbs-among-older-adults/>.

⁵⁷ Medicare Managed Care Manual Chapter 4—Benefits and Beneficiary Protections, Rev. 121, issued April 22, 2016, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf>.

As part of the implementation of section 1876(c)(3)(C) of the Act, the regulation governing cost plans at § 417.428(a) refers to Subpart V of part 422 for marketing guidance. Throughout this proposal, the changes discussed for MA organizations/MA plans and prescription drug plan (PDP) sponsors/Part D plans applies as well to cost plans subject to the same requirements as a result of this cross-reference.

Section 422.2260(1)–(4) of the Part C program regulations currently identifies marketing materials as any materials that: (1) Promote the MA organization, or any MA plan offered by the MA organization; (2) inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA plan offered by the MA organization; (3) explain the benefits of enrollment in an MA plan, or rules that apply to enrollees; and (4) explain how Medicare services are covered under an MA plan, including conditions that apply to such coverage. Section 423.2260(1)–(4) applies identical regulatory provisions to the Part D program.

Sections 422.2260(5) and 423.2260(5) provide specific examples of materials under the “marketing materials” definition, which include: General audience materials such as general circulation brochures, newspapers, magazines, television, radio, billboards, yellow pages, or the internet; marketing representative materials such as scripts or outlines for telemarketing or other presentations; presentation materials such as slides and charts; promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers); membership communication materials such as membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees; letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures etc.; and membership activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or no claim specific notification information). Finally, §§ 422.2260(6) and 423.2260(6) provide a list of materials that are not considered marketing materials, including materials that are targeted to current enrollees; are customized or limited to a subset of enrollees or apply to a specific situation; do not include information about the plan’s benefit structure; and apply to a specific situation or cover claims processing or other operational issues.

We are proposing several changes to Subpart V of the part 422 and 423 regulations. To better outline these proposed changes, they are addressed in four areas of focus: (1) Including “communication requirements” in the scope of Subpart V or parts 422 and 423, which will include new definitions for “communications” and “communication materials;” (2) amending §§ 422.2260 and 423.2260 to add (at a new paragraph (b)) a definition of “marketing” in place of the current definition of “marketing materials” and to provide lists identifying marketing materials and non-marketing materials; (3) adding new regulation text to prohibit marketing during the Open Enrollment Period proposed in section III.B.1 of this proposed rule; (4) technical changes to other regulatory provisions as a result of the changes to Subpart V. To the extent necessary, CMS relies on its authority to add regulatory and contract requirements to the cost plan, MA, and Part D programs to propose and (ultimately) adopt these changes. We note as well that sections 1851(h) and (j) of the Act (cross-referenced in sections 1860D–1 and 1860D–4(l)) of the Act address activities and direct that the Secretary adopt standards limiting marketing activities, which CMS interprets as permitting regulation of communications about the plan that do not rise to the level of activities and materials that specifically promote enrollment.

a. Revising the Scope of Subpart V To Include Communications and Communications Materials

The current version of Subpart V of parts 422 and 423 regulation focuses on marketing materials, as opposed to other materials currently referred to as “non-marketing” in the sub-regulatory Medicare Marketing Guidelines. This leaves a regulatory void for the requirements that pertain to those materials that are not considered marketing. Historically, the impact of not having regulatory guidance for materials other than marketing has been muted because the current regulatory definition of marketing is so broad, resulting in most materials falling under the definition. The overall effect of this combination—no definition of materials other than marketing and a broad marketing definition—is that marketing and communications with enrollees became synonymous.

With this CMS proposal to narrow the marketing definition, we believe there is a need to continue to apply the current standards to and develop guidance for those materials that fall outside of the proposed definition. We propose

changing the title of each Subpart V by replacing the term “Marketing” with “Communication.” We propose to define in §§ 422.2260(a) and 423.2260(a) definitions of “communications” (activities and use of materials to provide information to current and prospective enrollees) and “communications materials” (materials that include all information provided to current members and prospective beneficiaries). We propose that marketing materials (discussed later in this section) would be a subset of communications materials. In many ways, the proposed definition of communications materials is similar to the current definition of marketing materials; the proposed definition has a broad scope and would include both mandatory disclosures that are primarily informative and materials that are primarily geared to encourage enrollment.

CMS also proposes, through revisions to §§ 422.2268 and 423.2268, to apply some of the current standards and prohibitions related to marketing to all communications and to apply others only to marketing. Marketing and marketing materials would be subject to the more stringent requirements, including the need for submission to and review by CMS. Under this proposal, those materials that are not considered marketing, per the proposed definition of marketing, would fall under the less stringent communication requirements.

In addition to these proposals related to defined terms and revising the scope of Subparts V in parts 422 and 423, we are proposing changes to the current regulations at §§ 422.2264 and 423.2264 and §§ 422.2268 and 423.2268 that are related to our proposal to distinguish between marketing and communications.

With regard to §§ 422.2264 and 423.2264, we are proposing the following changes:

- Deletion of paragraph (a)(3), which currently provides for an adequate written explanation of the grievance and appeals process to be provided as part of marketing materials. In our view grievance and appeals communications would not be within the scope of marketing as proposed in this rule.
- Deletion of paragraph (a)(4), which provides for CMS to determine that marketing materials include any other information necessary to enable beneficiaries to make an informed decision about enrollment. The intent of this section was to ensure that materials which include measuring or ranking mechanisms such as Star Ratings were a part of CMS’s marketing review. We

propose deleting this section as the exclusion list to be codified at § 422.2260(c)(2)(ii) ensures materials that include measuring or ranking standards will be considered marketing, thus making §§ 422.2264(a)(4) and § 423.2264(a)(4) duplicative.

- Deletion of paragraph (e), which requires sponsoring organizations to provide translated materials in certain areas where there is a significant non-English speaking population. We propose to recodify these requirement as a general communication standard in §§ 422.2268 and 423.2268, at new paragraph (a)(7). As part of the redesignation of this requirement as a standard applicable to all communications and communication materials, we are also proposing revisions. First, we are proposing to revise the text so that it is stated as a prohibition on sponsoring organizations: For markets with a significant non-English speaking population, provide materials, as defined by CMS, *unless* in the language of these individuals. We propose adding the statement of “as defined by CMS” to the first sentence to allow the agency the ability to define the significant materials that would require translation. We propose deleting the word “marketing” so the second sentence now reads as “materials”, to make it clear that the updated section applies to the broader term of communications rather than the more narrow term of marketing.

In addition, we are proposing to revise §§ 422.2262(d) and 423.2262(d) to delete the term “ad hoc” from the heading and regulation text in favor of referring to “communication materials” to conform to the addition of communication materials under Subpart V.

Current regulations at §§ 422.2268 and 423.2268 list prohibited marketing activities. These activities include items such as providing meals to potential enrollees, soliciting door to door, and marketing in provider settings. With the proposal to distinguish between overall communications and marketing activities, we are proposing to break out the prohibitions into categories: those applicable to all communications (activities and materials) and those that are specific to marketing and marketing materials. In reviewing the various standards under the current regulations to determine if they would apply to communications or marketing, we looked at the each standard as it applied to the new definitions under Subpart V. Prohibitions that offer broader beneficiary protections and are currently applicable to a wide variety of

materials are proposed here to apply to communications activities and communication materials; this list of prohibitions is proposed as paragraph (a) Conversely, prohibitions that are currently targeted to activities and materials that are within the narrower scope of marketing and marketing materials are proposed at paragraph (b) as prohibitions on marketing. We are not proposing to expand the list of prohibitions but are proposing to notate which prohibitions are applicable to which category. The only substantive change is in connection with paragraph (a)(7), which we discuss earlier in this section. We welcome comment on our proposed distinctions between these types of prohibitions and whether certain standards or prohibitions from current §§ 422.2268 and 423.2268 should apply more narrowly or broadly than we have proposed.

b. Amending the Regulatory Definition of Marketing and Marketing Materials

In conjunction with adding new proposed communication requirements, we also propose a definition of “marketing” be codified in §§ 422.2260(b) and 423.2260(b). Under this proposal, we would delete the current text in that section defining only “marketing materials” to add a new definition of “marketing” and lists of materials that are “marketing materials” and that are not. Specifically, the term “marketing” would be defined as the use of materials or activities by the sponsoring organization (that is, the MA organization, Part D Sponsor, or cost plan, depending on the specific part) or downstream entities that are intended to draw a beneficiary’s attention to the plan or plans and influence a beneficiary’s decision making process when making a plan selection; this last criterion would also be met when the intent is to influence an enrollee’s decision to remain in a plan (that is, retention-based marketing).

The current regulations address both prohibited marketing activities and marketing materials. The prohibited activities are directly related to marketing activities, but the current definition of “marketing materials” is overly broad and has resulted in a significant number of documents being classified as marketing materials, such as materials promoting the sponsoring organization as a whole (that is, brand awareness) rather than materials that promote enrollment in a specific Medicare plan. We believe that Congress’ intent was to target those materials that could mislead or confuse beneficiaries into making an adverse enrollment decision. Since the original

adoption of §§ 422.2260 and 423.2260, CMS has reviewed thousands of marketing materials, tracked and resolved thousands of beneficiary complaints through the complaints tracking module (CTM), conducted secret shopping programs of MA plan sales events, and investigated numerous marketing complaints. These efforts have provided CMS insight into the types of plan materials that present the greatest risk of misleading or confusing beneficiaries. Based on this experience, we believe that the current regulatory definition of marketing materials is overly broad. As a result, materials that pose little to no threat of a detrimental enrollment decision fall under the current broad marketing definition. As such, the materials are also required to follow the associated marketing requirements, including submission to CMS for potential review under limited statutory timeframes. CMS believes that the level of scrutiny required on numerous documents that are not intended to influence an enrollment decision, combined with associated burden to sponsoring organizations and CMS, is not justified. By narrowing the materials that fall under the scope of marketing, this proposal will allow us to better focus its review on those materials that present the greatest likelihood for a negative beneficiary experience.

We propose to more appropriately implement the statute by narrowing the definition of marketing to focus on materials and activities that aim to influence enrollment decisions. We believe this is consistent with Congress’s intent. Moreover, the new definition differentiates between factually providing information about the plan or benefits (that is, the Evidence of Coverage (EOC)) versus persuasively conveying information in a manner designed to prompt the beneficiary to make a new plan decision or to stay with their current plan (for example, a flyer that touts a low monthly premium). As discussed later, the majority of member materials would no longer fall within the definition of marketing under this proposal. The EOC, subscriber agreements, and wallet card instructions are not developed nor intended to influence enrollment decisions. Rather, they are utilized for current enrollees to understand the full scope of and the rules associated with their plan. We believe the proposed new marketing definition appropriately safeguards potential and current enrollees while not placing an undue burden on sponsoring organizations. Moreover, those materials that would be

excluded from the marketing definition would fall under the proposed definition of communication materials, with what we believe are more appropriate requirements. CMS notes that enrollment and mandatory disclosure materials continue to be subject to requirements in §§ 422.60(c), 422.111, 423.32(b), and 423.128.

Second, we propose to revise the list of marketing materials, currently codified at §§ 422.2260(5) and 423.2260(5), and to include it in the proposed new §§ 422.2260(c)(1) and 423.2260(c)(1). The current list of examples includes: brochures; advertisements in newspapers and magazines, and on television, billboards, radio, or the internet, and billboards; social media content; marketing representative materials, such as scripts or outlines for telemarketing or other presentations; and presentation materials such as slides and charts. In conjunction with the proposed new definition of marketing, we are proposing to remove from the list of examples items such as membership communication materials, subscriber agreements, member handbooks, and wallet card instructions to enrollees, as they would no longer fall under the proposed regulatory definition of marketing. The proposed text complements the new definition by providing a concise non-exhaustive list of example material types that would be considered marketing.

Third, we propose to revise the list of exclusions from marketing materials, currently codified at §§ 422.2260(6) and 423.2260(6), and to include it in the proposed new §§ 422.2260(c)(2) and 423.2260(c)(2) to identify the types of materials that would not be considered marketing. Materials that do not include information about the plan's benefit structure or cost sharing or do not include information about measuring or ranking standards (for example, star ratings) will be excluded from marketing. In addition, materials that do mention benefits or cost sharing, but do not meet the definition of marketing as proposed here, would also be excluded from marketing. We also propose that required materials in § 422.111 and § 423.128 not be considered marketing, unless otherwise specified. Lastly, we are proposing to exclude materials specifically designated by us as not meeting the definition of the proposed marketing definition based on their use or purpose. The purpose of this proposed revision of the list of exclusions from marketing materials, as with the proposed marketing definition and proposed non-exhaustive list of marketing materials, is to maintain the

current beneficiary protections that apply to marketing materials but to narrow the scope to exclude materials that are unlikely to lead to or influence an enrollment decision.

In the proposed changes to the exclusions from marketing materials, we intend to exclude materials that do not include information about the plan's benefit structure or cost-sharing. We believe that materials that do not mention benefit structure or cost sharing would not be used to make an enrollment decision in a specific Medicare plan, rather they would be used to drive beneficiaries to request additional information that would fall under the new definition of marketing. Similarly, we want to be sure it is clear that the use of measuring or ranking standards, such as the CMS Star Ratings, even when not accompanied by other plan benefit structure or cost sharing information, could lead a beneficiary to make an enrollment decision. It should be noted that our authority for similar requirements can be found under the current §§ 422.2264(a)(4) and 423.2264(a)(4). We believe this is clearer and more appropriately housed under the regulatory definition of marketing. As such, together with the proposed update to excluded materials, we will make the technical change to remove (a)(4) from §§ 422.2264 and 423.2264. In addition, we propose to exclude materials that mention benefits or cost sharing but do not meet the proposed definition of marketing. The goal of this proposal is to exclude member communications that convey important factual information that is not intended to influence the enrollee's decision to make a plan selection or to stay enrolled in their current plan. An example is a monthly newsletter to current enrollees reminding them of preventive services at \$0 cost sharing.

In addition, we note the proposal excludes those materials required under § 422.111 (for MA plans) and § 423.128 (for Part D sponsors), unless otherwise specified by CMS because of their use or purpose. This proposal is intended to exclude post-enrollment materials that we require be disclosed and distributed to enrollees, such as the EOC. Such materials convey important plan information in a factual manner rather than to entice a prospective enrollee to choose a specific plan or an existing enrollee to stay in a specific plan. In addition, either these materials use model formats and text developed by us or are developed by plans based on detailed instructions on the required content from us; this high level of standardization by us on the front-end provides the necessary beneficiary

protections and negates the need for our review of these materials before distribution to enrollees.

The proposed changes do not release cost plans, MA organizations, or Part D sponsors from the requirements in sections 1876(c)(3)(C), 1851(h), and 1860D–1(b)(1)(B)(vi) of the Act to have application forms reviewed by CMS as well. To clarify this requirement, we are proposing to revise § 417.430(a)(1) and § 423.32(b), which pertain to application and enrollment processes, to add a cross reference to §§ 422.2262 and 423.2262, respectively. The cross references directly link enrollment applications back to requirements related to review and distribution of marketing materials. These proposed changes update an old cross-reference, codify existing practices, and are consistent with language already in § 422.60(c).

c. Prohibition of Marketing During the Open Enrollment Period

The 21st Century Cures Act (the Cures Act) amended section 1851(e)(2) of the Act by adding a new continuous open enrollment and disenrollment period (OEP) for MA and certain PDP members. See section III.A.X for CMS's other proposal related to that provision. As part of establishing this OEP, the Cures Act prohibits unsolicited marketing and mailing marketing materials to individuals who are eligible for the new OEP. We are proposing to add a new paragraph (b)(9) to both proposed §§ 422.2268 and 423.2268 to apply this prohibition on marketing. However, we request comment on how the agency could implement this statutory requirement. The new OEP is not available for enrollees in Medicare cost plans; therefore, these limitations would apply to MA enrollees and to any PDP enrollee who was enrolled in an MA plan the prior year. CMS is concerned that it may be difficult for a sponsoring organization to limit marketing to only those individuals who have not yet enrolled in a plan during the OEP. One mechanism could be to limit marketing entirely during that period, but we are concerned that such a prohibition would be too broad. We believe that using a "knowing" standard will both effectuate the statutory provision and avoid against overly broad implementation. We welcome comment on how a sponsoring organization could appropriately control who would or should be marketed to during the new OEP, such as through as mailing campaigns aimed at a more general audience.

d. Technical Changes to Other Regulatory Provisions as a Result of the Changes to Subpart V

As previously stated, because of the broad regulatory definition of marketing, the term marketing and communication became synonymous. With the proposed updates to Subpart V in both part 422 and part 423, a definition of the broader term communication would be added and the definition of marketing, as well as the materials that fall within the scope of that definition, would be narrowed. As a result, a number of technical changes will be needed to update certain sections of the regulation that use the term marketing. Accordingly, we propose the following technical changes in Part C:

- In § 422.54, we propose to update paragraphs (c)(1)(i) and (d)(4)(ii) to replace “marketing materials” with “communication materials.”
- In § 422.62, we propose to update paragraph (b)(3)(B)(ii) by replacing “in marketing the plans to the individual” with “in communication materials.”
- In § 422.102(d), we propose to use “supplemental benefits packaging” instead of “marketing of supplemental benefits.”
- In § 422.206(b)(2)(i), we propose to replace “§ 422.80 (concerning approval of marketing materials and election forms)” with “all applicable requirements under subpart V”.
- In § 422.503(b)(4)(ii), we propose to replace the term “marketing” with the term “communication.”
- In § 422.510(a)(4)(iii), we propose to remove the word “marketing” so that the reference is to the broader Subpart V.

CMS has had longstanding authority to initiate “marketing sanctions” in conjunction with enrollment sanctions as a means of protecting beneficiaries from the confusion that stems from receiving information provided by a plan that is—as a result of enrollment sanctions—unable to accept enrollments. In this rulemaking, CMS is proposing to replace the term “marketing” with “communications” in § 422.750 and 422.752 to reflect its proposal for Subpart V. The intent of this proposal to change the terminology is not to expand the scope of CMS’s authority with respect to sanction regulations. Rather, CMS intends to preserve the existing reach of its sanction authority it currently has—to prohibit any communications under the current broad definition of “marketing materials” from being issued by a sponsoring organization while that entity is under sanction. For this reason,

CMS is proposing the following changes to §§ 422.750 and 422.752:

- In § 422.750, we propose to revise paragraph (a)(3) to refer to suspension of “communication activities.”

- In § 422.752, we propose to replace the term “marketing” in paragraph (a)(11) and the heading for paragraph (b) with the term “communications.”

We are not proposing any changes to the use of the term “marketing” in §§ 422.384, 422.504(a)(17), 422.504(d)(2)(vi), or 422.514, as those regulations use the term in a way that is consistent with the proposed definition of the term “marketing,” and the underlying requirements and standards do not need to be extended to all communications from an MA organization.

We also propose the following technical changes in Part D:

- In § 423.38(c)(8)(i)(C), we propose to revise the paragraph to read: “The organization (or its agent, representative, or plan provider) materially misrepresented the plan’s provisions in communication materials.”
- In § 423.504(b)(4)(ii), we propose to replace “marketing” with “communications” to reflect the change to Subpart V.

For the reasons explained in connection with our proposal to revise the Part C sanction regulations, we also propose the following changes:

- In § 423.505(b)(25), we propose to replace “marketing” with “communications” to reflect the change to Subpart V.
- In § 423.509(a)(4)(V)(A), we propose to delete the word “marketing” and instead simply refer to Subpart V.

We are not proposing any changes to the use of the term “marketing” in §§ 423.505(d)(2)(vi), 423.871(c), or 423.756(c)(3)(ii), as those regulations use the term in a way that is consistent with the proposed definition of the term “marketing,” and the underlying requirements and standards do not need to be extended to all communications from a PDP sponsor.

We solicit comment on the proposed technical changes, particularly whether a proposed revision here would be more expansive than anticipated or have unintended consequences for sponsoring organizations or for CMS’s oversight and monitoring of the MA and Part D programs.

In conclusion, we believe that our proposal here—the proposed definitions of “communications,” “communications materials,” “marketing,” and “marketing materials;” and the various proposed changes to Subpart V; to distinguish

between prohibitions applicable to communications and those applicable to marketing; and to conform § 417.430(a)(1) and § 423.32(b) to § 422.60(c) and reflect the statutory direction regarding enrollment materials; all maintain the appropriate level of beneficiary protection. These proposals will facilitate and focus our oversight of marketing materials, while appropriately narrowing the scope of what is considered marketing. We believe beneficiary protections are further enhanced by adding communication materials and associated standards under Subpart V. These changes allow us to focus its oversight efforts on plan marketing materials that have the highest potential for influencing a beneficiary to make an enrollment decision that is not in the beneficiary’s best interest. We solicit comment on these proposals and whether the appropriate balance is achieved with the proposed regulation text.

6. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations (§§ 423.590 and 423.636)

Sections 1860D–4(g) and (h) of the Act require the Secretary to establish processes for initial coverage determinations and appeals similar to those used in the Medicare Advantage program. In accordance with section 1860D–4(g) of the Act, § 423.590 establishes Part D plan sponsors’ responsibilities for processing redeterminations, including adjudication timeframes. Pursuant to section 1860D–4(h) of the Act, § 423.600 sets forth the requirements for an independent review entity (IRE) for processing reconsiderations.

We are proposing changes to the adjudication timeframe for Part D standard redetermination requests for payment at § 423.590(b) and the related effectuation provision § 423.636(a)(2). Specifically, we are proposing to change the timeframe for issuing decisions on payment redeterminations from 7 calendar days from the date the plan sponsor receives the request to 14 calendar days from the date the plan sponsor receives the request. This proposed 14-day timeframe for issuing a decision related to a payment request would also apply to the IRE reconsideration pursuant to § 423.600(d). We are not proposing to make changes to the existing requirements for making payment. When applicable, the Part D plan sponsor must make payment no later than 30 days from receipt of the request

for redetermination, or the IRE reconsideration notice, respectively.

Some of the feedback received from the RFI published in the 2018 Call Letter related to simplifying and establishing greater consistency in Part D coverage and appeals processes. The proposed change to a 14 calendar day adjudication timeframe for payment redeterminations, which would also apply to payment requests at the IRE reconsideration level of appeal, will establish consistency in the adjudication timeframes for payment requests throughout the plan level and IRE processes, as § 423.568(c) requires a plan sponsor to notify the enrollee of its determination no later than 14 calendar days after receipt of the request for payment. We believe affording more time to adjudicate payment redetermination requests (including obtaining necessary documentation to support the request) will ease burden on plan sponsors because it could reduce the need to deny payment redeterminations due to missing information. We also expect the proposed change to the payment redetermination timeframe would reduce the volume of untimely payment redeterminations that must be auto-forwarded to the IRE.

In addition, having more time to gather information and process these requests could be beneficial to enrollees because decisions will be more fully informed, potentially resulting in fewer decisions having to undergo further appeal. While we acknowledge that some enrollees would have to wait longer for a decision, we note that the proposed changes are limited to payment requests where the enrollee has already received the drug, ensuring any delay would not adversely affect the enrollee's health. As noted previously, when coverage is approved, the plan would remain obligated to remit payment to affected enrollees within 30 days. Allowing plan sponsors and the IRE additional time to process payment appeal requests may assist these adjudicators in allocating resources in a manner that is most efficient and enrollee friendly, for example, ensuring adequate resources are directed to processing more time-sensitive pre-service requests where the enrollee has not yet obtained the drug, particularly during periods of increased case volume.

7. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (§ 422.590)

Section 1852(g) of Act requires MA organizations to have a procedure for making timely determinations regarding

whether an enrollee is entitled to receive a health service and any amount the enrollee is required to pay for such service. Under this statutory provision, the MA plan also is required to provide for reconsideration of that determination upon enrollee request.

In accordance with section 1852(g) of the Act, our current regulations at §§ 422.578, 422.582, and 422.584 provide MA enrollees with the right to request reconsideration of a health plan's initial decision to deny Medicare coverage. Pursuant to § 422.590, when the MA plan upholds initial payment or service denials, in whole or in part, it must forward member case files to an independent review entity (IRE) that contracts with CMS to review plan-level appeals decisions; that is, plans are required to automatically forward to the IRE any reconsidered decisions that are adverse or partially adverse for an enrollee without the enrollee taking any action.

Currently, MA plans are required to notify enrollees upon forwarding cases to the IRE, as set forth at § 422.590(f). CMS sub-regulatory guidance, set forth in Chapter 13 of the Medicare Managed Care Manual, specifically directs plans to mail a notice to the enrollee informing the individual that the plan has upheld its decision to deny coverage, in whole or in part, and thus is forwarding the enrollee's case file to the IRE for review. We have made a model notice available for plans to use for this purpose. (See Medicare Managed Care Manual, Chapter 13, § 10.3.3, 80.3, and Appendix 10.) In addition, the Part C IRE is required, under its contract with CMS, to notify the enrollee when the IRE receives the reconsidered decision for review. We are proposing to revise § 422.590 to remove paragraph (f) and redesignate the existing paragraphs (g) and (h) as (f) and (g), respectively. The Part C IRE is contractually responsible for notifying an enrollee that the IRE has received and will be reviewing the enrollee's case; thus, we believe the plan notice is duplicative and nonessential. Under this proposal, the IRE would be responsible for notifying enrollees upon forwarding all cases—including both standard and expedited cases. We will continue to closely monitor the performance of the IRE and beneficiary complaints related to timely and appropriate notification that the IRE has received and will be reviewing the enrollee's case.

We received feedback in response to the Request for Information included in the 2018 Call Letter related to simplifying and streamlining appeals processes. To that end, we believe this

proposed change will help further these goals by easing burden on MA plans without compromising informing the beneficiary of the progress of his or her appeal. If this proposal is finalized, and plans are no longer required to notify an enrollee that his or her case has been sent to the IRE, we would expect plans to redirect resources previously allocated to issuing this notice to more time-sensitive activities such as review of pre-service and post-service coverage requests, improved efficiency in appeals processing, and provision of health benefits in an optimal, effective, and efficient manner.

8. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

a. Legislative Background

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended title XVIII of the Act to establish a voluntary prescription drug benefit program at section 1860D–4(e) of the Act. Among other things, these provisions required the adoption of Part D e-prescribing 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. There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, 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. (Background) of the E-Prescribing and the Prescription Drug Program proposed rule, published February 4, 2005 (70 FR 6256).

b. Regulatory History

Transaction standards are periodically updated to take new knowledge, technology and other considerations into account. As CMS adopted specific versions of the standards when it adopted the foundation and final e-prescribing standards, there was a need to establish a process by which the standards could be updated or replaced

over time to ensure that the standards did not hold back progress in the industry. We discussed these processes in the November 7, 2005 final rule (70 FR 67579).

The discussion noted that the rulemaking process will generally be used to retire, replace or adopt a new e-prescribing standard, but it also provided for a simplified "updating process" when a non-HIPAA standard could be updated with a newer "backward-compatible" version of the adopted standard. In instances in which the user of the later version can accommodate users of the earlier version of the adopted non-HIPAA standard without modification, however, it noted that notice and comment rulemaking could be waived, in which case the use of either the new or old version of the adopted standard would be considered compliant upon the effective date of the newer version's incorporation by reference in the **Federal Register**. We utilized this streamlined process when we published an interim final rule with comment on June 23, 2006 (71 FR 36020). That rule recognized NCPDP SCRIPT 8.1 as a backward compatible update to the NCPDP SCRIPT 5.0 for the specified transactions, thereby allowing for use of either of the two versions in the Part D program. Then, on April 7, 2008, we used notice and comment rulemaking (73 FR 18918) to finalize the identification of the NCPDP SCRIPT 8.1 as a backward compatible update of the NCPDP SCRIPT 5.0, and, effective April 1, 2009, retire NCPDP SCRIPT 5.0 and adopt NCPDP SCRIPT 8.1 as the official Part D e-prescribing standard for the specified transactions. On July 1, 2010, CMS utilized the streamlined process to recognize NCPDP SCRIPT 10.6 as a backward compatible update of NCPDP SCRIPT 8.1 in an interim final rule (75 FR 38026).

We finalized the NCPDP SCRIPT 10.6 as a Backward Compatible Version of NCPDP SCRIPT 8.1, and retired NCPDP SCRIPT 8.1 and adopted the NCPDP SCRIPT 10.6 as the official Part D e-Prescribing Standard for the specified transactions in the CY 2013 Physician Fee Schedule, effective November 1, 2013. For a more detailed discussion, see the CY 2013 PFS final rule (77 FR 69329 through 69333).

c. Proposed adoption of NCPDP SCRIPT version 2017071 as the official Part D E-Prescribing Standard for certain specified transactions, retirement of NCPDP SCRIPT 10.6, proposed conforming changes elsewhere in 423.160, and correction of a historic typographical error in the regulatory

text which occurred when NCPDP SCRIPT 10.6 was initially adopted.

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,600 members who are interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

NCPDP has developed the NCPDP SCRIPT standard for use by prescribers, dispensers, pharmacy benefit managers (PBMs), payers and other entities who wish to electronically transmit information about prescriptions and prescription-related information. NCPDP has periodically updated its SCRIPT standard over time, and three separate versions of the NCPDP SCRIPT standard, versions 5.0, 8.1 and most recently 10.6 have been adopted by CMS for the part D e-prescribing program through the notice and comment rulemaking process. We believe that our current proposal to adopt the NCPDP SCRIPT 2017071 as the official part D e-prescribing standard for certain specified transactions, and to retire the current standard for those transactions would, among other things, improve communications between the prescriber and dispensers, and we welcome public comment on these proposals.

Our actions were, in part, precipitated by a May 24, 2017, letter from the NCPDP that requested our adoption of NCPDP SCRIPT Standard Version 2017071. This version was balloted and approved July 28, 2017. The letter noted the considerable amount of time that had passed since the last update to the current adopted standard (NCPDP SCRIPT 10.6), and that there were many changes to the NCPDP SCRIPT Standard version 2017071 that would benefit its users.

CMS reviewed the specifications for NCPDP SCRIPT Standard Version 2017071 and found that this version would allow users substantial improvements in efficiency. Version 2017071 supports communications regarding multi-ingredient compounds, thereby allowing compounded medication to be prescribed electronically. Previously prescriptions for compounds were handwritten and sent via fax to the dispenser, which often required follow up communications between the prescriber

and pharmacy. The ability to process prescriptions for compounds electronically in lieu of relying on more time intensive interpersonal interactions would be expected to improve efficiency.

While we do not propose mandating its use at this time, one transaction supported by the proposed version of NCPDP SCRIPT would also provide interested users with a Census transaction functionality which is designed to service beneficiaries residing in long term care. The Census feature would trigger timely notification of a beneficiary's absence from a long term care facility, which would enable discontinuation of daily medication dispensing when a leave of absence occurs, thereby preventing the dispensing of unneeded medications. Version 2017071 also contains an enhanced Prescription Fill Status Notification that allows the prescriber to specify if/when they want to receive the notifications from the dispenser. It now supports data elements for diabetic supply prescriptions and includes elements which could be required for the pharmacy during the dispensing process which may be of value to prescribers who need to closely monitor medication adherence.

We therefore believe that the functionalities offered by NCPDP SCRIPT 2017071 could offer efficiencies to the industry, and believe that it would be an appropriate e-prescribing standard for the transactions currently covered by the Medicare Part D program. Furthermore, NCPDP SCRIPT 2017071 supports transactions new to the part D e-prescribing program that we believe would prove beneficial to the industry. Therefore, in addition to the transactions for which prior versions of NCPDP SCRIPT were adopted (as reflected in the current regulations at 423.160(b)), we propose to require use of NCPDP SCRIPT 2017071 for the following transactions:

- Prescription drug administration message,
- New prescription requests,
- New prescription response denials,
- Prescription transfer message,
- Prescription fill indicator change,
- Prescription recertification,
- Risk Evaluation and Mitigation Strategy (REMS) initiation request,
- REMS initiation response, REMS request, and
- REMS response.

We believe that transitioning to the new 2017071 versions of the transactions already covered by the current part D e-prescribing standard (version 10.6 of the NCPDP SCRIPT) will impose de minimus cost on the

industry as the burden in using the updated standards is anticipated to be the same as using the old standards for the transactions currently covered by the program. We are also proposing adoption of version 2017071 of the NCPDP SCRIPT standards for the nine new transactions to replace manual processes that currently occur. Reducing the manual processes currently used to support these transactions will improve efficiency, accuracy, and user satisfaction with the system. While system implementation may result in minimal expenses, we believe that these minimal expenses will be more than offset by rendering these manual transactions obsolete. That is, we believe that prescribers and dispensers that are now e-prescribing largely invested in the hardware, software, and connectivity necessary to e-prescribe. We do not anticipate that the retirement of NCPDP SCRIPT 10.6 in favor of NCPDP SCRIPT 2017071 will result in significant costs.

As such, we are proposing to revise § 423.160(b)(1)(iv) so as to limit its application to transactions before January 1, 2019 and add a new § 423.160(b)(1)(v). The requirement at § 423.160(b)(1)(v) would identify the standards that will be in effect on or after January 1, 2019, for those that conduct e-prescribing for part D covered drugs for part D eligible beneficiaries. If finalized, those individuals and entities would be required to use NCPDP SCRIPT 2017071 to convey prescriptions and prescription-related information for the following transactions:

- Get message transaction.
- Status response transaction.
- Error response transaction.
- New prescription request transaction.
- Prescription change request transaction.
- Prescription change response transaction.
- Refill/Resupply prescription request transaction.
- Refill/Resupply prescription response transaction.
- Verification transaction.
- Password change transaction.
- Cancel prescription request transaction.
- Cancel prescription response transaction.
- Fill status notification.
- Prescription drug administration message.
- New prescription requests.
- New prescription response denials.
- Prescription transfer message.
- Prescription fill indicator change.
- Prescription recertification.

- Risk Evaluation and Mitigation Strategy (REMS) initiation request.
- REMS initiation response, REMS request
- REMS initiation response.
- REMS request.
- REMS response.

We are also proposing to adopt NCPDP SCRIPT 2017071 as the official part D e-prescribing standard for the medication history transaction at § 423.160(b)(4). As a result, we are also proposing to retire NCPDP SCRIPT versions 8.1 and 10.6 for medication history transactions transmitted on or after January 1, 2019.

Furthermore, we propose to amend § 423.160(b)(1) by modifying § 423.160(b)(1)(iv) to limit usage of NCPDP SCRIPT version 10.6 to transactions before January 1, 2019.

In addition, we propose to add § 423.160(b)(1)(v) to provide that NCPDP Version 2017071 must be used to conduct the covered transactions on or after January 1, 2019. Furthermore, we are proposing to amend § 423.160(b)(2) by adding § 423.160(b)(2)(iv) to name NCPDP SCRIPT Version 2017071 for the applicable transactions. Finally, we propose to incorporate NCPDP SCRIPT version 2017071 by reference in our regulations. We seek comment regarding our proposed retirement of NCPDP SCRIPT version 10.6 on December 31, 2018 and adoption of NCPDP SCRIPT Version 2017071 on January 1, 2019 as the official Part D e-prescribing standard for the e-prescribing functions outlined in our proposed § 423.160(b)(1)(v) and (b)(2)(v), and for medication history as outlined in our proposed § 423.160(b)(4), effective January 1, 2019. We are also soliciting comments regarding the impact of these proposed effective dates on industry and other interested stakeholders.

We are also proposing a technical correction of a prior regulation. On July 30, 2012, we published regulation (CMS-1590-P), which established version 10.6 as the Part D e-prescribing standard effective March 1, 2015 for certain electronic transactions that convey prescription or prescription related information, as listed in § 423.160(b)(2)(iii). However, despite the regulation clearly noting adoption of NCPDP SCRIPT 10.6 as the part D e-prescribing standard for the listed transactions, due to a typographical error, § 423.160(b)(1)(iv) references (b)(2)(ii) (NCPDP SCRIPT 8.1), rather than (b)(2)(iii) (NCPDP SCRIPT 10.6). We propose a correction of this typographical error by changing the reference at § 423.160 (b)(1)(iv) to reference (b)(2)(iii) instead of (b)(2)(ii).

In proposing updates to the Part D E-Prescribing Standards CMS has reviewed specification documents developed by the National Council for Prescription Drug Programs (NCPDP). The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. For a proposed rule, agencies must discuss in the preamble to the NPR ways that the materials the agency proposes to incorporate by reference are reasonably available to interested persons or how the agency worked to make the materials reasonably available. In addition, the preamble to the proposed rule must summarize the materials.

Consistent with those requirements CMS has established procedures to ensure that interested parties can review and inspect relevant materials. The proposed update to the Part D prescribing standards has relied on the NCPDP SCRIPT Implementation Guide Version 2017071 approved July 28, 2017. Members of the NCPDP may access these materials through the member portal at www.ncdp.org; non-NCPDP members may obtain these materials for information purposes by contacting the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244, Mailstop C1-26-05, or by calling (410) 786-3694.

9. Reduction of Past Performance Review Period for Applications Submitted by Current Medicare Contracting Organizations (§§ 422.502 and 423.503)

In April 2010, we clarified our authority to deny contract qualification applications from organizations that have failed to comply with the requirements of a Medicare Advantage or Part D plan sponsor contract they currently hold, even if the submitted application otherwise demonstrates that the organization meets the relevant program requirements. As part of that rulemaking, we established, at § 422.502(b)(1) and § 423.503(b)(1), that we would review an applicant's prior contract performance for the 14-month period preceding the application submission deadline (see 75 FR 19684 through 19686). We conduct that review in accordance with a methodology we publish each year⁵⁸ and use to score each applicant's performance by assigning weights based on the severity of its non-compliance in several

⁵⁸ https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/Final_2018_Application_Cycle_Past_Performance_Methodology.pdf.

performance categories. Under the annual contract qualification application submission and review process we conduct, organizations must submit their application by a date, usually in mid-February, announced by us. We now propose to reduce the past performance review period from 14 months to 12 months.

We originally established the 14-month review period because it covered the time period from the start of the preceding contract year through the date on which CMS receives contract applications for the upcoming contract year. We believed at the time that the combination of the most recent complete contract year and the 2 months preceding the application submission provided us with the most complete picture of the most relevant information about an applicant's past contract performance. Our application of this authority since its publication has prompted comments from contracting organizations that the 14-month period is too long and is unfair as it is applied. In particular, organizations have noted that non-compliance that occurs during January and February of a given year is counted against an organization in 2 consecutive past performance review cycles while non-compliance occurring in all other months is counted in only one review cycle. The result is that some non-compliance is "double counted" based solely on the timing of the non-compliance and can, depending on the severity of the non-compliance, prevent an organization from receiving CMS approval of their application for 2 consecutive years.

Rather than creating a gap in the look-back period, as we were concerned in 2010, 75 FR 19685, we now believe a 12-month look-back period provides a more accurate period to consider. We believe it is still important to capture in each review cycle an applicant's most recent contract performance. Therefore, we propose to revise § 422.502(b)(1) and § 423.503(b)(1) to reduce the review period from 14 to 12 months. This would effectively establish a new review period for every application review cycle of March 1 of the year preceding the application submission deadline through February 28 (February 29 in leap years) of the year in which the application is submitted and would eliminate the counting of instances of non-compliance in January and February of each year in 2 separate application cycles. We also propose to have this review period change reflected consistently in the Part C and D regulation by revising the provisions of § 422.502(b)(2) and § 423.503(b)(2) to

state that CMS may deny an application from an existing Medicare Advantage or Part D plan sponsor in the absence of a record of at least 12, rather than 14, months of Medicare contract performance by the applicant. We do not intend to change any other aspect of our consideration of past performance in the application process.

10. Preclusion List—Part D Provisions

a. Background

(1) 2014 Final Rule

On May 23, 2014, we published a final rule in the **Federal Register** titled "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (79 FR 29844). Among other things, this final rule implemented section 6405(c) of the Affordable Care Act, which provides the Secretary with the authority to require that prescriptions for covered Part D drugs be prescribed by a physician enrolled in Medicare under section 1866(j) of the Act (42 U.S.C. 1395cc(j)) or an eligible professional as defined at section 1848(k)(3)(B) of the Act (42 U.S.C. 1395w-4(k)(3)(B)). More specifically, the final rule revised § 423.120(c)(5) and added new § 423.120(c)(6), the latter of which stated that for a prescription to be eligible for coverage under the Part D program, the prescriber must have (1) an approved enrollment record in the Medicare fee for service program (that is, original Medicare); or (2) a valid opt out affidavit on file with a Part A/Part B Medicare Administrative Contractor (A/B MAC).

The purpose of this change was to help ensure that Part D drugs are prescribed only by qualified prescribers. In a June 2013 report titled "Medicare Inappropriately Paid for Drugs Ordered by Individuals Without Prescribing Authority" (OEI-02-09-00608), the Office of Inspector General (OIG) found that the Part D program improperly paid for drugs prescribed by persons who did not appear to have the authority to prescribe. We also noted in the final rule the reports we received of prescriptions written by physicians with suspended licenses having been covered by the Part D program. These reports raised concerns within CMS about the propriety of Part D payments and the potential for Part D beneficiaries to be prescribed dangerous or unnecessary drugs by individuals who lack the authority or qualifications to prescribe medications. Given that the Medicare FFS provider enrollment process, as outlined in 42 CFR part 424, subpart P, collects identifying information about

providers and suppliers who wish to enroll in Medicare, we believed that forging a closer link between Medicare's coverage of Part D drugs and the provider enrollment process would enable CMS to confirm the qualifications of the prescribers of such drugs. That is, requiring Part D prescribers to enroll in Medicare would provide CMS with sufficient information to determine whether a physician or eligible professional is qualified to prescribe Part D drugs.

We stated in the May 23, 2014 final rule that the compliance date for our revisions to new § 423.120(c)(6) would be June 1, 2015. We believed that this delayed date would give physicians and eligible professionals who would be affected by these provisions adequate time to enroll in or opt-out of Medicare. It would also allow CMS, A/B MACs, Medicare beneficiaries, and other impacted stakeholders sufficient opportunity to prepare for these requirements.

(2) 2015 Interim Final Rule

On May 6, 2015, we published in the **Federal Register** an interim final rule with comment period (IFC) titled "Medicare Program; Changes to the Requirements for Part D Prescribers" (80 FR 25958). This IFC made changes to certain requirements outlined in the May 23, 2014 final rule related to beneficiary access to covered Part D drugs.

First, we changed the compliance date of § 423.120(c)(6) from June 1, 2015 to January 1, 2016. This was designed to give all affected parties more time to prepare for the additional provisions included in the IFC before Part D drugs prescribed by individuals who are neither enrolled in nor opted-out of Medicare are no longer covered.

Second, we revised paragraph § 423.120(c)(6)(ii) to address a gap in § 423.120(c)(6) regarding certain types of prescribers; such prescribers included pharmacists who may be authorized under state law to prescribe medications but are ineligible to enroll in Medicare and thus, under § 423.120(c)(6), would not have their prescriptions covered. Revised paragraph (c)(6)(ii) stated that pharmacy claims and beneficiary requests for reimbursement for Part D prescriptions written by prescribers other than physicians and eligible professionals who are nonetheless permitted by state or other applicable law to prescribe medications (defined in § 423.100 as "other authorized prescribers") will not be rejected or denied, as applicable, by the pharmacy benefit manager (PBM) if all other requirements are met. This meant that

the enrollment requirement specified in § 423.120(c)(6) would not apply to other authorized prescribers—that is, to individuals who are ineligible to enroll in or opt out of Medicare because they do not meet the statutory definition of “physician” or “eligible professional” yet who are otherwise legally authorized to prescribe drugs.

Third, and to help ensure that beneficiaries would not experience a sudden lapse in Part D prescription coverage upon the January 1, 2016 effective date, we added a new paragraph § 423.120(c)(6)(v). This provision stated that a Part D sponsor or its PBM must, beginning on January 1, 2016 and upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor or PBM would otherwise be required to reject or deny, as applicable, under § 423.120(c)(6):

- Provide the beneficiary with:
 - ++ A 3-month provisional supply of the drug (as prescribed by the prescriber and if allowed by applicable law); and
 - ++ Written notice within 3 business days after adjudication of the claim or request in a form and manner specified by CMS; and
 - Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent the notice referred to in the previous paragraph.

The 3-month provisional supply and written notice were intended to (1) notify beneficiaries that a future prescription written by the same prescriber would not be covered unless the prescriber enrolled in or opted-out of Medicare, and (2) give beneficiaries time to make arrangements to continue receiving the prescription if the prescriber of the medication did not intend to enroll in or opt-out of Medicare.

(3) Preparations for Enforcement of Part D Prescriber Enrollment Requirement

Immediately after the publication of the previously mentioned May 23, 2014 final rule, we undertook major efforts to educate affected stakeholders about the forthcoming enrollment requirement. Particular focus was placed on reaching out to Part D prescribers with information regarding (1) the overall purpose of the enrollment process; (2) the important program integrity objectives behind § 423.120(c)(6); (3) the mechanisms by which prescribers may enroll in Medicare (for example, via the Internet based Provider Enrollment, Chain and Ownership System (PECOS); and (4) how to complete an enrollment application. Numerous prescribers have, in preparation for the enforcement of § 423.120(c)(6), enrolled in or opted out

of Medicare, and we are appreciative of their cooperation in this effort. However, based on internal CMS data, as of July 2016 approximately 420,000 prescribers—or 35 percent of the total 1.2 million prescribers of Part D drugs—whose prescriptions for Part D drugs would be affected by the requirements of § 423.120(c)(6) have yet to enroll or opt out. Of these prescribers, 32 percent are dentists, 11 percent are student trainees, 7 percent are nurse practitioners, 6 percent are pediatric physicians, and 5 percent are internal medicine physicians.

Several provider organizations, moreover, have expressed concerns about the enrollment requirements. They have contended that (1) most prescribers pose no risk to the Medicare program; and (2) certain types of physicians and eligible professionals prescribe Part D drugs only very infrequently. Their general position, in short, is that the burden to the prescriber community would outweigh the payment safeguard benefits of § 423.120(c)(6). After the publication of the IFC, and based on our desire to give prescribers and other stakeholders more time to prepare for the enrollment requirements, we announced a phased-in enforcement of the enrollment requirements and stated that full enforcement would be delayed until January 1, 2019. (Information was posted at the following link: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Prescriber-Enrollment-Information.html>.) However, the concerns of these provider organizations remain.

We do recognize these concerns. We wish to reduce as much burden as possible for providers without compromising our program integrity objectives. In addition, over 400,000 prescribers remain unenrolled and, as a consequence, approximately 4.2 million Part D beneficiaries (based on analysis performed on 2015 and 2016 PDE data) could lose access to needed prescriptions when full enforcement of the enrollment requirement begins on January 1, 2019 unless their prescriber enrolls or opt outs or they change prescribers. We believe that an appropriate balance is possible between burden reduction and the need to protect Medicare beneficiaries and the Trust Funds. To this end, we propose several changes to § 423.120(c)(6).

b. Proposed Provisions

In accordance with section 1871 of the Act, within 3 years of the publication of the May 6, 2015 IFC, we must either publish a final rule or

publish a notice of a different timeline. If we finalize the proposals described in this notice of proposed rulemaking, we would not finalize the provisions of the IFC. Instead, the proposals described in this publication would supersede our earlier rulemaking.

The effective date of our proposed provisions in § 423.120(c)(5) would be 60 days after the publication of a final rule. The effective date of our proposed revisions to § 423.120(c)(6) would be January 1, 2019.

(1) Prescriber NPI Validation on Part D Claims

(a) Provisions of § 423.120(c)(5)

Section 423.120(c)(5) states that before January 1, 2016, the following are applicable:

- In paragraph (c)(5)(i), we state that a Part D sponsor must submit to CMS only a prescription drug event (PDE) record that contains an active and valid individual prescriber NPI.

- In paragraph (c)(5)(ii), we state that a Part D sponsor must ensure that the lack of an active and valid individual prescriber NPI on a network pharmacy claim does not unreasonably delay a beneficiary’s access to a covered Part D drug, by taking the steps described in paragraph (c)(5)(iii) of this section.

- In paragraph (c)(5)(iii), we state that the sponsor must communicate at point-of-sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(iii).

- ++ In paragraph (c)(5)(iii)(A), we state that if the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to (1) confirm that the NPI is active and valid; or (2) correct the NPI.

- ++ In paragraph (c)(5)(iii)(B), we state that if the pharmacy:

- ++ Confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable; or

- ++ Cannot or does not correct or confirm that the NPI is active and valid, the sponsor must require the pharmacy to resubmit the claim (when necessary), which the sponsor must pay, if it is otherwise payable, unless there is an indication of fraud or the claim involves a prescription written by a foreign prescriber (where permitted by State law).

- In paragraph (c)(5)(iv), we state that a Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor—

- ++ Has complied with paragraphs (c)(5)(ii) and (iii) of this section;

++ Has verified that a submitted NPI was not in fact active and valid; and

++ The agreement between the parties explicitly permits such recoupment.

- In paragraph (c)(5)(v), we state that with respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.

These provisions, which focus on NPI submission and validation, are no longer effective because the January 1, 2016 end-date for their applicability has passed. Since that time, however, and as explained in detail in section (b)(1)(b) below, congressional legislation requires us to revisit some of the provisions in former paragraph (c)(5) and, as warranted, to re-propose them in what would constitute a new paragraph (c)(5). We believe that these new provisions would not only effectively implement the legislation in question but also enhance Part D program integrity by streamlining and strengthening procedures for ensuring the identity of prescribers of Part D drugs. This would be particularly important in light of our preclusion list proposals.

(b) Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

MACRA was signed into law on April 16, 2015, just before the IFC was finalized. Section 507 of MACRA amends section 1860D-4(c) of the Act (42 U.S.C. 1395w-104(6)) by requiring that pharmacy claims for covered Part D drugs include prescriber NPIs that are determined to be valid under procedures established by the Secretary in consultation with appropriate stakeholders, beginning with plan year 2016.

In light of the enactment of MACRA, on June 1, 2015, we issued a guidance memo, "Medicare Prescriber Enrollment Requirement Update" (memo). The memo noted that § 423.120(c)(5) would no longer be applicable beginning January 1, 2016 due to the IFC we had just published, but that its provisions reflected certain existing Part D claims procedures established by the Secretary in consultation with stakeholders through the National Council for Prescription Drug Programs (NCPDP) that would comply with section 507 of MACRA, except one.

The provisions in § 423.120(c)(5) that reflected the procedures that would comply with section 507 of MACRA are the following:

- Paragraph (c)(5)(iii).
- Paragraph (c)(5)(iii)(A).
- Paragraph (c)(5)(iii)(B)(1). (Note that paragraph (c)(5)(iii)(B)(2) would not comply with section 507 because the sponsor has no evidence that the NPI is active or valid.)
- Paragraph (c)(5)(iv).
- Paragraph (c)(5)(v).

Given this, we are proposing to include these provisions in new paragraph (c)(5). They would be enumerated as, respectively, new paragraphs (c)(5)(ii), (c)(5)(ii)(A), (c)(5)(ii)(B), (c)(5)(iii), and (c)(5)(iv). Current paragraphs (c)(5)(i), (c)(5)(ii), and (c)(5)(iii)(B)(2) would not be included in new paragraph (c)(5).

We also note that in the May 6, 2015 IFC, we revised § 423.120(c)(6)(i) to require a Part D plan sponsor to reject, or require its pharmaceutical benefit manager (PBM) to reject, a pharmacy claim for a Part D drug, unless the claim contains the NPI of the prescriber who prescribed the drug. This provision, too, reflects existing Part D claims procedures and policies that comply with section 507 of MACRA. We thus propose to retain this provision and seek comment on associated burdens or unintended consequences and alternative approaches. However, we wish to move it from paragraph (c)(6) to paragraph (c)(5) so that most of the NPI provisions in § 423.120 are included in one subsection. We believe this would improve clarity.

(2) Targeted Approach to Part D Prescribers

We believe that the most effective means of reducing the burden of the Part D enrollment requirement on prescribers, Part D plan sponsors, and beneficiaries without compromising our payment safeguard aims would be to concentrate our efforts on preventing Part D coverage of prescriptions written by prescribers who pose an elevated risk to Medicare beneficiaries and the Trust Funds. In other words, rather than require the enrollment of Part D prescribers regardless of the possible level of risk posed, we propose to focus on preventing payment for Part D drugs prescribed by demonstrably problematic prescribers.

There is precedent for such a risk based approach. For instance, consistent with § 424.518, A/B MACs are required to screen applications for enrollment in accordance with a CMS assessment of risk and assignment to a level of "limited," "moderate," or "high."

Applications submitted by provider and supplier types that have historically posed higher risks to the Medicare program are subjected to a more rigorous screening and review process than those that present limited risks. Moreover, § 424.518 states that providers and suppliers that have had certain adverse actions imposed against them, such as felony convictions or revocations of enrollment, are placed into the highest and most rigorous screening level. We recognize that the risk based approach in § 424.518 applies to enrollment application screening rather than payment denials. However, we believe that using a risk-based approach would enable CMS to focus on prescribers who pose threats to the Medicare program and its beneficiaries, while minimizing the burden on those who do not. The process we envision and propose, which would replace the prescriber enrollment requirement outlined in § 423.120(c)(6) with a claims payment-oriented approach, would consist of the following components:

- Step 1: We would research our internal systems and other relevant data for prescribers who have engaged in behavior for which CMS:

++ Has revoked the prescriber's enrollment and the prescriber is under a reenrollment bar; or

++ Could have revoked the prescriber (to the extent applicable) if he or she had been enrolled in Medicare.

Concerning revocations, we have the authority to revoke a provider's or supplier's Medicare enrollment for any of the applicable reasons listed in § 424.535(a). There are currently 14 such reasons. When revoked, the provider or supplier is barred under § 424.535(c) from reenrolling in Medicare for a period of 1 to 3 years, depending upon the severity of the underlying behavior. We have an obligation to protect the Trust Funds from providers and suppliers that engage in activities that could threaten the Medicare program, its beneficiaries, and the taxpayers. In light of the significance of behavior that could serve as grounds for revocation, we believe that prescribers who have engaged in inappropriate activities should be the focus of our Part D program integrity efforts under § 423.120(c)(6).

- Step 2—We would review, on a case-by-case basis, each prescriber who—

++ Is currently revoked from Medicare and is under a reenrollment bar. We would examine the reason for the prescriber's revocation.

++ Has engaged in behavior for which CMS could have revoked the

prescriber to the extent applicable if he or she had been enrolled in Medicare.

The prescribers to be reviewed would be those who, according to PDE data and CMS' internal systems, are eligible to prescribe drugs covered under the Part D program. That is, our review would not be limited to those persons who are actually prescribing Part D drug, but would include those that potentially could prescribe drugs. We believe that the inclusion of these individuals in our review would help further protect the integrity of the Part D program.

We are also seeking comment on an alternative by which we would first identify, through PDE data, those providers who are prescribing drugs to Medicare beneficiaries. This would significantly reduce the universe of prescribers who are on the preclusion list and reduce the government's surveillance of prescribers. We anticipate that this could create delays in our ability to screen providers due to data lags and may introduce some program integrity risks. We are particularly interested in hearing from the public on the potential risks this could pose to beneficiaries, especially in light of our efforts to address the opioids epidemic.

- Step 3—Based on the results of Steps 1 and 2, we would compile a “preclusion list” of prescribers who fall within either of the following categories:

- ++ Are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.

- ++ Have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

We propose to adopt this preclusion list approach as an alternative to enrollment in part to reflect the more indirect connection of prescribers in the Medicare Part D program. We seek comment on whether some of the bases for revocation should not apply to the preclusion list in whole or in part and whether the final regulation (or future guidance) should specify which bases are or are not applicable and under what circumstances.

(i) Preclusion List

Considering the program integrity risk that the two previously mentioned sets of prescribers present, we must be able to accordingly protect Medicare

beneficiaries and the Trust Funds. We thus propose to revise § 423.120(c)(6), as further specified in this proposed rule, to require that a Part D plan sponsor must reject, or must require its PBM to reject, a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug prescribed by an individual on the preclusion list. We believe we have the legal authority for such a provision because sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program; also, section 1860D–12(b)(3)(D) of the Act authorizes the Secretary to add additional Part D contract terms as necessary and appropriate, so long as they are not inconsistent with the Part D statute. We note also that our proposal is of particular importance when considering the current nationwide opioid crisis. We believe that the inclusion of problematic prescribers on the preclusion list could reduce the amount of opioids that are improperly or unnecessarily prescribed by persons who pose a heightened risk to the Part D program and Medicare beneficiaries.

All grounds for revocation under § 424.535(a) reflect behavior or circumstances that are of concern to us. However, considering the variety of factual scenarios that CMS may come across, we believe it is necessary for CMS to have the flexibility to take into account the specific circumstances involved when determining whether the underlying conduct is detrimental to the best interests of the Medicare program. Accordingly, CMS would consider the following factors in making this determination:

- The seriousness of the conduct involved;
- The degree to which the prescriber's conduct could affect the integrity of the Part D program; and
- Any other evidence that CMS deems relevant to its determination.

We emphasize that in situations where the prescriber was enrolled and then revoked, CMS' determination would not negate the revocation itself. The prescriber would remain revoked from Medicare.

We also recognize that unique circumstances behind the potential or actual inclusion of a particular prescriber on the preclusion list could exist. Of foremost importance would be situations pertaining to beneficiary access to Part D drugs. We believe that we should have the discretion not to include (or, if warranted, to remove) a particular individual on the preclusion list (who otherwise meets the standards for said inclusion) should exceptional

circumstances exist pertaining to beneficiary access to prescriptions. This could include circumstances similar to those described in section 1128(c)(3)(B) of the Act, whereby the Secretary may waive an OIG exclusion under section 1128(a)(1), (a)(3), or (a)(4) of the in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community. In making a determination as to whether such circumstances exist, we would take into account— (1) the degree to which beneficiary access to Part D drugs would be impaired; and (2) any other evidence that CMS deems relevant to its determination.

With respect to the foregoing, we solicit comment on the following issues:

- ++ Whether the actions referenced in § 424.535(a) are appropriate grounds for inclusion on the preclusion list.

- ++ Whether actions other than those referenced in § 424.535(a) should constitute grounds for inclusion on the preclusion and, if so, what those specific grounds are.

- ++ Suggestions for means of monitoring abusive prescribing practices and appropriate processes for including such prescribers on the preclusion list.

(b) Replacement of Enrollment Requirement With Preclusion List Requirement

We are proposing to delete the current regulations that require prescribers to enroll in or opt out of Medicare for a pharmacy claim (or beneficiary request for reimbursement) for a Part D drug prescribed by a physician or eligible professional to be covered. We also propose to generally streamline the existing regulations because, given that we would no longer be requiring certain prescribers to enroll or opt out, we would no longer need an exception for “other authorized providers,” as defined in § 423.100, for there would be no enrollment requirement from which to exempt them. Instead, we would require plan sponsors to reject claims for Part D drugs prescribed by prescribers on the preclusion list. We believe this latter approach would better facilitate our dual goals of reducing prescriber burden and protecting the Medicare program and its beneficiaries from prescribers who could present risks.

(ii) Updates to Preclusion List

The preclusion list would be updated on a monthly basis. Prescribers would be added or removed from the list based on CMS' internal data that indicate, for instance: (1) Prescribers who have recently been convicted of a felony that,

consistent with § 424.535(a)(33), CMS determines to be detrimental to the best interests of the Medicare program, and (2) prescribers whose reenrollment bars have expired. As a particular prescriber's status with respect to the preclusion list changes, the applicable provisions of § 423.120(c)(6) would control. To illustrate, suppose a prescriber in March 2020 is convicted of a felony that CMS deems detrimental to Medicare's best interests. Pharmacy claims for prescriptions written by the individual would thus be rejected by Part D sponsors or their PBMs upon the prescriber being added to the preclusion list. Conversely, a prescriber who was revoked under § 424.535(a)(4) but whose reenrollment bar has expired would be removed from the preclusion list; claims for prescriptions written by the individual would therefore no longer be rejected based solely on his or her inclusion on the preclusion list. CMS would regularly review the preclusion list to determine whether certain individuals should be added to or removed therefrom based on changes to their status.

Consistent with our application of a reenrollment bar to providers and suppliers that are enrolled in and then revoked from Medicare, we propose to keep an unenrolled prescriber on the preclusion list for the same length of time as the reenrollment bar that we could have imposed on the prescriber had he or she been enrolled and then revoked. For example, suppose an unenrolled prescriber engaged in behavior that, had he or she been enrolled, would have warranted a 2-year reenrollment bar. The prescriber would remain on the preclusion list for that same period of time. We note that in establishing such a time period, we would use the same criteria that we do in establishing reenrollment bars.

Prescribers who were revoked from Medicare or, for unenrolled prescribers, engaged in behavior that could serve as a basis for an applicable revocation prior to the effective date of this rule (if finalized) could, if the requirements of § 423.120(c)(6) are met, be added to the preclusion list upon said effective date even though the underlying action (for instance, felony conviction) occurred prior to that date. However, the Part D claim rejections by Part D sponsors and their PBMs under § 423.120(c)(6) would only apply to claims for Part D prescriptions filled or refilled on or after the date he or she was added to the preclusion list; that is, sponsors and PBMs would not be required to retroactively reject claims based on the effective date of the revocation or, for unenrolled prescribers, the date of the

behavior that could serve as a basis for an applicable revocation regardless of whether that date occurred before or after the effective date of this rule.

We do seek comment on a reasonable time period for Part D sponsors/PBMs to incorporate the preclusion list into their claims adjudication systems, and whether and how our proposed regulatory text needs to be modified to accommodate such a time period. We wish to avoid a situation where a Part D sponsor/PBM pays for prescriptions written by individuals on the preclusion list before the sponsors/PBMs have incorporated the list but later are unable to submit their PDEs, which CMS typically edits based on date of service.

(3) Provisional Coverage

The current text of § 423.120(c)(6)(v) states that a Part D sponsor or its PBM must, upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor would otherwise be required to deny in accordance with § 423.120(c)(6), furnish the beneficiary with (a) a provisional supply of the drug (as prescribed by the prescriber and if allowed by applicable law); and (b) written notice within 3 business days after adjudication of the claim or request in a form and manner specified by CMS. The purpose of this provisional supply requirement is to give beneficiaries notice that there is an issue with respect to future Part D coverage of a prescription written by a particular prescriber.

Although CMS' proposed changes to § 423.120(c)(6) would significantly reduce the number of affected prescribers and, by extension, the number of impacted beneficiaries, we remain concerned that beneficiaries who receive prescriptions written by individuals on the preclusion list might suddenly no longer have access to these medications without provisional coverage and without notice, which gives beneficiaries time to find a new prescriber. Therefore, we propose to maintain the provisional coverage requirement consistent with what was finalized in the IFC, but with a modification. Additionally, many commercial plans are pursuing policies to address the opioid epidemic, such as limiting the amount of initial opioid prescriptions. Given the opioid epidemic, we are considering other solutions for when a beneficiary tries to fill an opioid prescription from a provider on the preclusion list. We seek comment as to what limits or other guardrails CMS should set with respect to number of doses, initial dosing, and type of product for opioid prescriptions

for particular clinical presentations (including acute pain, chronic pain, hospice setting and so forth).

An alternative method of ensuring beneficiaries have access to opioids as necessary would be to require the sponsor immediately provide a transfer to a new provider when the first provider is on the preclusion list. The new provider should be able to make an assessment and either provide appropriate SUD treatment or continue the opioid or pain management regimen, as medically appropriate. We are interested to hear from commenters how to operationalize this and whether there is a better method to ensure appropriate medication is provided without transferring the beneficiary to a new provider. We are proposing a 90-day provisional coverage period in lieu of a 3-month drug supply/90-day time period established in existing § 423.120(c)(6), which was described on page 6 in the Technical Guidance on Implementation of the Part D Prescriber Enrollment Requirement (Technical Guidance) issued on December 29, 2015.⁵⁹ Under the existing regulation (which, as noted above, we have not enforced), a sponsor or MA-PD must track a separate 90-day consecutive time period for each drug covered as a provisional supply from the initial date-of-service; the sponsor or MA-PD must not reject a claim or deny a beneficiary's request for reimbursement until the 90-day time period has passed or a 3-month supply has been dispensed, whichever comes first. Under our proposal, however, a beneficiary would have one 90-day provisional coverage period with respect to an individual on the preclusion list. Accordingly, a sponsor/PBM would track one 90-day time period from the date the first drug is dispensed to the beneficiary pursuant to a prescription written by the individual on the preclusion list. This dispensing event would trigger a written notice and a 90-day time period for the beneficiary to fill any prescriptions from that particular precluded prescriber and to find another prescriber during that 90-day time period.

Our rationale for this change is that individuals on the preclusion list are demonstrably problematic. This has negative implications not only for the Trust Funds but also for beneficiary safety. Thus, it is imperative that a beneficiary switch to a new prescriber who is not on the preclusion list as soon as practicable. Under the current

⁵⁹ See <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Technical-Guidance-on-Implementation-of-the-Part-D-Prescriber-Enrollment-Requirement.pdf>.

prescriber enrollment requirement, the vast majority of prescribers who are not enrolled in or opted-out of Medicare likely do not pose a risk to the beneficiary or the Trust Funds, and therefore we can allow a 3-month provisional supply/90-day time period for each prescription written by such a prescriber. In addition, our proposed policy would eliminate the difficulty sponsors and PBMs have under the current “per drug” provisional supply policy in determining whether the beneficiary already received a provisional supply of a drug. We seek specific comment on the modifications we are proposing as to the provisional coverage and time period.

With respect to beneficiaries who would also be entitled to a transition, we are not proposing any change to the current policy. If a Part D sponsor determines when adjudicating a pharmacy claim that a beneficiary is entitled to provisional coverage because the prescriber is on the preclusion list, but the drug is off-formulary and the transition requirements set forth in § 423.120(b)(3) are also triggered, the beneficiary would not receive more than the applicable transition supply of the drug, unless a formulary exception is approved. We note that we considered proposing that the transition requirements would not apply during the provisional supply period in order to simplify the policy for situations when both apply to reduce beneficiary confusion. We seek comment on this or other alternatives for these situations.

We intend to allow the normal Part D rules (for example, edits, prior authorization, quantity limits) to apply during the 90-day provisional coverage period, but solicit comment on whether different limits should apply when opioids are involved, particularly when the reason for precluding the provider/prescriber relates to opioid prescribing.

(4) Appeals

In our revisions to § 423.120(c)(6), we propose to permit prescribers who are on the preclusion list to appeal their inclusion on this list in accordance with 42 CFR part 498. We believe that given the aforementioned pharmacy claim rejections that would be associated with a prescriber’s appearance on the preclusion list, due process warrants that the prescriber have the ability to challenge this via appeal. Any appeal under this proposed provision, however, would be limited strictly to the individual’s inclusion on the preclusion list. The proposed appeals process would neither include nor affect appeals of payment denials or enrollment revocations, for there are

separate appeals processes for these actions. In addition, we would send written notice to the prescriber of his or her inclusion on the preclusion list. The notice would contain the reason for the inclusion and would inform the prescriber of his or her appeal rights. This is to ensure that the prescriber is duly notified of the action, why it was taken, and his or her ability to challenge our determination.

Consistent with our proposed provision in § 423.120(c)(6) regarding appeal rights, we propose to update several other regulatory provisions regarding appeals:

- We propose to revise § 498.3(b) to add a new paragraph (20) stating that a CMS determination to include a prescriber on the preclusion list constitutes an initial determination. This revision would help enable prescribers to utilize the appeals processes described in § 498.5.

- In § 498.5, we propose to add a new paragraph (n) that would state as follows:

++ In paragraph (n)(1), we propose that any prescriber dissatisfied with an initial determination or revised initial determination that he or she is to be included on the preclusion list may request a reconsideration in accordance with § 498.22(a).

++ In paragraph (n)(2), we propose that if CMS or the prescriber under paragraph (n)(1) is dissatisfied with a reconsidered determination under § 498.5(n)(1), or a revised reconsidered determination under § 498.30, CMS or the prescriber is entitled to a hearing before an administrative law judge (ALJ).

++ In paragraph (n)(3), we propose that if CMS or the prescriber under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the prescriber may request review by the Departmental Appeals Board (DAB) and the prescriber may seek judicial review of the DAB’s decision.

These revisions are designed to include preclusion list determinations within the scope of appeal rights described in § 498.5. However, we solicit comment on whether a different appeals process is warranted and, if so, what its components should be.

In addition, given that a beneficiary’s access to a drug may be denied because of the application of the preclusion list to his or her prescription, we believe the beneficiary should be permitted to appeal alleged errors in applying the preclusion list.

c. Specific Regulatory Changes

Given the foregoing discussion, we propose the following regulatory changes:

- In § 423.100, we propose to delete the definition of “other authorized prescriber” and add the following:

++ Preclusion List means a CMS compiled list of prescribers who:

(1) Meet all of the following requirements: (A) The prescriber is currently revoked from the Medicare program under § 424.535.

(B) The prescriber is currently under a reenrollment bar under § 424.535(c).

(C) CMS determines that underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

(i) The seriousness of the conduct underlying the prescriber’s revocation;

(ii) The degree to which the prescriber’s conduct could affect the integrity of the Part D program; and

(iii) Any other evidence that CMS deems relevant to its determination; or

(2) Meet both of the following requirements:

(i) The prescriber has engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare.

(ii) CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

(i) The seriousness of the conduct involved.

(ii) The degree to which the prescriber’s conduct could affect the integrity of the Part D program; and

(iii) Any other evidence that CMS deems relevant to its determination

- In paragraph (c)(5)(i), we propose that a Part D plan sponsor must reject, or must require its pharmacy benefit manager (PBM) to reject, a pharmacy claim for a Part D drug unless the claim contains the active and valid National Provider Identifier (NPI) of the prescriber who prescribed the drug. This requirement is consistent with existing policy.

- In paragraph (c)(5)(ii), we propose that the sponsor must communicate at point-of sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(ii).

- In paragraph (c)(5)(ii)(A), we propose that if the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to—

++ Confirm that the NPI is active and valid; or

++ Correct the NPI.

• In paragraph (c)(5)(ii)(B), we propose that if the pharmacy confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable.

• In paragraph (iii), we propose that a Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor—

++ Has complied with paragraph (ii) of this section;

++ Has verified that a submitted NPI was not in fact active and valid; and

++ The agreement between the parties explicitly permits such recoupment.

• In paragraph (iv), we propose that with respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.

• In paragraph (c)(6)(i), we propose to state: "Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the preclusion list, defined in § 423.100." This would help ensure that Part D sponsors comply with our proposed requirement that claims involving prescribers who are on the preclusion list should not be paid.

• In paragraph (c)(6)(ii), we propose to state as follows: "Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must deny, or must require its PBM to deny, a request for reimbursement from a Medicare beneficiary if the request pertains to a Part D drug that was prescribed by an individual who is identified by name in the request and who is included on the preclusion list, defined in § 423.100." As with paragraph (c)(6)(i), this would help ensure that Part D sponsors comply with our proposed requirement that payments not be made for prescriptions written by prescribers who are on the preclusion list.

• In paragraph (c)(6)(iii), we propose to state: "A Part D plan sponsor may not submit a prescription drug event (PDE)

record to CMS unless it includes on the PDE record the active and valid individual NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in § 423.100, for the date of service." This is to help ensure that— (1) the prescriber can be properly identified, and (2) prescribers who are on the preclusion list are not included in PDEs.

• In paragraph (c)(6)(iv), we propose to address the provisional coverage period and notice provisions as follows:

"(iv)(A) A Part D sponsor or its PBM must not reject a pharmacy claim for a Part D drug under paragraph (c)(6)(i) of this section or deny a request for reimbursement under paragraph (c)(6)(ii) of this section unless the sponsor has provided the provisional coverage of the drug and written notice to the beneficiary required by paragraph (c)(6)(iv)(B) of this section.

(B) Upon receipt of a pharmacy claim or beneficiary request for

reimbursement for a Part D drug that a Part D sponsor would otherwise be required to reject or deny in accordance with paragraphs (c)(6)(i) or (ii) of this section, a Part D sponsor or its PBM must do the following: (1) Provide the beneficiary with the following, subject to all other Part D rules and plan coverage requirements:

(i) A 90-day provisional supply coverage period during which the sponsor must cover all drugs dispensed to the beneficiary pursuant to prescriptions written by the individual on the preclusion list. The provisional supply period begins on the date-of-service the first drug is dispensed pursuant to a prescription written by the individual on the preclusion list.

(ii) Written notice within 3 business days after adjudication of the first claim or request for the drug in a form and manner specified by CMS.

(2) Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(B)(1)(ii) of this section."

• In new § 423.120(c)(6)(v), we propose that CMS would send written notice to the prescriber via letter of his or her inclusion on the preclusion list. The notice would contain the reason for the inclusion on the preclusion list and would inform the prescriber of his or her appeal rights. A prescriber may appeal his or her inclusion on the preclusion list in accordance with 42 CFR part 498.

• In new § 423.120(c)(6)(vi), we propose that CMS has the discretion not to include a particular individual on (or, if warranted, remove the individual from) the preclusion list should it

determine that exceptional circumstances exist regarding beneficiary access to prescriptions. In making a determination as to whether such circumstances exist, CMS would take into account—(1) the degree to which beneficiary access to Part D drugs would be impaired; and (2) any other evidence that CMS deems relevant to its determination.

• In § 498.3(b), we propose to add a new paragraph (20) stating that a CMS determination that a prescriber is to be included on the preclusion list constitutes an initial determination.

• In § 498.5, we propose to add a new paragraph (n) that would state as follows:

++ In paragraph (n)(1), we propose that any prescriber dissatisfied with an initial determination or revised initial determination that he or she is to be included on the preclusion list may request a reconsideration in accordance with § 498.22(a).

++ In paragraph (n)(2), we propose that if CMS or the prescriber under paragraph (n)(1) is dissatisfied with a reconsidered determination under § 498.5(n)(1), or a revised reconsidered determination under § 498.30, CMS or the prescriber is entitled to a hearing before an ALJ.

++ In paragraph (n)(3), we propose that if CMS or the prescriber under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the prescriber may request review by the DAB and the prescriber may seek judicial review of the DAB's decision.

11. Preclusion List—Part C/Medicare Advantage Cost Plan and PACE Provisions

a. Background

(1) 2016 Final Rule

On November 15, 2016, CMS published a final rule in the **Federal Register** titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements" (81 FR 80169). This rule contained a number of requirements related to provider enrollment, including, but not limited to, the following:

• We added a new § 422.222 to require providers and suppliers that furnish health care items or services to

a Medicare enrollee who receives his or her Medicare benefit through an MA organization to be enrolled in Medicare and be in an approved status no later than January 1, 2019. (The term “MA organization” refers to both MA plans and MA plans that provide drug coverage, otherwise known as MA–PD plans.) We also updated §§ 417.478, 460.70, and 460.71 to reflect this requirement.

- We added a requirement in new § 422.204(b)(5) that required MA organizations to comply with the provider and supplier enrollment requirements referenced in § 422.222. A similar requirement was added to § 422.504.

- We revised §§ 422.510, 422.752, 460.40, and 460.50 to state that organizations and programs that do not ensure that providers and suppliers comply with the provider and supplier enrollment requirements may be subject to sanctions and termination.

- We revised § 422.501 to require that MA organization applications include documentation demonstrating that all applicable providers and suppliers are enrolled in Medicare in an approved status. We believed that these new requirements, as they pertained to MA, were necessary to help ensure that Medicare enrollees receive items or services from providers and suppliers that are fully compliant with the requirements for Medicare enrollment. We also believed it would assist our efforts to prevent fraud, waste, and abuse, and to protect Medicare enrollees, by allowing us to carefully screen all providers and suppliers (especially those that potentially pose an elevated risk to Medicare) to confirm that they are qualified to furnish Medicare items and services. Indeed, although § 422.204(a) requires MA organizations to have written policies and procedures for the selection and evaluation of providers and suppliers that conform with the credentialing and recredentialing requirements in § 422.204(b), CMS has not historically had direct oversight over all network providers and suppliers under contract with MA organizations. While there are CMS regulations governing how and when MA organizations can pay for covered services, those are tied to statutory provisions. We concluded that requiring Medicare enrollment in addition to the existing MA credentialing requirements would permit a closer review of MA providers and suppliers, which could, as warranted, involve rigorous screening practices such as risk-based site visits and, in some cases, fingerprint-based background checks, an approach we

already take in the Medicare Part A and Part B provider and supplier enrollment arenas. The fact that CMS also has access to information and data not available to MA organizations was also relevant to our decision.

(2) Preparations for Part C Enrollment

As with our Part D enrollment requirement, we promptly commenced outreach efforts after the publication of the November 15, 2016 final rule. We communicated with Part C provider associations and MA organizations regarding, among other things, the general purpose of the enrollment process, the rationale for § 422.222, and the mechanics of completing and submitting an enrollment application. According to recent CMS internal data, approximately 933,000 MA providers and suppliers are already enrolled in Medicare and meeting the MA provider enrollment requirements. However, roughly 120,000 MA-only providers and suppliers remain unenrolled in Medicare, and concerns have been raised by the MA community over the enrollment requirement, principally over the burden involved in enrolling in Medicare while having to also undergo credentialing by their respective health plans.

We understand and share these concerns. We believe that the Medicare enrollment requirement could result in a duplication of effort and, consequently, impose a burden on MA providers and suppliers as well as MA organizations and beneficiaries in the form of limiting access to providers. While we maintain that Medicare enrollment, in conjunction with MA credentialing, is the most thorough means of confirming a provider's compliance with Medicare requirements and of verifying the provider's qualifications to furnish services and items, we believe that an appropriate balance can be achieved between this program integrity objective and the desire to reduce the burden on the provider and supplier communities. Given this, we propose to utilize the same “preclusion list” concept in MA that we are proposing for Part D (described in section III.B.9.) and to eliminate the current enrollment requirement in § 422.222. We believe this approach would allow us to concentrate our efforts on preventing MA payment for items and services furnished by providers and suppliers that could pose an elevated risk to Medicare beneficiaries and the Trust Funds, an approach, as previously mentioned, similar to the risk-based process in § 424.518. This would, we

believe, minimize the burden on MA providers and suppliers.

b. Proposed Provisions

(1) Process

The process we envision and propose would, similar to the proposed Part D process, consist of the following components:

- Step 1: We would research our internal systems and other relevant data for individuals and entities that have engaged in behavior for which CMS:

- ++ Has revoked the individual's or entity's enrollment and the individual or entity is under a reenrollment bar; or
- ++ Could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare.

In light of the significance of any activity that would result in a revocation under § 424.535(a), we believe that individual and entities that have engaged in inappropriate behavior should be the focus of our Part C program integrity efforts.

- Step 2—CMS would review, on a case-by-case basis, each individual and entity that:

- ++ Is currently revoked from Medicare and is under a reenrollment bar. We would examine the reason for the revocation.

- ++ Has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if he or she had been enrolled in Medicare.

Similar to our approach with Part D and for the same reason, the individuals and entities to be reviewed would be those that— according to CMS' internal systems MA organization data, state board information, and other relevant data for individuals and entities who are or who could become eligible to furnish health care services or items. To avoid confusion, we refer to such parties in our proposed Part C preclusion list provisions as “individuals” and “entities” rather than “providers” and “suppliers.” This is because the latter two terms could convey the impression that the party in question must be actively furnishing health care services or items to be included on the preclusion list.

Similar to the Part D approach, we are also seeking comment on an alternative by which CMS would first identify through encounter data those providers or suppliers furnishing services or items to Medicare beneficiaries. This would significantly reduce the universe of prescribers who are on the preclusion list and reduce the government's surveillance of prescribers. We

anticipate that this could create delays in CMS' ability to screen providers or suppliers due to data lags and may introduce some program integrity risks. We are particularly interested in hearing from the public on the potential risks this could pose to beneficiaries.

Based on the results of Steps 1 and 2, we would compile a preclusion list of individuals and entities that fall within either of the following categories:

++ Are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.

++ Have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

We propose to update § 422.2 to add a definition of "preclusion list" consistent with both the foregoing discussion as well as our proposed definition of the same term for the Part D program.

We propose to adopt this preclusion list approach as an alternative to enrollment in part to reflect the more indirect connection of providers and suppliers in Medicare Advantage. We seek comment on whether some of the bases for revocation should not apply to the preclusion list in whole or in part and whether the final regulation (or future guidance) should specify which bases are or are not applicable and under what circumstances.

In addition, we note that while there would be separate regulatory provisions for Part C and Part D, there would not be two separate preclusion lists: one for Part C and one for Part D. Rather, there would be a single preclusion list that includes all affected individuals and entities. Having one joint list, we believe, would make the preclusion list process easier to administer.

(2) Denial of Payment

Section 422.222(a) currently states that providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a Medicare enrollee who receives his or her Medicare benefit through an MA organization. This requirement applies to all of the following providers and suppliers:

- Network providers and suppliers.

- First-tier, downstream, and related entities (FDR).

- Providers and suppliers in Cost HMOs or CMPs, as defined in 42 CFR part 417.

- Providers and suppliers participating in demonstration programs.

- Providers and suppliers in pilot program.

- Locum tenens suppliers.

- Incident-to suppliers.

We propose to revise this requirement to state that an MA organization shall not make payment for an item or service furnished by an individual or entity that is on the preclusion list (as defined in § 422.2). We also propose to remove the language beginning with "This requirement applies to all of the following providers and suppliers" along with the list of applicable providers, suppliers, and FDRs. This is consistent with our previously mentioned intention to use the terms "individuals" and "entities" in lieu of "providers" and "suppliers."

We also propose that both basic and supplemental benefits should be subject to the payment prohibition that is tied to the preclusion list. We believe that restricting the payment prohibition to only one of these two categories would undercut the effectiveness of our preclusion list proposal.

We solicit comment on the following issues:

++ Whether the actions referenced in § 424.535(a) are appropriate grounds for inclusion on the preclusion list.

++ Whether actions other than those referenced in § 424.535(a) should constitute grounds for inclusion on the preclusion and, if so, what those specific grounds are.

++ Suggestions for means of monitoring potentially abusive MA practices involving providers and suppliers, and appropriate processes for including such providers and suppliers on the preclusion list.

As stated earlier in reference to prescribers, the preclusion list would be updated on a monthly basis. Individuals and entities would be added or removed from the list based on CMS' internal data or other informational sources that indicate, for instance— (1) persons eligible to provide medical services who have recently been convicted of a felony that CMS determines to be detrimental to the best interests of the Medicare program; and (2) entities whose reenrollment bars have expired. As a particular individual's or entity's status with respect to the preclusion list changes, the applicable provisions of § 422.222 would control.

Individuals and entities that were revoked from Medicare or, for unenrolled individuals and entities, had engaged in conduct that could serve as a basis for an applicable revocation prior to the effective date of this rule (if finalized) could, if the requirements of § 422.222(a) are met, be added to the preclusion list upon said effective date even though the underlying action (for instance, felony conviction) occurred prior to that date. The proposed payment denials under § 422.222(a), however, would only apply to health care items or services furnished on or after the date the individual or entity was added to the preclusion list; that is, payment denials would not be made retroactive to the date of the revocation or, for unenrolled individuals and entities, the conduct that could serve as a basis for an applicable revocation occurring before the effective date of the final rule. Likewise, health care items and services furnished by individuals and entities revoked from Medicare or engaging in conduct that could serve as a basis for an applicable revocation after the rule's effective date and that are subsequently added to the preclusion list would not be subject to retroactive payment denials under § 422.222(a); only the date on which the affected individual or entity is added to the preclusion list would be used to determine payment and the start date of payment denials under this proposal. We believe that this approach is the most consistent with principles of due process.

(3) MA Organization Compliance

Section 422.222 currently states that MA organizations that do not ensure that providers and suppliers comply with paragraph (a) may be subject to sanctions under § 422.750 and termination under § 422.510. We propose to revise this to state that MA organizations that do not comply with paragraph (a) may be subject to sanctions under § 422.750 and termination under § 422.510. This is to help ensure that MA organizations do not make improper payments for items and services furnished by individuals and entities on the preclusion list.

(4) Related Revisions

As discussed previously, in the November 15, 2016 final rule, we added or updated a number of other MA regulatory provisions (for example, § 422.501 and 422.510) in order to fully incorporate our new enrollment requirements. Because we are proposing to replace these enrollment requirements with an approach centered upon a preclusion list—and to help

ensure that providers, suppliers, MA organizations, PACE organizations, and other applicable stakeholders comply with our proposed requirements—we believe that these other MA regulatory provisions must also be revised to reflect this change. To this end, we propose the following revisions:

- Section 422.204(a) states that an MA organization must have written policies and procedures for the selection and evaluation of providers and suppliers. These policies must conform with the credentialing and recertification requirements in § 422.204(b). Under paragraph (b)(5), an MA organization must follow a documented process with respect to providers and suppliers that have signed contracts or participation agreements that ensures compliance with the provider and supplier enrollment requirements in § 422.222. To achieve consistency with our preclusion list proposals and to help facilitate MA organizations' compliance therewith, we propose to:

- ++ Establish a new § 422.204(c) that would require MA organizations to follow a documented process that ensures compliance with the preclusion list provisions in § 422.222.

- ++ Delete § 422.204(b)(5) because it applies to the Part C enrollment process, which we are proposing to eliminate. Further, revising paragraph (b)(5) to address the preclusion list requirements could cause confusion, for paragraph (b) references providers and suppliers. We thus believe that creating a new paragraph (c) would better clarify our expectations.

- In 42 CFR part 417, subpart L, we address certain contractual requirements concerning health maintenance organizations (HMOs) and competitive medical plans (CMPs) that contract with CMS to furnish covered services to Medicare beneficiaries. Under § 417.478(e), the contract between CMS and the HMO or CMP must, among other things, provide that the HMO or CMP agrees to comply with “Sections 422.222 and 422.224, which require all providers and suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, to be enrolled in Medicare in an approved status and prohibits payment to providers and suppliers that are excluded or revoked.” Paragraph (e) adds that this requirement includes “locum tenens suppliers and, if applicable, incident-to suppliers.”

Furthermore, § 417.484(b)(3) requires that the contract must provide that the HMO or CMP agrees to require all related entities to agree that “All

providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, are enrolled in Medicare in an approved status.” We accordingly propose the following revisions:

- ++ We propose to revise § 417.478(e) to state as follows:

- ++ In new paragraph (e)(1), we propose to state that the prohibitions, procedures and requirements relating to payment to individual and entities on the preclusion list (defined in § 422.2 of this part) apply to HMOs and CMPs that contract with CMS under section 1876 of the Act.

- ++ In new paragraph (e)(2), we propose to state that in applying the provisions of §§ 422.2, 422.222, and 422.224 under paragraph (e)(1) of this section, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

- ++ We propose to revise § 417.484(b)(3) to state: “That payments must not be made to individuals and entities that are included on the preclusion list (as defined in § 422.2).”

- In 42 CFR part 460, we address requirements relating to Programs of All-Inclusive Care for the Elderly (PACE). The PACE program is a state option under Medicaid to provide for Medicaid payments to, and coverage of benefits under, PACE. We propose to make the following changes to Part 460:

- ++ Section 460.40 states that, in addition to other remedies authorized by law, CMS may impose any of the sanctions specified in §§ 460.42 and 460.46 if CMS determines that a PACE organization commits certain violations, one of which is outlined in paragraph (j) and reads: “Employs or contracts with any provider or supplier that is a type of individual or entity that can enroll in Medicare in accordance with section 1861 of the Act, that is not enrolled in Medicare in an approved status.” We propose to revise paragraph (j) to state: “Makes payment to any individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.”

- ++ Section 460.50(b) addresses grounds for which CMS or the state administering agency may terminate a PACE program agreement if CMS or the state administering agency determines that the conditions of paragraphs (b)(1) and (2) are met. In (b)(1), one of two conditions, outlined in paragraphs (b)(1)(i) and (ii), must be met. Paragraph (b)(1)(ii) states: “The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with

terms of its PACE program agreement, including employing or contracting with any provider or supplier that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, that is not enrolled in Medicare in an approved status.” We propose to revise paragraph (b)(1)(ii) by changing the current language beginning with “including” to read “including making payment to an individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.” We note that this change would not prohibit a PACE organization from employing or contracting with an individual or entity on the preclusion list. As previously discussed, the focus of our preclusion list proposals is on the denial of payment.

- ++ Section 460.68(a) lists certain categories of individuals who a PACE organization may not employ, as well as individuals and organizations with whom a PACE organization may not contract. Among these parties are those listed in paragraph (a)(4); specifically, those “that are not enrolled in Medicare in an approved status, if the providers or suppliers are of the types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act.” We propose to delete paragraph (a)(4), given our proposed removal of the Part C enrollment requirement.

- ++ Section 460.70(a) states that a PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization, except for emergency services as described in § 460.100; various requirements that a contract between a PACE organization and a contractor must meet are listed in § 460.70(b). Paragraph (b)(1) states that the PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, those listed in paragraphs (b)(1)(i) through (iv). Paragraph (b)(1)(iv) reads: “Providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a PACE participant who receives his or her Medicare benefit through a PACE organization.” Consistent with our proposed deletion of § 460.68(a)(4), we propose to delete § 460.70(b)(1)(iv). We note that we are not proposing to prohibit individuals and entities on the preclusion list from furnishing services

and items to PACE participants; we are merely proposing to prohibit payment for such services and items if provided by an individual or entity on the preclusion list.

++ Section 460.71(b) states that a PACE organization must develop a program to ensure that all staff furnishing direct participant care services meets the requirements outlined in paragraph (b). One of these requirements, listed in paragraph (b)(7), reads: “Providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, must be enrolled in Medicare and be in an approved status in Medicare in order to provide health care items or services to a PACE participant who receives his or her Medicare benefit through a PACE organization.” Similar to our proposed deletion of § 460.68(a)(4), we propose to delete paragraph (b)(7).

++ Section 460.86 addresses payments to excluded or revoked providers and suppliers as follows:

++ Paragraph (a) states that a PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is revoked from the Medicare program.

++ Paragraph (b) states: “If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is revoked from the Medicare program, the PACE organization must notify the enrollee and the excluded or revoked individual or entity in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is revoked from the Medicare program.”

We propose to revise these paragraphs as follows:

++ Paragraph (a) would state: “A PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2 of this chapter.” We are not proposing to include the current regulatory language “or revoked” in our revised paragraph. This is because, as outlined previously, there could be situations

under revised § 422.222 where a revoked individual or entity would not be included on the preclusion list.

++ Paragraph (b) would state: “If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list, defined in § 422.2 of this chapter, the PACE organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.”

• Section 422.501(c) states that in order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity (or an individual authorized to act for the entity (the applicant)), must fully complete all parts of a certified application. As part of the application, paragraph (c)(1)(iv) requires “(d)ocumentation that all providers or suppliers in the MA or MA–PD plan that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, are enrolled in an approved status.” Also, paragraph (c)(2) requires the following: “The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation that all providers and suppliers referenced in § 422.222 are enrolled in Medicare in an approved status.”

We propose to:

++ Revise paragraph (c)(1)(iv) to read: “Documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.”

++ Revise paragraph (c)(2) to replace the language beginning with “including providing documentation . . .” with “including providing documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.”

• Section 422.752(a) lists certain violations for which CMS may impose sanctions (as specified in § 422.750(a)) on any MA organization with a contract. One violation, listed in paragraph (a)(13), is that the MA organization “(f)ails to comply with § 422.222 and 422.224, that requires the MA

organization to ensure that providers and suppliers are enrolled in Medicare and not make payment to excluded or revoked individuals or entities.” We propose to revise paragraph (a)(13) to read: “Fails to comply with §§ 422.222 and 422.224, that requires the MA organization not to make payment to excluded individuals or entities, nor to individuals or entities on the preclusion list, defined in § 422.2.”

• Section 422.510(a)(4) lists various grounds by which CMS may terminate a contract with an MA organization. Paragraph (a)(4)(xiii) refers to the MA organization’s failure “to meet the preclusion list requirements in accordance with §§ 422.222 and 422.224.” We propose to revise this paragraph to read: “Fails to meet the preclusion list requirements in accordance with §§ 422.222 and 422.224.”

• Section 422.504 outlines provisions that the contract between the MA organization and CMS must contain. Under paragraph (a)(6), the MA organization must agree to adhere to, among other things, “Medicare provider and supplier enrollment requirements.” Pursuant to paragraph (i)(2)(v), moreover, the MA organization agrees to require all first tier, downstream, and related entities to agree that “they will require all of their providers and suppliers to be enrolled in Medicare in an approved status consistent with § 422.222.” We propose to revise these two paragraphs as follows:

++ Paragraph (a)(6) would be revised to replace the language “Medicare provider and supplier enrollment requirements” with “the preclusion list requirements in 422.222.”

++ Paragraph (i)(2)(v) would be revised to replace the language following “they will” with “ensure that payments are not made to individuals and entities included on the preclusion list, defined in § 422.2.”

• Section 422.224, which applies to MA organizations and pertains to payments to excluded or revoked providers or suppliers, contains provisions very similar to those in § 460.86:

++ Paragraph (a) states that an MA organization “may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 422.113) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is revoked from the Medicare program except as provided.”

++ Paragraph (b) states: “If an MA organization receives a request for

payment by, or on behalf of, an individual or entity that is excluded by the OIG or is revoked from the Medicare program, the MA organization must notify the enrollee and the excluded or revoked individual or entity in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is revoked in the Medicare program.

We propose to revise these paragraphs as follows:

++ Paragraph (a) would state: “An MA organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 422.113 of this chapter) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2.

++ Paragraph (b) would state: “If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or an individual or entity that is included on the preclusion list, defined in § 422.2, the MA organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.”

In addition to the aforementioned proposals, CMS proposes to amend existing data submission requirements for risk adjustment to require MA organizations to include provider NPIs as part of encounter data submissions; CMS intends to use the NPI data to identify individuals and entities that, depending on the results of CMS investigation, may be included on the preclusion list proposed in this section. Pursuant to section 1853(a)(1)(C) and (a)(3)(B) of the Act, CMS adjusts the capitation rates paid to MA organizations to account for such risk factors as age, disability status, gender, institutional status, and health status and requires MA organizations to submit data regarding the services provided to MA enrollees. Implementing regulations at 42 CFR 422.310 set forth the requirements for the submission of risk adjustment data that CMS uses to risk-adjust payments. MA organizations must submit data, in accordance with CMS instructions, to

characterize the context and purposes of items and services provided to their enrollees by a provider, supplier, physician, or other practitioner (OMB Control No. 0938–1152). Currently, risk adjustment data is submitted in two formats: comprehensive data equivalent to Medicare fee-for-service claims data (often referred to as encounter data); and data in abbreviated formats (often referred to as RAPS data).

CMS requires that MA organizations and other entities submit encounter data using the X12 837 5010 format to fulfill the reporting requirements at 42 CFR 422.310, where “X12” refers to healthcare transactions, “837” refers to an electronic format for institutional (“837–I”) and professional (“837–P”) encounters, and “5010” refers to the most recent version of this national standard. The X12 837 5010 is one of the national standard HIPAA transaction and code set formats for electronic transmission of healthcare transactions. Records that MA organizations and other submitters send to CMS in the X12 837 5010 format are known as “encounter data records.”

One of the required data elements on the X12 837 5010 encounter data record is the “Billing Provider.” The Billing Provider is identified through several data fields (for example, name field and address field), but a key data field for identifying the Billing Provider is the National Provider Identifier (NPI). The NPI was established as a national standard for a unique health identifier for health care providers, as part of HIPAA Administrative Simplification efforts for electronic transactions among trading partners. CMS announced its decision to implement the NPI for Medicare, in the final rule 69 FR 3434, published January 23, 2004. Billing Provider NPIs are required for X12N 837 5010 transactions (both institutional and professional), as established in the national implementation guides (known by the shorthand “TR3 guides”): *Standards for Electronic Data Interchange Technical Report Type 3, Health Care Claim: Institutional (837)* and *Standards for Electronic Data Interchange Technical Report Type 3, Health Care Claim: Professional (837)*. However, CMS has not incorporated this Billing Provider NPI requirement into its Part C MA regulations for submission of risk adjustment data. CMS has incorporated the Part D program requirement that plan sponsors submit NPIs on the Prescription Drug Event Record (77 FR 22072, published April 12, 2012).

We are proposing to amend § 422.310 by adding a new paragraph (d)(5) to require that, for data described in

paragraph (d)(1) as data equivalent to Medicare fee-for-service data (which is also known as MA encounter data), MA organizations must submit a National Provider Identifier in a Billing Provider field on each MA encounter data record, per CMS guidance. While the NPI is a required data element for the X12 837 5010 format (as set forth in the TR3 guides cited in the Background), CMS has not codified a regulatory requirement that MA organizations include the Billing Provider NPI in encounter data records. The proposed amendment would implement that requirement.

We propose to include the phrase “per CMS guidance” to allow CMS to take into account situations where there is no bill (no claim for payment) in an MA organization’s system. For example, CMS allows submission of chart review records (also submitted to CMS in the X12 837 5010 format) only for the purpose of submitting, correcting, and deleting diagnoses from encounter data records for the purposes of risk adjustment payment, based on medical record reviews (chart reviews). Thus, chart review records and encounters that are capitated (when there is no bill) would have different guidance for populating the Billing Provider NPI field than encounters for which a bill was received and adjudicated by the MA organization.

(5) Appeals

We propose to add a provision to § 422.222(a) that would permit individuals or entities that are on the preclusion list to appeal their inclusion on this list in accordance with 42 CFR part 498. Given the aforementioned payment denial that would ensue with the individual’s or entity’s inclusion on the preclusion list, due process warrants that the individual or entity have the ability to appeal this initial determination. Any appeal under this proposed provision, however, would be limited strictly to the individual’s or entity’s inclusion on the preclusion list. It would neither include nor affect appeals of payment denials or enrollment revocations, for there are separate appeals processes for these actions. Individuals and entities that file an appeal pursuant to § 422.222(a) would be able to avail themselves of any other appeals processes permitted by law.

CMS would send written notice to the individual or entity of their inclusion on the preclusion list. The notice would contain the reason for the inclusion and would inform the individual or entity of their appeal rights.

We also propose to update the following regulatory provisions regarding appeals. Note that these provisions would include references to preclusion list inclusions under § 422.222 (MA) and, as previously mentioned, § 423.120(c)(6).

- We propose to revise § 498.3(b) to add a new paragraph (20) stating that a CMS determination that an individual or entity is to be included on the preclusion list constitutes an initial determination. This change would help enable individuals and entities to utilize the appeals processes described in § 498.5:

- In § 498.5, we propose to add a new paragraph (n) that would state as follows:

- ++ In paragraph (n)(1), we propose that any individual or entity dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list may request a reconsideration in accordance with § 498.22(a).

- ++ In paragraph (n)(2), we propose that if CMS or the individual or entity under paragraph (n)(1) is dissatisfied with a reconsidered determination under § 498.5(n)(1), or a revised reconsidered determination under § 498.30, CMS or the individual or entity is entitled to a hearing before an ALJ.

- ++ In paragraph (n)(3), we propose that if CMS or the individual or entity under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the individual or entity may request review by the Departmental Appeals Board (DAB) and the individual or entity may seek judicial review of the DAB's decision.

These revisions are designed to include preclusion list determinations within the scope of appeal rights described in § 498.5. However, we solicit comment on whether a different appeals process is warranted and, if so, what its components should be.

In addition, given that a beneficiary's access to health care items or services may be impaired because of the application of the preclusion list to his or her item or service, we believe the beneficiary should be permitted to appeal alleged errors in applying the preclusion list. We solicit comment whether additional beneficiary protections, such as notices to enrollees when an individual or entity that has recently furnished services or items to the enrollee is placed on the preclusion list or a limited and temporary coverage approval when an individual or entity is first placed on the preclusion list but is in the middle of a course of previously

covered treatment, should also be included these rules upon finalization.

(6) Technical Changes

The title of § 422.222 reads: "Enrollment of MA organization network providers and suppliers; first-tier, downstream, and related entities (FDRs); cost HMO or CMP, and demonstration and pilot programs." We propose to change this to simply state "Preclusion list" so as to accord with our previously mentioned proposed changes. For this same reason, we propose to:

- ++ Change the title of § 422.224 from "Payment to providers or suppliers excluded or revoked" to "Payment to individuals and entities excluded by the OIG or included on the preclusion list."

- ++ Change the title of § 460.86 from "Payment to providers or suppliers excluded or revoked" to "Payment to individuals or entities excluded by the OIG or included on the preclusion list."

c. Specific Regulatory Changes

Given the foregoing discussion, we propose the following regulatory changes:

- In § 417.478, we propose to revise paragraph (e) as follows:

- ++ In new paragraph (e)(1), we propose to state that the prohibitions, procedures and requirements relating to payment to individuals and entities on the preclusion list (defined in § 422.2 of this chapter) apply to HMOs and CMPs that contract with CMS under section 1876 of the Act.

- ++ In new paragraph (e)(2), we propose to state that in applying the provisions of §§ 422.2, 422.222, and 422.224 under paragraph (e)(1) of this section, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

- In § 417.484, we propose to revise paragraph (b)(3) to state: "That payments must not be made to individuals and entities included on the preclusion list, defined in § 422.2."

- In § 422.2, we propose to add a definition of "preclusion list" that reads as follows:

- ++ Preclusion list means a CMS compiled list of individuals and entities that:

- (1) Meet all of the following requirements:

- (i) The individual or entity is currently revoked from Medicare under § 424.535.

- (ii) The individual or entity is currently under a reenrollment bar under § 424.535(c).

- (iii) CMS determines that the underlying conduct that led to the

revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS would consider the following factors:

- (A) The seriousness of the conduct underlying the individual's or entity's revocation.

- (B) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program.

- (C) Any other evidence that CMS deems relevant to its determination; or

- (2) Meet both of the following requirements:

- (i) The individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.

- (ii) CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

- (i) The seriousness of the conduct involved.

- (ii) The degree to which the individual's or entity's conduct could affect the integrity of the Medicare program; and

- (iii) Any other evidence that CMS deems relevant to its determination

- We propose to delete § 422.204(b)(5).

- We propose to establish a new § 422.204(c) that would require MA organizations to follow a documented process that ensures compliance with the preclusion list provisions in § 422.222.

- We propose to delete the existing version of § 422.222(a) and replace it with the following:

- ++ In § 422.222, we propose to change the title thereof to "Preclusion list".

- ++ In paragraph (a)(1), we propose to state that an MA organization shall not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in § 422.2.

- ++ In paragraph (a)(2), we propose to replace the existing language therein with a provision stating that CMS would send written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice would contain the reason for the inclusion and would inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in § 422.2, in accordance with Part 498.

- ++ In paragraph (b), we propose to state that an MA organization that does

not comply with paragraph (a) of § 422.222 may be subject to sanctions under § 422.750 and termination under § 422.510.

- In § 422.224, we propose to:

++ Change the title thereof to

“Payment to individuals and entities excluded by the OIG or included on the preclusion list.”

++ Revise paragraph (a) to state: “An MA organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 422.113 of this chapter) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2”.

++ Revise paragraph (b) to state: “If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or an individual or entity that is included on the preclusion list, defined in § 422.2, the MA organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.”

- We propose to revise § 422.310 to add a new paragraph (d)(5) to require that, for data described in paragraph (d)(1) as data equivalent to Medicare fee-for-service data (which is also known as MA encounter data), MA organizations must submit a National Provider Identifier in a Billing Provider field on each MA encounter data record, per CMS guidance.

- In § 422.501(c), we propose to:

++ Revise paragraph (c)(1)(iv) to read: “Documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.”

++ Revise paragraph (c)(2) to replace the language beginning with “including providing documentation . . .” with “including providing documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.”

- In section 422.504, we propose to:

++ Replace the language in paragraph (a)(6) that reads “Medicare provider and supplier enrollment requirements” with “the preclusion list requirements in § 422.222 and § 422.224.”

++ Revise paragraph (i)(2)(v) to read, “they will ensure that payments are not made to individuals and entities included on the preclusion list, defined in § 422.2.”

- In § 422.510(a)(4), we propose to revise paragraph (xiii) to read: “Fails to meet the preclusion list requirements in accordance with §§ 422.222 and 422.224.”

- In § 422.752, we propose to revise paragraph (a)(13) to read: “Fails to comply with §§ 422.222 and 422.224, that requires the MA organization not to make payment to excluded individuals and entities, nor to individuals and entities included on the preclusion list, defined in § 422.2.”

- In § 460.40, we propose to revise paragraph (j) to state: “Makes payment to any individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.”

- In § 460.50, we propose to revise paragraph (b)(1)(ii) by changing the current language following “including” to read “making payment to an individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.”

- We propose to delete § 460.68(a)(4).
- We propose to delete § 460.70(b)(1)(iv).

- We propose to delete § 460.71(b)(7).
- In § 460.86, we propose to revise paragraphs (a) and (b) to state as follows:

++ Paragraph (a) would state: “A PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the OIG or is included on the preclusion list, defined in § 422.2 of this chapter.”

++ Paragraph (b) would state: “If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list, defined in § 422.2 of this chapter, the PACE organization must notify the enrollee and the excluded individual or entity or the individual or entity that is included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.”

++ We also propose to change the title of § 460.86 to “Payment to individuals and entities that are excluded by the OIG or are included on the preclusion list.”

- In § 498.3(b), we propose to add a new paragraph (20) stating that a CMS determination that an individual or entity is to be included on the preclusion list constitutes an initial determination.

- In § 498.5, we propose to add a new paragraph (n) that would state as follows:

++ In paragraph (n)(1), we propose that any individual or entity dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list may request a reconsideration in accordance with § 498.22(a).

+ In paragraph (n)(2), we propose that if CMS or the individual or entity under paragraph (n)(1) is dissatisfied with a reconsidered determination under (n)(1), or a revised reconsidered determination under § 498.30, CMS or the individual or entity is entitled to a hearing before an ALJ.

++ In paragraph (n)(3), we propose that if CMS or the individual or entity under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the individual or entity may request review by the DAB and the individual or entity may seek judicial review of the DAB’s decision.

12. Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152)

Section 1852(e) of the Act requires that Medicare Advantage (MA) organizations have an ongoing Quality Improvement (QI) Program for the purpose of improving the quality of care provided to enrollees in the organization’s MA plans. The statute requires that the MA organization include a Chronic Care Improvement Program (CCIP) as part of the overall QI Program

Our regulations at § 422.152 outline the QI Program requirements for MA organizations, which include the development and implementation of both Quality Improvement Projects (QIPs), at paragraphs (a)(3) and (d), and a CCIP, at paragraphs (a)(2) and (c). Both provisions require that the MA organization’s QIP and CCIP address areas or populations identified by CMS.

The January 2005 final rule (70 FR 4587) addressed the QI provisions added to section 1852(e) of the Act by the Medicare Modernization Act of 2003 (MMA). In the final rule, we specified in § 422.152 that MA organizations must have ongoing QI Programs, which include chronic care programs. In addition, CMS provided MA organizations the flexibility to shape their QI efforts to the needs of their enrollees.

In the April 2010 final rule (75 FR 19677), CMS indicated concern that MA organizations were choosing QIPs and CCIPs that did not address QI areas that best reflected enrollee needs.

Additionally, there were concerns that some projects focused more on improving processes rather than improving clinical outcomes. Therefore, we modified the regulation to provide for CMS to identify focus areas for QIPs and population areas for CCIPs. MA organizations retained the flexibility to identify topics for development of QIPs and CCIPs based on the needs of their population, but also had to implement QIPs and CCIPs as directed by CMS, which could identify general areas of focus that supported CMS quality strategies and initiatives.

During this time, CMS was also concerned that MA organizations were employing inconsistent methods in developing criteria for QIPs and CCIPs. As a result, CMS further modified the regulation to require MA organizations to report progress in a manner identified by CMS. This allowed CMS to review results and extrapolate lessons learned and best practices consistently across the MA program.

After making these regulation modifications, CMS issued a number sub-regulatory QIP and CCIP guidance documents to ensure that MA organizations measured progress in a consistent and meaningful way. For example, the new Plan-Do-Study-Act QI model required MA organizations to place some structure and parameters around their QIPs and CCIPs, ultimately leading to more consistency.

Over time, CMS found its implementation of the QIP and CCIP requirements had become burdensome and complex, rather than streamlining and conforming MA organizations' implementation of QIPs and CCIPs. For example, the complex sub-regulatory guidance led to a wide range of MA organization interpretations, resulting in extraneous, irrelevant, voluminous, and redundant information being reported to CMS. We gained little value from this information. As a result, we scaled down our sub-regulatory guidance in order to gain more concise and useful information with which to evaluate the outcomes and show any sort of attribution. However, we also found that the complex guidance did not necessarily produce better outcomes in the review of annual updates.

Continued evaluation through annual review of plan reported updates of the QIPs and CCIPs has led CMS to believe that the QIPs in particular do not add significant value. Through annual review of plan-reported updates, CMS

has found that a number of QIPs implemented are duplicative of activities MA organizations are already doing to meet other plan needs and requirements, such as the CCIP and internal organizational focus on STAR Rating metrics. For example, we designated "Reducing All-Cause Hospital Readmissions" as the 2012 QIP topic. The QIPs for this topic often duplicated other CMS and MA organization care coordination initiatives aimed to improve transition of care across health care settings and reduce hospital readmissions. We found that many plans were already engaged in activities to reduce hospital readmissions because they are annually scored on their performance in this area (and many other areas) through Healthcare Effectiveness Data and Information Set (HEDIS). HEDIS are a set of plan performance and quality measures. Each year, MA organizations are required to report HEDIS data and are evaluated annually based on these measures. High performance on these measures also plays a large role in achieving high Star Ratings, which has beneficial payment consequences for MA organizations. This suggests that CMS direction and detailed regulation of QIPs is unnecessary as the Star Ratings program use of HEDIS measures (and other measures) incentivizes MA organizations sufficiently to focus on desired improvements and outcomes.

Therefore, we believe the removal of the QIP and the continued CMS direction of populations for required CCIPs would allow MA organizations to focus on one project that supports improving the management of chronic conditions, a CMS priority, while reducing the duplication of other QI initiatives. We propose to delete §§ 422.152(a)(3) and 422.152(d), which outline the QIP requirements. In addition, in order to ensure that remaining cross references for other provisions in this section remain accurate, we will reserve paragraphs (a)(3) and (d). The removal of these requirements would reduce burden on both MA organizations and CMS.

Even with this proposed removal of the QIP requirements, the MA requirements for QI Programs would remain in place and be robust and sufficient to ensure that the requirements of section 1852(e) of the Act are met. As a part of the QI Program, each MA organization would still be required to develop and maintain a health information system; encourage providers to participate in CMS and HHS QI initiatives; implement a program review process for formal evaluation of the impact and

effectiveness of the QI Program at least annually; correct all problems that come to its attention through internal, surveillance, complaints, or other mechanisms; contract with an approved Medicare Consumer Assessment of Health Providers and Systems (CAHPS®) survey vendor to conduct the Medicare CAHPS® satisfaction survey of Medicare plan enrollees; measure performance under the plan using standard measures required by CMS and report its performance to CMS; develop, compile, evaluate, and report certain measures and other information to CMS, its enrollees, and the general public; and develop and implement a CCIP. Further, CMS emphasizes here that MA organizations must have QI Programs that go beyond only performance of CCIPs that focus on populations identified by CMS. The CCIP is only one component of the QI Program, which has the purpose of improving care and provides for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality under section 1852(e) of the Act.

We believe this proposed change will allow MA organizations to maintain existing health improvement initiatives and take steps to reduce the risk of redundancies or duplication. The remaining elements of the QI Program, including the CCIP, will still maintain the intended purpose of the QI Program: That plans have the necessary infrastructure to coordinate care and promote quality, performance, and efficiency on an ongoing basis.

This proposal does not eliminate the CCIP requirements that MA organizations address populations identified by CMS and report project status to CMS as requested. Per the April 2010 rule (75 FR 19677), we still believe that these requirements are necessary to ensure that MA organizations are developing projects that positively impact populations identified by CMS and that progress is documented and reported in a way that is consistent with our requirements.

In conclusion, we are proposing to amend § 422.152 by:

- Deleting and reserving paragraphs (a)(3) and (d).

We solicit comments on this proposal, including whether additional revision to § 422.152 is necessary to eliminate redundancies CMS has identified in this preamble.

13. Reducing Provider Burden— Comment Solicitation

Health care providers are key partners in the delivery of Medicare benefits, and we are exploring ways to reduce burden

on providers (meaning institutions, physicians, and other practitioners) arising from requests for medical record documentation by MA organizations, particularly in connection with MA program requirements. We are interested in stakeholder feedback on the nature and extent of this burden of producing medical record documentation and on ideas to address the burden. We are particularly interested in burden experienced by solo providers. Please note that this is a solicitation for comment only and does not commit CMS to adopt any ideas submitted nor to making any changes to CMS audits or activities, including risk adjustment data validation (RADV) processes.

By law, CMS is required to adjust payments to MA organizations for their enrollees' risk factors, such as age, disability status, gender, institutional status, and health status. To this end, MA organizations are required in regulation (§ 422.310) to submit risk adjustment data to CMS—including diagnosis codes—to characterize the context and purposes of items and services provided to MA organization plan enrollees. Risk adjustment data refers to data submitted in two formats: Comprehensive data equivalent to Medicare fee-for-service claims data (often referred to as encounter data) and data in abbreviated formats (often referred to as RAPS data). Under § 422.310, risk adjustment data that is submitted must be documented in the medical record and MA organizations will be required to submit medical records to validate the risk adjustment data. Finally, at § 422.310(d)(4), MA organizations may include in their contracts with providers, suppliers, physicians, and other practitioners, provisions that require submission of complete and accurate risk adjustment data as required by CMS. These provisions may include financial penalties for failure to submit complete data.

To address concerns from providers about burdensome requests from MA organizations for their patients' medical record documentation, we are soliciting comment from stakeholders to more fully understand the issue and for ideas to accomplish reductions in provider burden. Specifically, we seek comment on the following:

- The nature and extent of medical record requests, including the following:
 - ++ Reasoning behind the request sent by the MA organization to the provider.
 - ++ Amount of time afforded to providers to respond to such requests.
 - ++ Frequency of requests for providers to submit medical records.

- ++ Volume of medical records in a given request.

- ++ Method of collection and submission of medical records.

- ++ How narrowly or broadly the requests are framed (for example, whether the request is for a single visit, a specific condition, and for what timeframe).

- ++ Extent to which requests are made pursuant to a *CMS-conducted* RADV audit, other CMS activities, or for other purposes (please specify what the other purposes are).

- ++ Considerations that may be unique to solo providers.

- ++ Impact on burden due to increased adoption of electronic health record systems.

- ++ Specific examples of medical record requests (for example, anecdotes and/or the requests themselves, appropriately redacted of confidential information and PII/PHI).

- The nature and extent of requests related to medical record attestations, including the following:

- ++ Reasoning behind the attestation request.

- ++ Amount of time afforded to providers to respond to such requests.

- ++ Frequency of requests for providers to sign attestations.

- ++ Volume of requests.

- ++ Level and duration for which attestations are requested (for example, for each medical record, for all medical records for a beneficiary for a particular date of service or for a particular year).

- ++ Whether there is reduced burden associated with electronic signatures.

- ++ Specific examples of medical record attestations and attestation requests.

- Ideas for improving the process around MA organizations requesting medical records and/or attestations that are not directly pursuant to CMS-conducted RADV audits. Specify the type of change the idea would necessitate: a statutory, regulatory, subregulatory, operational, or CMS-issued guidance such as best practices for MA organizations when requesting medical records and/or attestations, and how such a change may interact with other provisions, such as state law or Joint Commission requirements. If the ideas involve novel legal questions, analysis regarding our authority is welcome for our consideration. For each idea, describe the extent of provider burden reduction, quantitatively where possible, and any other consequences that implementing the idea may have on beneficiaries, providers, MA organizations, or CMS. Further, we encourage all relevant parties to respond to this request: MA organizations,

providers, associations for these entities, and companies assisting MA organizations, providers, and hospitals with handling medical record requests.

C. Implementing Other Changes

1. Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements

a. Background

Section 1103 of Title I, Subpart B of the Health Care and Education Reconciliation Act (Pub. L. 111–152) amends section 1857(e) of the Act to add medical loss ratio (MLR) requirements 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 23, 2013 **Federal Register** (78 FR 31284), we published a final rule that codified the MLR requirements for Part C MA organizations, and Part D sponsors (including organizations offering cost plans that provide the Part D benefit) in the regulations at 42 CFR part 422, subpart X and part 423, subpart X.

For contract year 2014 and subsequent contract years, MA organizations and Part D sponsors are required to report their MLRs and are subject to financial and other penalties 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 in section 1857(e)(4) of the Act 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.

Section 1001(5) of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10101(f) of the Health Care Reconciliation Act, also established a new MLR requirement under section 2718 of the Public Health Service Act (PHSA) that applies to issuers of employer group and individual market

private insurance. We will refer to the MLR requirements that apply to issuers of private insurance as the “commercial MLR rules.” Regulations implementing the commercial MLR rules are published at 45 CFR part 158.

This proposed rule sets forth our proposed modifications to certain MLR requirements in the Medicare Part C and Part D programs.

b. Proposed Regulatory Changes to the Calculation of the Medical Loss Ratio (§§ 422.2420, 422.2430, 423.2420, and 423.2430)

(1) Fraud Reduction Activities

As explained in the February 22, 2013 proposed rule (78 FR 12428), we used the commercial MLR rules as a reference point for developing 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. Although we believe it is important to maintain consistency between the commercial and Medicare MLR requirements, we also 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 area of alignment between the commercial and Medicare MLR rules is the treatment of expenditures related to fraud reduction efforts, which we defined to include both fraud prevention and fraud recovery in both rules (*see* 78 FR 12433). The Medicare MLR regulations adopted the same definitions of activities that improve healthcare quality (also referred to as quality improvement activities, or QIA), as had been adopted in the commercial MLR regulations at 45 CFR 158.150 and 158.151, in order to facilitate uniform accounting for the costs of these activities across lines of business (*see* 78 FR 12435). Consistent with this policy of alignment, the Medicare MLR regulations at §§ 422.2430(b)(8) and 423.2430(b)(8) adopted the commercial MLR rules’ exclusion of fraud prevention activities from QIA. The Medicare MLR regulations (§§ 422.2420(b)(2)(ix) and 423.2420(b)(2)(viii)) further aligned with the commercial MLR rules’ treatment of fraud-related expenditures by allowing the amount of claim payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses, to be included in the MLR numerator as an

adjustment to incurred claims. The Medicare MLR proposed rule (78 FR 12433) explained that we considered this approach to be appropriate because without such an adjustment, the recovery of paid fraudulent claims would reduce an MLR and could create a disincentive to engage in fraud reduction efforts. Allowing an adjustment to incurred claims to reflect claims payments recoveries up to the limit of fraud reduction expenses would help mitigate whatever disincentive might occur if fraud reduction expenses were treated solely as nonclaims and nonquality improving expenses. The Medicare MLR proposed rule echoed the December 7, 2011 commercial MLR final rule with comment period (76 FR 76577), where we had earlier expressed the view that allowing an unlimited adjustment for fraud reduction expenses would undermine the purpose of requiring issuers to meet the MLR standard.

We have reconsidered this position based on the specific characteristics of the MA and Part D programs, and are now proposing certain changes to the treatment of expenses for fraud reduction activities in the Medicare MLR calculation. First, we are proposing to revise the MA and Part D regulations by removing the current exclusion of fraud prevention activities from QIA at §§ 422.2430(b)(8) and 423.2430(b)(8). Second, we are proposing to expand the definition of QIA in §§ 422.2430 and 423.2430 to include all fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery. Third, we are proposing to no longer include in incurred claims the amount of claims payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses, in §§ 422.2420(b)(2)(ix) and 423.2420(b)(2)(viii). We note that the commercial MLR rules and the Medicaid MLR rules are outside the scope of this proposed rule.

We are proposing these changes to the Medicare MLR rules because we believe that limiting or excluding amounts invested in fraud reduction undermines the federal government’s efforts to combat fraud in the Medicare program, and reduces the potential savings to the government, taxpayers, and beneficiaries that robust fraud prevention efforts in the MA and Part D programs can provide. Fraud prevention activities can improve patient safety, deter the use of medically unnecessary services, and can lead to higher levels of health care quality, which is part of the reason why we require such

activities as a condition of participation in the MA and Part D programs.

MA organizations and Part D sponsors are required at §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi), respectively, to adopt an effective compliance program which includes measures that prevent, detect, and correct fraud. We believe that the proposed change to include all expenditures in connection with fraud reduction activities as QIA-related expenditures in the MLR numerator best aligns with this Medicare contracting requirement. We are concerned that the current rules could create a disincentive to invest in fraud reduction activities, which is only partly mitigated by the current adjustment to incurred claims for amounts recovered as a result of fraud reduction activities, up to the amount of fraud reduction expenses. We believe that it is particularly important that MA organizations and Part D sponsors invest in fraud reduction activities as the Medicare trust funds are used to finance the MA and Part D programs. We believe that including the full amount of expenses for fraud reduction activities as QIA will provide additional incentive to encourage MA organizations and Part D sponsors to develop innovative and more effective ways to detect and deter fraud.

We continue to believe that the minimum MLR requirement in section 1857(e)(4) of the Act is intended to create an incentive to reduce administrative costs, marketing, profits, and other such uses of the funds that plan sponsors receive, and to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans. However, we also believe that MA organizations’ and Part D sponsors’ fraud reduction activities can potentially provide significant value to the government and taxpayers by reducing trust fund expenditures. When MA organizations and Part D sponsors prevent fraud and recover amounts paid for fraudulent claims, this lowers the overall cost of providing coverage to MA and Part D enrollees. Because MA organizations’ and Part D sponsors’ monthly payments are based in part on their claims experience in prior years, if MA organizations and Part D sponsors pay fewer fraudulent claims, this should be reflected in their subsequent cost projections, which would ultimately result in lower payments to MA organizations and Part D sponsors out of the Medicare trust funds, and could also result in lower premiums or additional supplemental benefits for beneficiaries.

Given the proposed change to include expenditures for fraud reduction activities in the QIA portion of the MLR numerator, we no longer believe that it

would be necessary or appropriate to include in incurred claims the amount of claim payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses. As noted previously, we originally included an adjustment to incurred claims for claims payments recovered through fraud reduction efforts based on the rationale that, because the recovery of paid fraudulent claims reduces the amount of incurred claims in the MLR numerator, if expenditures for fraud reduction efforts were treated solely as nonclaims and nonquality improvement activities, this could create a disincentive to engage in fraud reduction activities. The adjustments to incurred claims under current §§ 422.2420(b)(2)(ix) and 423.2420(b)(2)(viii) mitigate the potential disincentive to invest in fraud reduction activities insofar as MA organizations' and Part D sponsors' recoveries of paid fraudulent claims do not result in a reduction to incurred claims. Because this adjustment to incurred claims is only available to the extent that an MA organization or Part D sponsor recovers paid fraudulent claims, it encourages MA organizations and Part D sponsors to invest in tracking down and recouping amounts that have already been paid, rather than in preventing payment of fraudulent claims. Under our proposal, claim payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses, would no longer be included in the MLR numerator as an adjustment to incurred claims. Instead, all expenditures for fraud reduction activities would be included in the MLR numerator as QIA, even if such expenditures exceed the amount recovered through fraud reduction efforts. As a result, MA organizations and Part D sponsors will no longer have an incentive to use contract revenue to pursue recovery of paid fraudulent claims instead of investing in fraud prevention. We believe that effective fraud reduction strategies will include efforts to prevent payment of fraudulent claims, and we believe that the proposed inclusion of all fraud reduction activities as QIA in the MLR numerator will strengthen the incentive to engage in these vital activities.

In summary, we are proposing the following regulatory revisions:

- Remove and reserve §§ 422.2420(b)(2)(ix) and 423.2420(b)(2)(viii).
- In §§ 422.2430 and 423.2430, redesignate existing paragraphs (a)(1) and (a)(2) as (a)(2) and (a)(3), respectively.

- In §§ 422.2430 and 423.2430, add new paragraph (a)(4) that lists activities that are automatically included in QIA.

- Designate the introductory text of §§ 422.2430(a) and 423.2430(a) as paragraph (a)(1), and revise newly designated paragraph (a)(1) to specify that, for an activity to be included in QIA, it must either fall into one of the categories listed in newly redesignated (a)(2) and meet all of the requirements in newly redesignated (a)(3), or be listed in paragraph (a)(4).

- Remove and reserve §§ 422.2430(b)(8) and 423.2430(b)(8).

We solicit comment on these proposed changes, particularly whether our proposal is based on the best understanding of the motives and incentives applicable to MA organizations and Part D sponsors to engage in fraud reduction activities. We also solicit comment on the types of activities that should be included in, or excluded from, fraud reduction activities. In addition, we solicit comment on alternative approaches to accounting for fraud reduction activities in the MLR calculation. In particular, we are interested in receiving input on:

- Whether fraud reduction activities should be included in quality improvement activities as proposed, or whether we should create a separate MLR numerator category for fraud reduction activities;
- Whether fraud reduction activities should be subject to any or all of the exclusions at §§ 422.2430(b) and 423.2430(b). Although our proposal removes the exclusion of fraud prevention activities from QIA at §§ 422.2430(b)(8) and 423.2430(b)(8), it is possible that fraud reduction activities would be subject to one of the other exclusions under §§ 422.2430(b) and 423.2430(b), such as the exclusion that applies to activities that are designed primarily to control or contain costs (§§ 422.2430(b)(1) and 423.2430(b)(1)) or the exclusion of activities that were paid for with grant money or other funding separate from premium revenue (§§ 422.2430(b)(1) and 423.2430(b)(3)).

(2) Medication Therapy Management (MTM) (§§ 422.2430 and 423.2430)

In the May 23, 2013 final rule (78 FR 31294), we stated that Medication Therapy Management (MTM) activities (defined at § 423.153(d)) qualify as QIA, provided they meet the requirements set forth in §§ 422.2430 and 423.2430. To meet these requirements, the activity must fall into one of the categories listed in current paragraph (a)(1) of those regulations, which means the activity must: (1) Improve health quality; (2)

increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results; (3) 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) 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. In our prior MLR rulemaking, we did not attempt to determine whether all MTM programs that comply with § 423.153(d) would necessarily meet the QIA requirements at § 422.2430 (for MA-PD contracts) and § 423.2430 (for stand-alone Part D contracts). Subsequent to publication of the May 23, 2013 final rule, we have received numerous inquiries seeking clarification regarding whether MTM programs are QIA. To address those questions and resolve any ambiguities or uncertainties, we are now proposing to specifically address MTM programs in the MLR regulations.

We propose to modify our regulations at §§ 422.2430 and 423.2430 by adding new paragraph (a)(4)(i), which specifies that all MTM programs that comply with § 423.153(d) and are offered by Part D sponsors (including MA organizations that offer MA-PD plans (described in § 422.2420(a)(2)) are QIA. Each Part D sponsor is required to incorporate an MTM program into its plans' benefit structure, and the MTM Program Completion Rate for Comprehensive Medication Reviews (CMR) measure has been included in the Star Ratings as a metric of plan quality since 2016. We believe that the MTM programs that we require improve quality and care coordination for Medicare beneficiaries. We also believe that allowing Part D sponsors to include compliant MTM programs as QIA in the calculation of the Medicare MLR would encourage sponsors to ensure that MTM is better utilized, particularly among standalone PDPs that may currently lack strong incentives to promote MTM.

Furthermore, we have expressed concern that Part D sponsors may be restricting MTM eligibility criteria to limit the number of qualified enrollees, and we believe that explicitly including MTM program expenditures in the MLR numerator as QIA-related expenditures could provide an incentive to reduce any such restrictions. This is particularly important in providing individualized disease management in conjunction with the ongoing opioid

crisis evolving within the Medicare population. We hope that, by removing any restrictions or uncertainty about whether compliant MTM programs will qualify for inclusion in the MLR numerator as QIA, the proposed changes will encourage Part D sponsors to strengthen their MTM programs by implementing innovative strategies for this potentially vulnerable population. We believe that beneficiaries with higher rates of medication adherence have better health outcomes, and that medication adherence can also produce medical spending offsets, which could lead to government and taxpayer savings in the trust fund, as well as beneficiary savings in the form of reduced premiums. We solicit comment on these proposed changes.

(3) Additional Technical Changes to Calculation of the Medical Loss Ratio (§§ 422.2420 and 423.2420)

We are also proposing technical changes to the MLR provisions at §§ 422.2420 and 423.2420. In § 422.2420(d)(2)(i), we are replacing the phrase “in § 422.2420(b) or (c)” with the phrase “in paragraph (b) or (c) of this section”. In § 423.2430, the regulatory text includes two paragraphs designated as (d)(2)(ii). We propose to resolve this error by amending § 423.2420 as follows:

- Revise paragraph (d)(2)(i) by adding at the end the text of the first paragraph designated as (d)(2)(ii).
- Remove the first paragraph designated as (d)(2)(ii).

c. Proposed Regulatory Changes to Medicare MLR Reporting Requirements (§§ 422.2460 and 423.2460)

Our general approach when developing the current Medicare MLR regulations was to align the Medicare MLR requirements with the commercial MLR requirements. Consistent with this policy, we attempted to model the Medicare MLR reporting format on the tools used to report commercial MLR data in order to limit the burden on organizations that participate in both markets. However, as noted previously, we also recognized that there are some areas where the unique characteristics of the MA and Part D programs make it appropriate for the Medicare MLR reporting requirements to deviate from the rules that apply to commercial MLR reporting. Most beneficiaries are enrolled in plans offered by MA organizations and Part D sponsors that also participate in the commercial market, and these entities are familiar with the commercial MLR forms that they have had to submit since 2012 for the 2011 benefit year. In practice, however, these forms and reports have not been identical. We have become

concerned, after having received two annual Medicare MLR reports at the time that this proposed rule is being published, that requiring health insurance issuers to complete a substantially different set of forms for Medicare MLR purposes has created an unnecessary additional burden. Our proposal to reduce the burden of the current Medicare requirement for MLR reporting aligns with the directive in the January 30, 2017 Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations.

It is with these concerns in mind that we are proposing to reduce the current reporting burden to require the minimum amount of information needed for MLR reporting by organizations with contracts to offer Medicare benefits. Specifically, we are proposing that the Medicare MLR reporting requirements would be limited to the following data fields, as shown in Table 12: Organization name, contract number, adjusted MLR (which would be populated as “Not Applicable” or “N/A” for non-credible contracts as determined in accordance with §§ 422.2440(d) and 423.2440(d)), and remittance amount. We solicit comment on these proposed changes.

TABLE 12—MLR REPORTING FOR FULLY CREDIBLE, PARTIALLY CREDIBLE, AND NON-CREDIBLE CONTRACTS

Organization	Contract No.	Adjusted MLR (%)	Remittance amount
ABC, Inc	H1234	90.1	\$0
XYZ, LLC	S4321	84.8	17,420
MAO1, LLC	H4321	N/A	N/A

We believe that it is important to note that although we are proposing a significant reduction in the amount of data that MA organizations and Part D sponsors must report to us, we are not proposing to change our authority under § 422.2480 or § 423.2480 to conduct selected audit reviews of the data reported under §§ 422.2460 and 423.2460 to determine that remittance amounts under §§ 422.2410(b) and 423.2410(b) and sanctions under §§ 422.2410(c), 422.2410(d), 423.2410(c), and 423.2410(d) were accurately calculated, reported, and applied. Moreover, MA organizations and Part D sponsors would continue to be required to retain documentation supporting the MLR figure reported and to make available to CMS, HHS, the Comptroller General, or their designees any information needed to determine

whether the data and amounts submitted with respect to the Medicare MLR are accurate and valid, in accordance with §§ 422.504 and 423.505.

In addition, we have realized that the MLR Reporting Requirements at § 422.2460 do not include provisions that correspond to the provisions currently codified at § 423.2460(b) and (c). In the February 22, 2013 proposed rule (78 FR 12435), we proposed that the total revenue reported by MA organizations and Part D sponsors for MLR purposes would be net of all projected reconciliations, and that each MA and Part D contract’s MLR would only be reported once and would not be reopened as a result of any payment reconciliation processes. In the May 23, 2013 final rule (78 FR 31293), we finalized these proposals without

change. Although we explicitly proposed that both MA organizations and Part D sponsors would be required to report their revenues net of all projected reconciliations (78 FR 12435), and we did not indicate that only Part D sponsors would be affected by our proposal for each contract’s MLR to be reported once and not reopened as a result of any payment reconciliation process (our discussion of this proposal in the final rule addressed how this policy would apply to both MA organizations and Part D sponsors (78 FR 31293)), regulatory provisions implementing the finalized proposals were only included in the Part D regulations, where they currently appear at § 423.2460(b) and (c); corresponding regulatory text was not added to the MA regulations. We are proposing to make a technical change to § 422.2460 by

incorporating provisions which parallel the language of current paragraphs (b) and (c) of § 423.2460 for purposes of the reporting requirements for contract year 2014 and subsequent contract years. This proposed technical change does not establish any new rules or requirements for MA organizations; it merely updates regulatory references that were overlooked in previous rulemaking.

In summary, we are proposing to revise the regulations at §§ 422.2460 and 423.2460 as follows:

- In § 422.2460, redesignate the existing regulation text as paragraph (a).

- Revise newly designated §§ 422.2460(a) and 423.2460(a) by adding “from 2014 through 2017” after the phrase “For each contract year” in the first sentence to limit the more detailed MLR reporting requirement to that period, making minor grammatical changes to clarify the text, and by adding “under this part” to modify the phrase “for each contract”.

- In § 423.2460, redesignate existing paragraphs (b) and (c) as paragraphs (c) and (d), respectively.

- In §§ 422.2460 and 423.2460, add a new paragraph (b) to require MA organizations and Part D plan sponsors with—

- ++ Fully credible and partially credible experience to report the MLR for each contract for the contract year along with the amount of any owed remittance; and

- ++ Non-credible experience, to report that such experience was non-credible.

For each, the proposed text cross-references the applicable regulations for the determination of credibility, and for the general remittance requirement.

- In newly redesignated § 423.2460(c), revise the text to refer to total revenue included in the MLR calculation rather than reports of that information.

- Add new paragraphs (c) and (d) to § 422.2460 that mirror the text in § 423.2460(c) and (d), as redesignated and revised.

d. Proposed Technical Changes to Medicare MLR Review and Non-Compliance and the Release of MLR Data (§§ 422.2410, 422.2480, 422.2490, 423.2410, 423.2480, and 423.2490)

We are proposing technical changes to the General Requirements, MLR review and non-compliance, and Release of MLR data provisions at §§ 422.2410, 422.2480, 422.2490, 423.2410, 423.2480, and 423.2490. These changes are being proposed in conformity with the more substantive regulatory text changes being proposed herein. These proposed technical changes do not establish any

new rules or requirements for MA organizations or Part D sponsors. The proposed technical changes revise references to MLR reports in conformity with our proposal to scale back Medicare MLR reporting so that we only require the submission of a limited number of data points, as opposed to a full report.

2. Medicare Advantage Contract Provisions (§ 422.504)

Under the authority of section 1857(b) of the Act, CMS may enter into a contract with a Medicare Advantage (MA) organization, through which the organization agrees to comply with applicable requirements and standards. CMS has established and codified provisions of contracts between the MA organization and CMS at § 422.504. This proposed rule seeks to correct an inconsistency in the text that identifies the contract provisions deemed material to the performance of an MA contract.

Section 422.504(a) sets forth regulations and instructions at paragraphs (1) through (15) that are material to the performance of the MA contract in accordance to § 422.504(a)(16). This is inconsistent with the introductory regulatory text at § 422.504(a), which provides, “An MA organization’s compliance with paragraphs (a)(1) through (a)(13) of this section is material to performance of the contract.” Further, both paragraphs (a) and (a)(15) fail to mention paragraphs (a)(17) and (a)(18).

We propose to correct the inconsistent language by revising the language in the introductory text in § 422.504(a) and deleting paragraph § 422.504(a)(16). With this revision, We will renumber current paragraphs §§ 422.504(a)(17) and (a)(18). The proposed revision to the paragraph (a) introductory text would provide that compliance with all contract terms listed in paragraph (a) is material.

3. Late Contract Non-Renewal Notifications (§§ 422.506, 422.508, and 423.508)

Pursuant to section 1857(c)(1) of the Act, CMS enters into contracts with MA organizations for a period of 1 year. As implemented by CMS pursuant to that provision, these contracts automatically renew absent notification by either CMS or the MA organization to terminate the contract at the end of the year. Section 1860D–12(b)(3)(B) of the Act makes this same process applicable to CMS contracts with Part D plan sponsors. CMS has implemented these provisions in regulations that permit MA organizations and Part D plan sponsors to non-renew their contracts, with CMS

approval and consent necessary depending on the timeframe of the sponsoring organization’s notice to CMS that a non-renewal is desired. We are proposing to clarify its operational policy that any request to terminate a contract after the first Monday in June is considered a request for termination by mutual consent.

Under § 422.506(a)(2)(i) and § 423.507(a)(2)(i), contract non-renewals effective at the end of the 1-year contract term must be submitted to CMS in writing by the first Monday in June. There may be instances where CMS accepts a late non-renewal notice after the first Monday in June for an MA contract if the non-renewal is consistent with the effective and efficient administration of the contract under § 422.506(a)(3). There is no corresponding regulatory provision affording CMS such discretion for Part D contracts.

We have seen that many MA organizations do not understand that CMS treats non-renewals requested after the first Monday in June as an organization’s request for a mutual termination pursuant to § 422.508 when determining whether it is in the best interest of the Medicare program to permit non-renewals in applying § 422.506(a)(3). Organizations that request a non-renewal of their contract after the first Monday in June, must receive written confirmation from CMS of the termination by mutual consent pursuant to § 422.508(a) (and § 423.508(a) if an MA–PD plan) to be effectively relieved of their obligation to participate in the MA or Part D programs during the upcoming contract year. CMS has received a number of late non-renewal requests and has received questions from MA organizations inquiring why their request was not treated as a contract non-renewal, but rather as a termination by mutual consent.

We propose to modify § 422.506(a)(3) to remove language that indicates late non-renewals may be permitted by CMS so that there would only be one process—mutual termination under §§ 422.508—that is applicable if CMS is not taking action under § 422.506(b) or § 422.510. Also, we propose to amend §§ 422.508 and 423.508 to clarify that organizations that request to non-renew a contract after the first Monday in June are in effect requesting that CMS agree to mutually terminate their contract.

4. Contract Request for a Hearing (§§ 422.664(b) and 423.652(b))

Under the authority of section 1857(a) of the Act, CMS enters into contracts with MA organizations which authorize

them to offer MA plans to Medicare beneficiaries. Similarly, CMS contracts with Part D plan sponsors according to section 1860D–12(a) of the Act. CMS determines that an organization is qualified to hold an MA contract through the application process established at 42 CFR 422, Subpart K. CMS evaluates the qualifications of potential Part D plan sponsors according to Subpart K of 42 CFR, part 423. If CMS denies an application, organizations have the right to appeal CMS's decision (under § 422.502(c)(3)(iii) and § 423.503(c)(3)(iii) using the procedures in subparts N of part 422 and part 423). This proposed rule seeks to correct an inconsistency in the text that identifies CMS's deadline for rendering its determination on appeals of application denials.

According to § 422.660(c) and § 423.650(c), CMS must issue a determination on appealed application denials by September 1 in order to enter into an MA contract for coverage starting January 1 of the following year. We codified this September 1 deadline in the April 15, 2010, final rule (45 FR 19699). As stated in the in the 2009 proposed rule (74 FR 54650 and 54651), we proposed to modify § 422.660(c) and § 423.660(c), which then specified that the notice of any decision favorable to a Part C or D applicant must be issued by July 15 for the contract in question to be effective on January 1 of the following year. However, in that rulemaking, we inadvertently overlooked other regulatory provisions that address the date by which a favorable decision must be made on an appeal of a CMS determination that an entity is not qualified for a Part C or Part D contract.

There is an inconsistency in regulations regarding the date by which an MA organization must receive a decision from CMS on an appeal. Section 422.660(c) specifies that a notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract to be effective on January 1. However, § 422.664(b)(1) specifies that if a final decision is not reached by July 15, CMS will not enter into a contract with the applicant for the following year. Similarly, there is an inconsistency in regulations regarding the date by which a Part D sponsor must receive a CMS decision on an appeal. Section 423.650(c) specifies that a notice of any decision favorable to the MA organization appealing a determination that it is not qualified to enter into a contract with CMS must be issued by

September 1 to be effective on January 1. However, § 423.652(b)(1) specifies that if a final decision is not reached on CMS's determination for an initial contract by July 15, CMS will not enter into a contract with the applicant for the following year.

We propose to modify § 422.664(b)(1) and § 423.652(b)(1) to align with the September 1 date codified in § 422.660(c) and § 423.650(c), which was codified on April 15, 2010.

5. Physician Incentive Plans—Update Stop-Loss Protection Requirements (§ 422.208)

Pursuant to section 1852(j)(4), MA organizations that operate physician incentive plans must meet certain requirements, which CMS has implemented in § 422.208. MA organizations must provide adequate and appropriate stop-loss insurance to all physicians or physician groups that are at substantial financial risk under the MA organization's physician incentive plan (PIP). The current stop-loss insurance deductible limits are identified in a table codified at § 422.208(f)(2)(iii).

Under the current regulation, an MA organization that operates a PIP must provide stop-loss protection for 90 percent of actual costs of referral services that exceed the per patient deductible limit to all physicians and physician groups at financial risk under the PIP. The stop-loss protection may be per patient or aggregate. The current regulation contains a chart that identifies per-patient stop-loss deductible limits for single combined; separate institutional; and separate professional insurance. The current regulation establishes requirements for stop-loss attachment points (deductibles) based on the patient panel size and does not distinguish between at-risk or non-at-risk patients in that panel. There is no requirement for an MA organization to provide stop-loss protection when the physician or physician group has a panel of risk patients of more than 25,000; we are not proposing to change to this requirement. In recent years, CMS has received a number of requests to update the stop-loss insurance limits associated with PIP arrangements to better account for medical costs and utilization changes that have occurred since the final rule was published in the June 29, 2000 **Federal Register** (65 FR 40325) on.

We are not proposing to change the requirements that the MAO (in connection with the PIP) must provide aggregate stop-loss protection for 90 percentage of actual costs of referral services that are greater than 25 percent

of potential income to all physicians and physician groups at financial risk under the PIP and that no stop-loss protection is required when the panel size of the physician or physician group is above 25,000. We are proposing three changes to update the existing regulation:

- Update the stop-loss deductible limits at § 422.208(f)(2)(iii) and codify the methodology that CMS would use to update the stop-loss deductible limits in the future to account for changes in medical cost and utilization;

- Authorize, at paragraph § 422.208(f)(3), MA organizations to use actuarially equivalent arrangements to protect against substantial financial loss under the PIP due to the risks associated with serving particular groups of patients.

- Modify paragraph 422.208(f)(2) to allow non-risk patient equivalents (NPEs), such as Medicare Fee-For-Service patients (FFS), who obtain some services from the physician or physician group to be included when determining the deductible.

We do not believe that other substantive requirements set forth in the PIP regulation, such as the determination of substantial financial risk based on a risk threshold of 25 percent of potential payments (see § 422.208(d)(2)), need to be updated regularly or have been rendered obsolete in the years since the regulation was initially adopted. Although we are not proposing a change to the determination of “substantial financial risk,” we appreciate that the regulatory standard (25% of potential payments) in § 422.208(d)(2) was adopted many years ago. Therefore, we seek comment on whether the definitions of “substantial financial risk” and “risk threshold” contained in the current regulation should be revisited, including whether the current identification of 25 percent of potential payments codified in paragraph (d)(2) remains appropriate as the standard in light of changes in medical cost.

b. Update Deductible Limits and Codify Methodology

Because of increases in medical costs and changes in utilization since the current regulatory standards for PIP stop-loss insurance were adopted, we are concerned that the current regulation requires stop-loss insurance on more generous and more expensive terms than is necessary. Our goal in developing this proposal was to identify the point at which most, if not all, physicians and physician groups would be subject to the substantial loss so that the requirement for the provision of

stop-loss protection and the parameters of that protection would be tailored to address that risk. We intend to avoid regulatory requirements that require protection that is broader than the minimum required under the statute. In developing the new minimum attachment points for the stop-loss protection that is required under the statute, one goal is to provide flexibility to MA organizations and the physicians and physician groups that participate in PIPs in selecting between combined stop-loss insurance and separate professional services and institutional services stop loss insurance.

In order to develop the specific attachment points, we engaged in a data-driven analysis using Part A and Part B claims data from 340,000 randomly selected beneficiaries from 2016. We assumed a multi-specialty practice and we estimated medical group income based on FFS claims, including payments for all Part A and

Part B services. We used the central limit theorem to calculate the distribution of claim means for a multi-specialty group of any given panel size. This distribution was used to obtain, with 98% confidence, the point at which a multi-specialty group of a given panel size would, through referral services, lose more than 25% of its income derived from services that the physician or physician group personally rendered. We used projections of total income based on services provided personally by individual physicians and directly by physician groups because that is how we interpret “potential payments” as defined in the existing regulation. The point at which loss would exceed 25% of potential payments was set as the single combined per patient deductible in Table 13, which we describe in our proposed text at § 422.208(f)(2)(iii); we are not proposing to codify the table, but to codify the methodology for creating it

so that the table itself may be updated by CMS as necessary. Nonetheless, Table 13 would be the table applicable for contract years beginning on or after January 1, 2019 until CMS reapplied the methodology and published an updated table under our proposal. We performed the analysis for multiple panel sizes, which are listed on Table 13. Table 13 also includes a ‘net benefit premium’ (NBP) column, which is used under our proposal to identify the attachment points for separate stop-loss insurance for institutional services and professional services. This NBP column is not needed for identification of the minimum attachment point (maximum deductible) for combined aggregate insurance. The NBP is computed by dividing the total amount of stop-loss claims (90 percent of claims above the deductible) for that panel size by the panel size.

TABLE 13—COMBINED STOP-LOSS INSURANCE DEDUCTIBLES

Panel size	Single combined deductible	Net benefit premium (NBP) PMPY
400	\$5,000	\$5,922
800	10,000	4,891
1400	15,000	4,122
2,000	20,000	3,514
3,300	30,000	2,612
4,600	40,000	1,984
5,800	50,000	1,539
6,900	60,000	1,216
7,900	70,000	977
10,100	100,000	553
12,300	150,000	267
13,500	200,000	159
14,800	300,000	79
16,100	500,000	428
16,800	1,000,000	12
17,400–25,000	2,000,000	4
>25,000	No Stop Loss	0

We propose, at paragraph § 422.208 (f)(2)(iii), other significant provisions. Proposed paragraph § 422.208 (f)(2)(iii)(A) provides that the table (published by CMS using the methodology proposed in paragraph § 422.208(f)(2)(iv)) identifies the maximum attachment point/maximum deductible for per-patient-combined insurance coverage that must be provided for 90% of the costs above the deductible or an actuarial equivalent amount. For panel sizes and deductible amounts not shown in the tables, we

propose that linear interpolation may be used to identify the required deductible for panel sizes between the table values. In addition, proposed paragraph § 422.208(f)(2)(iii)(B) provides that the table applies only for capitated risk.

In order to provide the attachment points for separate per patient insurance for institutional services and professional services, we propose to use the NBP from Table 13. This second table provides separate deductibles for physician and institutional services. Table 14 was calculated using a

methodology similar to the calculation of Table 13. The source for our estimate of medical group income and institutional income is derived from CMS claims files which includes payments for all Part A and Part B services. The central limit theorem was used to obtain the distribution of claim means, and deductibles were obtained at the 98 percent confidence level. We propose to codify the methodology and assumptions for Table 14 in § 422.208 (f)(2)(vi) and (f)(2)(vii).

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TABLE 14: SEPARATE STOP-LOSS INSURANCE DEDUCTIBLES

	Institutional Deductibles (In Thousands)																
	[Cells contain exact Net Benefit Premiums]																
	5	10	15	20	30	40	50	60	70	100	150	200	300	500	1,000	2,000	No Stop Loss
1	5,899	5,022	4,351	3,817	3,021	2,471	2,083	1,804	1,598	1,233	987	894	824	778	762	757	752
2	5,705	4,829	4,157	3,624	2,828	2,277	1,890	1,610	1,404	1,039	794	700	630	584	569	563	558
3	5,593	4,717	4,045	3,512	2,716	2,165	1,778	1,498	1,292	927	682	588	518	472	457	451	446
5	5,468	4,591	3,920	3,386	2,590	2,040	1,653	1,373	1,167	802	556	463	393	347	331	326	321
8	5,375	4,499	3,828	3,294	2,498	1,948	1,560	1,281	1,075	710	464	371	301	254	239	234	229
10	5,338	4,462	3,790	3,257	2,461	1,910	1,523	1,243	1,037	672	427	333	263	217	202	196	191
12	5,311	4,434	3,763	3,230	2,433	1,883	1,496	1,216	1,010	645	400	306	236	190	175	169	164
15	5,281	4,404	3,733	3,199	2,403	1,853	1,466	1,186	980	615	370	276	206	160	144	139	134
20	5,248	4,371	3,700	3,167	2,370	1,820	1,433	1,153	947	582	337	243	173	127	112	106	101
25	5,227	4,350	3,679	3,145	2,349	1,799	1,412	1,132	926	561	316	222	152	106	90	85	80
35	5,201	4,324	3,653	3,119	2,323	1,773	1,385	1,106	900	535	289	196	126	80	64	59	54
50	5,181	4,304	3,633	3,099	2,303	1,753	1,366	1,086	880	515	269	176	106	60	44	39	34
75	5,166	4,289	3,618	3,084	2,288	1,738	1,351	1,071	865	500	254	161	91	45	29	24	19
100	5,159	4,283	3,611	3,078	2,282	1,731	1,344	1,064	858	493	248	154	84	38	23	17	12
200	5,151	4,274	3,603	3,070	2,274	1,723	1,336	1,056	850	485	240	146	76	30	15	9	4
No stop loss	5,147	4,270	3,599	3,066	2,269	1,719	1,332	1,052	846	481	236	142	72	26	11	5	0

Professional Deductible (in thousands)

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The physician or physician group would look up the combined deductible in the second column of Table 13 and select the corresponding NBP in the

third column. If necessary, linear interpolation would be used. Finally, the physician or physician group would select any cell in the table in Table 14 whose numerical entry is greater than or equal to that NBP. The row and column labels for this cell are the corresponding professional and institutional deductibles for that selection. Any such selection would meet the requirement of the basic rule stated in paragraph (f)(2)(i). We are proposing to codify the use of this table of deductibles for separate stop-loss insurance professional services and institutional services based on the NBP in paragraph (f)(2)(v).

We solicit comment on our proposal, specifically the following:

- Whether our proposed regulation text at paragraphs (f)(2)(iv), (vi) and (vii) details the methodology for developing Tables 13 and 14 in sufficient detail.
- Whether our proposed regulation text clearly identifies how the tables would be used.
- Whether we should finalize a specific schedule, such as annually or every 3 years for updating the tables using the proposed methodologies in order to ensure that the maximum deductibles are consistent with medical cost and utilization trends.

d. Actuarially Equivalent Arrangements

Over the past several years, MA organizations, have requested an update to the tables as well as additional flexibilities around protection arrangements other than combined and separate per-patient stop-loss insurance. CMS believes that providing the flexibility to MA organizations to use actuarially equivalent arrangements is appropriate as the nature of the PIP negotiated between the MA organization and physicians or physician groups might necessitate other arrangements to properly and adequately protect physicians from substantial financial risk. Examples where actuarially equivalent modifications might be necessary, include: Global capitation arrangements that include some, but not all Parts A and B services; stop-loss policies with different coinsurances; stop-loss policies that use medical loss ratios (MLR), which generally pay specific stop-loss amounts only to the extent that the overall aggregate MLR for the physician group exceeds a certain amount; stop-loss policies for exclusively primary care physicians; and risk arrangements on a quota share basis, which occurs when less than full capitation risk is transferred from a plan to a physician or physician group. Therefore, we propose to add § 422.208(f)(3) to permit MA

organizations to use other stop-loss protection arrangements; the proposal would allow actuaries to develop actuarially equivalent special insurances that are: Appropriately developed for the population and services furnished; in accordance with generally accepted actuarial principles and practices; and certified as meeting these requirements by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board. Under this proposal, CMS would review the attestation of the actuary certifying the special insurance arrangement. We solicit comment whether these proposed standards provide sufficient flexibility to MA organizations and physicians.

c. Non-Risk Patient Equivalents Included in Panel Size

We believe that the number of a physician group's non-risk patients should be taken into account when setting stop loss deductibles for risk patients. For example a group with 50,000 non-risk patients and 5,000 risk patients needs less protection than a group with only 3,000 non-risk patients and 5,000 risk patients. We propose, at § 422.208(f)(2)(iii) and (v), to allow non-risk patient equivalents (NPEs), such as Medicare Fee-For-Service patients, who obtain some services from the physician or physician group to be included in the panel size when determining the deductible. Under our proposal, NPEs are equal to the projected annual aggregate payments to a physician or physician group for non-global risk patients, divided by an estimate of the average capitation per member per year (PMPY) for all non-global risk patients, whether or not they are capitated. Both the numerator and denominator are for physician services that are rendered by the physician or physician group. We propose that the deductible for the stop-loss insurance that is required under this regulation would be the lesser of: (1) The deductible for globally capitated patients plus up to \$100,000 or (2) the deductible calculated for globally capitated patients plus NPEs. The deductible for these groups would be separately calculated using the tables and requirements in our proposed regulation at paragraph (f)(2)(iii) and (v) and treating the two groups (globally capitated patients and globally capitated patients plus NPEs) separately as the panel size. We propose the same flexibility for combined per-patient stop-loss insurance and the separate stop-loss insurances. We solicit comment on this proposal.

6. Changes to the Agent/Broker Compensation Requirements (§§ 422.2274 and 423.2274)

Sections 103(b)(1)(B) and 103(b)(2) of the Medicare Improvements for Patients and Providers Act (MIPPA) revised section 1851(j)(2)(D) of the Act to charge the Secretary with establishing guidelines to "ensure that the use of compensation creates incentives for agents/brokers to enroll individuals in the MA plan that is intended to best meet their health care needs." Section 103(b)(2) of MIPPA revised section 1860D-4(l)(2) of the Act to apply these same guidelines to Part D sponsors. We believe agents/brokers play a significant role in providing guidance and are, as such, in a unique position to influence beneficiary choice. CMS implemented these MIPPA-related changes in a May 23, 2014 final rule (79 FR 29960). The 2014 final rule revised the provisions previously established in the interim final rule (IFR) adopted on September 18, 2008 (73 FR 554226).

The IFR had established the previous compensation structure for agents/brokers as it applied to the MA and Part D programs. In particular, the IFR limited compensation for renewal enrollments to no greater than 50 percent of the rate paid for the initial enrollment on a 6-year cycle. This structure had proven to be complicated to implement and monitor, as it required the MA organization or Part D sponsor to track the compensation paid for every enrollee's initial enrollment and calculate the renewal rate based on that initial payment. To the extent that there was confusion about the required levels of compensation or the timing of compensation, it seemed that there was an uneven playing field for MA organizations and Part D sponsors operating in the same geographic area.

In addition to the many inquiries from MA organizations and Part D sponsors regarding the correct calculation of agent/broker compensation, CMS found it necessary to take compliance actions against MA organizations and Part D sponsors for failure to comply with the compensation requirements. CMS's audit findings and monitoring efforts performed after implementation of the IFR showed that MA organizations and Part D sponsors were having difficulty correctly administering the compensation requirements.

Also, we were concerned that the structure as it existed before the 2014 revisions created an incentive for agents/brokers to move enrollees from a plan of one parent organization to a plan of another parent organization, even for like plan-type changes. That

compensation structure resulted in different payments when a beneficiary moved from one plan to another like plan in a different organization. In such situations, the new parent organization would pay the agent 50 percent of the current initial rate of the new parent organization; not 50 percent of the initial rate paid by the prior parent organization. Thus, in cases where the fair market value (FMV) for compensation had increased, or the other parent organization paid a higher commission, an incentive existed for the agent to move beneficiaries from one parent organization to another, rather than supporting the beneficiary's continued enrollment in the prior parent organization.

In a 2014 proposed rule (79 FR 1918), we proposed to simplify agent/broker compensation rules to help ensure that plan payments were correct and establish a level playing field that further limited the incentive for agents/brokers to move enrollees for financial gain rather than for the beneficiary's best interest. In the final rule published on May 23, 2014, we codified technical changes to the language established by the IFR relating to agent/broker compensation, choosing instead to link payment rates for renewal enrollments to current FMV rates rather than the rate paid for the original (that is, initial) enrollment. These changes also effectively removed the 6-year cycle from the payment structure. We codified these changes in §§ 422.2274(a), (b), and (h) for MA organizations and §§ 423.2274(a), (b), and (h) for Part D sponsors.

At that time, we should have also proposed to remove the language at § 422.2274(b)(2)(i), § 422.2274(b)(2)(ii), § 423.2274(b)(2)(i), and § 423.2274(b)(2)(ii), but we failed to do so. Since then, this language is no longer relevant, as the current compensation structure is not based on the initial payment. However, it has created confusion among plan staff and brokers.

We propose to make a technical correction to the existing regulatory language at § 422.2274(b) and § 423.2274(b). We propose to remove the language at §§ 422.2274(b)(2)(i), 422.2274(b)(2)(ii), 423.2274(b)(2)(i), and 423.2274(b)(2)(ii). Additionally, we would renumber the existing provisions under § 422.2274(b) and § 423.2274(b) for clarity.

7. Changes to the Agent/Broker Requirements (§§ 422.2272(e) and 423.2272(e))

Section 1851(h)(7) of the Act directs CMS to act in collaboration with the

states to address fraudulent or inappropriate marketing practices. In particular, section 1851(h)(7)(A)(i) of the Act requires that MA organizations only use agents/brokers who have been licensed under state law to sell MA plans offered by those organizations. Section 1860D-4(l)(4) of the Act references the requirements in section 1851(h)(7) of the Act and applies them to Part D sponsors. We have codified the requirement in §§ 422.2272(c) and 423.2272(c).

In the April 15, 2011, final rule (76 FR 21503 and 21504), we codified a provision in §§ 422.2272(e) and 423.2272(e) that required MA organizations and Part D sponsors to terminate any employed agent/broker who became unlicensed. The provision also required MA organizations and Part D sponsors to notify any beneficiaries enrolled by the unqualified agent/broker of that agent/broker's status. Finally, the provision specified that the MA organization or Part D sponsor must comply with any request from the beneficiary regarding the beneficiary's options to confirm enrollment or make a plan change if the beneficiary requests such upon notification of the agent/broker's status.

Since implementation of the provision in §§ 422.2272(e) and 423.2272(e), we have become aware that the regulation does not allow latitude for punitive action in situations when a license lapses. The MA organization or Part D sponsor may terminate the agent/broker and immediately rehire the individual thereafter if licensure has been already reinstated or prohibit the agent/broker from ever selling the MA organization's or Part D sponsor's products again. Discussions with the industry indicate that these two options are impractical due to their narrow limits. We believe agents/brokers play a significant role in providing guidance to beneficiaries and are in a unique position to positively influence beneficiary choice. However, the statute directs CMS to require MA organizations and Part D sponsors to only use agents/brokers who are licensed under state law. We do not intend to change the regulation, at §§ 422.2272(c) and 423.2272(c), requiring agent/broker licensure as a condition of being hired by a plan, and will continue to review the licensure status of agents/brokers during those monitoring activities that focus on MA organizations' and Part D sponsors' marketing activities. CMS believes MA organizations and Part D sponsors should determine the level of disciplinary action to take against agents/brokers who fail to maintain

their license and have sold MA/Part D products while unlicensed, so long as the MA organization or Part D plan complies with the remaining statutory and regulatory requirements.

We propose to delete §§ 422.2272(e) and 423.2272(e), the provisions that limit what MA organizations and Part D sponsors can do when they have discovered that a previously licensed agent/broker has become unlicensed. Nonetheless, CMS may pursue compliance actions upon discovery of MA organizations and Part D sponsors who allow unlicensed agents/brokers to continue selling their products in violation of §§ 422.2272(c) and 423.2272(c).

Note that deleting paragraph (e) from §§ 422.2272 and 423.2272 removes language describing the opportunity beneficiaries have to select a different MA or Part D plan when the broker who enrolled them was unlicensed at the time the beneficiaries enrolled. Removing paragraph (e) from §§ 422.2272 and 423.2272 does not eliminate the special enrollment period (SEP) that enrollees receive when it is later discovered that their agent/broker was not licensed at the time of the enrollment as that SEP exists under the authority of § 422.62(b)(4).

8. Codification of Certain Medicare Premium Adjustments as Initial Determinations (§ 405.924)

Current regulations at § 405.924(a) set forth Social Security Administration (SSA) actions that constitute initial determinations under section 1869(a)(1) of the Act. These actions at § 405.924(a) include determinations with respect to entitlement to Medicare hospital (Part A) or supplementary medical insurance (Part B), disallowance of an application for entitlement; a denial of a request for withdrawal of an application for Medicare Part A or Part B, or denial of a request for cancellation of a request for withdrawal; or a determination as to whether an individual, previously determined as entitled to Part A or Part B, is no longer entitled to these benefits, including a determination based on nonpayment of premiums.

In addition to the actions set forth at § 405.924(a), SSA, the Office of Medicare Hearings and Appeals (OMHA), and the Departmental Appeals Board (DAB) also treat certain Medicare premium adjustments as initial determinations under section 1869(a)(1) of the Act. These Medicare premium adjustments include Medicare Part A and Part B late enrollment and reenrollment premium increases made in accordance with sections 1818, 1839(b) of the Act, §§ 406.32(d),

408.20(e), and 408.22 of this chapter, and 20 CFR 418.1301. Due to the effect that these premium adjustments have on individuals' entitlement to Medicare benefits, they constitute initial determinations under section 1869(a)(1) of the Act.

Accordingly, we are proposing to add a new paragraph (5) to § 405.924(a) to clarify that these premium adjustments, made in accordance with sections 1818 and 1839(b) of the Act, §§ 406.32(d) and 408.22 of this chapter, and 20 CFR 418.1301, constitute initial determinations under section 1869(a)(1) of the Act. Because this proposed change seeks only to codify existing processes related to premium adjustments, and not to alter existing processes or procedures, it applies only to Part A and Part B late enrollment and reenrollment penalties. Based on 1860D–13(b)(6)(C) of the Act, CMS does not consider Part D late enrollment and reenrollment penalties to be initial determinations. As a result, their appeal rights stop at the reconsideration level.

9. Eliminate Use of the Term “Non-Renewal” To Refer to a CMS-Initiated Termination (§§ 422.506, 422.510, 423.507 and 423.509)

Section 1857(c)(2) of the Act provides the bases upon which CMS may make a decision to terminate a contract with an MA organization. Under section 1860D 12(b)(3) of the Act, these same bases are available for a CMS termination of a Part D sponsor contract, as section 1860D–12(b)(3) of the Act incorporates into the Part D program the Part C bases by reference to section 1857(c)(2). Also, sections 1857(h) and 1860D 12(b)(3)(F) of the Act provide the procedures CMS must follow in carrying out MA organization or Part D sponsor contract terminations.

Although the Act only expressly refers to terminations, through rulemaking and subregulatory guidance, we have created two different processes relating to severing the contractual agreement between CMS and an MA organization or Part D sponsor. In accordance with sections 1857(h) and 1860D–12(b)(3)(F) of the Act, we have adopted regulations providing for distinct contract termination and bases and procedures for nonrenewal if contracts. Our regulations at §§ 422.506 and 422.510 provide for the nonrenewal and termination, respectively, of CMS contracts with MA organizations. The Part D regulations provide for similar procedures with respect to Part D sponsor contracts at §§ 423.507 and 423.509.

Each nonrenewal provision is divided into two parts, one governing

nonrenewals initiated by a sponsoring organization and another governing nonrenewals initiated by CMS. Two features of the nonrenewal provisions have created multiple meanings for the term “nonrenewal” in the operation of the Part C and D programs, contributing, in some instances, to confusion within CMS and among contracting organizations surrounding the use of the term. The first feature is the difference between non renewals initiated by sponsoring organizations and those initiated by CMS with respect to the need to establish cause for such an action. The second is the partial overlap between CMS' termination authority and our nonrenewal authority. We propose to revise our use of terminology such that that the term “nonrenewal” only refers to elections by contracting organizations to discontinue their contracts at the end of a given year. We propose to remove the CMS initiated nonrenewal authority stated at paragraph (b) from both §§ 422.506 and 423.507 and modify the existing CMS initiated termination authority at §§ 422.510 and 423.509 to reflect this change.

MA organizations and Part D plan sponsors may elect to end the automatic renewal provision in Part C or Part D contracts and discontinue those contracts with CMS without cause, simply by providing notice in the manner and within the timeframes stated at § 422.506(a) and § 423.507(a). Thus, organizations are free to make a business decision to end their Medicare contract at the end of a given year and need not provide CMS with a rationale for their decision. By contrast, CMS may not end an MA organization or Part D plan sponsor's contract through nonrenewal without establishing that the contracting organization's performance has met the criteria for at least one of the stated bases for a CMS initiated contract nonrenewal in paragraphs (b) of those sections.

Contracting organizations often respond to changes in the Medicare markets or changes in their own business objectives by making decisions to end or modify their participation in the Part C and D programs. Thus, these organizations exercise their nonrenewal rights under § 422.506(a) and § 423.507(a) much more frequently than CMS conducts contract non renewals under § 422.506(b) and § 423.507(b). As a result, within CMS and among industry stakeholders, the term “nonrenewal” has effectively come to refer almost exclusively to MA organization and Part D plan sponsor initiated contract non renewals.

The termination authority allows us to provide notice of such an action at any time and make it effective at least 30 days after providing such notice to the contracting organization. By contrast, CMS may issue a nonrenewal notice of a contract no later than August 1, and the nonrenewal takes effect at the end of the current contract year. Yet, the result of both actions taken by CMS is the discontinuation, for cause (although the basis of that cause might be different), of an organization's MA or Part D contract.

The similarities between nonrenewal and termination are demonstrated by the extensive but not complete overlap in bases for CMS action under both processes. For example, both nonrenewal authorities incorporate by reference the bases for CMS initiated terminations stated in § 422.510 and § 423.509. The remaining CMS initiated nonrenewal bases (any of the bases that support the imposition of intermediate sanctions or civil money penalties (§§ 422.506(b)(iii) and § 423.507(b)(1)(ii)), low enrollment in an individual MA plan or PDP (§§ 422.506(b)(iv) and 423.507(b)(1)(iii)), or failure to fully implement or make significant progress on quality improvement projects (§ 422.506(b)(i))) were all promulgated in accordance with our statutory termination authority at sections 1857(c)(2) and 1860D–12(b)(3) of the Act and are all more specific examples of an organization's substantial failure to carry out the terms of its MA or Part D contract or its carrying out the contract in an inefficient or ineffective manner. Therefore, we propose striking these provisions from the nonrenewal portion of the regulation and adding them to the list of bases for CMS initiated contract terminations.

Finally, there are aspects of the notice requirements related to the CMS initiated nonrenewal authority that are useful in the administration of the Part C and D programs and which we propose preserving in the revised termination provision. Specifically, § 422.506(b)(2)(ii) requires notice to be provided by mail to a contracting organization's enrollees at least 90 days prior to the effective date of the nonrenewal, while § 422.510(b)(1)(ii) requires affected plan enrollees to be notified within 30 days of the effective date of the termination. We see a continuing benefit to the administration of the Part C and D programs in retaining the authority to ensure that, when possible, enrollees can be made aware of their plan's discontinuation at least by October 1 of a given year so that they can make the necessary plan choice

during the annual election period. Therefore, we propose adding provisions at §§ 422.510(b)(2)(v) and 423.509(b)(2)(v) to require that enrollees receive notice no later than 90 days prior to the December 31 effective date of a contract termination when we make such determination on or before August 1 of the same year.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (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 requirement is submitted to

the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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 of this document that contain information collection requirements (ICRs).

A. Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2016 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 15—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefits and overhead (\$hr)	Adjusted hourly wage (\$/hr)
Business Operations Specialist	13–1000	34.54	34.54	69.08
Compliance Officers	13–1041	33.77	33.77	67.54
Computer and Information Systems Managers	11–3021	70.07	70.07	140.14
Computer Programmer	15–1131	40.95	40.95	81.90
Health Diagnostic and Treating Practitioners	29–1199	40.77	40.77	81.54
Insurance Claim and Policy Processing Clerk	43–9041	19.61	19.61	39.22
Lawyers	23–1011	67.25	67.25	134.50
Medical and Health Service Manager	11–9111	52.58	52.58	105.16
Medical Secretary	43–6013	16.85	16.85	33.70
Office and Administrative Support Workers, All Other	43–9199	17.33	17.33	34.66
Physicians and Surgeons	29–1060	101.04	101.04	202.08
Physicians and Surgeons, all other	29–1069	98.83	98.83	197.66
Software Developers and Programmers	15–1130	48.11	48.11	96.22
Word Processors and Typists	43–9022	19.22	19.22	38.44

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. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Passive Enrollment Flexibilities To Protect Continuity of Integrated Care for Dually Eligible Beneficiaries (§ 422.60(g))

In section II.A.9 of this proposed rule, we are proposing a limited expansion of passive enrollment authority. More specifically, the new provisions at § 422.60(g) would allow CMS, in consultation with a state Medicaid agency, to implement passive

enrollment procedures in situations where criteria identified in the regulation text are met. We propose the criteria based on our policy determination that passive enrollment is appropriate in those cases to promote integrated care and continuity of care for full-benefit dual eligible beneficiaries who are currently enrolled in an integrated D–SNP.

Under passive enrollment procedures, a beneficiary who is offered a passive enrollment is deemed to have elected enrollment in a plan if he or she does not affirmatively elect to receive Medicare coverage in another way. Plans to which individuals are passively enrolled under the proposed provision would be required to comply with the existing requirement under § 422.60(g) to provide a notification. The notice must explain the beneficiaries' right to choose another plan, describe the costs and benefits of the new plan, how to access care under the plan, and the beneficiary's ability to decline the enrollment or choose another plan. Providing notification would include

mailing notices and responding to any beneficiary questions regarding enrollment.

We anticipate that there will be relatively few instances each year in which passive enrollment occurs under the new provisions at § 422.60(g). This is informed by our experience in implementing passive enrollments under the existing regulations at § 422.60(g), where in recent years there have been only one to two contract terminations annually where CMS allows passive enrollment. We estimate that approximately one percent of the 373 active D–SNPs would meet the criteria identified in the regulation text, and operate in a market where all of the conditions of passive enrollment are met and where CMS, in consultation with a state Medicaid agency, implements passive enrollment. Therefore, under the new provisions at § 422.60(g), we anticipate only four additional instances in which CMS allows passive enrollment each year.

We estimate it would take 10 hours at \$69.08/hr for a business operations

specialist to develop the initial notice. We also estimate it would take 1 minute for a business operations specialist to electronically generate and submit a notice for each beneficiary that is offered passive enrollment. We estimate that approximately 5,520 full-benefit dual eligible beneficiaries would be sent a notice in each instance in which passive enrollment occurs, which reflects the average enrollment of currently active D-SNP plans. Four instances of passive enrollment annually would result in 22,080 beneficiaries being sent the notice (5,520 × 4 organizations) each year.

To develop the initial notice, we estimate a one-time burden of 40 hours (4 organizations × 10 hr) at a cost of \$2,763.20 (40 hr × \$69.08/hr) or \$690.80 per organization (\$2,763.20/4 organizations). To electronically generate and submit a notice to each beneficiary, we estimate a total burden of 368 hours (22,080 beneficiaries × 1 min/60) at a cost of \$25,421.44 (368 hr × \$69.08/hr) or \$6,355.36 per organization (\$25,421.44/4 organizations) annually.

Since we estimate fewer than 10 respondents, the information collection requirements are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995. However, we seek comment on our estimates for the overall number of respondents and the associated burden.

2. ICRs Regarding the Restoration of the MA Open Enrollment Period (§§ 422.60, 422.62, 422.68, 423.38, and 423.40)

In section II.B.1. of this rule, we are proposing to codify the requirements for open enrollment and disenrollment opportunities at §§ 422.60, 422.62, 422.68, 423.38, and 423.40 that would eliminate the existing MADP and establish a MA Open Enrollment Period (OEP). This new OEP revises a previous OEP which would allow MA-enrolled individuals the opportunity to make a one-time election during the first 3 months of the calendar year to switch MA plans, or disenroll from an MA plan and obtain coverage through Original Medicare. Although no new data would be collected, the burden associated with this requirement would be the time and effort that it takes an MA organization to process an increased number of enrollment and disenrollment requests by individuals using this OEP, which is first available in 2019.

To estimate the potential increase in the number of enrollments and disenrollments from the new OEP, we considered the percentage of MA-enrollees who used the old OEP that was available from 2007 through 2010.

For 2010, the final year the OEP existed before the MADP took effect, we found that approximately 3 percent of individuals used the OEP. While the parameters of the old OEP and new OEP differ slightly, we believe that this percentage is the best approximation to determine the burden associated with this change. In January 2017, there were approximately 18,600,000 individuals enrolled in MA plans. Using the 3 percent adjustment, we expect that 558,000 individuals (18.6 million MA beneficiaries × 0.03), would use the OEP to make an enrollment change.

a. Beneficiary Estimate (Current OMB Control Number 0938–0753 (CMS–R–267))

We estimate it would take a beneficiary approximately 30 minutes (0.5 hours) at \$7.25/hour to complete an enrollment request. While there may be some cost to the respondents, there are individuals completing this form who are working currently, may not be working currently or never worked. Therefore, we used the current federal minimum wage outlined by the U.S. Department of Labor (<https://www.dol.gov/whd/minimumwage.htm>) to calculate costs. The burden for all beneficiaries is estimated at 279,000 hours (558,000 beneficiaries × 0.5 hour) at a cost of \$2,022,750 (279,000 hour × \$7.25/hour) or \$3.63 per beneficiary (\$2,022,750/558,000 beneficiaries).

b. MA Organization Estimate (Current OMB Ctrl# 0938–0753 (CMS–R–267))

There are currently 468 MA organizations in 2017. Not all MA organizations are required to be open for enrollment during the OEP. However, for those that are, we estimate that this enrollment period would result in approximately 1,192 enrollments per organization (558,000 individuals/468 organizations) during the OEP each year.

We estimate it would take approximately 5 minutes at \$69.08/hour for a business operations specialist to determine eligibility and effectuate the changes for open enrollment. The burden for all organizations is estimated at 46,500 hours (558,000 beneficiaries × 5 min/60) at a cost of \$3,212,220 (46,500 hour × \$69.08/hour) or \$6,864 per organization (\$3,212,220/468 MA organizations).

Once the enrollment change is completed, we estimate that it will take 1 minute at \$69.08/hour for a business operations specialist to electronically generate and submit a notice to convey the enrollment or disenrollment decision for each of the 558,000 beneficiaries. The total burden to

complete the notices is 9,300 hours (558,000 notices × 1 min/60) at a cost of \$642,444 (9,300 hour × \$69.08/hour) or \$1.15 per notice (\$642,444/558,000 notices) or \$1,372.74 per organization (\$642,444/468 MA organizations).

The burden associated with electronic submission of enrollment information to CMS is estimated at 1 minute at \$69.08/hour for a business operations specialist to submit the enrollment information to CMS during the open enrollment period. The total burden is estimated at 9,300 hours (558,000 notices × 1 min/60) at a cost of \$642,444 (9,300 hour × \$69.08/hour) or \$1.15 per notice (\$642,444/558,000 notices) or \$1,372.74 per organization (\$642,444/468 MA organizations).

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 \$34.66/hour for an office and administrative support worker to perform record retention for the open enrollment period. In aggregate we estimate an annual burden of 46,500 hours (558,000 beneficiaries × 5 min/60) at a cost of \$1,606,110 (46,500 hour × \$34.66/hour) or \$3,431.86 per organization (\$1,606,110/468 MA organizations).

We estimate a total annual burden for all MA organizations resulting from this proposed provision to be 111,600 hours (46,500 hour + 9,300 hour + 9,300 hour + 46,500 hour) at a cost of \$6,103,218 (\$3,212,220 + \$642,444 + \$642,444 + \$1,606,110). Per organization, we estimate an annual burden of 238 hours (111,600 hour/468 MA organizations) at a cost of \$13,041 (\$6,103,218/468 organizations). For beneficiaries we estimate a total annual burden of 279,000 hours at a cost of \$2,022,750 and a per beneficiary burden of 30 minutes at \$3.63.

The proposed requirements and burden will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

3. ICRs Regarding Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage (§§ 422.66 and 422.68) OMB Control Number 0938–0753 (CMS–R–267)

In section II.A.8. of this rule we propose to revise § 422.66 and 422.68 by: Codifying the requirements for default enrollment that are currently set out in subregulatory guidance,⁶⁰

⁶⁰ Chapter 2 of the Medicare Managed Care Manual found at <https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCare/EligEnroll/index.html?redirect=/MedicareMangCare/EligEnroll/>.

revising current practice to limit the use of this type of enrollment mechanism, and clarifying the effective date for ICEP elections. This would provide an MA organization the option to enroll its Medicaid managed care enrollees who are newly eligible for Medicare into an integrated D-SNP administered by the same MA organization that operates the Medicaid managed care plan. While our proposal restricts its use to individuals in the organization's Medicaid managed care plan that can be enrolled into an integrated D-SNP, the estimated burden for an organization that desires to use default enrollment and obtain CMS approval would not change. For those MA organizations that want to use this enrollment mechanism and request and obtain CMS approval, the administrative requirements would remain unchanged from the current practice. Enrollment requirements and burden are currently approved by OMB under control number 0938-0753 (CMS-R-267). Since this proposed rule would not impose any new or revised requirements/burden, we are not making any changes to that control number.

4. ICRs Regarding Timing and Method of Disclosure Requirements (§§ 422.111(a)(3) and (h)(2)(ii) and 423.128(a)(3) and 423.128(d)(2)) (OMB Control Number 0938-1051)

a. Timing of Disclosure (§§ 422.111(a)(3) and 423.128(a)(3))

In section II.B.4. of this rule, we propose to revise the timing and method of disclosing the information as required under § 422.111(a) and (b) and the timing of such disclosures under § 423.128(a) and (b). These regulations provide for disclosure of plan content information to beneficiaries. We would revise §§ 422.111(a)(3) and 423.128(a)(3) by requiring MA plans and Part D sponsors to provide the information in §§ 422.111(b) and 423.128(b) by the first day of the annual enrollment period, rather than 15 days before that period. Plans must still distribute the ANOC 15 days prior to the AEP. In other words, the proposed provision would provide the option of either submitting the EOC with the ANOC or waiting until the first day of the AEP, or sooner, for distribution. The provision simply gives plans that may need some flexibility the ability to rearrange schedules and defer a deadline. Consequently, there is no change in burden.

b. Method of Disclosure (§§ 422.111(h)(2) and 423.128(d)(2)) (OMB Control Number 0938-1051)

Sections 422.111(h)(2)(i) and 423.128(d)(2)(i) require that plans

maintain a Web site which contains the information listed in §§ 422.111(b) and 423.128(b). Section 422.111(h)(2)(ii) states that the posting of the EOC, Summary of Benefits, and provider network information on the plan's Web site "does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees." There is no parallel to § 422.111(h)(2)(ii) in § 423.128 for Part D sponsors. Further, § 423.128(a) includes language providing that disclosures required under that section be "in the manner specified by CMS."

In § 422.111(h)(2)(ii), we propose to modify the sentence which states that posting the EOC, Summary of Benefits, and provider network information on the plan's Web site does not relieve the plan of its responsibility to provide hard copies of these documents to beneficiaries "upon request." In addition, we propose to add the phrase "in the manner specified by CMS" in paragraph (a). These proposed revisions would give CMS the authority to permit MA plans the flexibility to provide the information in § 422.111(b) electronically when specified by CMS as a permissible delivery option, and better aligns with the provisions under § 423.128. We intend to continue to specify hardcopy mailing, as opposed to electronic delivery, for most documents that convey the type of information described in paragraph (b). CMS intends that provider and pharmacy directories, the plan's Summary of Benefits, and EOC documents would be those for which electronic posting and delivery of a hard copy upon request are permissible. Electronic delivery would reduce plan burden by reducing printing and mailing costs. Additionally, the IT systems of the plans are already set up to format and print these documents. Also, plans must provide hard copies upon request. To estimate the cost of printing these documents, we note that the CMS Trustee's report, accessible at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/>, lists 47.8 million beneficiaries in MA, Section 1876 cost,⁶¹ and Prescription Drug contracts for contract year 2019.

Based on reports from the *Internet Society.org* and Pew Research Center,⁶² we estimate that 33 percent of

⁶¹ Per 42 CFR 417.427, cost plans must comply with § 422.111 and § 423.128.

⁶² Global Internet Report, 2017, Internet Society, http://www.internetsociety.org/globalinternetreport/2016/?gclid=EA1aIQobChMI-tz1nN_W1QIVgoKzCh1EVggBEAAYASAAEglpj_D_BwE and "Tech Adoption Climbs Among Older Adults," Pew

these beneficiaries who are in MA and Prescription Drug contracts would prefer to opt in to receiving hard copies to receiving electronic copies. Thus, the savings comes from the 67 percent of beneficiaries who are in MA and Prescription Drug contracts that will not opt in to having printed copies mailed to them, namely 67 percent \times 47.8 = 32,026,000 individuals.

The major expenses in printing an EOC include paper, toner, and mailing costs. The typical EOC has 150 pages. Typical wholesale costs of paper are between \$2.50 and \$5.00 for a ream of 500 sheets. We assume \$2.50 per ream of 500 sheets. Since each EOC has 150 pages, we are estimating a cost of \$0.75 per EOC [$\$2.50 / (150 \text{ pages per EOC} / 500 \text{ sheets per ream})$]. Thus, we estimate that the total savings from paper is \$24,019,500 (32,026,000 EOCs \times \$0.75 per EOC).

Toner costs can range from \$50 to \$200 and each toner can last 4,000 to 10,000 pages. We conservatively assumes a cost of \$50 for 10,000 pages. Each toner would print 66.67 EOCs (10,000 pages per toner / 150 pages per EOC) at a cost of \$0.005 per page ($\$50 / 10,000 \text{ pages}$) or \$0.75 per EOC ($\$0.005 \text{ per page} \times 150 \text{ pages}$). Thus, we estimate that the total savings on toner is \$24,019,500 ($\$0.75 \text{ per EOC} \times 32,026,000 \text{ EOCs}$).

Regarding mailing costs, since a ream of paper with 2,000 8.5 inches by 11 inches pages weighs 20 pounds or 320 ounces it then follows that 1 sheet of paper weighs 0.16 ounces (320 ounces / 2,000 pages). Therefore, a typical EOC of 150 pages weighs 24 ounces (0.16 ounces/page \times 150 pages) or 1.5 pounds. Since commercial mailing rates are 13.8 cents per pound, the total savings in mailings is \$6,629,382 ($\$0.138 / \text{pounds} \times 1.5 \text{ pound} \times 32,026,000 \text{ EOCs}$).

In aggregate, we estimate a savings (to plans for not producing and mailing hardcopy EOCs) of \$54,668,382 ($\$24,019,500 + \$24,019,500 + \$6,629,382$). We will submit the proposed requirements and burden to OMB for approval under OMB control number 0938-1051 (CMS-10260).

5. ICRs Regarding the Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152) (OMB Control Number 0938-1023)

In section II.B.12. of this rule, we are proposing the removal of the Quality Improvement Project (QIP) requirements (and CMS-direction of QIPs) from the Quality Improvement (QI) Program

Research Center, <http://www.pewinternet.org/2017/05/17/tech-adoption-climbs-among-older-adults/>.

requirements, which would result in an annual savings of \$12,663.75 to MA organizations. The driver of the anticipated savings is the removal of requirements to attest having a QIP annually.

To derive our savings, we estimate that it takes 1 MA organization staff member (BLS: Compliance Officer) 15 minutes (0.25 hour) at \$67.54/hour to submit a QIP attestation. Currently, there are 750 MA contracts, and each contract is required to submit a QIP attestation. Therefore, we anticipate that there will be 750 QIP attestations annually.

Using these assumptions, we estimate that the removal of the QIP provision will result in a total savings of 187.5 hours (750 contracts \times 0.25 hour) at \$12,663.75 (187.5 hour \times \$67.54/hour) or \$16.89 per contact (\$12,663.75/750 contracts).

The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1023 (CMS–10209).

6. ICRs Regarding Medicare Advantage Quality Rating System (§§ 422.162, 422.164, 422.166, 422.182, 422.184, and 422.186)

In section II.A.11. of this rule, we are proposing to codify the existing measures and methodology for the Part C and D Star Ratings program. The proposed provisions would not change any respondent requirements or burden pertaining to any of CMS' Star Ratings-related PRA packages including: OMB control number 0938–0701 for CAHPS (CMS–10203), OMB control number 0938–0732 for HOS (CMS–R–246), OMB control number 0938–1028 for HEDIS (CMS–10219), OMB control number 0938–1054 for Part C Reporting Requirements (CMS–10261), and OMB control number 0938–0992 for Part D Reporting Requirements (CMS–10185).

Since this rule would not impose any new or revised requirements/burden, we are not making changes to any of the aforementioned control numbers.

7. ICRs Regarding Medicare Advantage Plan Minimum Enrollment Waiver (§ 422.514(b))

CMS regulations provide Medicare Advantage (MA) organizations, including provider sponsored organizations, with the opportunity to request a waiver of CMS's minimum enrollment requirements at § 422.514(a) during the first 3 years of the contract. Regulations also require that MA organizations reapply for the minimum enrollment waiver in the second and third years of their contract. However, since CMS has not received or approved any waivers outside of the application process, CMS proposes to remove the requirement for MA organizations to reapply for the minimum enrollment waiver during years 2 and 3 of the contract under § 422.514(b)(2) and (3). CMS also proposes to modify § 422.514(b)(2) to clarify that CMS will only accept a waiver through the application process and allow the minimum enrollment waiver, if approved by CMS, to remain effective for the first 3 years of the contract. The requirement and burden associated with the submission of the minimum enrollment waiver in the application is currently approved by OMB under control number 0938–0935 (CMS–10237) which does not need to be revised.

8. ICRs Regarding Revisions to §§ 422 and 423 Subpart V, Communication/Marketing Materials and Activities

In section II.B.5. of this rule, we are proposing to narrow the definition of "marketing materials" under §§ 422.2260 and 423.2260 to only include materials and activities that aim to influence enrollment decisions. We believe the proposed definitions appropriately safeguard potential and current MA/PDP enrollees from inappropriate steering of beneficiary choice, while not including materials that pose little risk to current or potential enrollees and are not traditionally considered "marketing." Revisions to §§ 422.2260 and 423.2260

would provide a narrower definition than is currently provided for "marketing materials." Consequently, this change decreases the number of marketing materials that must be reviewed by CMS before use. Additionally, the proposal would more specifically outline the materials that are and are not considered marketing materials.

We believe the net effects of the proposed changes would reduce the burden to MA organizations and Part D sponsors by reducing the number of materials required to be submitted to us for review.

To estimate the savings, we reviewed the most recent 12-month period of marketing material submissions from the Health Plan Management System, July 2016 through and including June 2017. As documented in the currently approved PRA package, we also estimate that it takes a plan 30 minutes at \$69.08/hour for a business operations specialist to submit the marketing materials. To complete the savings analysis, we also must estimate the number of marketing materials that would have been submitted to and reviewed by CMS under the current regulatory marketing definition (note that while all materials that meet the regulatory definition of marketing must be submitted to CMS, not all marketing materials are prospectively reviewed by CMS). Certain marketing materials qualify for "File and Use" status, which means the material can be submitted to CMS and used 5 days after submission, without being prospectively reviewed by CMS. We estimate 90 percent of marketing materials are exempt from our prospective review because of the file and use process. Thus, we only prospectively review about 10 percent of the marketing materials submitted.

Marketing materials are coded using 4- or 5-digit numbers, based on marketing material type. The relevant codes and counts are summarized in Table 16.

BILLING CODE 4120–01–P

TABLE 16: MARKETING MATERIAL SUBMISSION BURDEN ANALYSIS

Marketing Code	Description	Total Number of Materials Submitted Under Marketing Code	Description of Excluded Material(s)*	Number of Excluded Materials	Number of Materials that would no longer be Submitted	Hours per Response	Total Hours Saved	Wage Rate (Per Hour)	Cost Saved (in \$)
1000	Enrollment and related documents	16495	Enrollment forms	981	15,514	0.5	7,757	\$69.08	535,853.56
1100	ANOC/EOC/LIS Rider	6794		5,162	1,632	0.5	816	\$69.08	56,369.28
2000	Disenrollment	5942	n/a	0	5942	0.5	2,971	\$69.08	205,236.68
3000	Grievances	1564	n/a	0	1564	0.5	782	\$69.08	54,020.56
4000	Advertisements	43965	General advertising that includes benefits information	32,974	10,991	0.5	5,495.5	\$69.08	379,629
5000	Formulary Drug	1429	n/a		1,429	0.5	714.5	\$69.08	49,397.66
6000	Presentations/Scripts/Surveys	2836	Enrollment scripts	1,169	1,407	0.5	703.5	\$69.08	48,597.78
8000	Creditable Coverage/LEP	559			559	0.5	279.5	\$69.08	19,307.86
16000, 17000	Medicare Medicaid Plans		n/a	0	0	0.5	0	\$69.08	0
30000	PACE		n/a	0	0	0.5	0	\$69.08	0
Total		80,110		40,286	39,824	0.5	19,912	\$69.08	\$1,348,372.52

*Excluded materials are materials that still will require review.

By reducing the number of marketing materials submitted to CMS by 39,824

documents (80,110 current – 40,286 excluded) we estimate a savings of

19,912 hours (39,824 materials * 0.5 hours per material) at a cost savings of \$1,348,372.52 (19,912 hours * 69.08 per hour). Some key points in the calculations are as follows:

- There were a total of 80,110 marketing materials submitted to CMS during the 12-month period sampled. These materials already exclude PACE program marketing materials (30000 Code) which are governed by a different authority and not affected by the proposed provision. The 80,110 figure also excludes codes 16000 and 1700 Medicare-Medicaid Plan (MMP) materials. The MMP materials are not being counted as the decision for review rests with the states and CMS.

- The statute is clear that “applications,” which CMS also refers to as enrollment or election forms, must be reviewed. Thus the 981 materials submitted under marketing code 1070, enrollment forms, must be subtracted from the 80,110.

- Marketing code 1100 includes the combined ANOC/EOC as well as the D-SNP standalone ANOC. CMS intends to split the ANOC and EOC and will still require the ANOC be submitted as a marketing material, whereas the EOC will no longer be considered marketing and not require submission. To account for the ANOC submission, CMS estimates that 5,162 ANOCs will still require submission.

- We do not expect any disenrollment or grievance forms (the 2000 and 3000 codes) to be required submissions under this proposal.

- Marketing code 4000 covers all advertisements which constitute 55 percent (43,965) of the 80,110 materials. The majority of these advertisements deal with benefits and enrollment. We estimate 25 percent of the 43,965 code 4000 documents (that is, 10,991 documents) would fall outside of the new regulatory definition of marketing and no longer require submission. Thus, we must subtract these 32,974 (43,965 – 10,991) from the 80,110.

- Marketing code 5000 covers formulary drugs. Although, as is currently the case, formularies will continue to be submitted to us for review in capacities outside of marketing, they will no longer fall under the new regulatory definition of marketing and hence would not be submitted separately for review as marketing materials.

- Marketing code 6000 includes sales scripts which are predominantly used to encourage enrollment, and would likely still fall under the scope of the new marketing definition. As such, we must subtract 1,169 documents (code 6013)

from the 80,110 total marketing materials.

- Marketing code 8000 includes creditable coverage and late enrollment penalty (LEP) notices that will fall outside of the new regulatory definition of marketing and no longer require submission. Over the 12-month period sampled, this represents 559 material submissions.

The proposed requirements and burden will be submitted to OMB under control number 0938–1051 (CMS–10260).

9. ICRs Regarding Medical Loss Ratio Reporting Requirements (§§ 422.2460 and 423.2460)

In section II.C.1. of this rule, we note that under current §§ 422.2460 and 423.2460, for each contract year, MA organizations and Part D sponsors must report to CMS the information needed to verify the MLR and remittance amount, if any, for each contract, such as: Incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 422.2410 or § 423.2410. Our proposed amendments to §§ 422.2460 and 423.2460 would reduce the MLR reporting burden by requiring that MA organizations and Part D sponsors report, for each contract year, only the MLR and the amount of any remittance owed to us for each contract with credible or partially credible experience. For each non-credible contract, MA organizations and Part D sponsors would be required to report only that the contract is non-credible.

Our analysis of the estimated administrative costs related to the MLR reporting requirements is based on the average number of MA and Part D contracts subject to the reporting requirements for each contract year. The average number of MA and Part D contracts subject to the annual MLR reporting requirements for contract years 2014 to 2018 is 587. The total number of MA and Part D contracts is relatively stable year over year. To calculate the estimated administrative costs of MLR reporting under the proposed amendments to §§ 422.2460 and 423.2460, we assume that 587 MA and Part D contracts would be subject to the MLR reporting requirements in each contract year.

Our estimate for the amount of time that MAOs and Part D sponsors would spend on administrative tasks related to the MLR reporting requirements under this proposed rule is based on our current burden estimates that are approved by OMB under control

number 0938–1232 (CMS–10476), where we estimated that, on average, MA organizations and Part D sponsors would spend approximately 47 hours per contract on administrative work related to Medicare MLR reporting, including: Collecting data, populating the MLR reporting forms, conducting a final internal review, submitting the reports to the Secretary, and conducting internal audits. Inadvertently, our currently approved estimate did not specify (or break out) the portion of the overall reporting burden that could be attributed solely to the tasks of preparing and submitting the MLR report. We are correcting that oversight by estimating that the burden for preparing and submitting the MLR report is approximately 11.5 hours (or 24.4 percent of the estimated 47 total hours spent on all administrative work related to the MLR reporting requirements) per contract.

We arrived at the 11.5-hour estimate by considering the amount of time it would take an MA organization or Part D sponsor to perform each of the following tasks: (1) Review the MLR report filing instructions and external materials referenced therein and to input all figures and plan-level data in accordance with the instructions; (2) draft narrative descriptions of methodologies used to allocate expenses; (3) perform an internal review of the MLR report form prior to submission; (4) upload and submit the MLR report and attestation; and (5) correct or provide explanations for any suspected errors or omissions discovered by CMS or our contractor during initial review of the submitted MLR report.

We estimate that our proposal to scale back the MLR reporting requirements would reduce the amount of time spent on administrative work by 11 hours, from 47 hours to 36 hours.

Table 17 compares the estimated administrative costs related to the MLR reporting requirements under the current regulation and under this proposed rule. As indicated, this proposed rule estimates that MA organizations and Part D sponsors will spend on average 36 hours per MA or Part D contract on administrative work, compared to 47 hours per contract under the current rule. We estimate the average cost per hour of MLR reporting using wage data for computer and information systems managers, as we believe that the tasks associated with MLR reporting generally fall within the fields of data processing, computer programming, information systems, and systems analysis. Based on computer and information systems managers wage

data from BLS, we estimate that MA organizations and Part D sponsors would incur annual MLR reporting costs of approximately \$5,045 per contract on average under our proposal, as opposed

to \$6,587 per contract under the current regulations. Consequently, the proposed changes would, on average, reduce the annual administrative costs by \$1,542 per contract. Across all MA and Part D

contracts, we estimate that the proposed changes would reduce the annual administrative burden related to MLR reporting by 6,457 hours, resulting in a savings of \$904,884.

TABLE 17—ESTIMATED ADMINISTRATIVE BURDEN RELATED TO MEDICAL LOSS RATIO (MLR) REPORTING REQUIREMENTS

Type of burden	Total number of contracts/reports	Estimated average hours per report	Estimated total hours	Estimated average cost per hour	Estimated total cost	Estimated average cost per contract/report
Ongoing Costs (current regulations)	587	47	27,589	\$140.14	\$3,866,322	\$6,587
Ongoing Costs (proposed regulation changes).	587	36	21,132	140.14	2,961,438	5,045
Change	No change	11	6,457	No change	904,884	1,542

Notes: The source data has been modified to reflect estimated costs for MA organizations and Part D sponsors. Values may not be exact due to rounding.

The proposed requirements and burden will be submitted to OMB for approval under control number 0938–1232 (CMS–10476).

10. ICRs Regarding Establishing Limitations for the Part D Special Enrollment Period for Dual Eligible Beneficiaries (§ 423.38(c)(4)) OMB Under Control Number 0938–0964

In section II.A.11. of this rule, we propose to revise § 423.38(c)(4) to limit the SEP for dual- and LIS-eligible individuals. The provision would make the SEP for FBDE or other subsidy-eligible individuals available only in the following circumstances:

- For beneficiaries who are making an allowable onetime-per-calendar-year election.
- For beneficiaries who have been assigned to a plan by CMS or a state (that is, through auto enrollment, facilitated enrollment, passive enrollment, or reassignment) and decide to change plans following notification of the change or within 2 months of the election effective date.
- For beneficiaries who have a change in their dual or LIS-eligible status.

In instances where an individual is not able to utilize the dual SEP because of the proposed limitations, we anticipate that there will be no change in burden. Under current requirements, if a beneficiary uses the dual SEP to disenroll from their plan, the plan would send a notice to the beneficiary to acknowledge the voluntary disenrollment request. If the beneficiary is subject to the dual SEP limitation, the plan would send a notice to deny their voluntary disenrollment request. The requirement to acknowledge the beneficiary request and address the resolution would be the same in both scenarios, but the content of the notice would be different. Enrollment processing and notification

requirements are codified at § 423.32(c) and (d) and are not being revised as part of this rulemaking. Therefore, no new or additional information collection requirements are being imposed. Moreover, the requirements and burden are currently approved by OMB under control number 0938–0964 (CMS–10141). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number.

11. ICRs Related to Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128) OMB Under Control Number 0938–0964

In section II.A.15 of this rule, we propose to expedite certain generic substitutions and other midyear formulary changes and except applicable generic substitutions from the transition process. Excepting generic substitutions that would otherwise require transition fills from the transition process would lessen the burden for Part D sponsors because they would no longer need to provide such fills. Permitting Part D sponsors to immediately substitute newly approved generic drugs or to make other formulary changes sooner than has been required would allow Part D sponsors to take action sooner, but would not increase nor decrease paperwork.

While the proposed provisions would additionally require general notice that certain generic substitutions could take place immediately, Part D sponsors are already creating the documents in which that notice would appear such as formularies and EOCs. Similarly, § 423.128(d)(2)(ii) already requires Web sites to include information about drug removals and changes to cost-sharing. In other words, the proposed general notice requirement would not require

efforts in addition to routine updates to beneficiary communications materials and Web sites. In theory, if Part D sponsors that would have been denied requests to make generic changes could do so under the proposed provision, they would have somewhat more of a burden since the proposed provision does require notice including direct notice to affected enrollees. However, our practice has been to approve all or virtually all generic substitutions that would meet the requirements of this proposed provision—which again means that the proposed provisions would just permit those substitutions to take place sooner.

The general notice requirements and burden are currently approved by OMB under control number 0938–0964 (CMS–10141). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number.

12. ICRs Related to Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in Medicare Advantage, Cost Plans, and PACE

a. Preclusion List Requirements for Part D Sponsors

(1) Burden and Costs

In sections II.D.10 and 11. of this proposed rule, we are proposing in § 423.120(c)(6) to require that Part D sponsors cover a provisional supply of a drug before they reject a claim based on a prescriber's inclusion on the preclusion list. The proposed provision would also require that Part D sponsors provide written notice to the beneficiary of the prescriber's presence on the preclusion list and take reasonable efforts to furnish written notice to the prescriber. The burden associated with these provisions would be the time and

effort necessary for Part D adjudication systems to be programmed and for model notices to be created, generated, and disseminated.

(a) Part D System Programming

We estimate that it would take all 30 sponsors and PBMs with Part D adjudication systems a total of approximately 93,600 hours in 2019 for software developers and programmers to program their systems to comply with the requirements of § 423.120(c)(6). In 2020 and 2021, we do not anticipate any system costs. The sponsors and PBMs would need approximately 6 to 12 months to perform system changes and testing. The total hour figures are based on a 6-month preparation and testing period. There are roughly 1,040 full-time working hours in a 6-month period. Using an estimate of 3 full-time software developers and programmers at \$96.22/hour resulted in the aforementioned 93,600 hour figure (3 workers × 1,040 hour × 30 sponsors/PBMs) at a cost of \$9,006,192 (93,600 × \$96.22/hour) for 2019. There would be no burden associated with 2020 and 2021.

(b) Creation of Template Notices to Beneficiaries and Prescribers

As stated in the May 6, 2015 IFC, we estimate that 212 parent organizations would need to create two template notices to notify beneficiaries and prescribers under proposed § 423.120(c)(6). We project that it would take each organization 3 hours at \$69.08/hour for a business operations specialist to create the two model notices. For 2019, we estimate a one-time total burden of 636 hours (212 organizations × 3 hours) at a cost of \$43,935 (636 hour × \$69.08/hour) or \$207.24 per organization (\$43,935/212 organizations). There would be no burden associated with 2020 and 2021.

The proposed system programming and notice development requirements and burden will be submitted to OMB for approval under control number 0938–0964 (CMS–10141).

(c) Preparation and Issuance of the Notices

We estimate that it would take an average of 5 minutes (0.083 hour) at \$39.22/hour for an insurance claim and policy processing clerk to prepare and distribute the notices. We estimate that an average of approximately 800 prescribers would be on the preclusion

list in early 2019 with roughly 80,000 Part D beneficiaries affected; that is, 80,000 beneficiaries would have been receiving prescriptions written by these prescribers and would therefore receive the notice referenced in § 423.120(c)(6). In 2019 we estimate a total burden of 6,640 hours (0.083 hour × 80,000 responses) at a cost of \$260,421 (6,640 hour × \$39.22/hour) or \$1,228.40 per organization (\$260,421/212 organizations).

In 2020 and 2021, we estimate that roughly 150 prescribers each year would be added to the preclusion list, though this would be largely offset by the same number of prescribers being removed from the list (for example, based on reenrollment after the expiration of a reenrollment bar or decision to remove them from the preclusion list) with 15,000 affected beneficiaries. In aggregate, we estimate an annual burden of 1,245 hours (15,000 beneficiaries × 0.083 hours) at a cost of \$48,829 (1,245 hour × \$39.22/hour) or \$325.53 per prescriber (\$48,829/150 prescribers).

The proposed notice preparation and distribution requirements and burden will be submitted to OMB for approval under control number 0938–0964 (CMS–10141).

TABLE 18—ESTIMATED BURDEN OF PART D—NOTICE PREPARATION AND DISTRIBUTION [In hours]

	2019	2020	2021	3-year average
Provisional Supply—Programming	93,600	0	0	31,200
Provisional Supply—Template Creation	636	0	0	212
Provisional Supply—Letter Preparation	6,640	1,245	1,245	3,043
Total	100,876	1,245	1,245	34,455

TABLE 19—ESTIMATED BURDEN OF PART D—NOTICE PREPARATION AND DISTRIBUTION [In \$]

	2019	2020	2021	3-year average
Provisional Supply—Programming	\$9,006,192	\$0	\$0	\$3,002,064
Provisional Supply—Template Creation	43,935	0	0	14,645
Provisional Supply—Notice Preparation	260,421	48,829	48,829	119,360
Total	9,310,548	48,829	48,829	3,136,069

(2) Savings

We believe that savings would accrue for the prescriber community from our proposed elimination of the requirement that prescribers enroll in Medicare in order to prescribe Part D drugs.

As previously explained in this proposed rule, approximately 420,000 prescribers have yet to enroll in Medicare via the CMS–855O application

(OMB 0938–1135). We estimate that it would take 0.5 hours for a prescriber to complete a CMS–855O application. This is based on the following assumptions:

- A medical secretary would take 0.42 hours to prepare the application.
- A physician would take 0.08 hours to review and sign the application.

This would result in a per application cost of \$30.32 ((0.42 hours × \$33.70) +

(0.08 hours × \$202.08). Multiplying this figure by 420,000 applications results in a total savings of \$12,734,400. We believe that these savings would accrue in 2019.

(3) Net Costs and Savings

We believe that a result of our proposed elimination of the Part D

enrollment requirement, the following net savings for prescribers would ensue:

TABLE 20—NET COSTS/SAVINGS
[In \$]

	2019	2020	2021	3-year average
Costs	\$9,310,548	\$48,829	\$48,829	\$3,136,069
Savings	12,734,400	0	0	4,244,800
Net*	3,423,852	(48,829)	(48,829)	1,108,731

* Net costs denoted in parentheses.

b. Preclusion List Requirements for Part C

As previously explained in this proposed rule, approximately 120,000 MA providers and suppliers have yet to enroll in Medicare via the CMS-855 application. Of these providers and suppliers, and based on internal CMS statistics, we estimate that 90,000 would

complete the CMS-855I (OMB No. 0938-0685), which is completed by physicians and non-physician practitioners; 24,000 would complete the CMS-855B (OMB control number 0938-0685), which is completed by certain Part B organizational suppliers; and 6,000 would complete the CMS-855A (OMB No. 0938-0685), which is

completed by Part A providers and certain Part B certified suppliers. Therefore, we believe that savings would accrue for providers and suppliers from our proposed elimination of our MA/Part C enrollment. Table 21 estimates the burden hours associated with the completion of each form.

TABLE 21—CMS-855 APPLICATION BURDEN

Submission type	Number of respondents no longer required to enroll	Hours for completion by office personnel	Hours for a physician to review and sign	Hours for an authorized official to review and sign	Total hours for completion
CMS-855I	90,000	2.5	0.5	n/a	3
CMS-855B	24,000	4	n/a	1	5
CMS-855A	6,000	5	n/a	1	6

In projecting the savings involved, we assume a medical and health services manager would serve as the provider's or supplier's "authorized official" and would sign the CMS-855A or CMS-855B application on the provider's or supplier's behalf.

Therefore, we project the following total hour and cost burdens:

- CMS-855I: We estimate a total reduction in hour burden of 270,000 hours (90,000 applicants × 3 hours). With the cost of each application processed by a medical secretary and physician as being \$185.29 ((\$33.70 × 2.5 hours) + (\$202.08 × 0.5 hours)), we estimate a savings of \$16,676,100 (90,000 applications × \$185.29).

- CMS-855B: We estimate a total reduction in hour burden of 120,000 hours (24,000 applicants × 5 hours). With the cost of each application processed by a medical secretary and signed off by a medical and health services manager as being \$239.96 ((\$33.70 × 4 hours) + (\$105.16 × 1 hour)), we estimate a total savings of \$5,759,040 (24,000 applications × \$105.16).

- CMS-855A: We estimate a total reduction in hour burden of 36,000 hours (6,000 applicants × 6 hours). With

the cost of each application processed by a medical secretary and signed off by a medical and health services manager as being \$273.66 ((\$33.70 × 5 hours) + (\$105.16 × 1 hour)), we estimate a total savings of \$6,567,840 (24,000 applications × \$273.66).

Given the foregoing, we estimate that providers and suppliers would experience a total reduction in hour burden of 426,000 hours (270,000 + 120,000 + 36,000) and a total cost savings of \$32,102,980 (\$9,667,660 + \$5,759,040 + \$16,676,100). We expect these reductions and savings to accrue in 2019 and not in 2020 or 2021.

Nonetheless, over the OMB 3-year approval period of 2019–2021, we expect an annual reduction in hour burden of 142,000 hours and an annual savings of \$10,700,933 (\$32,102,800/3) under OMB Control No. 0938-0685.

We also propose to revise § 422.310 to add a new paragraph (d)(5) to require that, for data described in paragraph (d)(1) as data equivalent to Medicare fee-for-service data (which is also known as MA encounter data), MA organizations must submit a National Provider Identifier in a Billing Provider field on each MA encounter data record, per CMS guidance. We do not expect

any additional burden from this particular proposal, for this activity is consistent with existing policy.

13. ICRs Regarding the Part D Tiering Exceptions ((\$ 423.560 and § 423.578(a) and (c))

In section II.A.9. of this rule, we are proposing various changes to § 423.578(a) and (c) related to the requirements for tiering exceptions criteria that Part D plan sponsors are required to establish. These changes include establishing a revised framework for treatment of tiering exception requests based on whether the requested drug is a brand name or generic drug or biological product, and where the same type of drug alternatives are located on the plan's formulary. The proposed changes also include clarification of appropriate cost-sharing assigned to approved tiering exception requests when preferred alternative drugs are on multiple lower-cost tiers. At the coverage determination level, if a plan issues a decision that is partially or fully adverse to the enrollee, it is already required to send written notice of that decision. The existing requirement to send written notice of an adverse coverage determination would

not change under the proposed changes related to tiering exceptions. We do not expect the proposed changes to significantly impact the overall volume or the approval rate of tiering exceptions requests, which represent a consistently low percentage of total request volume.

While the requirement to send a written denial notice is subject to the PRA, the requirement and burden are currently approved by OMB under control number 0938-0976 (CMS-10146). Since this rule would not impose any new or revised requirements/burden, we are not making any changes to that control number.

14. ICRs Regarding the Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions (§ 423.153(f))

As discussed in section of this rule, proposed § 423.153(f) would implement provisions of section 704 of CARA, which allows Part D plan sponsors to establish a drug management program that includes “lock-in” as a tool to manage an at-risk beneficiary’s access to coverage of frequently abused drugs. Part D plan sponsors would be required to notify at-risk beneficiaries about their plan’s drug management program. Part D plan sponsors are already expected to send a notice to some beneficiaries when the sponsor decides to implement a beneficiary-specific POS claim edit for opioids (OMB under control number 0938-0964 (CMS-10141)). However, the OMB control number 0938-0964 only accounts for the notices that are currently sent to beneficiaries who have a POS edit put in place to monitor opioid access (which would count as the initial notice described in the preamble and defined in § 423.153(f)(4)) and would not capture the second notice that at-risk beneficiaries would receive confirming their determination as such or the alternate second notice that potentially at-risk beneficiaries would receive to inform them that they were not determined to be at risk.

Since 2013, there have been 4,617 POS edits submitted into MARx by plan sponsors for 3,961 unique beneficiaries as a result of the drug utilization review policy. Given that there has not been a steady increase or decrease in edits, we have used the average, 923 edits annually, to assess burden under this rule. If we assume that the number of edits or access to coverage limitations will double due to the addition of pharmacy and prescriber “lock-in” to OMS, to approximately 1,846 such limitations, we estimate 3,693 initial, and second notices (number of limitations (1,846) multiplied by the

number of notices (2)) total corresponding to such edits/limitations. We estimate it would take an average of 5 minutes (0.083 hours) at \$39.22/hour for an insurance claim and policy processing clerk to prepare each notice. We estimate an annual burden of 307 hours (3,693 notices × 0.083 hour) at a cost of \$12,040.54 (307 hour × \$39.22/hour).

Part D plan sponsors are required to upload these new notice templates into their internal claims systems. We estimate that 219 Part D plan sponsors (31 PDP parent organizations and 188 MA-PD parent organizations, based on plan year 2017 plan participation) would be subject to this requirement. We estimate that it will take on average 5 hours at \$81.90/hour 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). This would result in a total burden of 1,095 hours (5 hours × 219 sponsors) at a cost of \$89,680.50 (1,095 hour × \$81.90/hour).

In aggregate, the burden to upload and prepare these additional notices is 1,402 hours (307 hours + 1,095 hours) at a cost of \$101,721 (\$12,040 + \$89,681).

Proposed revisions to § 423.38(c)(4) would limit the SEP for dual- or other LIS-eligible individuals who are identified as a potential at-risk beneficiary subject to the requirements of a drug management program, as outlined in § 423.153(f). As already codified in § 423.38(c)(4), this proposed SEP limitation would be extended to “other subsidy-eligible individuals” so that both full and partial subsidy individuals are treated uniformly. Once an individual is identified as a potential at-risk beneficiary, that individual will not be permitted to use this election period to make a change in enrollment.

Contingent with a Part D sponsor opting to implement a drug management program, Part D sponsors will identify, and submit to CMS, an individual’s “potential” at-risk status and, if applicable, confirmed at-risk status. The Part D sponsor will include notification of the limitation of the duals’ SEP in the required notice to the beneficiary that he or she has been identified as a potential at-risk beneficiary.

Therefore, the burden associated with the notification of the inability to use the duals’ SEP is covered under the previous statement of burden.

Furthermore, we are proposing to codify that an at-risk beneficiary will have an election opportunity if their dual- or LIS-eligible status changes, that is, if they gain, lose or have a change in the level of the subsidy assistance. Also,

if a beneficiary is eligible for another election period (for example, AEP, OEP, or other SEP), this SEP limitation would not prohibit the individual from making an election. This proposed provision, by creating a limitation for dually- and other LIS-eligible at-risk beneficiaries after the initial notification, would decrease sponsor burden in processing disenrollment and enrollment requests for dual- and LIS-eligible beneficiaries who wish to change plans.

We estimate that 1,846 beneficiaries would meet the criteria proposed to be identified as an at-risk beneficiary and have a limitation implemented. About 76 percent of the 1,846 beneficiaries are estimated to be LIS. Approximately 10 percent of LIS-eligible enrollees use the duals’ SEP to make changes annually. Thus we estimate, at most, 140 changes per year (1,846 beneficiaries × 0.76 × 0.1) will no longer take place because of the proposed duals’ SEP limitation. There are currently 219 Part D sponsors. This amounts to an average of 0.6 changes per sponsor per year (140 changes/219 sponsors). In 2016, there were more than 3,5888 Part D plan switches, and as such, a difference of 0.6 enrollments or disenrollments per sponsor will not impact the administrative processing infrastructure or human resources needed to process enrollments and disenrollments. Therefore, there is no change in burden for sponsors to implement this component of the provision.

We are proposing that reviews of at-risk determinations made under the processes at § 423.153(f) be adjudicated under the existing Part D benefit appeals process and timeframes set forth in part 423 Subparts M and U. Consistent with existing rules for redeterminations, an enrollee who wishes to dispute an at-risk determination would have 60 days from the date of the notice of the determination to make such request, must affirmatively request IRE review of an adverse plan level appeal decision made under a plan sponsor’s drug management program, and would have rights to an expedited redetermination. Revisions to regulations in part 423 Subparts M (§§ 423.558, 423.560, 423.562, 423.564, 423.580, 423.582, 423.584, 423.590, 423.602, 423.636, and 423.638) and U (§§ 423.1970, 423.2018, 423.2020, 423.2022, 423.2032, 423.2036, 423.2038, 423.2046, 423.2056, 423.2062, 423.2122 and 423.2126) are being proposed to account for reviews of at-risk determinations. The filing of an appeal is an information collection requirement 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 appeal is exempt from the requirements and collection burden estimates of the PRA; however, the burden estimate for

appeals is included in the regulatory impact analysis.

In aggregate, these components of this provision would result in an annual net cost of \$101,012.

The aforementioned requirements and burden, excluding beneficiary appeals, will be submitted to OMB for approval under control number 0938–0964 (CMS–10141).

TABLE 22—ESTIMATED BURDEN FOR THE CARA PROVISIONS

[In hours]

	2019	2020	2021	3-year average
Preparation and Upload Notices	1,402	0	0	467.3
SEP Limitation	0	0	0	0
Appeals	N/A	N/A	N/A	N/A
Total	1,402	0	0	467.3

TABLE 23—ESTIMATED BURDEN FOR THE CARA PROVISIONS

[In \$]

	2019	2020	2021	3-Year average
Preparation and Upload Notices	\$101,012	\$0	\$0	\$33,670.7
SEP Limitation	0	0	0	0
Appeals	N/A	N/A	N/A	N/A
Total	101,012	0	0	33,670.7

C. Summary of Proposed Information Collection Requirements and Burden

TABLE 24—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulatory section(s) in title 42 of the CFR	OMB control No.*	Respondents	Responses	Burden per response	Total annual burden (hours)	Labor cost of reporting (hours)	Total cost (\$)
422.60, 422.62, 422.68, 423.38, and 423.40 eligibility determination.	0938–0753	468	558,000	5 min	46,500	\$69.08	\$3,212,220
422.60, 422.62, 422.68, 423.38, and 423.40 notification.	0938–0753	468	558,000	1 min	9,300	69.08	642,444
422.60, 422.62, 422.68, 423.38, and 423.40 report to CMS.	0938–0753	468	558,000	1 min	9,300	69.08	642,444
422.60, 422.62, 422.68, 423.38, and 423.40 record keeping.	0938–0753	468	558,000	5 min	46,500	34.66	1,606,110
422.152 QIP	0938–1023	468	(750)	(15 min)	(188)	67.54	(12,664)
422.2260 and 423.2260 marketing materials.	0938–1051	805	(67,061)	(30 min)	(26,959)	69.08	(1,862,397)
422.2460 and 423.2460 MLR reporting.	0938–1232	587	(587)	(11 hr)	(6,457)	140.14	(904,884)
423.120(c)(6) create model notices.	0938–0964	212	212	3 hr	636	69.08	43,935
423.120(c)(6) 2019 prepare and distribute the notices.	0938–0964	212	80,000	0.083 hr	6,640	39.22	260,421
423.120(c)(6) 2020 and 2021 prepare and distribute the notices.	0938–0964	212	15,000	0.083 hr	1,245	39.22	48,829
423.153(f) notice preparation	0938–0964	219	3,693	0.083 hr	307	39.22	12,041
423.153(f) notice upload	0938–0964	219	3,693	5 hr	1,095	81.90	89,681
423.153(f) contract: Part D plan sponsors.	0938–0964	31	31	10 hr	310	134.50	41,695
423.153(f) contract: MA–PDs	0938–0964	188	188	20 hr	3,760	134.50	505,720
<i>Subtotal: Private Sector Burden.</i>	<i>805</i>	<i>2,266,419</i>	<i>varies</i>	<i>91,989</i>	<i>varies</i>	<i>4,325,595</i>
422.62, 423.38, and 423.40 complete enrollment.	0938–0753	18,600,000	558,000	30 min	279,000	7.25	2,022,750

TABLE 24—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS—Continued

Regulatory section(s) in title 42 of the CFR	OMB control No. *	Respondents	Responses	Burden per response	Total annual burden (hours)	Labor cost of reporting (hours)	Total cost (\$)
<i>Subtotal: Burden on Beneficiaries.</i>	18,600,000	558,000	30 min	279,000	7.25	2,022,750
422.111(a)(3) and (h)(2)(ii) and 423.128(a)(3) EOC paper.	0938–1051	n/a	(32,026,000)	n/a	n/a	n/a	(24,019,500)
422.111(a)(3) and (h)(2)(ii) and 423.128(a)(3) EOC toner.	0938–1051	n/a	(32,026,000)	n/a	n/a	n/a	(24,019,500)
422.111(a)(3) and (h)(2)(ii) and 423.128(a)(3) EOC mailing.	0938–1051	n/a	(32,026,000)	n/a	n/a	n/a	(6,629,382)
<i>Subtotal: Non-Labor Burden</i>	n/a	(32,026,000)	n/a	n/a	n/a	(54,668,382)
Total	18,600,805	(29,201,581)	varies	370,989	varies	(48,320,037)

* OMB control numbers and corresponding CMS ID numbers: 0938–0753 (CMS–R–267), 0938–1023 (CMS–10209), 0938–1051 (CMS–10260), 0938–1232 (CMS–10476), and 0938–0964 (CMS–10141).

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 the OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS’ Web site at Web site address at <https://www.cms.gov/Regulations-andGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html>, or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential 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–4182–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.

V. Regulatory Impact Analysis

A. Statement of Need

This proposed rule approaches to improve the quality, accessibility and affordability of the Medicare Part C and Part D programs and to improve the CMS customer experience. While satisfaction with these programs remain high, these proposals are responsive to input we received from stakeholders while administering the program, as well as through a Request for Information process earlier this year. Additionally, this regulation includes a

number of provisions that will help address the opioid epidemic and mitigate the impact of increasing drug prices in the Part D program.

B. Overall Impact

We examined the impact of this final 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), Section 1102(b) of the Social Security Act, Section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

The Regulatory Flexibility Analysis (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.

The health insurance industry was examined in depth in the RIA prepared for the proposed rule on establishment of the MA program (69 FR 46866, August 3, 2004). It was determined, in that analysis, that there were few, if any, “insurance firms,” including HMOs that fell below the size thresholds for “small” business established by the Small Business Administration (SBA). We assume that the “insurance firms” are synonymous with health plans that conduct standard transactions with other covered entities and are, therefore,

the entities that will have costs associated with the new requirements finalized in this rule. At the time the analysis for the MA program was conducted, the market for health insurance was and remains, dominated by a handful of firms with substantial market share.

However, we estimate that the costs of this rule on “small” health plans do not approach the amounts necessary to be a “significant economic impact” on firms with revenues of tens of millions of dollars. Therefore, this rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any rule or regulation proposed under Title XVIII, Title XIX, or Part B 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 rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (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 2017, that threshold is approximately \$148 million. This proposed rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of \$148 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final

rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this rule does not impose any substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on MA Plans and Part D Sponsors, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. There are currently 468 MA plans and Part D Sponsors.

We assume each plan will have one designated staff member who will read the entire rule.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$105.16 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/2016/may/naics4_621100.htm). Assuming an average reading speed, we estimate that it would take approximately 15.6 hours for each person to review this proposed rule. For each MA plan that reviews the rule, the estimated cost is therefore, \$1,640 (15.6 hours × \$105.16). Therefore, we estimate that the total cost of reviewing this regulation is \$767,520 (\$1,640 × 468 reviewers).

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

C. Anticipated Effects

1. CARA Provisions

Proposed § 423.153(f) would implement provisions of section 704 of CARA, which allows Part D plan sponsors to establish a drug management program that includes “lock-in” as a tool to manage an at-risk beneficiary’s access to coverage of frequently abused drugs.

Under CARA, potentially at-risk beneficiaries are to be identified under guidelines developed by CMS with stakeholder input. Also, the Secretary must ensure that the population of at-risk beneficiaries can be effectively managed by Part D plans. CMS considered a variety of options as to how to define the clinical guidelines. We provide the estimated population of potential at-risk beneficiaries under different guidelines that take into account that the beneficiaries may be overutilizing opioids, coupled with use of multiple prescribers and/or pharmacies to obtain them, based on retrospective review, which makes the population appropriate to consider for “lock-in” and a description of the various options. We note that the measurement year for the estimates was 2015.

For background, the current Part D Opioid Overutilization policy and Overutilization Monitoring System (OMS) has been successful at reducing high risk opioid overutilization. Under this policy, plans retrospectively identify beneficiaries at high risk of an adverse event due to opioids and use of multiple prescribers and pharmacies. CMS created the OMS to monitor plans’ effectiveness in complying with the policy. The OMS criteria incorporate the CDC Guideline for Prescribing Opioids for Chronic Pain (March 2016) (CDC Guideline) to identify beneficiaries who are possibly overutilizing opioids and are at high risk but the CDC Guideline is not a prescribing limit. CDC identifies 50 Morphine Milligram (MME) as a threshold for increased risk of opioid overdose, and to generally avoid increasing the daily dosage to 90 MME.

Plans are expected to perform case management for each beneficiary identified in OMS and respond using standardized responses. If viewed as helpful by a prescriber, plans may implement a beneficiary-specific claim edit at the point-of-sale to prevent coverage of opioids outside of the amount deemed medically necessary by the prescriber. Plans may also implement an edit in the absence of prescriber response to case management.

TABLE 25—GUIDELINES TO IDENTIFY AT-RISK BENEFICIARIES

Option	Average MME	Number of opioid prescribers and opioid dispensing pharmacies		Estimated number of potentially at-risk Part D beneficiaries
1	≥90	4+	4+	33,053
	≥90	6+	1+	
2	≥90	4+	4+	52,998
	≥90	5+	1+	
3	≥90	3+	3+	103,832
	≥90	5+	1+	
4	≥90	3+	3+	152,652
	≥90	4+	1+	
5	≥90	3+	3+	319,133
	≥90	3+	1+	
	Average MME	Number of opioid prescribers or opioid dispensing pharmacies		Estimated number of potentially at-risk Part D beneficiaries
6	≥50	5+	5+	153,880
	Any MME level	7+	7+	

Under Option 1, CMS would propose to integrate the CARA lock-in provisions with our current Part D Opioid Overutilization Policy/Overutilization Monitoring System (OMS). We will propose to initially define frequently

abused drugs as all and only opioids for the treatment of pain. The guidelines to identify at-risk beneficiaries would be the current Part D OMS criteria finalized for 2018 after stakeholder input. Plans that adopt a drug management program

would have to engage in case management of the opioid use of all enrollees who meet these criteria, which would be reported through OMS and plans must provide a response for each case. The estimated number of potential

at-risk beneficiaries in 2019 using Option 1 is 33,053. Option 1 would allow plans to use pharmacy/prescriber lock in as an additional tool to address the opioid overutilization of identified at-risk beneficiaries.

Option 2, 3, 4, and 5 are operationally the same as Option 1, including 90 MME, but would identify approximately 52,998 to 319,133 beneficiaries in 2019 due to different clinical guidelines related to the number of opioid prescribers and opioid dispensing pharmacies. These options would result in up to 10 times the program size compared to Option 1.

Finally, under Option 6, the guidelines to identify potentially at-risk beneficiaries would not be fully integrated into our current OMS criteria. This option would identify beneficiaries whose opioid use is at the 50 MME level instead of 90, and the estimated number of potentially at-risk beneficiaries in 2019 is 153,880. Of these, approximately 29,000 would meet these criteria and the current OMS criteria. We seek comment on proposed Option 1 or if any of the alternative options may be currently viewed as manageable for Part D sponsors to implement.

In addition, while these criteria would identify far more potentially at-risk beneficiaries, we may have to implement these options in a way that plans that adopt a drug management program would not have to review the opioid use of all enrollees who meet these criteria. This would mean a change in the structure of the successful OMS or a separate administrative structure for prescription drug management programs.

As noted in section II. of this rule, we have chosen to propose Option 1. This approach is a cautious approach for the initial implementation year of the CARA "lock-in" provisions. We believe these provisions will result in the following savings to the program.

We estimate that the CARA provisions would result in a net savings of \$10 million (the estimated savings of \$13 million less the total estimated costs of \$2,836,651 = \$10,163,349, rounded to the nearest million) in 2019. The following are details on each of these savings.

We assume, based on past experience with OMS, that about 61 percent of at-risk beneficiaries may reduce prescriptions for frequently abused drugs and will no longer meet the clinical criteria. This means that prescriber and pharmacy lock-in would impact the remaining 39 percent of at-risk beneficiaries or 39 percent \times 33,000 at-risk beneficiaries = 12,870 at-risk beneficiaries. We estimate that the

average number of scripts per year on frequently abused drugs for those at-risk beneficiaries is about 48 and the average cost per script is about \$106 in 2016. Our data show that those beneficiaries who would meet the proposed criteria for identification as an at-risk beneficiary and have a limitation placed on their access to opioids, have 4 opioids scripts per month on average. OACT anticipates between 10 and 30 percent reduction in prescriptions for frequently abused drugs would be possible through drug management programs and picked the average, 20 percent. Therefore, we believe there could be a 20 percent reduction in the prescriptions for frequently abused drugs for those 12,870 beneficiaries, resulting in a projected savings of about \$13 million to Medicare in 2019.

Part D plan sponsors would also be required to send at-risk beneficiaries multiple notices to notify them of about their plan's drug management program. Part D plan sponsors are already expected to send a notice to some beneficiaries when the Part D plan sponsors decide to implement a beneficiary-specific POS claim edit for opioids. Therefore, we anticipate limited additional burden for Part D plan sponsors to send certain at-risk beneficiaries an additional notice to indicate their lock-in status.

Since 2013, there have been 4,617 POS edits submitted into MARx by plan sponsors for 3,961 unique beneficiaries as a result of the drug utilization review policy. That results in approximately 923 edits annually. If we assume that the number of edits or access to coverage limitations will double due to the addition of pharmacy and prescriber "lock-in" to OMS, to approximately 1,846 such limitations, we estimate 3,692 initial and second notices (number of limitations (1,846) multiplied by the number of notices (2)) total corresponding to such edits/limitations. For purposes of this estimate, we assume that all beneficiaries who receive initial notices will be placed on an access limitation. We estimate it would take an average of 5 minutes (0.083 hours) at \$39.22/hour for an insurance claim and policy processing clerk to prepare each notice. The burden of 307 hours (3,692 notices \times 0.083 hour) at a cost of \$12,040.54 (307 hour \times \$39.22/hr) in 2019 was estimated in section III of this rule.

Part D plan sponsors are required to upload these new notice templates into their internal claims systems. We estimate that 219 Part D plan sponsors (31 PDP parent organizations and 188 MA-PD parent organizations) will be subject to this requirement. We estimate

that it will take on average 5 hours at \$81.90/hour for a computer programmer to upload the notices into their claims systems. This would result in a total burden of 1,095 hours (5 hours \times 219 sponsors) at a cost of \$89,680.50 (1,095 hour \times \$81.90/hr). In aggregate, the burden to prepare and upload these additional notices was estimated as 1,402 hours (307 hours + 1,095 hours) at a cost of \$101,721 (\$12,040 + \$89,681) in 2019 in section III. of this proposed rule.

Part D plan sponsors may also renegotiate the contracts with network pharmacies and network prescribers in the case of MA-PDs. For Part D plan sponsors that contract with pharmacies only, we estimate it would take 10 hours at \$134.50/hour for lawyers to conduct the PDP contract negotiations with network pharmacies. Considering 31 sponsors we estimate a total burden of 310 hours at a cost of \$41,695 (310 hour \times \$134.50/hour). For MA-PDs who also contract with prescribers, we estimate that the annual burden for negotiating a contract with network providers who can prescribe controlled substances to be 3,760 hours (188 MA-PDs \times 20 hours per sponsor) at a cost of \$505,720 (3,760 hour \times \$134.50/hour). The total estimated burden associated with the contract negotiations from both PDP and MA-PD sources in 2019 was estimated as 4,070 hours (310 hours + 3,760 hours) at a cost of \$547,415 (\$41,695 + \$505,720).

We estimate that, in order to implement pharmacy or prescriber lock-in, Part D plan sponsors would have to program edits into their pharmacy claims systems so that once they restrict an at-risk beneficiaries' access to coverage for frequently abused drugs through applying pharmacy or prescriber lock-in, claims at a non-selected pharmacies or associated with prescriptions for frequently abused drugs from non-selected prescribers would be rejected. We believe that most Part D plan sponsors with Medicaid or private lines of business will have existing lock-in programs in those lines of business to pull efficiencies from. We estimate it would take a total number of 26,280 labor hours across all 219 Part D plan sponsors (31 PDP parent organizations and 188 MA-PD parent organizations) at a wage of \$81.90 an hour for computer programmers to program these edits into their existing systems. Thus, the total cost to program these edits is 26,280 hours \times \$81.90 = \$2,152,332.

The right of an enrollee to appeal an at-risk determination will also have an associated cost. As explained, we estimate a total hourly burden of 178

hours at an annual estimated cost of \$35,183 in 2019. As previously discussed, we estimate that 1,846 beneficiaries would meet the criteria for being identified as an at-risk beneficiary. Based on validated program data for 2015, 24 percent of all adverse coverage determinations were appealed to level 1. Given the nature of drug management programs, the extensive level of case management conducted by plans prior to making the at-risk determination, and the opportunity for an at-risk beneficiary to submit preferences to the plan prior to lock-in implementation, we believe it is reasonable to assume that this rate of appeal will be reduced by at least 50 percent for at-risk determinations made under a drug management program. Therefore, this estimate is based on an assumption that about 12 percent of the beneficiaries estimated to be subject to an at-risk determination (1,846) will appeal the determination. Hence, we estimate that there will be 222 level 1 appeals ($1,846 \times 12$ percent). We estimate it takes 48 minutes (0.8 hours) to process a level 1 appeal. There is a statutory requirement that a physician with appropriate expertise make the determination for an appeal of an adverse initial determination based on medical necessity. Thus, we estimate an hourly burden of 178 hours ($222 \text{ appeals} \times 0.8$) at a cost of \$197.66 per hour for physicians to perform these appeals. Thus the total cost in 2019 is estimated as $\$35,183 = 178 \text{ hours} \times \197.66 .

In aggregate, this provision would result in a net savings of \$13 million – ($\$101,721 + \$547,415 + \$2,152,332 + \$35,183$) = \$13 million – $\$2,836,651 = \$10,163,349$ (or \$10,000,000 if rounded to nearest million) in 2019.

2. Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503 and 423.504)

The proposed provision would amend the regulation so that first-tier, downstream and related entities (FDR) no longer are required to take the CMS compliance training, which lasts 1 hour, and so that MA organizations and Part D sponsors no longer have a requirement to ensure that FDRs have compliance training. However, it is still the sponsoring organization's responsibility to manage relationships with its FDRs and ensure compliance with all applicable laws, rules and regulations. Furthermore, we would continue to hold sponsoring organizations accountable for the failures of its FDRs to comply with Medicare program requirements.

We believe that by deleting this provision we will reduce burden for

sponsoring organizations and their FDRs. We estimate that the burden reduction will be roughly 1 hour for each FDR employee who would be required to complete the CMS training on an annual basis, under the current regulation at §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C). We do not know how many employees were required to take the CMS training, nor do we know the exact numbers of FDRs that were subject to the requirement. Sponsoring organizations have discretion in not only which of their contracted organizations meet the definition of an FDR, but also discretion in which employees of that FDR are subject to the training. But we know from public comments that PBMs, hospitals, pharmacies, labs, physician practice groups and even some billing offices were routinely subjected to the training. Unfortunately, the Medicare Learning Network (MLN) Matters® Web site is not able to track the number of people that took CMS' training, so we cannot use that as a data source. CMS has reviewed the Organization for Economic Co-operation and Development's (OECD) 2015 statistics which show a total of 20,076,000 people employed in the health and social services fields in the United States, although certainly not all of them were subject to CMS' training requirement (See http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT). Hospitals are one sector of the health industry that has been particularly vocal about the burden the current training requirement has placed on them and their staff. If we use hospitals as an example to estimate potential burden reduction, the OECD Web site states that there are 5,627 hospitals in the United States, employing 6,210,602 people. That is an average of 1,103 people per hospital. There are approximately 4,800 hospitals registered with Original Medicare. If we assume that each one of those hospitals holds at least one contract with a MA health plan and all of their employees were subjected to the training ($4,800 \times 1,103 \times 1 \text{ hour}$) that is 5,294,400 hours of burden that would be eliminated by this proposal. If we add pharmacists, pharmacy technicians, billing offices, physician practice groups, we would expect further burden reduction. OECD has data for a few more sectors of the industry, including 295,620 pharmacists, 3,626,060 nurses and 820,251 physicians in the United States. Many of the physicians and nurses are likely represented in the 6 million employed by hospitals. Unfortunately we don't have data sources for all sectors of the industry. However, using

hospital staff as a starting point and OECD's total figure of 20 million working in the health and social service fields, we estimate the burden reduction is likely 6 to 8 million hours each year. Again, we have no way to determine exactly how many FDRs there are or exactly how many staff would be expected to take the training under the current regulation, but we hope this example demonstrates the reduction in burden this proposal would mean for the industry. We request comment that would allow for more complete monetization of cost savings in the analysis of the final rule.

Although sponsors must still monitor FDRs and implement corrective actions when mistakes are found, we believe that they are currently already doing this. Therefore no additional burden complementing the reduction in burden is anticipated from this proposal to eliminate the CMS training.

3. Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§ 422.254 and 422.256)

For CY 2018 bids, 2,743 non-D–SNP non-employer plans (that is, HMO, HMO–POS, Local PPO, PFFS, and RPPO) used in house and/or consulting actuaries to address the meaningful difference requirement based on CY 2018 bid information. The most recent Bureau of Labor Statistics report states that actuaries made an average of \$54.87 an hour in 2016, and we estimate that 2 hours per plan are required to fully address the meaningful difference requirement. The estimated hours are based on assumptions developed in consultation with our Office of the Actuary. We additionally allow 100 percent for benefits and overhead costs of actuaries, resulting in an hourly wage of $\$54.87 \times 2 = \109.74 . Therefore, we estimate a savings of 2 hours per plan $\times 2,743 \text{ plans} = 5,486 \text{ hours}$ reduction in hourly burden with a savings in cost of $5,486 \text{ hours} \times \$109.74 = \$602,033.64$, rounded down to \$0.6 million to be saved annually under this proposal.

The number of plan bids received by CMS may increase because of a variety of factors, such as payments, bidding and service area strategies, serving unique populations, and in response to other program constraints or flexibilities. However, CMS expects that eliminating the meaningful difference requirement will improve the plan options available for beneficiaries, but do not believe the number of similar plan options offered by the same MA organization in each county will necessarily increase significantly or create more confusion in beneficiary decision-making related specifically to

the number of plan options. New flexibilities in benefit design and more sophisticated approaches to consumer engagement and decision-making should help beneficiaries, caregivers, and family members make informed plan choices.

CMS does not believe this proposed change will have a significant impact on health care providers. The number of plans offered by organizations in each county are not expected to increase significantly as a result of this change and health care provider contracts with MA organizations typically include all of the organization's plans rather than having separate contracts for each plan. In addition, CMS does not expect a significant increase in time spent in bid review as a direct result of eliminating meaningful difference nor increased provider burden.

4. Physician Incentive Plans—Update Stop-Loss Protection Requirements (§ 422.208)

Some physician contracts with MA organizations provide that the MA organization pay the physician a capitated amount to assume financial responsibility for services (for example, hospital costs) that they do not personally render. CMS refers to capitations to physicians that include services the physicians do not render as “global capitation.” When physicians are globally capitated to the extent that they can lose more than 25 percent of

their income, they are required to be covered by stop-loss insurance. We propose to replace the current insurance schedule in the regulation with updated stop-loss insurance requirements that would allow insurance with higher deductibles. The new schedule would result in a significant reduction to the cost of obtaining stop-loss insurance. The higher deductibles are consistent with the increase in medical costs due to inflation.

To determine the cost of different stop-loss insurance policies, we used claim distributions from original Medicare enrollees. Then, we assumed an average loading for administrative and profit of 20 percent. Using these assumptions, we estimate that plans and physicians would save an average of \$100 per globally capitated member per year in total costs. The derivation of this \$100 figure is as follows:

Under the current regulation at § 422.208(f)(2)(iii), stop-loss insurance for the provider (at the MA organization's expense) is needed only if the number of members in the physician's group at global risk under the MA plan is less than 25,000. The average number of members in the under 25,000 group estimated under the current regulation is 6,000 members. Ideally, to obtain an average, we should weight the panel sizes in the chart at § 422.208(f)(2)(iii) by the number of physician practices and the number of

capitated patients per practice per plan. However, this information is not available. Therefore, we used the median of the panel sizes listed in the chart at § 422.208(f)(2)(iii), which is about 8,000. Since the per member per year (PMPY) stop-loss premiums are greater for a smaller number of patients, we lowered this 8,000 to 6,000 to reflect the fact that the distribution of capitated patients is skewed to the left. We use this rough estimate of 6,000 for its estimates.

For these 6,000 members, the current regulation at § 422.208(f)(2)(iii) (the chart) shows the physician needs stop-loss insurance for \$37,000 in a combined attachment point (deductible). The \$37,000 is obtained by using linear interpolation on the chart at § 422.208(f)(2)(iii), replacing panel sizes with midpoints of ranges and rounding to the nearest 1,000. To find the premium for a stop-loss insurance with a deductible of \$37,000, we use Table 26, which reflects current insurance rates, that is, what would be charged today. By using linear interpolations on the columns with \$30,000 and \$40,000 and rounding to the nearest \$1,000, we see that the PMPY premium for insurance with \$37,000 combined attachment points is \$2,000 PMPY. This \$2,000 premium reflects the baseline charge today for a combined deductible of \$37,000.

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TABLE 26: COMBINED ATTACHMENT POINTS BEFORE INCLUDING NPEs

Professional & Institutional Combined	5,000	10,000	15,000	20,000	30,000	40,000	50,000	60,000	70,000	100,000	150,000	200,000	300,000	500,000	1,000,000	2,000,000	No Stop Loss
Number of Risk Patients	400	800	1,400	2,000	3,300	4,600	5,800	6,900	7,900	10,100	12,300	13,500	14,800	16,100	16,800	17,400 to 25,000	> 25,000
Net Benefit Premium PMPY	5.922	4.891	4.122	3.514	2.612	1.984	1.539	1.216	977	553	267	159	79	28	12	4	0

NOTE: This table is valid for contract year 2019. Future year updates, if necessary, may be found in the annual Rate Announcement and Call Letter. Attachments points may be increased up to \$100,000 by using NPEs.

Next, we compute the premium under the proposed rule. We still assume an average of 6,000 capitated members. However, the proposed rule allows higher deductibles corresponding to medical inflation. By using linear interpolation on the columns headed with 50,000 and 60,000 combined attachment points and rounding. We see that a deductible (combined attachment point) of \$57,000 corresponds to 6,000 capitated members and a premium of \$1,500 PMPY.

The savings in premium between using § 422.208(f)(iii) to calculate deductibles (combined attachment point) and using Table A to calculate deductibles is $\$2000 - \$1500 = \$500$ PMPY. We assume that the average loading for profit and administrative costs is roughly 20 percent. So our PMPY savings is $20 \text{ percent} \times 500 = \100 PMPY. The remaining $\$500 - \$100 = \$400$ in savings is on net benefits. That reduction does not produce any savings since the plans and physicians are simply trading claims for premiums.

In 2007, we estimated that 7 percent of enrollees were receiving services under capitated arrangements. Although we do not have more current data, based on CMS observation of managed care industry trends, we believe that the percentage is now higher, and we assume that 11 percent of enrollees are now paid under global capitation. There are currently 18.6 million MA beneficiaries. We estimate that about $18.6 \text{ million} \times 11 \text{ percent} = 2,046,000$ MA members are paid under some degree of global capitation. Thus, the total aggregate projected annual savings under this proposal is roughly $\$100 \text{ PMPY} \times 2,046,000 \text{ million beneficiaries paid under global capitation} = \204.6 million .

The \$204.6 million savings is removed from the plan bid, but not the CMS benchmark. If the benchmark exceeds the bid, Medicare pays the MA organization the bid (capitation rate and risk adjustment) plus a percentage of the difference between the benchmark and the bid, called the rebate. The rebate is based on quality ratings and allows Medicare to share in the savings to the plans; our experience with rebates shows that the average rebate is on the order of 2/3. We assumed that of the \$204.6 million in annual savings, Medicare would save $35 \text{ percent} \times \$204.6 \text{ million} = \$71,610,000$, and the remaining $65 \text{ percent} \times \$204.6 \text{ million} = \$132,990,000$ would be paid to the plans. The plan portion of the savings we project for this proposal would fund extra benefits or possibly reduce cost sharing for plan members.

The figures for 2019 were updated for 2020 to 2023 using enrollment and inflation factors found in the CMS trustees report, accessible at: <https://www.cms.gov/reportstrustfunds>.

5. Changes to the Agent/Broker Requirements (§§ 422.2272(e) and 423.2272(e))

We propose to delete the limitation placed on MA organizations and Part D sponsors as to how they can respond to an agent/broker who has become unlicensed. We propose to delete a requirement that the MA plan or Part D plan terminate an unlicensed agent or broker and contact beneficiaries to notify them if they had been enrolled by the unlicensed agent or broker. We already require MA organizations and Part D sponsors to use only licensed agents/brokers. We have established the requirement to have a licensed agent or broker in a 2008 final rule (73 FR 54219). That burden assessment is not changing due to the proposal to remove paragraph (e) from these sections. The impact analysis for the specific provision at paragraph (e) of §§ 422.2272 and 423.2272 was established in rule-making in April 2011 (76 FR 21534). As for the impact of review and compliance activities that remain to plans after removing the narrow scope of compliance actions available to MA organizations and Part D sponsors, we do not believe this change would have a significant increase in burden or financial impact. Removing this requirement allows state Department of Insurance (DOI) requirements to take precedence in this situation. While some MA organizations and Part D sponsors may choose to make operational changes to ensure compliance, these changes are not based on this rule, but are required to meet existing requirements.

6. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage

We propose to revise our regulations at § 422.66 to permit default enrollment of Medicaid managed care plan members into an MA special needs plan for dual eligible beneficiaries. Upon a Medicaid managed care plan member becoming eligible for Medicare, qualification for enrollment into the MA special needs plan for dual eligibles is contingent on the following:

- State support for the default enrollment process, and
- The organization's ability to identify such individuals at least 90 days in advance of their Medicare eligibility; and

- To issue written notification of the enrollment a minimum of 60 days in advance.

Our proposal represents the partial codification of existing policy on seamless conversion enrollment that has been specified in subregulatory guidance for contract years 2006 and subsequent years, but with additional parameters and limits. Among the new limits proposed for seamless conversion default enrollments are allowing such enrollments only from the organization's Medicaid managed care plan into an integrated D-SNP and requiring facilitation from applicable state (in the form of a contract term and provision of data). This will result in the discontinuation of the use of the seamless conversion enrollment mechanism by some of the approved MA organizations. However, as this enrollment mechanism is voluntary and not required for participation in the MA program, we do not believe the proposed changes would have any impact to the Medicare Trust Funds. We invite comments on the potential impact of the proposed changes on MA organizations, Medicaid managed care plans and beneficiaries.

7. Restoration of the MA Open Enrollment Period (§§ 422.60, 422.62, 422.68, 423.38 & 423.40)

We expect that increasing the amount of time that MA-enrolled individuals are given to switch plans will result in slightly more beneficiaries selecting plans that receive Quality-Bonus Payments (QBP). This assessment reflects our observation that beneficiaries tend to choose plans with higher quality ratings when given the opportunity. The projected costs to the Government by extending the open enrollment period for the first 3 months of the calendar year are \$9 million for CY 2019, \$10 million in 2020, \$10 million in 2021, \$11 million in 2022, and \$12 million in 2023.

In order to estimate the additional costs for the projection window 2019–2023, we first made an assumption that approximately 24,600 MA-enrolled individuals will switch health plans from one without a QBP to one with a QBP during the extended open enrollment period. The 24,600 enrollee assumption was determined by using a combination of published research and by observing historical enrollment information. Published research¹ shows that 10 percent of MA enrollees voluntarily switch MA plans and that MA enrollees who voluntarily switch plans change to plans with slightly higher star ratings than their original plan, with a modest improvement of

0.11 stars, on average. The Office of the Actuary confirmed these findings by analyzing CMS enrollment data and provided further detail. We estimate that of the 10 percent of MA plan enrollees who switch plans, 15 percent move to a higher rated plan. Of those who go to a higher rated plan, we estimate 40 percent move from a non-QBP plan to a QBP plan. We also estimate that one-fifth of these enrollees would take advantage of the new open enrollment period.

We apply these assumptions to the estimated MA enrollment for 2019, 20,512,000, which can be obtained from

the CMS Trustee’s Report available at <https://www.cms.gov/reportstrustfunds/>. We find that 24,600 (20,512,000 × 10 percent × 15 percent × 40 percent × 20 percent) people are expected to enroll in the proposed open enrollment period.

The \$9 million in additional costs for 2019 was calculated by multiplying the 24,600 impacted enrollment by the expected 2019 bonus amount (\$637.20). The Office of the Actuary experiences an average rebate percentage of 66 percent and an 86 percent backing out of the projected Part B premium. Hence, the net savings to the trust funds is estimated as \$9 million = 24,600

enrollees × \$637.20 (Bonus payment) × 66 percent (rebate percentage) × 86 percent (Reduction in Part B premium), rounding to \$9 million.

Then, we applied trends from the Trustees Report to the 2019 estimate in order to project the costs for years 2020 to 2023. The data from the Medicare Payments to Private Health Plans, by Trust Fund (Table IV.C.2. of the 2017 Medicare Trustees Report) was used as the basis for the trends. The trend estimates are presented in the Table 27 that demonstrates the calculations and displays the cost estimates for each year 2019–2023.

TABLE 27—CALCULATION OF NET COSTS TO THE MEDICARE TRUST FUNDS FOR THE EXTENDED OPEN ENROLLMENT PERIOD

Year	2019 Base year (million)	Trend factor 2020	Trend factor 2021	Trend factor 2022	Trend factor 2023	Net costs (rounded to nearest million)
2019	9					9
2020	9	1.078				10
2021	9	1.078	1.084			10
2022	9	1.078	1.084	1.089		11
2023	9	1.078	1.084	1.089	1.086	12

8. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations

We believe the proposed changes will result in a reduction of burden to Part D plan sponsors since they will have additional time to adjudicate requests for payment. We also expect a reduction in burden for the independent review entity (IRE) since the additional time for Part D plan sponsors to process these requests will result in fewer untimely payment redeterminations that must be auto-forwarded to the IRE. Based on recent program data, about 2,000 retrospective payment redetermination cases are auto-forwarded to the Part D IRE each plan year. If the proposed 14-day timeframe for payment redeterminations is implemented, we estimate that about 75 percent of the payment redetermination cases that are currently auto-forwarded to the Part D IRE due to the plan not being able to meet the adjudication timeframe will not be auto-forwarded under the 14 day timeframe; the longer timeframe will afford Part D plan sponsors an additional 7 days to process a payment request, including obtaining necessary supporting documentation, and to notify the enrollee of its decision. As a result, overall plan sponsor burden will be reduced by not having to auto-forward about 1,500 payment redetermination cases to the Part D IRE in a given plan

year and the Part D IRE’s workload will be reduced by the same number of cases. We estimate that it takes Part D plan sponsors an average of 15 minutes (0.25 hours) to assemble and forward a case file to the IRE, for an estimated savings of 375 hours (1500 cases × 0.25 hours). Using an adjusted hourly wage of \$34.66 based on the Bureau of Labor Statistics May 2016 Web site for occupation code 43–9199, “All other office and administrative support workers,” (based on a mean hourly salary of \$17.33, which when multiplied by a factor of two to include overhead, and fringe benefits, resulting in \$34.66 an hour) the total estimated savings to plans is \$12,998 (375 hours × \$34.66). Since the proposed changes involve requests for payment where the enrollee has already received the drug, we do not believe the proposed changes will impose undue burden on enrollees.

9. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE

The proposed changes at § 422.590(f) would result in a slight reduction of burden to Part C plans by no longer requiring a Notice of Appeal Status for each case file forwarded to the IRE. The estimated savings of this proposed change is based on reduced plan administration costs. Using the number of partially and fully adverse cases, we estimate Part C plans forwarded 47,108 cases to the IRE in 2015. We estimate it

will take 5 minutes (0.083 hours) to complete this notice. We used an adjusted hourly wage of \$34.66 based on the Bureau of Labor Statistics May 2016 Web site for occupation code 43–9199, “All other office and administrative support workers,” which gives a mean hourly salary of \$17.33, which when multiplied by a factor of two to include overhead, and fringe benefits, resulting in \$34.66 an hour. Thus, the reduction in administrative time spent would be 0.083 hours × 47,108 cases = 3,926 hours with a consequent savings of 3,926 hours × \$34.66 per hour = \$136,064.

We do not believe the proposed change will adversely impact health plan enrollees. The notice we are proposing to eliminate is duplicative and enrollees will be notified by the IRE that their case was received by the IRE for review.

10. Revisions to §§ 422 and 423 Subpart V, Communication/Marketing Materials and Activities

CMS is proposing to narrow the definition of “marketing materials” under §§ 422.2260 and 423.2260 to only include materials and activities that aim to influence enrollment decisions. CMS believes the proposed definitions appropriately safeguard potential and current MA/PDP enrollees from inappropriate steering of beneficiary choice, while not including materials

that pose little risk to current or potential enrollees and are not traditionally considered “marketing.” The proposed change would add text to §§ 422.2260 and 423.2260 and provide a narrower definition than is currently provided for “marketing materials.” Consequently, this definition decreases the number of marketing materials that must be reviewed by CMS before use. Additionally, the proposal would more specifically outline the materials that are and are not considered marketing materials.

We believe the net effects of the proposed changes would reduce the burden to MA organizations and Part D Sponsors by reducing the number of materials required to be submitted to CMS for review.

In section IV.F. of this proposed rule, we estimated the reduced burden to industry at \$1.3 million. There is also a reduced burden to the federal government since CMS staff are no longer obligated to review these materials. Although all marketing materials are submitted for potential review by the MA plans to CMS, not all materials are reviewed, since some MA plans, because of a history of compliance, have a “file and use” status which exempts their materials from routine reviews. We estimate that only 10 percent of submitted marketing materials are reviewed by CMS staff. Consequently, the savings to the federal government is 10 percent × 1.3 million = 0.13 million.

11. Part C & D Star Ratings

There has been a recent trend in the number of enrollees that have moved from lower Star Ratings contracts that

do not receive a Quality Bonus Payment (QBP) to higher rated contracts that do receive a QBP as part of contract consolidations. The proposal is to codify the methodology of the assigned Star Ratings and to add requirements addressing when contracts have consolidated. The methodology and measures being proposed here are generally from recent practice and policies finalized under the section 1853(b) of the Act Rate Announcement. With regard to consolidations, the Star Ratings assigned would be based on the enrollment weighted average of the measure scores of the surviving and consumed contract(s) so that the ratings reflect the performance of all contracts (surviving and consumed) involved in the consolidation. We believe that the proposal would dissuade many plans from consolidating contracts since it would be possible for some plans to lose QBPs under certain scenarios. If less contracts consolidate to higher Star Ratings, less QBPs would be paid to plans and this would result in Trust Fund savings.

In order to estimate the savings amounts for the projection window 2019–2023, we first observed the number of enrollees that have been impacted by contract consolidations for the prior 3 contract years (2016 through 2018) using a combination of bid and CMS enrollment/crosswalk data. The number of enrollees observed are those that have moved from a non-QBP contract to a QBP contract and were found to be approximately 830,000 in 2016, 530,000 in 2017, and 160,000 in 2018. We assumed that the number of enrollees moving from a non-QBP

contract to a QBP contract would be 200,000 starting in 2019 and increasing by 3 percent per year throughout the projection period. The 200,000 starting figure was chosen by observing the decreasing trend in the historical data as well as placing the greatest weight on the most recent data point. The 3 percent growth rate is approximately the projected growth in the MA eligible population during the 2019–2023 period.

Similarly, we calculated the net per member per month (PMPM) dollar impact of the QBP for those enrollees in contracts that consolidated to be \$44.73 in 2018. Again, the PMPM impact was projected for the 2019–2023 period using the projected annual trend of 5 percent per year which is similar to the projected growth rate for MA expenditures and can be found in the 2017 Trustees Report. We also made an assumption that even under the proposed Star Rating methodology changes, there would still be 50 percent of the projected impacted enrollees that would consolidate or individually move from a non-QBP contract to a QBP contract when advantageous to the health plan (lessening the overall savings impact). Combining the assumptions previously described, as well as accounting for the average rebate percentage of 66 percent and backing out the projected Part B premium, the net savings to the trust funds were calculated to be \$32 million for 2019, \$35 million in 2020, \$37 million in 2021, \$40 million in 2022, and \$44 million in 2023. The calculations for the five annual estimates are presented in Table 28.

TABLE 28—CALCULATIONS OF NET SAVINGS PER YEAR FOR STAR RATINGS

Year	Enrollment (3% annual trend)	PMPM cost (5% annual trend)	Number months per year	Percent not consolidating (%)	Average rebate percentage (%)	Backing out of Part B premium (%)	Net Savings (\$ in millions)
2019	200,000	44.73 × 1.05	12	50	66	86	32
2020	200,000 × 1.03	44.73 × 1.05 ²	12	50	66	86	35
2021	200,000 × 1.03 ²	44.73 × 1.05 ³	12	50	66	86	37
2022	200,000 × 1.03 ³	44.73 × 1.05 ⁴	12	50	66	86	40
2023	200,000 × 1.03 ⁴	44.73 × 1.05 ⁵	12	50	66	86	44

12. Any Willing Pharmacy Standard Terms and Conditions and Better Define Pharmacy Types

a. Anticipated Effects

In considering the cost implications of this proposal, we received varied perspectives from stakeholders. Part D plan sponsors, PBMs, and

manufacturers contend limited dispensing networks with accreditation requirements generate cost savings and add value. Specialty pharmacies contend the added value avoids additional costs. Independent community pharmacies, and beneficiaries contend broader

competition and transparency will generate savings.

Because this provision clarifies existing any willing pharmacy requirements, consistent with OACT estimates, we do not anticipate additional government or beneficiary cost impacts from this provision.

TABLE 29—ESTIMATED AGGREGATE COSTS AND SAVINGS TO THE HEALTH CARE SECTOR BY PROVISION FOR CALENDAR YEARS 2019 THROUGH 2023

Provision	Regulation section(s)	Calendar year (\$ in millions)					Total CYs 2019–2023 (\$ in millions)
		2019	2020	2021	2022	2023	
Federal Government (Medicare) Impacts							
Any Willing Pharmacy Standard Terms and Conditions and Better Define Pharmacy Types.	Various	0	0	0	0	0	0

b. Benefits

Proposed clarification of Any Willing Pharmacy rules, and clarification of the definition of retail pharmacy would account for recent changes in the pharmacy practice landscape and ensure that existing statutorily-required Any Willing Pharmacy provisions are extended to innovative pharmacy business and care delivery models.

Rural areas are predominantly served by independent community pharmacies. The National Community Pharmacist's Association (NCPA) estimates that "independent pharmacies represent 52 percent of all rural retail pharmacies and there are over 1800 independent community pharmacies operating as the only retail pharmacy within their rural communities^{63 64}." Additionally, these pharmacies are increasingly interested to diversify their business models to dispense specialty drugs. Consequently, we believe this proposal may support small businesses in rural areas and may help maintain beneficiary access to specialty drugs from community pharmacies.

13. Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings With Meaningful Differences (§ 423.265)

The proposed revision of 423.265 eliminates the requirement for two enhanced benefit plans offered by a PDP organization in a service area to be "substantially different". If finalized this will result in increased plan flexibilities and a potential increase in beneficiary plan choice. We expect this provision to reduce plan burden and could provide a very modest savings to plans sponsors of approximately \$60,000. The savings represent an estimate of the time not spent by certifying actuaries to ensure that a

meaningful difference threshold is met between two PDP EA offerings. Based on the preliminary CY 2018 landscape, if all PDP organizations that submitted an EA benefit design had also submitted the maximum of two EA plans, the result would be approximately 275 EA to EA plan pairings that would have required actuary time spent in evaluation of the meaningful difference requirement. We further estimate that it would take an actuary 2 hours to write a meaningful difference requirement. Based on the Bureau of Labor Statistics (BLS) latest wage estimates, <https://www.bls.gov/oes/current/oes152011.htm>, the mean hourly wage for actuaries, occupation code 15–2011 is \$54.87 which when multiplied by 2 to allow 100 percent for overhead and fringe benefits is \$109.74 an hour. Thus our total estimated burden is 275 EAs × 2 Hours per EA = 550 hours at a cost of 550 × \$109.74 = \$60357. While there is potential savings for PDP plan sponsors under this proposal, these savings could be offset for organizations who make the business decision to prepare and submit additional bids if this proposal is finalized. If the EA to EA threshold was the sole barrier to a PDP sponsor offering a second EA plan, (that is, the sponsor currently only offers one enhanced plan), based on the CY2018 PDP landscape, we could anticipate a modest increase of approximately 125 additional enhanced plans (15 percent increase). Although we believe it unlikely that all PDP sponsors would opt to add an additional plan.

14. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans and PACE

The costs and savings, as reflected in the total net savings, associated with our preclusion list proposals would be those identified in the collection of information section of this rule: Specifically, (1) the system costs associated with the Part D preclusion list; (2) costs associated with the preparation and sending of written

notices to affected Part D prescribers and beneficiaries; and (3) the savings that would accrue from individuals and entities no longer being required to enroll in or opt-out of Medicare to prescribe Part D drugs or furnish Part C services and items. Specifically, we project a total net savings, as described in detail in the collection of information portion of this rule, over the first 3 years of this rule of \$35,526,652 (\$3,423,852 for Part D + \$32,102,800 for Part C), or a 3-year annual average of \$11,842,217. Costs associated with an alternative approach are found in the Alternatives Considered portion of this section. We would be responsible for the development and monitoring of the preclusion list using its own resources. This would be funded as part of our screening activities. We do not anticipate a change in the number of individuals or entities billing for service, for we would only be denying payment to those parties that meet the conditions of the preclusion list. Costs associated with an alternative approach are found in the Alternatives Considered section of this rule.

We welcome public comment on these estimates, for stakeholder feedback could assist us in developing more concrete projections.

15. Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152)

This provision would result in a total savings of \$19,305 to the federal government. The driver of the savings is the removal of burden for federal employees to review Quality Improvement Project (QIP) attestations. MA organizations are required to annually attest that they have an ongoing QIP in progress and the Central Office reviews these attestation submissions. To estimate amounts, we considered how many QIP attestations are performed annually.

We estimate that—

- Central Office staff will require one person reviewing for 0.25 hours to review a single QIP attestation. The Central Office staff typically have higher

⁶³ National Community Pharmacist's Association letter to CMS Administrator, Seema Verma, June 7, 2017. Available at <http://www.ncpa.co/pdf/ncpa-medicaid-recommend-cms-june-2017.pdf>.

⁶⁴ National Community Pharmacist's Association comment letter to CMS–4159–P, March 2014. Available at <http://www.ncpa.co/pdf/NCPA-Comments-to-CMS-Proposed-Rule-2015FINAL-3.7.14.pdf>.

GS levels. We assume a GS grade 13, step 5, with a mean wage of \$51.48, which with an allowance of 100 percent for overhead and fringe benefits becomes \$102.96. This is based on the 2017 publicly available wages found on the Office of Personnel Management Web site at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2017/general-schedule/>.

- We calculate the savings to the federal government by multiplying the number of anticipated QIP attestation submissions (750) times the number of CMS staff it takes to complete a review— (1) times the adjusted wage for that staff (\$102.96) (750 × 1 × \$102.96 × 0.25 hour), which equals \$19,305.

Thus, the total savings of this provision are \$31,968, of which \$12,663.75 are savings to the industry, as indicated in section III. of this proposed rule, and \$19,305 are savings to the federal government.

16. Reducing the Burden of the Medical Loss Ratio Reporting Requirements

Our proposal to significantly reduce the amount of MLR data submitted to CMS would eliminate the need for CMS to continue to pay a contractor, approximately \$390,000 a year for the following:

- To perform initial analyses, or desk reviews, of the detailed MLR reports submitted by MA organizations.
- Part D sponsors in order to identify omissions and suspected inaccuracies and to communicate their findings to MA organizations and Part D sponsors in order to resolve potential compliance issues.

In addition, because we would be receiving only the minimum amount of data from MAOs and Part D sponsors, we expect that we would reduce the amount we pay to contractors for software development, data management, and technical support related to MLR reporting. We currently pay a contractor \$300,000 each year for these services. Although we expect that MAOs and Part D sponsors would continue to use the HPMS or a similar system to submit and attest to their simplified MLR submissions, we would no longer need to maintain and update MLR reporting software with validation features, to receive certain data extract files, or to provide support for desk review functionality. We estimate, by eliminating these services, we would reduce our payments to contractors by approximately \$100,000 a year.

In total, we estimate that the proposed changes to the MLR reporting requirements will save the government \$490,000 a year. As noted in the Collection of Information section of this

proposed rule, the proposed changes to the MLR reporting requirement will save MA organizations and Part D sponsors \$904,884 a year. Thus, the total annual savings of this proposal are \$1,446,417: \$490,000 to the government and \$904,884 to MA organizations and Part D sponsors.

We do not anticipate that our proposal to modify the regulations at §§ 422.2430 and 423.2430 to specify that Medication Therapy Management (MTM) programs that comply with § 423.153(d) are quality improvement activities (QIA) will significantly reduce stakeholder burden. As explained in section II.C.1.b.(2). of this proposed rule, we stated in the May 23, 2013 final rule (78 FR 31294) that MTM activities qualify as QIA, provided they meet the requirements set forth in §§ 422.2430 and 423.2430. We expect that most if not all MTM programs that comply with § 423.153(d) would already satisfy the QIA requirements set forth in current §§ 422.2430 and 423.2430. Therefore, we do not anticipate that the proposal to explicitly include MTM programs in QIA will have a significant impact on burden.

17. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

The proposed provisions would specifically permit Part D sponsors that meet our requirements to remove brand name drugs (or change their cost-sharing status) when replacing them with (or adding) newly approved generics without providing advance notice or submitting formulary change requests. We would also permit Part D sponsors to make such changes at any time of the year rather than waiting for them to take effect 2 months after the start of the plan year. A related proposal would except from our transition policy applicable generic substitutions and additions with cost-sharing changes. Lastly, we are proposing to decrease the days of enrollee notice and refill required in cases in which (aside from generic substitutions and drugs deemed unsafe or removed from the market) drug removal or changes in cost-sharing will affect enrollees.

The FDA has noted that generics are typically sold at substantial discounts from the branded price. (“Generic Drugs: Questions and Answers,” see FDA Web site, <https://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm>, accessed June 22, 2017.) However, we do not believe that significant savings will necessarily result from these proposed provisions, because

historically Part D sponsors have been able to anticipate the generic launches well and migrate the brand scripts to generics smoothly once the generic drugs become available. The proposal could provide some administrative relief for Part D sponsors, although the savings won't be very significant.

In addition regardless of any first year effect, we do not believe there could be any significant effect for subsequent years. Our proposed changes would permit immediate specified generic substitutions throughout the plan year or a 30 rather than a 60 day notice period for certain substitutions. Part D sponsors submit for review each year an entirely new formulary and presumably the timing of substitutions would overlap across plan years a minimal amount of times.

18. Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

a. Savings

Proposed codification of follow-on biological products as generics for the purposes of LIS cost sharing and non-LIS catastrophic cost sharing will reduce marketplace confusion about what level of cost-sharing Part D enrollees should be charged for follow-on biological products. By establishing cost sharing at the lower level, this provision would also improve Part D enrollee incentives to use follow-on biological products instead of reference biological products. As discussed previously, this would reduce costs to Part D enrollees and generate savings for the Part D program.

In addition, we believe that reducing confusion in the marketplace surrounding this issue will improve beneficiary protections while improving enrollee incentives to choose follow-on biological products over reference biological products. (This proposed provision to classify follow-on biological products as generic drugs are for the purposes of cost sharing for non-LIS cost sharing in the catastrophic portion of the benefit and LIS enrollees in any phase of the benefit.) Improved incentives to choose lower cost alternatives will reduce costs to Part D enrollees and the Part D program. OACT estimates this proposal will provide a modest savings of \$10 million in 2019, with savings increasing by approximately \$1 million each year through 2028.

OACT anticipates some natural shift from reference biological products to follow-on biological products, but follow-on biological products' price differential and market share are lower

than that observed for small molecule generic drugs. Currently, Zarxio® data provide the only meaningful comparison available to date, as very limited data exist on the other six approved (as of September 14, 2017) follow-on biological products. The market dynamic between Neupogen® and Zarxio® has behaved consistent

with OACT's anticipation and OACT expects other follow-on biological products to follow the similar pattern. Based on 2017 year-to-date data on the per script price difference between Neupogen® and Zarxio®, OACT estimated follow-on biological products to be 16 percent less expensive than their reference biological product.

OACT estimates this proposal will result in a minor shift of an additional 5 percent of prescriptions to follow-on biological products by LIS enrollees under this proposal. Consequently, savings are not estimated to be significant at this time.

TABLE 30—ESTIMATED AGGREGATE COSTS AND SAVINGS TO THE HEALTH CARE SECTOR BY PROVISION FOR CALENDAR YEARS 2019 THROUGH 2023

Provision	Regulation section(s)	Calendar year (\$ in millions)					Total CYs 2019–2023 (\$ in millions)
		2019	2020	2021	2022	2023	
Federal Government (Medicare) Impacts							
Treatment of Follow-On Biological Products as Generics for LIS Cost Sharing and Non-LIS Catastrophic Cost Sharing.	423.4	10	11	12	13	14	60

b. Benefits of Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

Proposed codification of follow-on biological products as generics for the purposes of LIS cost sharing and non-LIS catastrophic cost sharing will reduce marketplace confusion about what level of cost-sharing Part D enrollees should be charged for follow-on biological products. By establishing cost sharing at the lower level, this provision would also improve Part D enrollee incentives to use follow-on biological products instead of reference biological products. As discussed previously, this would reducing costs to Part D enrollees and generate savings for the Part D program.

19. Changes to the Days' Supply Required by the Part D Transition Process

We do not believe our proposal in this section would impose any new burden on any stakeholder. Since Part D sponsors and their PBMs already have prescription drug pharmacy claims systems programmed to provide transition to plan enrollees in the outpatient setting, they would only have to make a technical change to these systems that consists of changing the required number of days' supply if it is not already 30 days. In addition, Part D sponsors and their PBMs would have to cease treating these enrollees in the LTC setting separately from enrollees in the outpatient setting for purposes of transition. We also do not believe this proposal would impose any new burden on LTC facilities and the pharmacies that serve them. If finalized, we believe this regulation would eliminate the additional time that LTC facilities and pharmacies have to transition Part D

patients that we now believe they do not need to effectuate the transition.

We believe this provision will produce cost-savings to the Medicare Part D program because it requires fewer drugs to be dispensed under transition, particularly in the LTC setting. However, we are unable to estimate the cost-savings, because it largely depends upon which and how many drugs are dispensed as transition drugs to Part D beneficiaries in the LTC setting in the future. Also, we are unable to determine which PDEs involve transition supplies in LTC in order to provide an estimate of future savings based on past experience with transition supplies in LTC in the Part D program.

G. Alternatives Considered

1. Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

The critical policy decision was how broadly or narrowly to classify follow-on biological products as generics. Overly broad classification might easily overstep the distinctions between generic drugs and follow-on biologics in statute and those drawn by the United States Food and Drug Administration (FDA), leading to confusion in the marketplace, and potentially jeopardizing Part D enrollee safety. Inappropriate utilization of biological products and increased need for additional medical services, in turn, increase costs to the Part D program. A narrow classification can appropriately resolve marketplace confusion while also improving Part D enrollee incentives to choose lower cost alternatives.

2. Any Willing Pharmacy Standard Terms and Conditions and Better Define Pharmacy Types

The critical policy decision was how to strike the right balance to clarify confusion in the marketplace, afford Part D plan sponsor flexibility, and incorporate recent innovations in pharmacy business and care delivery models without prematurely and inappropriately interfering with highly volatile market forces.

3. Preclusion List

We considered a preclusion list that would embody preventive provisions that would place on the preclusion list not just those providers and suppliers who are prescribing Part D drugs or who are providing services to Medicare beneficiaries who are receiving their Medicare benefit from a MA plan. The savings and cost estimates associated with that alternative are based on the following. Prescription drug event (PDE) and encounter data identifies providers who furnish Part C services and items and prescribe Part D drugs to Medicare beneficiaries. Given the frequency with which MA organizations and Part D sponsors typically submit data to CMS, we estimate a delay of approximately 1 month in obtaining this data. Delays in the availability of this data and the screening and evaluation of the providers and prescribers will result in delays in the identification and inclusion of providers or prescribers on the preclusion list, which would occur after the service, item or drug was provided to the Medicare beneficiary. We estimate that it will cost the Trust Fund approximately \$44.7 million if we do not proactively screen providers and prescribers and delay screening until after the PDE and encounter data is

available. We estimate an additional 1.4 million providers or prescribers would not be screened if we only rely on PDE and encounter data. The current Medicare provider population consists of approximately 2 million providers and historically we have revoked 0.4 percent of its existing Medicare enrolled providers. However this percentage could be higher or lower for the population of prescribers solely enrolled for prescribing. There are approximately 480,000 part C and D unenrolled providers and prescribers, 120,000 of which are billing Part C. Using the percentage of historical revocations, we estimate approximately 1,920 new revocations. Based on the approximate

1-month delay in the availability of the PDE and encounter data, three months for screening and an additional 3 months to evaluate the offenses, we anticipate approximately a 7-month delay in the provider or prescriber's inclusion on the preclusion list following the service, item or drug being provided to the beneficiary, if we do not perform proactive screening. The 7-month timeframe is dependent on whether the PDE and encounter data is timely. Using a cost avoidance of \$3,324 per month average per provider and applying it to the estimated 1,920 new revocations, a delay in screening would cost the Trust Fund approximately \$44.7 million (3,324 × 7 × 1,920). The

\$3,324 estimate is based on Medicare fee-for-service revocation data and may be higher or lower depending on whether the provider is an individual or organization and their provider type.

H. Accounting Statement

As required by OMB Circular A-4 (available at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/), in Table 31 we have prepared an accounting statement showing the savings and transfers associated with the provisions of this final rule for CYs 2019 through 2023. Table 31 is based on Table 32 which lists savings, costs, and transfers by provision.

TABLE 31—ACCOUNTING STATEMENT: CLASSIFICATIONS OF ESTIMATED SAVINGS, COSTS, AND TRANSFERS FROM CALENDAR YEARS 2019 TO 2023
[\$ in millions]

Category	Savings			Whom to whom
	Discount rate		Period covered	
	7%	3%		
Net Annualized Monetized Savings	82.34	82.02	CYs 2019–2023	Federal government, MA organizations and Part D Sponsors.
Annualized Monetized Savings	87.26	86.79	CYs 2019–2023	Federal government, MA organizations and Part D Sponsors.
Annualized Monetized Cost	– 4.92	– 4.77	CYs 2019–2023	Federal government, MA organizations and Part D Sponsors.
Net Annualized Monetized Savings	13.80	13.82	CYs 2019–2023	Trust Fund.
Annualized Monetized Savings	13.80	13.82	CYs 2019–2023	Trust Fund.
Annualized Monetized Cost	0.00	0.00	CYs 2019–2023	Trust Fund.
Net Annualized Monetized Savings	68.54	68.20	CYs 2019–2023	Industry.
Annualized Monetized Savings	73.46	72.98	CYs 2019–2023	Industry.
Annualized Monetized Cost	– 4.92	– 4.77	CYs 2019–2023	Industry.
Transfers	155.90	154.95	CYs 2019–2023	Federal Government, MA plans and Part D Sponsors.

Note: Monetized figures in 2018 dollars. Positive numbers indicate aggregate annual savings at the giving percentage. Transfers are a separate line item. Savings and cost have been broken out separately for industry, the trust fund and aggregate. For example, the industry provisions with positive amounts had a level monetized amount of 72.32 at the 3 percent level but a cost of 11.87 at the 3 percent level resulting in an aggregate of 72.32 – 11.87 = 60.45. Minor (cent) errors are due to rounding.

The following Table 32 summarizes savings, costs, and transfers by

provision and formed a basis for the accounting table.

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TABLE 32: SAVINGS, COSTS, AND TRANSFERS BY PROVISION

	2019 Industry	2019 Trust Fund	2019 Transfers	2020 Industry	2020 Trust Fund	2020 Transfers	2021 Industry	2021 Trust Fund	2021 Transfers	2022 Industry	2022 Trust Fund	2022 Transfers	2023 Industry	2023 Trust Fund	2023 Transfers
Totals	90.3	13.6	231.5	57.7	13.63	250.5	60.8	13.63	271.8	63.9	13.6	295.0	67.1	14.6	
Tot savings	102.4	13.6		60.5	13.63		63.6	13.63		66.7	13.6		69.9	14.6	
Tot costs	-12.1	0	-15.1	-2.8	0	-16.1	-2.8	0	-16.1	-2.8	0	-17	-3	0	
Total Transfers			231.5			250.5			271.8			295			321.6
CARA	-2.8	13	0	-2.8	13	0	-2.8	13	0	-2.8	13	0	-2.8	14	0
OEP			-15.1			-16.1			-16.1			-17.1			-18.1
MLR	0.9	0.5	0	0.9	0.5	0	0.9	0.5	0	0.9	0.5	0	0.9	0.5	0
Disclosure	54.7			57.6			60.7			63.8			67		
Marketing	1.3	0.13	0	1.3	0.13	0	1.3	0.13	0	1.3	0.13	0	1.3	0.13	0
Meaningful Difference (Part C)	0.6			0.6			0.6			0.6			0.6		
Meaningful Difference (Pt D)	0.1			0.1			0.1			0.1			0.1		
Stop Loss (PIP)			204.6			220.6			238.9			259.1			281.7
Part C/D Preclusion	44.8			0			0			0			0		
Part C/D Preclusion	-9.3			0			0			0			0		
Follow on Biologics			10			11			12			13			14
Star Ratings			32			35			37			40			44

Note: This tables summarizes cost and savings by provision. Provisions not in the table are scored as 0. Numbers indicate millions of dollars. Positive numbers indicate savings while negative numbers indicate cost.

I. Conclusion

This proposed rule has a net savings of between \$80 to \$100 million for each of the next 5 years. The savings are equivalent to a level amount of about \$80 million per year for both 7 percent and 3 percent interest rates. These aggregate savings are to industry (\$68.20 million at the 3 percent level = \$72.98 million savings—\$4.77 million cost), and the Federal government and the Trust Fund (\$13.82 million at the 3 percent level which reflects savings to the trust fund without any cost). Transfers between the Federal Government and Industry are between \$230 and \$320 million and are equivalent to a monetized level amount of about \$270 million per year at the 3-percent and 7-percent levels. Both industry and the Federal government save from program efficiencies and reduced work.

J. Reducing Regulation and Controlling Regulatory Costs

This rule, if finalized as proposed, is expected to be an E.O. 13771 regulatory action. Details on the estimated costs and cost savings can be found in the preceding analysis.

IV. Response to Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, 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, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and

Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Incorporation by Reference, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, and Reporting and recordkeeping requirements

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, and 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 read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section § 405.924 is amended by adding paragraph (a)(5) to read as follows:

§ 405.924 Actions that are initial determinations.

(a) * * *

(5) An adjustment of premium for hospital or supplementary medical insurance as outlined in §§ 406.32(d), 408.20(e), and 408.22 of this chapter, and 20 CFR 418.1301.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 3. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), secs. 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. 300e, 300e–5, and 300e–9), and 31 U.S.C. 9701.

■ 4. Section 417.430 is amended by revising paragraph (a)(1) to read as follows:

§ 417.430 Application procedures.

(a) * * *

(1) The application form must comply with CMS instructions regarding content and format and be approved by CMS as described in § 422.2262 of this chapter. The application must be completed by an HMO or CMP eligible (or soon to become eligible) individual and include authorization for disclosure between HHS and its designees and the HMO or CMP.

* * * * *

■ 5. Section 417.472 is amended by adding paragraph (k) to read as follows:

§ 417.472 Basic contract requirements.

* * * * *

(k) All cost contracts under section 1876 of the Act must agree to be rated under the quality rating system specified at subpart D of part 422, and for cost plans that provide the Part D prescription benefit, under the quality rating system specified at part 423 subpart D, of this chapter. Cost contracts are not required to submit data on or be rated on specific measures determined by CMS to be inapplicable to their contract or for which data are not available, including hospital readmission and call center measures.

■ 6. Section 417.478 is amended by revising paragraph (e) to read as follows:

§ 417.478 Requirements of other laws and regulations.

* * * * *

(e)(1) The prohibitions, procedures and requirements relating to payment to individuals and entities on the preclusion list, defined in § 422.2 of this chapter, apply to HMOs and CMPs that contract with CMS under section 1876 of the Act.

(2) In applying the provisions of §§ 422.2, 422.222, and 422.224 of this chapter under paragraph (e)(1) of this section, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

■ 7. Section 417.484 is amended by revising paragraph (b)(3) to read as follows:

§ 417.484 Requirement applicable to related entities.

* * * * *

(b) * * *

(3) That payments must not be made to individuals and entities included on the preclusion list, defined in § 422.2 of this chapter.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 8. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 9. Section 422.2 is amended by adding the definition of “Preclusion list” in alphabetical order to read as follows:

§ 422.2 Definitions.

* * * * *

Preclusion list means a CMS-compiled list of individuals and entities that—

(1) Meet all of the following requirements:

(i) The individual or entity is currently revoked from Medicare under § 424.535.

(ii) The individual or entity is currently under a reenrollment bar under § 424.535(c).

(iii) CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

(A) The seriousness of the conduct underlying the individual’s or entity’s revocation.

(B) The degree to which the individual’s or entity’s conduct could affect the integrity of the Medicare program.

(C) Any other evidence that CMS deems relevant to its determination; or

(2) Meet both of the following requirements:

(i) The individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable had they been enrolled in Medicare.

(ii) CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

(A) The seriousness of the conduct involved.

(B) The degree to which the individual’s or entity’s conduct could affect the integrity of the Medicare program; and

(C) Any other evidence that CMS deems relevant to its determination.

* * * * *

■ 10. Section 422.54 is amended by revising paragraphs (c)(1)(i) and (d)(4)(ii) to read as follows:

§ 422.54 Continuation of enrollment for MA local plans.

* * * * *

(c) * * *

(1) * * *

(i) Obtain CMS’s approval of the continuation area, the communication materials that describe the option, and the MA organization’s assurances of access to services.

* * * * *

(d) * * *

(4) * * *

(ii) Organizations that require enrollees to give advance notice of intent to use the continuation of enrollment option, must stipulate the notification process in the communication materials.

* * * * *

■ 11. Section 422.60 is amended—

■ a. In paragraph (a)(2) by removing the reference “§ 422.62(a)(3), (a)(4), and (a)(5) if” and adding in its place the reference “§ 422.62(a)(3) and (4) if”; and

■ b. Revising paragraph (g).

The revision reads as follows:

§ 422.60 Election process.

* * * * *

(g) *Passive enrollment by CMS—(1) Circumstances in which CMS may implement passive enrollment.* CMS may implement passive enrollment procedures in any of the following situations:

(i) Immediate terminations as provided in § 422.510(b)(2)(i)(B).

(ii) CMS determines that remaining enrolled in a plan poses potential harm to the members.

(iii) CMS determines, after consulting with the State Medicaid agency that contracts with the dual eligible special needs plan described in paragraph (g)(2)(i) of this section, and that meets the requirements of paragraph (g)(2) of this section, that the passive enrollment will promote integrated care and continuity of care for a full-benefit dual eligible beneficiary (as defined in § 423.772 of this chapter and entitled to Medicare Part A and enrolled in Part B under title XVIII) who is currently enrolled in an integrated dual eligible special needs plan.

(2) *MA plans that may receive passive enrollments.* CMS may implement passive enrollment described in paragraph (g)(1)(iii) only into MA–PD plans that meet all the following requirements:

(i) Operate as a fully integrated dual eligible special needs plan as defined in § 422.2, or a specialized MA plan for special needs individuals that meets a high standard of integration, as described in § 422.102(e).

(ii) Have substantially similar provider and facility networks and Medicare- and Medicaid-covered benefits as the plan (or plans) from which the beneficiaries are passively enrolled.

(iii) Have an overall quality rating of at least 3 stars under the rating system described in § 422.166 through § 422.166 for the year prior to the plan year passive enrollments take effect or is a low enrollment contract or new MA plan as defined in § 422.252.

(iv) Not have any prohibition on new enrollment imposed by CMS.

(v) Have limits on premiums and cost-sharing appropriate to full-benefit dual eligible beneficiaries.

(vi) Have the operational capacity to passively enroll beneficiaries and agree to receive the enrollments.

(3) *Passive enrollment procedures.*

Individuals will be considered to have elected the plan selected by CMS unless they—

(i) Decline the plan selected by CMS, in a form and manner determined by CMS, or

(ii) Request enrollment in another plan.

(4) *Beneficiary notification.* The MA organization that receives the passive enrollment must provide to the enrollee a notice that describes the costs and benefits of the plan and the process for accessing care under the plan and clearly explains the beneficiary’s ability to decline the enrollment or choose another plan. Such notice must be provided to all potential passively enrolled enrollees prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical), in a form and manner determined by CMS.

(5) *Special election period.*

Individuals not otherwise eligible for a special election period at the time of passive enrollment will be provided with a special election period, in accordance with § 422.62(b)(4).

■ 12. Section § 422.62 is amended by—

■ a. Revising paragraphs (a)(3) through (5);

■ b. Removing paragraphs (a)(6) and (7); and

■ c. Revising paragraph (b)(3)(ii).

The revisions read as follows:

§ 422.62 Election of coverage under an MA plan.

(a) * * *

(3) *Open enrollment period for individuals enrolled in MA—(i) For 2019 and subsequent years.* Except as provided in paragraphs (a)(3)(ii) and (iii) and (a)(4) of this section, an individual who is enrolled in an MA plan may make an election once during the first

3 months of the year to enroll in another MA plan or disenroll to obtain Original Medicare. An individual who chooses to exercise this election may also make a coordinating election to enroll in or disenroll from Part D, as specified in § 423.38(e).

(ii) *Newly eligible MA individual.* For 2019 and subsequent years, a newly MA eligible individual who is enrolled in a MA plan may change his or her election once during the period that begins the month the individual is entitled to both Part A and Part B and ends on the last day of the third month of the entitlement. An individual who chooses to exercise this election may also make a coordinating election to enroll in or disenroll from Part D, as specified in § 423.38(e).

(iii) *Single election limitation.* The limitation to one election or change in paragraphs (a)(3)(i) and (ii) of this section does not apply to elections or changes made during the annual coordinated election period specified in paragraph (a)(2) of this section, or during a special election period specified in paragraph (b) of this section.

(4) *Open enrollment period for institutionalized individuals.* After 2005, 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 for in paragraph (d) of this section for MA MSA plans) in the number of elections or changes he or she may make. Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an MA eligible institutionalized individual may at any time elect an MA plan or change his or her election from an MA plan to Original Medicare, to a different MA plan, or from original Medicare to an MA plan.

(5) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* Through 2018, at any time from January 1 through February 14, an individual who is enrolled in an MA plan may elect Original Medicare once during this 45-day period. An individual who chooses to exercise this election may also make a coordinating election to enroll in a PDP as specified in § 423.38(d) of this chapter.

(b) * * *
(3) * * *

(ii) The organization (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communication materials as outlined in subpart V of this part.

* * * * *

■ 13. Section 422.66 is amended by revising paragraphs (c) and (d)(1) and (5) to read as follows:

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

* * * * *

(c) *Election by default: Initial coverage election period—(1) Basic rule.* Subject to paragraph (c)(2) of this section, an individual who fails to make an election during the initial coverage election period is deemed to have elected original Medicare.

(2) *Default enrollment into MA special needs plan—(i) Conditions for default enrollment.* During an individual's initial coverage election period, an individual may be deemed to have elected a MA special needs plan for individuals entitled to medical assistance under a State plan under Title XIX offered by the organization provided all the following conditions are met:

(A) At the time of the deemed election, the individual remains enrolled in an affiliated Medicaid managed care plan. For purposes of this section, an affiliated Medicaid managed care plan is one that is offered by the MA organization that offers the MA special needs plan for individuals entitled to medical assistance under Title XIX or is offered by an entity that shares a parent organization with such MA organization;

(B) The state has approved the use of the default enrollment process in the contract described in § 422.107 and provides the information that is necessary for the MA organization to identify individuals who are in their initial coverage election period;

(C) The MA organization offering the MA special needs plan has issued the notice described in paragraph (c)(2)(iv) of this section to the individual;

(D) Prior to the effective date described in paragraph (c)(2)(iii) of this section, the individual does not decline the default enrollment and does not elect to receive coverage other than through the MA organization; and
(E) CMS has approved the MA organization to use default enrollment under paragraph (c)(2)(ii) of this section.

(ii) *CMS approval of default enrollment.* An MA organization must obtain approval from CMS before implementing any default enrollment as described in this section. CMS may suspend or rescind approval when CMS determines the MA organization is not in compliance with the requirements of this section.

(iii) *Effective date of default enrollment.* Default enrollment in the MA special needs plan for individuals entitled to medical assistance under a State plan under Title XIX is effective the month in which the individual is first entitled to both Part A and Part B.

(iv) *Notice requirement for default enrollments.* The MA organization must provide notification that describes the costs and benefits of the MA plan and the process for accessing care under the plan and clearly explains the individual's ability to decline the enrollment, up to and including the day prior to the enrollment effective date, and either enroll in Original Medicare or choose another plan. Such notification must be provided to all individuals who qualify for default enrollment under paragraph (c)(2) of this section no fewer than 60 calendar days prior to the enrollment effective date described in paragraph (c)(2)(iii) of this section.

(d) * * *

(1) *Basic rule.* An MA plan offered by an MA organization must accept any individual (regardless of whether the individual has end-stage renal disease) who requests enrollment during his or her Initial Coverage Election Period and is enrolled in a health plan offered by the MA organization during the month immediately preceding the MA plan enrollment effective date, and who meets the eligibility requirements at § 422.50.

* * * * *

(5) *Election.* An individual who requests seamless continuation of coverage as described in paragraph (d)(1) of this section may complete a simplified election, in a form and manner approved by CMS that meets the requirements in § 422.60(c)(1).

* * * * *

■ 14. Section 422.68 is amended by revising paragraphs (a), (c), and (f) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(a) *Initial coverage election period.* An election made during an initial coverage election period as described in § 422.62(a)(1) is effective as follows:

(1) If made prior to the month of entitlement to both Part A and Part B, it is effective as of the first day of the month of entitlement to both Part A and Part B.

(2) If made during or after the month of entitlement to both Part A and Part B, it is effective the first day of the calendar month following the month in which the election is made.

* * * * *

(c) *Open enrollment periods.* For an election, or change in election, made during an open enrollment period, as described in § 422.62(a)(3) through (5), coverage is effective as of the first day

of the first calendar month following the month in which the election is made.

* * * * *

(f) *Annual 45-day period for disenrollment from MA plans to Original Medicare.* Through 2018, an election made from January 1 through February 14 to disenroll from an MA plan to Original Medicare, as described in § 422.62(a)(5), is effective the first day of the first month following the month in which the election is made.

■ 15. Section 422.100 is amended—

- a. In paragraph (f)(2), by removing the phrase “to services. and” and adding in its place the phrase “to services.”; and
- b. By revising paragraphs (f)(4), (f)(5) introductory text, (f)(5)(ii), and (f)(6).

The revisions read as follows:

§ 422.100 General requirements.

* * * * *

(f) * * *

(4) Except as provided in paragraph (f)(5) of this section, MA local plans (as defined in § 422.2) must have an out-of-pocket maximum for Medicare Parts A and B services that is no greater than the annual limit set by CMS using Medicare Fee-for-Service data. CMS sets the annual limit to strike a balance between limiting maximum beneficiary out of pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.

(5) With respect to a local PPO plan, the limit specified under paragraph (f)(4) of this section applies only to use of network providers. Such local PPO plans must include a total catastrophic limit annually determined by CMS using Medicare Fee-for-Service and to establish appropriate beneficiary out-of-pocket expenditures for both in-network and out-of-network Parts A and B services that is—

* * * * *

(ii) Not greater than the annual limit set by CMS using Medicare Fee-for-Service data to establish appropriate beneficiary out-of-pocket expenditures. CMS will set the annual limit to strike a balance between limiting maximum beneficiary out of pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.

(6) Cost sharing for Medicare Part A and B services specified by CMS does not exceed levels annually determined by CMS to be discriminatory for such services. CMS may use Medicare Fee-for-Service data to evaluate the possibility of discrimination and to establish non-discriminatory out-of-

pocket limits and also use MA encounter data to inform patient utilization scenarios used to help identify MA plan cost sharing standards and thresholds that are not discriminatory.

* * * * *

■ 16. Section 422.101 is amended by revising paragraphs (d)(2) and (3) to read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(d) * * *

(2) *Catastrophic limit.* MA regional plans are required to establish a catastrophic limit on beneficiary out-of-pocket expenditures for in-network benefits under the Medicare Fee-for-Service program (Part A and Part B benefits) that is no greater than the annual limit set by CMS using Medicare Fee-for-Service data to establish appropriate out-of-pocket limits. CMS sets the annual limit to strike a balance between limiting maximum beneficiary out of pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.

(3) *Total catastrophic limit.* MA regional plans are required to establish a total catastrophic limit on beneficiary out-of-pocket expenditures for in-network and out-of-network benefits under the Medicare Fee-for-Service program (Part A and Part B benefits).

(i) This total out-of-pocket catastrophic limit, which would apply to both in-network and out-of-network benefits under Medicare Fee-for-Service, may be higher than the in-network catastrophic limit in paragraph (d)(2) of this section, but may not increase the limit described in paragraph (d)(2) of this section and may be no greater than the annual limit set by CMS using Medicare Fee-for-Service data.

(ii) CMS sets the annual limit to strike a balance between limiting maximum beneficiary out of pocket costs and potential changes in premium, benefits, and cost sharing, with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.

* * * * *

■ 17. Section 422.102 is amended by revising paragraph (d) to read as follows:

§ 422.102 Supplemental benefits.

* * * * *

(d) *Supplemental benefits packaging.* MA organizations may offer enrollees a group of services as one optional supplemental benefit, offer services

individually, or offer a combination of groups and individual services.

* * * * *

■ 18. Section 422.111 is amended by revising paragraphs (a) introductory text, (a)(3), and (h)(2)(ii) to read as follows:

§ 422.111 Disclosure requirements.

(a) *Detailed description.* An MA organization must disclose the information specified in paragraph (b) of this section in the manner specified by CMS—

* * * * *

(3) At the time of enrollment and at least annually thereafter, by the first day of the annual coordinated election period.

* * * * *

(h) * * *

(2) * * *

(ii) Copies of its evidence of coverage, summary of benefits, and information (names, addresses, phone numbers, and specialty) on the network of contracted providers. Posting does not relieve the MA organization of its responsibility under paragraph (a) of this section to provide hard copies to enrollees upon request.

* * * * *

§ 422.152 [Amended]

■ 19. Section 422.152 is amended by removing and reserving paragraphs (a)(3) and (d).

■ 20. Sections 422.160, 422.162, 422.164 and 422.166 are added to Subpart D to read as follows:

Subpart D—Quality Improvement

* * * * *

- Sec.
- 422.160 Basis and scope of the Medicare Advantage Quality Rating System.
- 422.162 Medicare Advantage Quality Rating System.
- 422.164 Adding, updating, and removing measures.
- 422.166 Calculation of Star Ratings.

§ 422.160 Basis and scope of the Medicare Advantage Quality Rating System.

(a) *Basis.* This subpart is based on sections 1851(d), 1852(e), 1853(o) and 1854(b)(3)(iii), (v), and (vi) of the Act and the general authority under section 1856(b) of the Act requiring the establishment of standards consistent with and to carry out Part C.

(b) *Purpose.* Ratings calculated and assigned under this subpart will be used by CMS for the following purposes:

- (1) To provide comparative information on plan quality and performance to beneficiaries for their use in making knowledgeable enrollment and coverage decisions in the Medicare program.

(2) To provide quality ratings on a 5-star rating system to be used in determining quality bonus payment (QBP) status and in determining rebate retention allowances.

(3) To provide a means to evaluate and oversee overall and specific compliance with certain regulatory and contract requirements by MA plans, where appropriate and possible to use data of the type described in § 422.162(c).

(c) *Applicability.* The regulations in this subpart will be applicable beginning with the 2019 measurement period and the associated 2021 Star Ratings that are released prior to the annual coordinated election period for the 2021 contract year and used to assign QBP ratings for the 2022 payment year.

§ 422.162 Medicare Advantage Quality Rating System.

(a) *Definitions.* In this subpart the following terms have the meanings:

CAHPS refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.

Case-mix adjustment means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.

Categorical Adjustment Index (CAI) means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy, or have disability status in that contract (or plan as applicable).

Clustering refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as

dissimilar as possible to observations in any other group. Clustering of the measure-specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify the four cut points resulting in the creation of five levels (one for each Star Rating), such that scores in the same Star Rating level are as similar as possible and scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.

Consolidation means when an MA organization that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.

Consumed contract means a contract that will no longer exist after a contract year's end as a result of a consolidation.

Display page means the CMS Web site on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.

Domain rating means the rating that groups measures together by dimensions of care.

Dual-eligible (DE) means a beneficiary who is enrolled in both Medicare and Medicaid.

HEDIS is the Healthcare Effectiveness Data and Information Set which is a widely used set of performance measures in the managed care industry, developed and maintained by the National Committee for Quality Assurance (NCQA). HEDIS data include clinical measures assessing the effectiveness of care, access/availability measures, and service use measures.

Highest rating means the overall rating for MA-PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.

Highly-rated contract means a contract that has 4 or more stars for its highest rating when calculated without the improvement measures and with all

applicable adjustments (CAI and the reward factor).

HOS means the Medicare Health Outcomes Survey which is the first patient reported outcomes measure that was used in Medicare managed care. The goal of the Medicare HOS program is to gather valid, reliable, and clinically meaningful health status data in the Medicare Advantage (MA) program for use in quality improvement activities, pay for performance, program oversight, public reporting, and improving health. All managed care organizations with MA contracts must participate.

Low income subsidy (LIS) means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see § 423.34 of this chapter for definition of a low-income subsidy eligible individual).

Measurement period means the period for which data are collected for a measure or the performance period that a measure covers.

Measure score means the numeric value of the measure or an assigned 'missing data' message.

Measure star means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1–5 star scale.

Overall rating means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.

Part C summary rating means a global rating that summarizes the health plan quality and performance on Part C measures.

Part D summary rating means a global rating that summarizes prescription drug plan quality and performance on Part D measures.

Plan benefit package (PBP) means a set of benefits for a defined MA or PDP service area. The PBP is submitted by Part D plan sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.

Reliability means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality ("signal") rather than random variation ("noise"); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).

Reward factor means a rating-specific factor added to the contract's summary or overall ratings (or both) if a contract has both high and stable relative performance.

Statistical significance assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same.

Surviving contract means the contact that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.

Traditional rounding rules mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3, or 4, then the value should be rounded down by deleting the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place deleted.

(b) *Contract ratings*—(1) *General*. CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA–PD contract, and a Part C summary rating for each MA-only contract using the 5-star rating system described in this subpart. Measures are assigned stars at the contract level and weighted in accordance with § 422.166(a). Domain ratings are the unweighted mean of the individual measure ratings under the topic area in accordance with § 422.166(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with § 422.166(c). Overall Star Ratings are calculated by using the weighted mean of the individual measure ratings in accordance with § 422.166(d) with both the reward factor and CAI applied as applicable, as described in § 422.166(f).

(2) *Plan benefit packages*. All plan benefit packages (PBPs) offered under an MA contract have the same overall and/or summary Star Ratings as the contract under which the PBP is offered by the MA organization. Data from all the PBPs offered under a contract are used to calculate the measure and domain ratings for the contract except for Special Needs Plan (SNP)-specific measures collected at the PBP level. A contract level score is calculated using an enrollment-weighted mean of the PBP scores and enrollment reported as part of the measure specification in each PBP.

(3) *Contract consolidations*. (i) In the case of contract consolidations involving two or more contracts for health or drug services of the same plan type under the same parent organization, CMS assigns Star Ratings for the first and second years following

the consolidation based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) as provided in paragraph (b)(3)(iv) of this section. Paragraph (b)(3)(iii) of this section is applied to subsequent years that are not addressed in paragraph (b)(3)(ii) of this section for assigning the QBP rating.

(ii) For the first year after a consolidation, CMS will determine the QBP status of a contract using the enrollment-weighted means (using traditional rounding rules) of what would have been the QBP Ratings of the surviving and consumed contracts based on the contract enrollment in November of the year the preliminary QBP ratings were released in the Health Plan Management System (HPMS).

(iii) In subsequent years following the first year after the consolidation, CMS will determine QBP status based on the consolidated entity's Star Ratings displayed on Medicare Plan Finder.

(iv) The Star Ratings posted on Medicare Plan Finder for contracts that consolidate are as follows:

(A) For the first year after consolidation, CMS will use enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except the survey-based 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.

(B) For the second year after consolidation, CMS will use 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 the following data sources: HEDIS, CAHPS, and HOS. HEDIS and HOS measure data will be scored as reported. CMS will ensure that the CAHPS survey sample will include enrollees in the sample frame from both the surviving and consumed contracts.

(c) *Data sources*. (1) CMS bases Part C Star Ratings on the type of data specified in section 1852(e) of the Act and on CMS administrative data. Part C Star Ratings measures reflect structure, process, and outcome indices of quality. This includes information of the following types: Clinical data, beneficiary experiences, changes in physical and mental health, benefit administration information and CMS administrative data. Data underlying Star Ratings measures may include survey data, data separately collected and used in oversight of MA plans'

compliance with MA requirements and data submitted by plans.

(2) MA organizations are required to collect, analyze, and report data that permit measurement of health outcomes and other indices of quality. MA organizations must provide unbiased, accurate, and complete quality data described in paragraph (c)(1) of this section to CMS on a timely basis as requested by CMS.

§ 422.164 Adding, updating, and removing measures.

(a) *General*. CMS adds, updates, and removes measures used to calculate the Star Ratings as provided in this section. CMS lists the measures used for a particular Star Rating each year in the Technical Notes or similar guidance document with publication of the Star Ratings.

(b) *Review of data quality*. CMS reviews the quality of the data on which performance, scoring and rating of a measure is based before using the data to score and rate performance or in calculating a Star Rating. This includes review of variation in scores among MA organizations and Part D plan sponsors, and the accuracy, reliability, and validity of measures and performance data before making a final determination about inclusion of measures in each year's Star Ratings.

(c) *Adding measures*. (1) CMS will continue to review measures that are in alignment with the private sector, such as measures developed by NCQA and the Pharmacy Quality Alliance (PQA), or endorsed by the National Quality Forum for adoption and use in the Part C and Part D Quality Ratings System. CMS may develop its own measures as well when appropriate to measure and reflect performance specific to the Medicare program.

(2) In advance of the measurement period, CMS will announce potential new measures and solicit feedback through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and then subsequently will propose and finalize new measures through rulemaking.

(3) New measures added to the Part C Star Ratings program will be on the display page on www.cms.gov for a minimum of 2 years prior to becoming a Star Ratings measure.

(4) A measure will remain on the display page for longer than 2 years if CMS finds reliability or validity issues with the measure specification.

(d) *Updating measures*—(1) *Non-substantive updates*. For measures that are already used for Star Ratings, CMS will update measures so long as the

changes in a measure are not substantive. CMS will announce non-substantive updates to measures that occur (or are announced by the measure steward) during or in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Non-substantive measure specification updates include those that—

- (i) Narrow the denominator or population covered by the measure;
- (ii) Do not meaningfully impact the numerator or denominator of the measure;
- (iii) Update the clinical codes with no change in the target population or the intent of the measure;
- (iv) Provide additional clarifications:
 - (A) Adding additional tests that would meet the numerator requirements;
 - (B) Clarifying documentation requirements;
 - (C) Adding additional instructions to identify services or procedures; or
 - (v) Add alternative data sources.

(2) *Substantive updates.* For measures that are already used for Star Ratings, in the case of measure specification updates that are substantive updates not subject to paragraph (d)(1) of this section, CMS will propose and finalize these measures through rulemaking similar to the process for adding new measures. CMS will initially solicit feedback on whether to make substantive measure updates through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Once the update has been made to the measure specification by the measure steward, CMS may continue collection of performance data for the legacy measure and include it in Star Ratings until the updated measure has been on display for 2 years. CMS will place the updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings as specified in paragraph (c) of this section.

(e) *Removing measures.* (1) CMS will remove a measure from the Star Ratings program as follows:

- (i) When the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes; or
- (ii) A measure shows low statistical reliability.

(2) CMS will announce in advance of the measurement period the removal of a measure based upon its application of this paragraph through the process

described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period.

(f) *Improvement measure.* CMS will calculate improvement measure scores based on a comparison of the measure scores for the current year to the immediately preceding year as provided in this paragraph; the improvement measure score would be calculated for Parts C and D separately by taking a weighted sum of net improvement divided by the weighted sum of the number of eligible measures.

(1) *Identifying eligible measures.* Annually, the subset of measures to be included in the Part C and Part D improvement measures will be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. CMS identifies measures to be used in the improvement measures if the measures meet all of the following:

- (i) CMS will include only measures available for the current and previous year in the improvement measures and that have numeric value scores in both the current and prior year.
- (ii) CMS will exclude any measure for which there was a substantive specification change from the previous year.

(iii) CMS will exclude any measures that are already focused on improvement in MA organization performance from year to year.

(iv) The Part C improvement measure will include only Part C measure scores; the Part D improvement measure will include only Part D measure scores.

(2) *Determining eligible contracts.* CMS will calculate an improvement score only for contracts that have numeric measure scores for both years in at least half of the measures identified for use applying the standards in paragraphs (f)(1)(i) through (iv) of this section.

(3) *Special rules for calculation of the improvement score.* For any measure used for the improvement measure for which a contract received 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant change and included in the count of measures used to determine eligibility for the measure (that is, for the denominator of the improvement measure score).

(4) *Calculation of the improvement score.* The improvement measure will be calculated as follows:

(i) The improvement change score (the difference in the measure scores in the two year period) will be determined for each measure that has been designated an improvement measure and for which a contract has a numeric score for each of the 2 years examined.

(ii) Each contract's improvement change score per measure will be categorized as a significant change or not a significant change by employing a two-tailed t-test with a level of significance of 0.05.

(iii) The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.

(iv) The improvement measure score will then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.

(v) The improvement measure score will be converted to a measure-level Star Rating using hierarchical clustering algorithms.

(vi) The Part D improvement measure scores for MA-PDs and PDPs will be determined using cluster algorithms in accordance with §§ 422.166(a)(2)(ii) through (iv) and 423.186(a)(2)(ii) through (iv) of this chapter. The Part D improvement measure thresholds for MA-PDs and PDPs would be reported separately.

(g) *Data integrity.* (1) CMS will reduce a contract's measure rating when CMS determines that a contract's measure data are inaccurate, incomplete, or biased; such determinations may be based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that have an impact on the accuracy, impartiality, or completeness of the data used for one or more specific measure(s).

(i) CMS will reduce HEDIS measures to 1 star when audited data are submitted to NCQA with a designation of "biased rate" or BR based on an auditor's review of the data or a designation of "nonreport" or NR.

(ii) CMS will reduce measures based on data that an MA organization must submit to CMS under § 422.516 to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with CMS data validation

standards for data directly used to calculate the associated measure.

(iii) For the appeals measures, CMS will use statistical criteria to estimate the percentage of missing data for each contract using data from multiple sources such as a timeliness monitoring study or audit information to scale the star reductions to determine whether the data at the independent review entity (IRE) are complete. The criteria would allow CMS to use scaled reductions for the Star Ratings for the applicable appeals measures to account for the degree to which the IRE data are missing.

(A) The data submitted for the Timeliness Monitoring Project (TMP) or audit that aligns with the Star Ratings year measurement period will be used to determine the scaled reduction.

(B) The determination of the Part C appeals measure IRE data reduction is done independently of the Part D appeals measure IRE data reduction.

(C) The reductions range from a one-star reduction to a four-star reduction; the most severe reduction for the degree of missing IRE data would be a four-star reduction.

(D) The thresholds used for determining the reduction and the associated appeals measure reduction are as follows:

- (1) 20 percent, 1 star reduction.
- (2) 40 percent, 2 star reduction.
- (3) 60 percent, 3 star reduction.
- (4) 80 percent, 4 star reduction.

(E) If a contract receives a reduction due to missing Part C IRE data, the reduction is applied to both of the contract's Part C appeals measures.

(F) If a contract receives a reduction due to missing Part D IRE data, the reduction is applied to both of the contract's Part D appeals measures.

(G) The scaled reduction is applied after the calculation for the appeals measure-level Star Ratings. If the application of the scaled reduction results in a measure-level star rating less than 1 star, the contract will be assigned 1 star for the appeals measure.

(H) The Part C Calculated Error is determined using the quotient of number of cases not forwarded to the IRE and the total number of cases that should have been forwarded to the IRE. (The number of cases that should have been forwarded to the IRE is the sum of the number of cases in the IRE during the data collection or data sample period and the number of cases not forwarded to the IRE during the same period.)

(I) The Part D Calculated Error is determined by the quotient of the number of untimely cases not auto-

forwarded to the IRE and the total number of untimely cases.

(J) The projected number of cases not forwarded to the IRE in a 3-month period is calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or audit data by a constant determined by the data collection or data sample time period. The value of the constant will be 1.0 for contracts that submitted 3 months of data; 1.5 for contracts that submitted 2 months of data; and 3.0 for contracts that submitted 1 month of data.

(K) Contracts would be subject to a possible reduction due to lack of IRE data completeness if both of the following conditions are met:

(1) The calculated error rate is 20 percent or more.

(2) The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.

(L) A confidence interval estimate for the true error rate for the contract is calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent and an associated z of 1.959964 for a contract that is subject to a possible reduction.

(M) A contract's lower bound is compared to the thresholds of the scaled reductions to determine the IRE data completeness reduction.

(N) The reduction is identified by the highest threshold that a contract's lower bound exceeds.

(2) CMS will reduce a measure rating to 1 star for additional concerns that data inaccuracy, incompleteness, or bias have an impact on measure scores and are not specified in paragraphs (g)(1)(i) through (iii) of this section, including a contract's failure to adhere to HEDIS, HOS, or CAHPS reporting requirements.

§ 422.166 Calculation of Star Ratings.

(a) *Measure Star Ratings*—(1) *Cut points*. CMS will determine cut points for the assignment of a Star Rating for each numeric measure score by applying either a clustering or a relative distribution and significance testing methodology. For the Part D measures, CMS will determine MA-PD and PDP cut points separately.

(2) *Clustering algorithm for all measures except CAHPS measures*. (i) The method minimizes differences within star categories and maximizes differences across star categories using the hierarchical clustering method.

(ii) In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters.

(iii) The clustering algorithm for the improvement measure scores is done in two steps to determine the cut points for the measure-level Star Ratings. Clustering is conducted separately for improvement measure scores greater than or equal to zero and those with improvement measure scores less than zero.

(A) Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating.

(B) Improvement scores less than zero would be assigned either 1 or 2 stars for the improvement Star Rating.

(3) *Relative distribution and significance testing for CAHPS measures*. The method combines evaluating the relative percentile distribution with significance testing and accounts for the reliability of scores produced from survey data; no measure Star Rating is produced if the reliability of a CAHPS measure is less than 0.60.

Low reliability scores are defined as those with at least 11 respondents and reliability greater than or equal to 0.60 but less than 0.75 and also in the lowest 12 percent of contracts ordered by reliability. The following rules apply:

(i) A contract is assigned 1 star if both of the following criteria in paragraphs (a)(3)(i)(A) and (B) of this section are met and the criterion in paragraph (a)(3)(i)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is lower than the 15th percentile; and

(B) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score;

(C) The reliability is not low; or

(D) Its average CAHPS measure score is more than one standard error below the 15th percentile.

(ii) A contract is assigned 2 stars if it does not meet the 1 star criteria and meets at least one of the following criteria:

(A) Its average CAHPS measure score is lower than the 30th percentile and the measure does not have low reliability; or

(B) Criterion (b) its average CAHPS measure score is lower than the 15th percentile and the measure has low reliability; or

(C) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score and below the 60th percentile.

(iii) A contract is assigned 3 stars if it meets at least one of the following criteria:

(A) Its average CAHPS measure score is at or above the 30th percentile and lower than the 60th percentile, and it is not statistically significantly different

from the national average CAHPS measure score; or

(B)(1) Its average CAHPS measure score is at or above the 15th percentile and lower than the 30th percentile;

(2) The reliability is low; and

(3) The score is not statistically significantly lower than the national average CAHPS measure score.

(C)(1) Its average CAHPS measure score is at or above the 60th percentile and lower than the 80th percentile;

(2) The reliability is low; and

(3) The score is not statistically significantly higher than the national average CAHPS measure score.

(iv) A contract is assigned 4 stars if it does not meet the 5-star criteria and meets at least one of the following criteria:

(A) Its average CAHPS measure score is at or above the 60th percentile and the measure does not have low reliability.

(B) Its average CAHPS measure score is at or above the 80th percentile and the measure has low reliability.

(C) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score and above the 30th percentile.

(v) A contract is assigned five stars if both of the following criteria in paragraphs (a)(3)(v)(A) and (B) of this section are met and the criterion in paragraph (a)(3)(v)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is at or above the 80th percentile.

(B) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score.

(C) The reliability is not low.

(D) Its average CAHPS measure score is more than one standard error above the 80th percentile.

(4) Measure scores are converted to a 5-star scale ranging from 1 (worst rating) to 5 (best rating), with whole star increments for the cut points.

(b) *Domain Star Ratings.* (1)(i) CMS groups measures by domains solely for purposes of public reporting the data on Medicare Plan Finder. They are not used in the calculation of the summary or overall ratings. Domains are used to group measures by dimensions of care that together represent a unique and important aspect of quality and performance.

(ii) The 5 domains for the MA Star Ratings are: Staying Healthy; Screenings, Tests and Vaccines; Managing Chronic (Long Term) Conditions; Member Experience with Health Plan; Member Complaints and Changes in the Health Plan's Performance; and Health Plan Customer

Service. The 4 domains for the Part D Star Ratings are: Drug Plan Customer Service; Member Complaints and Changes in the Drug Plan's Performance; Member Experience with the Drug Plan; and Drug Safety and Accuracy of Drug Pricing.

(2) CMS calculates the domain ratings as the unweighted mean of the Star Ratings of the included measures.

(i) A contract must have scores for at least 50 percent of the measures required to be reported for that contract type for that domain to have a domain rating calculated.

(ii) The domain ratings are on a 1- to 5- star scale ranging from 1 (worst rating) to 5 (best rating) in whole star increments using traditional rounding rules.

(c) *Part C summary ratings.* (1) CMS will calculate the Part C summary ratings using the weighted mean of the measure-level Star Ratings for Part C, weighted in accordance with paragraph (e) of this section with an adjustment to reward consistently high performance and the application of the CAI under paragraph (f) of this section.

(2)(i) A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have the summary rating calculated.

(ii) The Part C improvement measure is not included in the count of the minimum number of rated measures.

(3) The summary ratings are on a 1- to 5- star scale ranging from 1 (worst rating) to 5 (best rating) in half-star increments using traditional rounding rules.

(d) *Overall MA-PD rating.* (1) The overall rating for a MA-PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with an adjustment to reward consistently high performance and the application of the CAI, under paragraph (f) of this section.

(2)(i) An MA-PD must have both Part C and Part D summary ratings and scores for at least 50 percent of the measures required to be reported for the contract type to have the overall rating calculated.

(ii) The Part C and D improvement measures are not included in the count of measures needed for the overall rating.

(iii) Any measures that share the same data and are included in both the Part C and Part D summary ratings will be included only once in the calculation for the overall rating.

(iv) The overall rating is on a 1- to 5- star scale ranging from 1 (worst rating)

to 5 (best rating) in half-increments using traditional rounding rules.

(v) Low enrollment contracts (as defined in § 422.252) and new MA plans (as defined in § 422.252) do not receive an overall and/or summary rating. They are treated as qualifying plans for the purposes of QBPs as described in § 422.258(d)(7) and as announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853 (b) of the Act.

(e) *Measure weights*—(1) *General rules.* Subject to paragraphs (e)(2) and (3) of this section, CMS will assign weights to measures based on their categorization as follows.

(i) Improvement measures receive the highest weight of 5.

(ii) Outcome and Intermediate outcome measures receive a weight of 3.

(iii) Patient experience and complaint measures receive a weight of 1.5.

(iv) Access measures receive a weight of 1.5.

(v) Process measures receive a weight of 1.

(2) *Rules for new measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. In subsequent years, the measure will be assigned the weight associated with its category.

(3) *Special rule for Puerto Rico.* Contracts that have service areas that are wholly located in Puerto Rico will receive a weight of zero for the Part D adherence measures for the summary and overall rating calculations and will have a weight of 3 for the adherence measures for the improvement measure calculations.

(f) *Completing the Part C summary and overall rating calculations.* CMS will adjust the summary and overall rating calculations to take into account the reward factor (if applicable) and the categorical adjustment index (CAI) as provided in this paragraph.

(1) *Reward factor.* This rating-specific factor is added to the both the summary and overall ratings of contracts that qualify for the reward factor based on both high and stable relative performance for the rating level.

(i) The contract's performance will be assessed using its weighted mean and its ranking relative to all rated contracts in the rating level (overall for MA-PDs; Part C summary for MA-PDs and MA-only; and Part D summary for MA-PDs and PDPs) for the same Star Ratings year. The contract's stability of performance will be assessed using the weighted variance and its ranking relative to all rated contracts in the rating type (overall for MA-PDs; Part C

summary for MA-PDs and MA-only; and Part D summary for MA-PDs and PDPs). The weighted mean and weighted variance are compared separately for MA-PD and standalone Part D contracts. The measure weights are specified in § 422.166(e). Since highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean are calculated both with and without the improvement measures. For an MA-PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance and weighted mean for the rating type (Part C summary, Part D summary) with the improvement measure.

(ii) Relative performance of the weighted variance (or weighted variance ranking) will be categorized as being high (at or above 70th percentile), medium (between the 30th and 69th percentile) or low (below the 30th percentile). Relative performance of the weighted mean (or weighted mean ranking) will be categorized as being high (at or above the 85th percentile), relatively high (between the 65th and 84th percentiles), or other (below the 65th percentile).

(iii) The combination of the relative variance and relative mean is used to determine the value of the reward factor to be added to the contract's summary and overall ratings as follows:

(A) A contract with low variance and a high mean will have a reward factor equal to 0.4.

(B) A contract with medium variance and a high mean will have a reward factor equal to 0.3.

(C) A contract with low variance and a relatively high mean will have a reward factor equal to 0.2.

(D) A contract with medium variance and a relatively high mean will have a reward factor equal to 0.1.

(E) A contract with all other combinations of variance and relative mean will have a reward factor equal to 0.0.

(iv) The reward factor is determined and applied before application of the CAI adjustment under paragraph (f)(2) of this section; the reward factor is based on unadjusted scores.

(2) *Categorical Adjustment Index.* CMS applies the categorical adjustment index (CAI) as provided in this paragraph to adjust for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy or are dual eligible (LIS/DE) or have disability status. The factor is calculated as the

mean difference in the adjusted and unadjusted ratings (overall, Part C, Part D for MA-PDs, Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type.

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment (if applicable).

(A) The adjustment factor is monotonic (that is, as the proportion of LIS/DE and disabled increases in a contract, the adjustment factor increases in at least one of the dimensions) and varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and disabled beneficiaries.

(B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year. The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year. A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period. Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

(C) MA-PD contracts may have up to three rating-specific CAI adjustments: One for the overall Star Rating and one for each of the summary ratings (Part C and Part D).

(D) An MA-only contract may be adjusted only once for the CAI for the Part C summary rating.

(E) The CAI values are rounded and displayed with 6 decimal places.

(ii) In determining the CAI values, a measure will be excluded as a candidate for inclusion for adjustment if the measure meets any of the following:

(A) The measure is already case-mix adjusted for socioeconomic status.

(B) The focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue.

(C) The measure is scheduled to be retired or revised.

(D) The measure is applicable only to SNPs.

(iii) CMS will announce the measures identified for inclusion in the calculations of the CAI under this paragraph through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. The measures for

inclusion in the calculations of the CAI values will be selected based on the analysis of the dispersion of the LIS/DE within-contract differences using all reportable numeric scores for contracts receiving a rating in the previous rating year. CMS calculates the results of each contract's estimated difference between the LIS/DE and non-LIS/DE performance rates per contract using logistic mixed effects models that includes LIS/DE as a predictor, random effects for contract and an interaction term of contract. For each contract, the proportion of beneficiaries receiving the measured clinical process or outcome for LIS/DE and non-LIS/DE beneficiaries would be estimated separately. The following decision criteria is used to determine the measures for adjustment:

(A) A median absolute difference between LIS/DE and non-LIS/DE beneficiaries for all contracts analyzed is 5 percentage points or more.

(B) The LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts.

(C) The Part D measures for MA-PDs and PDPs will be analyzed independently, but the Part D measures selected for adjustment will include measures that meet the selection criteria for either delivery system.

(iv) The adjusted measures score for the selected measures are determined using the results from regression models of beneficiary-level measure scores that adjust for the average within-contract difference in measure scores for MA or PDP contracts.

(A) A logistic regression model with contract fixed effects and beneficiary-level indicators of LIS/DE and disability status is used for the adjustment.

(B) The adjusted measure scores are converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.

(v) The rating-specific CAI values will be determined using the mean differences between the adjusted and unadjusted Star Ratings (overall, Part C summary, Part D summary for MA-PDs and Part D summary for PDPs) in each final adjustment category.

(A) For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled using the enrollment data that parallels the previous Star Ratings year's data would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled).

(B) The initial categories are created using all groups formed by the initial LIS/DE and disabled groups.

(C) The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled).

(D) The mean difference within each final adjustment category by rating-type (Part C, Part D for MA-PD, Part D for PDPs or overall) would be the CAI values for the next Star Ratings year.

(vi) CMS develops the model for the modified contract-level LIS/DE percentage for Puerto Rico using the following sources of information:

(A) The most recent data available at the time of the development of the model of both 1-year American Community Survey (ACS) estimates for the percentage of people living below the Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL. The data to develop the model will be limited to the 10 states, drawn from the 50 states plus the District of Columbia with the highest proportion of people living below the FPL, as identified by the 1-year ACS estimates.

(B) The Medicare enrollment data from the same measurement period as the Star Ratings' year. The Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries with mailing addresses in the 10 highest poverty states.

(vii) A linear regression model is developed to estimate the percentage of LIS/DE for a contacts that solely serve the population of beneficiaries in Puerto Rico.

(A) The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent.

(B) All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.

(C) The model's coefficient and intercept are updated annually and published in the Technical Notes.

(g) *Applying the improvement measure scores.* (1) CMS runs the calculations twice for each highest level rating for each contract-type (overall rating for MA-PD contracts and Part C summary rating for MA-only contracts), with all applicable adjustments (CAI and the reward factor), once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to

include the improvement measures in a contract's final highest rating, CMS applies the following rules:

(i) Contracts with 2 or fewer stars for their highest rating when calculated without improvement and with all applicable adjustments (CAI and the reward factor) will not have their rating calculated with the improvement measure(s).

(ii) If the highest rating for each contract-type is 4 stars or more without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(iii) If the highest rating is between 2 stars and 4 stars with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).

(2) The Part C summary rating for MA-PDs will include the Part C improvement measure and the Part D summary rating for MA-PDs will include the Part D improvement measure.

(h) *Posting and display of ratings.* For all ratings at the measure, domain, summary and overall level, posting and display of the ratings is based on there being sufficient data to calculate and assign ratings. If a contract does not have sufficient data to calculate a rating, the posting and display would be the flag "Not enough data available." If the measurement period is prior to one year past the contract's effective date, the posting and display would be the flag "Plan too new to be measured".

(1) Medicare Plan Finder Performance icons. Icons are displayed on Medicare Plan Finder to note performance as provided in this paragraph (h):

(i) *High-performing icon.* The high performing icon is assigned to an MA-only contract for achieving a 5-star Part C summary rating and an MA-PD contract for a 5-star overall rating.

(ii) *Low-performing icon.* (A) A contract receives a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon is calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years. If the contract had any combination of Part C or Part D summary ratings of 2.5 or lower in all 3 years of data, it is marked with a low performing icon. A contract must have a rating in either Part C or Part D for all 3 years to be considered for this icon.

(B) CMS may disable the Medicare Plan Finder online enrollment function (in Medicare Plan Finder) for Medicare

health and prescription drug plans with the low performing icon; beneficiaries will be directed to contact the plan directly to enroll in the low-performing plan.

(2) *Plan preview of the Star Ratings.* CMS will have plan preview periods before each Star Ratings release during which MA organizations can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder.

■ 21. Section 422.204 is amended by removing paragraph (b)(5) and adding paragraph (c).

The addition reads as follows:

§ 422.204 Provider selection and credentialing.

* * * * *

(c) An MA organization must follow a documented process that ensures compliance with the preclusion list provisions in § 422.222.

■ 22. Amend § 422.206 by revising paragraph (b)(2)(i) to read as follows:

§ 422.206 Interference with health care professionals' advice to enrollees prohibited.

(b) * * *

(2) * * *

(i) To CMS, with its application for a Medicare contract, within 10 days of submitting its bid proposal or, for policy changes, in accordance with all applicable requirements under subpart V of this part.

* * * * *

■ 23. Section 422.208 is amended by revising paragraph (f)(2)(iii) and adding paragraphs (f)(2)(iv) through (vii) and (f)(3) to read as follows:

§ 422.208 Physician incentive plans: requirements and limitations.

* * * * *

(f) * * *

(2) * * *

(iii)(A) Stop-loss protection must cover 90 percent of costs above the deductible or an actuarial equivalent amount of the costs of referral services that exceed the per-patient deductible limit. The single combined deductible, for policies that pay 90 percent of costs above the deductible or an actuarial equivalent amount, for stop-loss insurance for the various panel sizes for contract years beginning on or after January 1, 2019 is determined using the table published by CMS that is developed using the methodology in paragraph (f)(2)(iv) of this section. For panel sizes not shown in the table, use linear interpolation between the table values.

(B) To apply this table, a physician or physician group may use linear interpolation to compute the deductible

for the globally capitated patients (DGCP) as well as the deductible for globally capitated patients plus NPEs (DGCPNPE). The deductible for the stop-loss insurance required to be provided for the physician or physician group is then based on the lesser of DGCP+100,000 and DGCPNPE.

(iv) The table referenced in paragraph (f)(2)(iii) of this section will be created, updated, and published by CMS in guidance (such as an attachment to the Rate Announcement issued under section 1853(b) of the Act), as necessary, using the following methodology:

(A) The table and the methodology in this paragraph (f)(2)(iv) only address capitation arrangements in the PIP and that other stop-loss insurance needs to be used for non-capitated arrangements.

(B) If it is not a global capitation arrangement or is a different stop/loss arrangement, the tables developed using this methodology do not apply. The table is calculated using the following methodology and assumptions:

(1) CMS used the population of all Fee For Service (FFS) Part A and Part B claims for the most available recent year and assumed a multi-specialty practice since all physician claims were allowed.

(2) CMS's estimate of medical group income was derived from CMS claims files, which include payments for all Part A and Part B services.

(3) The central limit theorem was used to obtain the distribution of claim means for a multi-specialty group of any given panel size.

(4) The distribution was used to obtain, with 98 percent confidence, the point at which a multi-specialty group of a given panel size would, through referral services, lose more than 25 percent of the net income derived from services that the physicians personally rendered.

(i) This point is set as the deductible in the table described in paragraph (f)(2)(iii) of this section.

(ii) The 'net benefit premium' (NBP) column in that table is not used for computation of combined insurance but is used to determine the separate deductibles for physician/professional services and institutional services.

(iii) The NBP is computed by dividing the total amount of stop loss claims (90 percent of claims above the deductible) for that panel size by the panel size.

(v)(A) Insurance using separate deductibles for professional and institutional claims is permissible for contract years beginning on or after January 1, 2019 so long as the separate deductibles for institutional services and professional services are consistent with the table published by CMS using the methodology and assumptions in

paragraphs (f)(2)(vi) and (vii) of this section. For deductible amounts not shown in the table use linear interpolation between the table values. The tables and methodology in paragraph (f)(2)(iv) of this section only address capitation arrangements in the PIP and that other stop-loss insurance needs to be used for non-capitated arrangements. If it is not a global capitation arrangement or a different stop/loss arrangement, these tables do not apply.

(B) The maximum deductibles for each category of services (institutional and professional claims) are identified by using the net benefit premium (NBP) for the patient panel size from the table described in paragraph (f)(2)(iii) of this section. If the NBP is identified using interpolation from the values in the table described in paragraph (f)(2)(iii) of this section, interpolation is also used from the NBP values in the table described in paragraph (f)(2)(v)(A) of this section that are closest to the NBP identified by using the table described in paragraph (f)(2)(iii) of this section. TAs with combined stop-loss insurance, panel size may include non-risk patients. As with combined stop-loss insurance, the deductible for separate insurance that must be provided for the physician or physician group is the lesser of DGCP+100,000 and DGCPNPE.

(vi) The table described in (f)(2)(v) of this section is calculated using a methodology similar to the calculation of the table described in paragraph (f)(2)(iii) of this section.

(A) The population of all Part A and Part B claims was obtained.

(B) The source for our estimate of medical group income and institutional income is derived from CMS claims files which includes payments for all Part A and Part B services.

(C) The central limit theorem is used to obtain the distribution of claim means and deductibles are obtained at the 98 percent confidence level.

(vii) In determining the number of global risk patients for the types of services covered under Parts A and B of Medicare, commercial and Medicaid patients who are at global risk and in the same stop-loss risk pool may be included.

(A) The number of non-risk patient equivalents (NPEs) is equal to the projected annual aggregate payments to the physician or physician group for non-global risk patients, divided by an estimate of the average capitation per member per year (PMPY) for all non-global risk patients, whether or not they are capitated. Both numerator and denominator are for physician services

that are rendered by the physician or physician group.

(B) The lowest deductible shown in the tables described in paragraphs (f)(2)(iii) and (v) of this section would generally not be available for sale from an insurance company. The number of risk patients and the net premiums are shown for the case where the MA plan might directly insure a contracted physician or physician group with protection at these lower deductibles.

(3) *Special insurance.* If there is a different type of stop-loss policy obtained by the physician group, it must be actuarially equivalent to the coverage shown in the tables described in paragraphs (f)(2)(iii) and (v) of this section. Actuarially equivalent deductibles are acceptable if the insurance is actuarially certified by an attesting actuary who fulfills all of the following requirements.

(i) Develops the deductibles to be actuarially equivalent to those coverages in the tables.

(ii) Makes the computations in accordance with generally accepted actuarial principles and practices.

(iii) Is certified as meeting the requirements in paragraphs (f)(3)(i) and (ii) of this section by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

* * * * *

■ 24. Section 422.222 is revised to read as follows:

§ 422.222 Preclusion list.

(a)(1) An MA organization must not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in § 422.2.

(2) CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion and inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in § 422.2, in accordance with part 498 of this chapter.

(b) An MA organization that does not comply with paragraph (a) of this section may be subject to sanctions under § 422.750 and termination under § 422.510.

■ 25. Section 422.224 is revised to read as follows:

§ 422.224 Payment to individuals and entities excluded by the OIG or included on the preclusion list.

(a) An MA organization may not pay, directly or indirectly, on any basis, for

items or services (other than emergency or urgently needed services as defined in § 422.113 of this chapter) furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2.

(b) If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or an individual or entity that is included on the preclusion list, defined in § 422.2, the MA organization must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.

§ 422.254 [Amended]

■ 26. Section 422.254 is amended by removing paragraph (a)(4) and redesignating paragraph (a)(5) as paragraph (a)(4).

§ 422.256 [Amended]

■ 27. Section 422.256 is amended by removing paragraph (b)(4).

§ 422.258 [Amended]

■ 28. Section 422.258 is amended in paragraph (d)(7) introductory text by removing the phrase “section 1852(e) of the Act)” and adding in its place the phrase “section 1852(e) of the Act) specified in subpart 166 of this part 422”.

■ 29. Section 422.260 is amended by revising paragraph (a) and revising the definition of “Quality bonus payment (QBP) determination methodology” in paragraph (b) to read as follows:

§ 422.260 Appeals of quality bonus payment determinations.

(a) Scope. The provisions of this section pertain to the administrative review process to appeal quality bonus payment status determinations based on section 1853(o) of the Act. Such determinations are made based on the overall rating for MA-PDs and Part C summary rating for MA-only contracts for the contract assigned under subpart D of this part

(b) Quality bonus payment (QBP) determination methodology means the quality ratings system specified in subpart 166 of this part 422 for assigning quality ratings to provide comparative information about MA plans and evaluating whether MA organizations qualify for a QBP. (Low

enrollment contracts and new MA plans are defined in § 422.252.)

■ 30. Section 422.310 by adding paragraph (d)(5) to read as follows:

§ 422.310 Risk adjustment data.

(d) For data described in paragraph (d)(1) of this section as data equivalent to Medicare fee-for-service data, which is also known as MA encounter data, MA organizations must submit a NPI in a billing provider field on each MA encounter data record, per CMS guidance.

■ 31. Section 422.501 is amended by revising paragraphs (c)(1)(iv) and (2) to read as follows:

§ 422.501 Application requirements.

(iv) Documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.

§ 422.502 [Amended]

■ 32. Section 422.502 is amended in paragraphs (b)(1) and (2) by removing the phrase “14 months” and adding in its place “12 months” each time it appears.

■ 33. Section 422.503 is amended— a. In paragraph (b)(4)(ii), by removing the phrase “financial and marketing activities” and adding in its place “financial and communication activities”; and

b. Revising paragraph (b)(4)(vi)(C). The revision reads as follows:

§ 422.503 General provisions.

(C)(1) Each MA organization must establish and implement effective training and education for its compliance officer and organization employees, the MA organization’s chief executive and other senior administrators, managers and governing body members.

(2) Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee and new appointment to a chief executive, manager, or governing body member.

■ 34. Section 422.504 is amended by—

- a. Revising paragraphs (a) introductory text and (a)(6).
b. Removing paragraph (a)(16).
c. Redesignating paragraphs (a)(17) and (18) as paragraphs (a)(16) and (17), respectively; and
d. Revising newly redesignated paragraph (a)(17).
e. Revising paragraph (i)(2)(v).

The revisions read as follows:

§ 422.504 Contract provisions.

(a) Agreement to comply with regulations and instructions. The MA organization agrees to comply with all the applicable requirements and conditions set forth in this part and in general instructions. Compliance with the terms of this paragraph is material to the performance of the MA contract. The MA organization agrees—

(6) To comply with all applicable provider and supplier requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, limits on physician incentive plans, and the preclusion list requirements in §§ 422.222 and 422.224.

(17) To maintain a Part C summary plan rating score of at least 3 stars under the 5-star rating system specified in part 422 subpart D. A Part C summary plan rating is calculated as provided in § 422.166.

(i) They will ensure that payments are not made to individuals and entities included on the preclusion list, defined in § 422.2.

§ 422.506 [Amended]

- 35. Section 422.506 is amended by—
a. Removing paragraph (a)(3);
b. Redesignating paragraphs (a)(4) and (5) as paragraphs (a)(3) and (4); and
c. Removing and reserving paragraph (b).

■ 36. Section 422.508 is amended by adding paragraph (a)(3) to read as follows:

§ 422.508 Modification or termination of contract by mutual consent.

(a) * * *

(3) If the organization submits a request to end the term of its contract after the deadline provided in § 422.506(a)(2)(i), the contract may be terminated by mutual consent in accordance with paragraphs (a) through (d) of this section. CMS may mutually consent to the contract termination if the contract termination does not negatively affect the administration of the Medicare program.

* * * * *

■ 37. Section 422.510 is amended by revising paragraphs (a)(4)(viii) and (xiii) and adding paragraphs (a)(4)(xiv) and (xv) and (b)(2)(v) to read as follows:

§ 422.510 Termination of contract by CMS.

(a) * * *

(4) * * *

(viii) Substantially fails to comply with the requirements in subpart V of this part.

* * * * *

(xiii) Fails to meet the preclusion list requirements in accordance with § 422.222 and 422.224.

(xiv) The MA organization has committed any of the acts in § 422.752(a) that support the imposition of intermediate sanctions or civil money penalties under Subpart O of this part.

(xv) Following the issuance of a notice to the MA organization no later than August 1, CMS must terminate, effective December 31 of the same year, an individual MA plan if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(b) * * *

(2) * * *

(v) In the event that CMS issues a termination notice to an MA organization on or before August 1 with an effective date of the following December 31, the MA organization must issue notification to its Medicare enrollees at least 90 days before to the effective date of the termination.

* * * * *

■ 38. Section 422.514 is amended by revising paragraph (b) to read as follows:

§ 422.514 Minimum enrollment requirements.

* * * * *

(b) *Minimum enrollment waiver.* For a contract applicant that does not meet the applicable requirement of paragraph (a) of this section at application for an MA contract, CMS may waive the

minimum enrollment requirement for the first 3 years of the contract. To receive a waiver, a contract applicant must demonstrate to CMS's satisfaction that it is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract during the first 3 years of the contract. Factors that CMS takes into consideration in making this evaluation include the extent to which—

(1)(i) The contract applicant management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section; or

(ii) The contract applicant has the financial ability to bear financial risk under an MA contract. In determining whether an organization is capable of bearing risk, CMS considers factors such as the organization's management experience as described in this paragraph (b)(1) and stop-loss insurance that is adequate and acceptable to CMS; and

(2) The contract applicant is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

* * * * *

§ 422.590 [Amended]

■ 39. Section 422.590 is amended by removing paragraph (f) and redesignating paragraphs (g) and (h) as paragraphs (f) and (g), respectively.

§ 422.664 [Amended]

■ 40. Section 422.664 is amended in paragraph (b)(1) by removing the phrase "July 15" and adding in its place "September 1".

■ 41. Section 422.750 is amended by revising paragraph (a)(3) to read as follows:

§ 422.750 Types of intermediate sanctions and civil money penalties.

(a) * * *

(3) Suspension of communication activities to Medicare beneficiaries by an MA organization, as defined by CMS.

* * * * *

■ 42. Section 422.752 is amended by revising paragraphs (a)(11) and (13) and (b) to read as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) * * *

(11) Fails to comply with communication restrictions described in

subpart V of this part or applicable implementing guidance.

* * * * *

(13) Fails to comply with §§ 422.222 and 422.224, that requires the MA organization not to make payment to excluded individuals and entities, nor to individuals and entities on the preclusion list, defined in § 422.2.

(b) *Suspension of enrollment and communications.* If CMS makes a determination that could lead to a contract termination under § 422.510(a), CMS may impose the intermediate sanctions at § 422.750(a)(1) and (3).

* * * * *

Subpart V—Medicare Advantage Communication Requirements

■ 43. The subpart heading for Subpart V is revised to read as set forth above.

■ 44. Section 422.2260 is revised to read as follows:

§ 422.2260 Definitions.

For the purposes of this section—
Communications means activities and use of materials to provide information to current and prospective enrollees.

Communication materials means all information provided to current and prospective enrollees. Marketing materials are a subset of communication material.

Marketing means the use of materials or activities that meet the following:

(1) By the MA organization or downstream entities.

(2) Intended to draw a beneficiary's attention to a MA plan or plans.

(3) Influence a beneficiary's decision-making process when making a MA plan selection or influence a beneficiary's decision to stay enrolled in a plan (that is, retention-based marketing).

Marketing materials include, but are not limited to the following:

(1) Materials such as brochures; posters; advertisements in media such as newspapers, magazines, television, radio, billboards, or the Internet; and social media content.

(2) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(3) Presentation materials such as slides and charts.

Marketing materials exclude materials that—

(1) Do not include information about the plan's benefit structure or cost sharing;

(2) Do not include information about measuring or ranking standards (for example, star ratings);

(3) Mention benefits or cost sharing, but do not meet the definition of marketing in this section; or

(4) Unless otherwise specified by CMS because of their use or purpose, are required under § 422.111.

■ 45. Section 422.2262 is amended by revising paragraph (d) to read as follows:

§ 422.2262 Review and distribution of marketing materials.

* * * * *

(d) Enrollee communication materials. Enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may no longer be used.

■ 46. Section 422.2264 is revised to read as follows:

§ 422.2264 Guidelines for CMS review.

In reviewing marketing material or election forms under § 422.2262, CMS determines that the materials—

(a) Provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling:

(1) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(2) Adequate written description of any supplemental benefits and services.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area and if applicable, continuation areas.

(c) Include in written materials notice that the MA organization is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the plan.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

■ 47. Section 422.2268 is amended by:
■ a. Removing the introductory text; and
■ b. Revising paragraphs (a) and (b).

The revisions read as follows:

§ 422.2268 Standards for MA organization communications and marketing.

(a) In conducting communication activities, MA organizations may not do any of the following:

(1) Provide information that is inaccurate or misleading.

(2) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the MA organization.

(3) Claim the MA organization is recommended or endorsed by CMS or Medicare or that CMS or Medicare recommends that the beneficiary enroll in the MA plan. It may explain that the organization is approved for participation in Medicare.

(4) Employ MA plan names that suggest that a plan is not available to all Medicare beneficiaries. This prohibition must not apply to MA plan names in effect on July 31, 2000.

(5) Display the names and/or logos of co-branded network providers on the organization's member identification card, unless the provider names, and/or logos are related to the member selection of specific provider organizations (for example, physicians, hospitals).

(6) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.

(7) For markets with a significant non-English speaking population, provide materials, as defined by CMS, unless in the language of these individuals. Specifically, MA organizations must translate 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.

(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 (as defined in the CMS Marketing Guidelines) value, 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) Market non-health care related products to prospective enrollees during any MA or Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(4) 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.

(5) 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.

(6) Distribute marketing materials for which, before expiration of the 45-day period, the MA organization receives from CMS written notice of disapproval because it is inaccurate or misleading,

or misrepresents the MA organization, its marketing representatives, or CMS.

(7) Conduct sales presentations or distribute and accept MA plan enrollment forms in provider offices or other areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.

(8) Conduct sales presentations or distribute and accept plan applications at educational events.

(9) Display the names and/or logos of provider co-branding partners on marketing materials, unless the materials clearly indicate that other providers are available in the network.

(10) Knowingly target or send marketing materials to any MA enrollee during the Open Enrollment Period.

(11) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(12) 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.

(13) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(14) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the providers, provider groups, or pharmacies accept and display materials from all health plans with which the providers, provider groups, or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidance.

(15) Provide meals to potential enrollees, which is prohibited, regardless of value.

* * * * *

§ 422.2272 [Amended]

■ 48. Section § 422.2272 is amended by removing paragraph (e).

§ 422.2274 [Amended]

■ 49. Section 422.2274 is amended by—
■ a. Redesignating paragraph (b)(1)(iii) as paragraph (b)(1)(iv).
■ b. Redesignating paragraph (b)(2)(iii) as paragraph (b)(1)(iii).
■ c. Removing paragraph (b)(2); and
■ d. Redesignating paragraph (b)(3) as paragraph (b)(2).

§ 422.2410 [Amended]

■ 50. Section 422.2410 is amended in paragraph (a) by removing the phrase

“an MLR” and adding in its place the phrase “the information required under § 422.2460”.

§ 422.2420 [Amended]

- 51. Section 422.2420 is amended—
- a. By removing and reserving paragraph (b)(2)(ix); and
- b. In paragraph (d)(2)(i), removing the phrase “in § 422.2420(b) or (c)” and adding in its place the phrase “in paragraph (b) or (c) of this section”.
- 52. Section 422.2430 is amended by—
- a. Redesignating paragraph (a) introductory text and paragraphs (a)(1) and (2) as paragraphs (a)(1), (2), and (3), respectively;
- b. Adding a paragraph (a) subject heading and revising newly redesignated paragraph (a)(1);
- c. Adding paragraph (a)(4); and
- d. Removing and reserving paragraph (b)(8).

The revision and addition read as follows:

§ 422.2430 Activities that improve health care quality.

- (a) *Activity requirements.* (1) Activities conducted by an MA organization to improve quality must either—
- (i) Fall into one of the categories in paragraph (a)(2) of this section and meet all of the requirements in paragraph (a)(3) of this section; or
- (ii) Be listed in paragraph (a)(4).

* * * * *

(4)(i) For an MA contract that includes MA–PD plans (described in § 422.2420(a)(2)), Medication Therapy Management Programs meeting the requirements of § 423.153(d) of this chapter.

(ii) Fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery.

* * * * *

- 53. Section 422.2460 is revised to read as follows:

§ 422.2460 Reporting requirements.

(a) For each contract year, from 2014 through 2017, each MA organization must submit to CMS, in a timeframe and manner specified by CMS, a report that includes but is not limited to the data needed by the MA organization to calculate and verify the MLR and remittance amount, if any, for each contract, under this part, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 422.2410.

(b) For contract year 2018 and for each subsequent contract year, each MA

organization must submit to CMS, in a timeframe and manner specified by CMS, the following information:

(1) *Fully credible and partially credible contracts.* For each contract under this part that has fully credible or partially credible experience, as determined in accordance with § 422.2440(d), the MA organization must report to CMS the MLR for the contract and the amount of any remittance owed to CMS under § 422.2410.

(2) *Non-credible contracts.* For each contract under this part that has non-credible experience, as determined in accordance with § 422.2440(d), the MA organization must report to CMS that the contract is non-credible.

(c) Total revenue included as part of the MLR calculation must be net of all projected reconciliations.

(d) The MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

§ 422.2480 [Amended]

- 54. Section 422.2480 is amended—
- a. In the introductory text by removing the phrase “reviews of reports submitted” and adding in its place “review of data submitted”.
- b. In paragraph (d) introductory text by removing the phrase “Reports submitted” and adding in its place the phrase “Data submitted”.

§ 422.2490 [Amended]

- 55. Section 422.2490 is amended in paragraph (a) by removing the phrase “information contained in reports submitted” and adding in its place the phrase “information submitted”.

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

- 56. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh).

- 57. Amend § 423.4 by revising the definition of “Generic drug” to read as follows:

§ 423.4 Definitions.

* * * * *

Generic drug means—

(1) A drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is approved; and

(2) For purposes of cost sharing under sections 1860D–2(b)(4) and 1860D–14(a)(1)(D) of the Act only, a biological product for which an application under

section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved.

* * * * *

- 58. Amend § 423.32 by revising paragraph (b) introductory text and redesignating paragraphs (b)(i) and (ii) as (b)(1) and (2).

The revision reads as follows:

§ 423.32 Enrollment process.

* * * * *

(b) *Enrollment form or CMS-approved enrollment mechanism.* The enrollment form or CMS-approved enrollment mechanism must comply with CMS instructions regarding content and format and must have been approved by CMS as described in § 423.2262.

* * * * *

- 59. Section 423.38 is amended by—
- a. Revising paragraph paragraphs (c) introductory text, (c)(4), and (c)(8)(i)(C);
- b. Adding paragraph (c)(9);
- c. Revising paragraph (d); and
- d. Adding paragraph (e).

The revisions and additions read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) *Special enrollment periods.* A Part D eligible individual may enroll in a PDP or disenroll from a PDP and enroll in another PDP or MA–PD plan (as provided at § 422.62(b) of this chapter), as applicable, under any of the following circumstances:

* * * * *

(4) The individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in § 423.772, who has not been identified as a “potential at-risk beneficiary” or “at-risk beneficiary” as defined in § 423.100 and—

- (i) Making an allowable onetime-per-calendar-year election; or
- (ii) Making an election after notification of a CMS or State-initiated enrollment action or within 2 months of that enrollment action’s effective date.

* * * * *

(8) * * *

(i) * * *

(C) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan’s provisions in communication materials as outlined in subpart V.

* * * * *

(9) The individual is making an election within 2 months of a gain, loss, or change to Medicaid or LIS eligibility, or notification of such a change, whichever is later.

(d) *Enrollment period to coordinate with MA annual 45-day disenrollment*

period. Through 2018, an individual enrolled in an MA plan who elects Original Medicare from January 1 through February 14, as described in § 422.62(a)(5), may also elect a PDP during this time.

(e) Enrollment period to coordinate with MA open enrollment period. For 2019 and subsequent years, an individual who makes an election as described in § 422.62(a)(3), may make an election to enroll in or disenroll from Part D coverage. An individual who elects Original Medicare during the MA open enrollment period may elect to enroll in a PDP during this time.

■ 60. Section 423.40 is amended by revising paragraph (d) and adding paragraph (e) to read as follows:

§ 423.40 Effective dates.

* * * * *

(d) PDP enrollment period to coordinate with the MA annual disenrollment period. Through 2018, an enrollment made from January 1 through February 14 by an individual who has disenrolled from an MA plan as described in § 422.62(a)(5) will be effective the first day of the month following the month in which the enrollment in the PDP is made.

(e) PDP enrollment period to coordinate with the MA annual disenrollment period. For 2019 and subsequent years, an enrollment made by an individual who elects Original Medicare during the MA open enrollment period as described in § 422.62(a)(3), will be effective the first day of the month following the month in which the election is made.

■ 61. Section § 423.100 is amended—

- a. By revising the definition of "Affected enrollee";
b. By adding in alphabetical order definitions for "At risk beneficiary", "Clinical guidelines", "Exempted beneficiary", "Frequently abused drug", and "Mail-Order pharmacy";
c. By removing the definition of "Other authorized prescriber";
d. By adding in alphabetical order definitions for "Potential at-risk beneficiary", "Preclusion List", and "Program size"; and
e. By revising the definition of "Retail pharmacy".

The revisions and additions read as follows:

§ 423.100 Definitions.

* * * * *

Affected enrollee means a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing and such drug

removal or cost-sharing change affects the Part D enrollee's access to the drug during the current plan year.

* * * * *

At-risk beneficiary means 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 under a Part D plan sponsor's drug management program in accordance with the requirements of § 423.153(f); or
(2) 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 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, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification.

* * * * *

Clinical guidelines, for the purposes of a drug management program under § 423.153(f), are criteria—

- (1) To identify potential at-risk beneficiaries who may be determined to be at-risk beneficiaries under such programs; and
(2) That are developed in accordance with § 423.153(f)(16) and published in guidance annually.

* * * * *

Exempted beneficiary means with respect to a drug management program, an enrollee who—

- (1) Has elected to receive hospice care;
(2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or
(3) Has a cancer diagnosis.

Frequently abused drug means a controlled substance under the Federal Controlled Substances Act that the Secretary determines is frequently abused or diverted, taking into account all of the following factors:

- (1) The drug's schedule designation by the Drug Enforcement Administration.
(2) Government or professional guidelines that address that a drug is frequently abused or misused.
(3) An analysis of Medicare or other drug utilization or scientific data.

* * * * *

Mail-order pharmacy means a licensed pharmacy that dispenses and

delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing.

* * * * *

Potential at-risk beneficiary means a Part D eligible individual—

- (1) Who is identified using clinical guidelines (as defined in § 423.100); or
(2) 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, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification.

Preclusion list means a CMS compiled list of prescribers who—

- (1) Meet all of the following requirements:
(i) The prescriber is currently revoked from the Medicare program under § 424.535.
(ii) The prescriber is currently under a reenrollment bar under § 424.535(c).
(iii) CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program. In making this determination under this paragraph, CMS considers the following factors:

- (A) The seriousness of the conduct underlying the prescriber's revocation;
(B) The degree to which the prescriber's conduct could affect the integrity of the Part D program; and
(C) Any other evidence that CMS deems relevant to its determination; or.

(2) Meet both of the following requirements:

- (i) The prescriber has engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare.
(ii) CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

In making this determination under this paragraph, CMS considers the all of the following factors:

- (A) The seriousness of the conduct involved.
(B) The degree to which the prescriber's conduct could affect the integrity of the Part D program.
(C) Any other evidence that CMS deems relevant to its determination.

* * * * *

Program size means the estimated population of potential at-risk beneficiaries in drug management

programs (described in § 423.153(f)) operated by Part D plan sponsors that the Secretary determines can be effectively managed by such sponsors as part of the process to develop clinical guidelines.

* * * * *

Retail pharmacy means any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy.

* * * * *

■ 62. Section 423.120 is amended by—

- a. Redesignating paragraph (b)(3)(i) introductory text and paragraphs (b)(3)(i)(A) through (D) as paragraphs (b)(3)(i)(A) introductory text and (b)(3)(i)(A)(1) through (4);
- b. Adding a new paragraph (b)(3)(i)(B);
- c. Revising paragraph (b)(3)(iii);
- d. In paragraph (b)(5)(i) introductory text, by removing the figure “60” and adding in its place the figure “30” and by adding the phrase “(for purposes of this paragraph (b)(5) these entities are referred to as “CMS and other specified entities”) after the word “pharmacists”;
- e. In paragraph (b)(5)(i)(A), by removing the phrase “60 days” and adding in its place the phrase “2 months”;
- f. In paragraph (b)(5)(i)(B), by removing the figure “60” and adding in its place the figure “30”;
- g. In paragraph (b)(5)(iii), by removing the phrase “, CMS, State Pharmaceutical Assistance Programs (as defined in § 423.454), entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists” and adding in its place the phrase “and CMS and other specified entities”;
- h. Adding paragraph (b)(5)(iv);
- i. In paragraph (b)(6), by removing the phrase “under paragraphs (b)(5)(iii) of this section” and adding in its place the phrase “under paragraphs (b)(5)(iii) and (iv) of this section”; and
- j. Revising paragraphs (c)(5) and (6).

The additions and revisions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

- (b) * * *
- (3) * * *

(B) Not apply in cases in which a Part D sponsor substitutes a generic drug for a brand name drug as permitted under

paragraphs (b)(5)(iv) and (b)(6) of this section.

* * * * *

(iii) Ensure the provision of a temporary fill when an enrollee requests a fill of a non-formulary drug during the time period specified in paragraph (b)(3)(ii) of this section (including Part D drugs that are on a plan’s formulary but require prior authorization or step therapy under a plan’s utilization management rules) by providing a one-time, temporary supply of at least a month’s supply of medication, unless the prescription is written by a prescriber for less than a month’s supply and requires the Part D sponsor to allow multiple fills to provide up to a total of a month’s supply of medication.

* * * * *

(5) * * *

(iv) A Part D sponsor may immediately remove a brand name drug (as defined in § 423.4) from its Part D formulary or change the brand name drug’s preferred or tiered cost-sharing without meeting the deadlines and refill requirements of paragraph (b)(5)(i) of this section provided that the Part D sponsor does all of the following:

(A) At the same time that it removes such brand name drug or changes its preferred or tiered cost-sharing, it adds a therapeutically equivalent (as defined in § 423.100) generic drug (as defined in § 423.4) to its formulary with the same or lower cost-sharing and the same or less restrictive utilization management criteria.

(B) The Part D sponsor previously could not have included such therapeutically equivalent generic drug on its formulary when it requested CMS formulary approval consistent with § 423.120(b)(2) because such generic drug was not yet available on the market.

(C) Before making any permitted generic substitutions, the Part D sponsor provides general notice to all current and prospective enrollees in its formulary and other applicable beneficiary communication materials advising them that—

(1) Such changes may be made at any time when a new generic is added in place of a brand name drug, and there may be no advance direct notice to the affected enrollees;

(2) If such a substitution should occur, affected enrollees will receive direct notice including information on the specific drugs involved and steps they may take to request coverage determinations and exceptions under §§ 423.566 and 423.578; and

(D) Before making any permitted generic substitutions, the Part D sponsor

provides advance general notice to CMS and other specified entities.

(E) The Part D sponsor provides notice of any such formulary changes to affected enrollees and CMS and other specified entities consistent with the requirements of paragraphs (b)(5)(i) (as applicable) and (ii) of this section. This would include direct notice to the affected enrollees.

* * * * *

(c) * * *

(5)(i) A Part D plan sponsor must reject, or must require its pharmacy benefit manager (PBM) to reject, a pharmacy claim for a Part D drug unless the claim contains the active and valid National Provider Identifier (NPI) of the prescriber who prescribed the drug.

(ii) The sponsor must communicate at point-of sale whether or not a submitted NPI is active and valid in accordance with this paragraph (c)(5)(ii).

(A) If the sponsor communicates that the NPI is not active and valid, the sponsor must permit the pharmacy to—

(1) Confirm that the NPI is active and valid; or

(2) Correct the NPI.

(B) If the pharmacy confirms that the NPI is active and valid or corrects the NPI, the sponsor must pay the claim if it is otherwise payable.

(iii) A Part D sponsor must not later recoup payment from a network pharmacy for a claim that does not contain an active and valid individual prescriber NPI on the basis that it does not contain one, unless the sponsor—

(A) Has complied with paragraph (ii) of this section;

(B) Has verified that a submitted NPI was not in fact active and valid; and

(C) The agreement between the parties explicitly permits such recoupment.

(iv) With respect to requests for reimbursement submitted by Medicare beneficiaries, a Part D sponsor may not make payment to a beneficiary dependent upon the sponsor’s acquisition of an active and valid individual prescriber NPI, unless there is an indication of fraud. If the sponsor is unable to retrospectively acquire an active and valid individual prescriber NPI, the sponsor may not seek recovery of any payment to the beneficiary solely on that basis.

(6)(i) Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the preclusion list, defined in § 423.100.

(ii) Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must deny, or must require its

PBM to deny, a request for reimbursement from a Medicare beneficiary if the request pertains to a Part D drug that was prescribed by an individual who is identified by name in the request and who is included on the preclusion list, defined in § 423.100.

(iii) A Part D plan sponsor may not submit a prescription drug event (PDE) record to CMS unless it includes on the PDE record the active and valid individual NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in § 423.100, for the date of service.

(iv)(A) A Part D sponsor or its PBM must not reject a pharmacy claim for a Part D drug under paragraph (c)(6)(i) of this section or deny a request for reimbursement under paragraph (c)(6)(ii) of this section unless the sponsor has provided the provisional coverage of the drug and written notice to the beneficiary required by paragraph (c)(6)(iv)(B) of this section.

(B) Upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor would otherwise be required to reject or deny in accordance with paragraph (c)(6)(i) or (ii) of this section, a Part D sponsor or its PBM must do the following:

(1) Provide the beneficiary with the following, subject to all other Part D rules and plan coverage requirements:

(i) A provisional supply coverage period during which the sponsor must cover all drugs dispensed to the beneficiary in accordance with prescriptions written by the individual on the preclusion list. The provisional supply period begins on the date-of-service the first drug is dispensed in accordance with a prescription written by the individual on the preclusion list.

(ii) Written notice within 3 business days after adjudication of the first claim or request for the drug in a form and manner specified by CMS.

(2) Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(B)(1)(ii) of this section.

(v)(A) CMS sends written notice to the prescriber via letter of his or her inclusion on the preclusion list. The notice must contain the reason for the inclusion on the preclusion list and inform the prescriber of his or her appeal rights.

(B) A prescriber may appeal his or her inclusion on the preclusion list under this section in accordance with 42 CFR part 498.

(vi) CMS has the discretion not to include a particular individual on (or if warranted, remove the individual from)

the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to prescriptions. In making a determination as to whether such circumstances exist, CMS takes into account—

(A) The degree to which beneficiary access to Part D drugs would be impaired; and

(B) Any other evidence that CMS deems relevant to its determination.

* * * * *

■ 63. Section 423.128 is amended by revising paragraph (d)(2)(iii) to read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(d) * * *

(2) * * *

(iii) Provides current and prospective Part D enrollees with notice that is timely under § 423.120(b)(5) regarding any removal or change in the preferred or tiered cost-sharing status of a Part D drug on its Part D plan's formulary.

* * * * *

■ 64. Section 423.153 is amended by adding a sentence at the end of paragraph (a) and adding paragraph (f) to read as follows:

§ 423.153 Drug utilization management, quality assurance, and medication therapy management programs (MTMPs).

(a) * * *

A Part D plan sponsor may establish a drug management program for at-risk beneficiaries enrolled in their prescription drug benefit plans to address overutilization of frequently abused drugs, as described in paragraph (f) of this section.

* * * * *

(f) *Drug management programs.* A drug management program must meet all the following requirements:

(1) *Written policies and procedures.* A sponsor must document its drug management program in written policies and procedures that are approved by the applicable P&T committee and reviewed and updated as appropriate. These policies and procedures must address all aspects of the sponsor's drug management program, including but not limited to the following:

(i) The appropriate credentials of the personnel conducting case management required under paragraph (f)(2) of this section.

(ii) The necessary and appropriate contents of files for case management required under paragraph (f)(2) of this section.

(iii) Monitoring reports and notifications about incoming enrollees

who meet the definition of an at-risk beneficiary and a potential at-risk beneficiary in § 423.100 and responding to requests from other sponsors for information about at-risk beneficiaries and potential at-risk beneficiaries who recently disenrolled from the sponsor's prescription drug benefit plan.

(2) *Case management/clinical contact/prescriber verification—(i) General rule.* The sponsor's clinical staff must conduct case management for each potential at-risk beneficiary for the purpose of engaging in clinical contact with the prescribers of frequently abused drugs and verifying whether a potential at-risk beneficiary is an at-risk beneficiary. Except as provided in paragraph (f)(2)(ii) of this section, the sponsor must do all of the following:

(A) Send written information to the beneficiary's prescribers that the beneficiary meets the clinical guidelines and is a potential at risk beneficiary.

(B) Elicit information from the prescribers about any factors in the beneficiary's treatment that are relevant to a determination that the beneficiary is an at-risk beneficiary, including whether prescribed medications are appropriate for the beneficiary's medical conditions or the beneficiary is an exempted beneficiary.

(C) In cases where the prescribers have not responded to the inquiry described in paragraph (f)(2)(i)(B) of this section, make reasonable attempts to communicate telephonically with the prescribers within a reasonable period after sending the written information.

(ii) *Exception for identification by prior plan.* If a beneficiary was identified as a potential at-risk or an at-risk beneficiary by his or her most recent prior plan and such identification has not been terminated in accordance with paragraph (f)(14) of this section, the sponsor meets the requirements in paragraph (f)(2)(i) of this section, so long as the sponsor obtains case management information from the previous sponsor and such information is clinically adequate and up to date.

(3) *Limitation on access to coverage for frequently abused drugs.* Subject to the requirements of paragraph (f)(4) of this section, a Part D plan sponsor may do all of the following:

(i) Implement a point-of-sale claim edit for frequently abused drugs that is specific to an at-risk beneficiary.

(ii) In accordance with paragraphs (f)(10) and (11) of this section, limit an at-risk beneficiary's access to coverage for frequently abused drugs to those that are—

(A) Prescribed for the beneficiary by one or more prescribers;

(B) Dispensed to the beneficiary by one or more network pharmacies; or
(C) Specified in both paragraphs (f)(3)(ii)(A) and (C) of this section.

(iii)(A) If the sponsor implements an edit as specified in paragraph (f)(3)(i) of this section, the sponsor must not cover frequently abused drugs for the beneficiary in excess of the edit, unless the edit is terminated or revised based on a subsequent determination, including a successful appeal.

(B) If the sponsor limits the at-risk beneficiary's access to coverage as specified in paragraph (f)(3)(ii) of this section, the sponsor must cover frequently abused drugs for the beneficiary only when they are obtained from the selected pharmacy(ies) or prescriber(s) or both, as applicable—

(1) In accordance with all other coverage requirements of the beneficiary's prescription drug benefit plan, unless the limit is terminated or revised based on a subsequent determination, including a successful appeal; and

(2) Except as necessary to provide reasonable access in accordance with paragraph (f)(12) of this section.

(4) *Requirements for limiting access to coverage for frequently abused drugs.* (i) A sponsor may not limit the access of an at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section, unless the sponsor has done all of the following:

(A) Conducted case management as required by paragraph (f)(2) of this section and updated it, if necessary.

(B) Obtained the agreement of the prescribers of frequently abused drugs for the beneficiary that the specific limitation is appropriate.

(C) Provided the notices to the beneficiary in compliance with paragraphs (f)(5) and (6) of this section.

(ii) If the sponsor has complied with the requirement of paragraph (f)(2)(i)(C) of this section, and the prescribers were not responsive after 3 attempts by the sponsor to contact them by telephone within 10 business days, then the sponsor has met the requirement of paragraph (f)(4)(i)(B) of this section.

(iii) The sponsor has met the case management requirement in paragraph (f)(2)(i) of this section if—

(A) The beneficiary meets paragraph (2) of the definition of a potential at-risk beneficiary or an at-risk beneficiary; and

(B) The sponsor has obtained the applicable case management information from the sponsor of the beneficiary's most recent plan and updated it as appropriate.

(iv) A Part D sponsor must not limit an at-risk beneficiary's access to

coverage for frequently abused drugs to those that are prescribed for the beneficiary by one or more prescribers under paragraph (f)(3)(ii)(A) of this section unless—

(A) At least 6 months has passed from the date the beneficiary was first identified as a potential at-risk beneficiary from the date of the applicable CMS identification report; and

(B) The beneficiary meets the clinical guidelines and was reported by the most recent CMS identification report.

(5) *Initial notice to a beneficiary.* (i) A Part D sponsor that intends to limit the access of a potential at-risk beneficiary to coverage for frequently abused drugs under paragraph (f)(3) of this section must provide an initial written notice to the beneficiary.

(ii) The notice must do all of the following:

(A) Use language approved by the Secretary.

(B) Be in a readable and understandable form.

(C) Provide all of the following information:

(1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as a potential at-risk beneficiary.

(2) A description, of all State and Federal public health resources that are designed to address prescription drug abuse to which the beneficiary has access, including mental health and other counseling services and information on how to access such services, including any such services covered by the plan under its Medicare benefits, supplemental benefits, or Medicaid benefits (if the plan integrates coverage of Medicare and Medicaid benefits).

(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 § 423.580 *et seq.*

(4) A request that the beneficiary submit to the sponsor within 30 days of the date of this initial notice any information that the beneficiary believes is relevant to the sponsor's determination, including which prescribers and pharmacies the beneficiary would prefer the sponsor to select if the sponsor implements a limitation under paragraph (f)(3)(ii) of this section.

(5) An explanation of the meaning and consequences of being identified as an at-risk beneficiary, including the following:

(i) An explanation of the sponsor's drug management program, the specific limitation the sponsor intends to place on the beneficiary's access to coverage for frequently abused drugs under the program.

(ii) The timeframe for the sponsor's decision

(iii) If applicable, any limitation on the availability of the special enrollment period described in § 423.38.

(6) Clear instructions that explain how the beneficiary can contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(5)(ii)(C)(4) of this section.

(7) Contact information for other organizations that can provide the beneficiary with assistance regarding the sponsor's drug management program.

(8) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

(iii) The Part D plan sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required under paragraph (f)(5)(i) of this section.

(6) *Second notice.* (i) Upon making a determination that a beneficiary is an at-risk beneficiary and to limit the beneficiary's access to coverage for frequently abused drugs under paragraph (f)(3) of this section, a Part D sponsor must provide a second written notice to the beneficiary.

(ii) The second notice must do all of the following:

(A) Use language approved by the Secretary.

(B) Be in a readable and understandable form.

(C) Provide all of the following information:

(1) An explanation that the beneficiary's current or immediately prior Part D plan sponsor has identified the beneficiary as an at-risk beneficiary.

(2) An explanation that the beneficiary is subject to the requirements of the sponsor's drug management program, including—

(i) The limitation the sponsor is placing on the beneficiary's access to coverage for frequently abused drugs and the effective and end date of the limitation; and

(ii) If applicable, any limitation on the availability of the special enrollment period described in § 423.38.

(3) The prescriber(s) or pharmacy(ies) or both, if and as applicable, from which the beneficiary must obtain frequently abused drugs in order for them to be covered by the sponsor.

(4) An explanation of the beneficiary's right to a redetermination under § 423.580 *et seq.*, including—

(i) A description of both the standard and expedited redetermination processes; and

(ii) The beneficiary's right to, and conditions for, obtaining an expedited redetermination.

(5) An explanation that the beneficiary may submit to the sponsor, if the beneficiary has not already done so, the prescriber(s) and pharmacy(ies), as applicable, from which the beneficiary would prefer to obtain frequently abused drugs.

(6) Clear instructions that explain how the beneficiary may contact the sponsor, including how the beneficiary may submit information to the sponsor in response to the request described in paragraph (f)(6)(ii)(C)(5) of this section.

(7) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

(iii) The Part D plan sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required by paragraph (f)(6)(i) of this section.

(7) *Alternate second notice.* (i) If, after providing an initial notice to a potential at-risk beneficiary under paragraph (f)(4) of this section, a Part D sponsor determines that the potential at-risk beneficiary is not an at-risk beneficiary, the sponsor must provide an alternate second written notice to the beneficiary.

(ii) The alternate second notice must do all of the following:

(A) Use language approved by the Secretary.

(B) Be in a readable and understandable form.

(C) Provide all of the following information:

(1) The sponsor has determined that the beneficiary is not an at-risk beneficiary.

(2) The sponsor will not limit the beneficiary's access to coverage for frequently abused drugs.

(3) If applicable, the SEP limitation no longer applies.

(4) Clear instructions that explain how the beneficiary may contact the sponsor.

(5) Other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

(ii) The Part D sponsor must make reasonable efforts to provide the beneficiary's prescriber(s) of frequently abused drugs with a copy of the notice required in accordance with paragraph (f)(7)(i) of this section.

(8) *Timing of notices.* (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 and not more than the earlier of the date the sponsor makes the relevant determination or 90 days after the date of the initial notice described in paragraph (f)(5) of this section.

(ii) Immediately upon the beneficiary's enrollment in the gaining plan, the gaining plan sponsor may immediately provide a second notice described in paragraph (f)(6) of this section to a beneficiary for whom the gaining sponsor received a notice that the beneficiary was identified as an at-risk beneficiary by his or her most recent prior plan, and such identification had not been terminated in accordance with paragraph (f)(14) of this section, if the sponsor is implementing either of the following:

(A) A beneficiary-specific point-of-sale claim edit as described in paragraph (f)(3)(i) of this section.

(B) A limitation on access to coverage as described in paragraph (f)(3)(ii) of this section, if such limitation would require the beneficiary to obtain frequently abused drugs from the same location of pharmacy and/or the same prescriber, as applicable, that was selected under the immediately prior plan under paragraph (f)(9) of this section.

(9) *Beneficiary preferences.* Except as described in paragraph (f)(10) of this section, if a beneficiary submits preferences for prescribers or pharmacies or both from which the beneficiary prefers to obtain frequently abused drugs, the sponsor must do the following:

(i) Review such preferences.

(ii) If the beneficiary is—

(A) Enrolled in a stand-alone prescription drug benefit plan and specifies a prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or network pharmacy(ies) or both for the beneficiary based on beneficiary's preference(s).

(B) Enrolled in a Medicare Advantage prescription drug benefit plan and specifies a network prescriber(s) or network pharmacy(ies) or both, select or change the selection of prescriber(s) or pharmacy(ies) or both for the beneficiary based on the beneficiary's preference(s).

(iii) The sponsor must inform the beneficiary of the selection in—

(A) The second notice; or

(B) If the second notice is not feasible due to the timing of the beneficiary's submission, in a subsequent written notice, issued no later than 14 days after receipt of the submission.

(10) *Exception to beneficiary preferences.* (i) If the Part D sponsor determines that the selection or change of a prescriber or pharmacy under paragraph (f)(9) of this section would contribute to prescription drug abuse or drug diversion by the at-risk beneficiary, the sponsor may change the selection without regard to the beneficiary's preferences if there is strong evidence of inappropriate action by the prescriber, pharmacy, or beneficiary.

(ii) If the sponsor changes the selection, the sponsor must provide the beneficiary with—

(A) At least 30 days advance written notice of the change; and

(B) A rationale for the change.

(11) *Reasonable access.* In making the selections under paragraph (f)(12) of this section, a Part D plan sponsor must ensure both of the following:

(i) That the beneficiary continues to have reasonable access to frequently abused drugs, taking into account—

(1) Geographic location;

(2) Beneficiary preference;

(3) The beneficiary's predominant usage of a prescriber or pharmacy or both;

(4) The impact on cost-sharing; and

(5) Reasonable travel time.

(ii) Reasonable access to frequently abused drugs in the case of—

(A) Individuals with multiple residences;

(B) Natural disasters and similar situations; and

(C) The provision of emergency services.

(12) *Selection of prescribers and pharmacies.* (i) A Part D plan sponsor must select, as applicable—

(A) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network prescriber who is authorized to prescribe frequently abused drugs for the beneficiary, unless the plan is a stand-alone PDP and the selection involves a prescriber(s), in which case, the prescriber need not be a network prescriber; and

(B) One, or, if the sponsor reasonably determines it necessary to provide the beneficiary with reasonable access, more than one, network pharmacy that may dispense such drugs to such beneficiary.

(ii)(A) For purposes of this paragraph (f)(12) of this section, in the case of a pharmacy that has multiple locations that share real-time electronic data, all such locations of the pharmacy must collectively be treated as one pharmacy.

(B) For purposes of this paragraph (f)(12) of this section, in the case of a group practice, all prescribers of the group practice must be treated as one prescriber.

(13) *Confirmation of selections(s)*. (i) Before selecting a prescriber or pharmacy under this paragraph, a Part D plan sponsor must notify the prescriber or pharmacy, as applicable, that the beneficiary has been identified for inclusion in the drug management program for at-risk beneficiaries and that the prescriber or pharmacy or both is (are) being selected as the beneficiary's designated prescriber or pharmacy or both for frequently abused drugs.

(ii) The sponsor must receive confirmation from the prescriber(s) or pharmacy(ies) or both that the selection is accepted before conveying this information to the at-risk beneficiary, unless the prescriber or pharmacy has agreed in advance in its network agreement with the sponsor to accept all such selections and the agreement specifies how the prescriber or pharmacy will be notified by the sponsor of its selection.

(14) *Termination of identification as an at-risk beneficiary*. The identification of an at-risk beneficiary as such must terminate as of the earlier of the following:

(i) The date the beneficiary demonstrates through a subsequent determination, including but not limited to, a successful appeal, that the beneficiary is no longer likely, in the absence of the limitations under this paragraph, to be an at-risk beneficiary.

(ii) The end of a 12-calendar month period calculated from the effective date of the limitation, as specified in the notice provided under paragraph (f)(6) of this section.

(15) *Data disclosure*. (i) CMS identifies each potential at-risk beneficiary to the sponsor of the prescription drug plan in which the beneficiary is enrolled.

(ii) A Part D sponsor that operates a drug management program must disclose any data and information to CMS and other Part D sponsors that CMS deems necessary to oversee Part D drug management programs at a time, and in a form and manner specified by CMS. The data and information disclosures must do all of the following:

(A) Respond to CMS within 30 days of receiving a report about a potential at-risk beneficiary from CMS.

(B) Provide information to CMS about any potential at-risk beneficiary that a sponsor identifies within 30 days from the date of the most recent CMS report

identifying potential at-risk beneficiaries;

(C) Provide information to CMS within 7 business days of the date of the initial notice or second notice that the sponsor provided to a beneficiary, or within 7 days of a termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs.

(D) Transfer case management information upon request of a gaining sponsor as soon as possible but not later than 2 weeks from the gaining sponsor's request when—

(1) An at-risk beneficiary or potential at-risk beneficiary disenrolls from the sponsor's plan and enrolls in another prescription drug plan offered by the gaining sponsor; and

(2) The edit or limitation that the sponsor had implemented for the beneficiary had not terminated before disenrollment.

(16) *Clinical guidelines*. Potential at-risk beneficiaries and at-risk beneficiaries are identified by CMS or the Part D sponsor using clinical guidelines that—

(i) Are developed with stakeholder consultation;

(ii) Are based on the acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs used, or any combination of this factors;

(iii) Are derived from expert opinion and an analysis of Medicare data; and

(iv) Include a program size estimate.

■ 65. Section 423.160 is amended by

■ a. Revising paragraph (b)(1)(iv);

■ b. Adding paragraph (b)(1)(v);

■ c. Revising paragraph (b)(2)(iii);

■ d. Adding paragraph (b)(2)(iv);

■ e. Revising paragraph (b)(4); and

■ f. Adding paragraph (c)(1)(vii).

The revisions and additions read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) * * *

(1) * * *

(iv) From March 1, 2015 until January 1, 2019, the standards specified in paragraphs (b)(2)(iii), (b)(3), (b)(4)(i), (b)(5)(iii), and (b)(6).

(v) On or after January 1, 2019, the standards specified in paragraphs (b)(2)(iii) and (b)(3), (b)(4)(ii), (b)(5)(iii), and (b)(6) of this section.

(2) * * *

(iii) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 10, Release 6 (Version 10.6), November 12,

2008 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:

(A) Get message transaction.

(B) Status response transaction.

(C) Error response transaction.

(D) New prescription transaction.

(E) Prescription change request transaction.

(F) Prescription change response transaction.

(G) Refill/Resupply prescription request transaction.

(H) Refill/Resupply prescription response transaction.

(I) Verification transaction.

(J) Password change transaction.

(K) Cancel prescription request transaction.

(L) Cancel prescription response transaction.

(M) Fill status notification.

(iv) The National Council for Prescription Programs SCRIPT standard, Implementation Guide Version 2017071 approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(i) of this section), to provide for the communication of a prescription or related prescription-related information between prescribers and dispensers for the following:

(A) Get message transaction.

(B) Status response transaction.

(C) Error response transaction.

(D) New prescription transaction.

(E) Prescription change request transaction.

(F) Prescription change response transaction.

(G) Refill/Resupply prescription request transaction.

(H) Refill/Resupply prescription response transaction.

(I) Verification transaction.

(J) Password change transaction.

(K) Cancel prescription request transaction.

(L) Cancel prescription response transaction.

(M) Fill status notification.

(N) Prescription drug administration message.

(O) New prescription requests.

(P) New prescription response denials.

(Q) Prescription transfer message.

(R) Prescription fill indicator change.

(S) Prescription recertification.

(T) REMS initiation request.

(U) REMS initiation response.

(V) REMS request.

(W) REMS response.

* * * * *

(4) *Medication history*. Medication history to provide for the

communication of Medicare Part D medication history information among Medicare Part D sponsors, prescribers and dispensers:

(i) Until January 1, 2017, Either the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide Version 8, Release 1 (Version 8.1), October 2005 (incorporate by reference in paragraph (c)(1)(v) of this section, or the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 10.6, approved November 12, 2008 (incorporated by reference in paragraph (c)(1)(vi) of this section.

(ii) On or after January 1, 2019, the National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(vii) of this section).

* * * * *

(c) * * *

(1) * * *

(vii) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017.

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■ 66. Sections 423.180, 423.182, 423.184 and 423.186 are added Subpart D to read as follows:

Subpart D—Cost Control and Quality Improvement Requirements

* * * * *

Sec.

423.180 Basis and scope of the Part D Quality Rating System.

423.182 Part D Quality Rating System.

423.184 Adding, updating, and removing measures.

423.186 Calculation of star ratings.

§ 423.180 Basis and scope of the Part D Quality Rating System.

(a) *Basis*. This subpart is based on sections 1851(d), 1852(e), 1853(o) and 1854(b)(3)(iii), (v), and (vi) of the Act and the general authority under section 1856(b) of the Act requiring the establishment of standards consistent with and to carry out Part D.

(b) *Purpose*. Ratings calculated and assigned under this subpart will be used by CMS for the following purposes:

(1) To provide comparative information on plan quality and performance to beneficiaries for their use in making knowledgeable enrollment and coverage decisions in the Medicare program.

(2) To provide quality ratings on a 5-star rating system.

(3) To provide a means to evaluate and oversee overall and specific compliance with certain regulatory and contract requirements by Part D plans, where appropriate and possible to use data of the type described in § 423.182(c).

(c) *Applicability*. The regulations in this subpart will be applicable beginning with the 2019 measurement period and the associated 2021 Star Ratings that are released prior to the annual coordinated election period for the 2021 contract year.

§ 423.182 Part D Quality Rating System.

(a) *Definitions*. In this subpart the following terms have the meanings:

CAHPS refers to a comprehensive and evolving family of surveys that ask consumers and patients to evaluate the interpersonal aspects of health care. CAHPS surveys probe those aspects of care for which consumers and patients are the best or only source of information, as well as those that consumers and patients have identified as being important. CAHPS initially stood for the Consumer Assessment of Health Plans Study, but as the products have evolved beyond health plans the acronym now stands for Consumer Assessment of Healthcare Providers and Systems.

Case-mix adjustment means an adjustment to the measure score made prior to the score being converted into a Star Rating to take into account certain enrollee characteristics that are not under the control of the plan. For example age, education, chronic medical conditions, and functional health status that may be related to the enrollee's survey responses.

Categorical Adjustment Index (CAI) means the factor that is added to or subtracted from an overall or summary Star Rating (or both) to adjust for the average within-contract (or within-plan as applicable) disparity in performance associated with the percentages of beneficiaries who are dually eligible for Medicare and enrolled in Medicaid, beneficiaries who receive a Low Income Subsidy, or have disability status in that contract (or plan as applicable).

Clustering refers to a variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as possible to observations in any other group. Clustering of the measure-specific scores means that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify the four cut points resulting in the creation of five levels (one for each Star

Rating), such that scores in the same Star Rating level are as similar as possible and scores in different Star Rating levels are as different as possible. Technically, the variance in measure scores is separated into within-cluster and between-cluster sum of squares components. The clusters reflect the groupings of numeric value scores that minimize the variance of scores within the clusters. The Star Ratings levels are assigned to the clusters that minimize the within-cluster sum of squares. The cut points for star assignments are derived from the range of measure scores per cluster, and the star levels associated with each cluster are determined by ordering the means of the clusters.

Consolidation means when an MA organization that has at least two contracts for health and/or drug services of the same plan type under the same parent organization in a year combines multiple contracts into a single contract for the start of the subsequent contract year.

Consumed contract means a contract that will no longer exist after a contract year's end as a result of a consolidation.

Display page means the CMS Web site on which certain measures and scores are publicly available for informational purposes; the measures that are presented on the display page are not used in assigning Part C and D Star Ratings.

Domain rating means the rating that groups measures together by dimensions of care.

Dual-eligible (DE) means a beneficiary who is enrolled in both Medicare and Medicaid.

Highest rating means the overall rating for MA-PDs, the Part C summary rating for MA-only contracts, and the Part D summary rating for PDPs.

Highly-rated contract means a contract that has 4 or more stars for its highest rating when calculated without the improvement measures and with all applicable adjustments (CAI and the reward factor).

Low-income subsidy (LIS) means the subsidy that a beneficiary receives to help pay for prescription drug coverage (see § 423.34 for definition of a low-income subsidy eligible individual).

Measurement period means the period for which data are collected for a measure or the performance period that a measure covers.

Measure score means the numeric value of the measure or an assigned 'missing data' message.

Measure star means the measure's numeric value is converted to a Star Rating. It is displayed to the nearest whole star, using a 1–5 star scale.

Overall rating means a global rating that summarizes the quality and performance for the types of services offered across all unique Part C and Part D measures.

Part C summary rating means a global rating that summarizes the health plan quality and performance on Part C measures.

Part D summary rating means a global rating that summarizes prescription drug plan quality and performance on Part D measures.

Plan benefit package (PBP) means a set of benefits for a defined MA or PDP service area. The PBP is submitted by Part D plan sponsors and MA organizations to CMS for benefit analysis, bidding, marketing, and beneficiary communication purposes.

Reliability means a measure of the fraction of the variation among the observed measure values that is due to real differences in quality (“signal”) rather than random variation (“noise”); it is reflected on a scale from 0 (all differences in plan performance measure scores are due to measurement error) to 1 (the difference in plan performance scores is attributable to real differences in performance).

Reward factor means a rating-specific factor added to the contract’s summary or overall ratings (or both) if a contract has both high and stable relative performance.

Statistical significance assesses how likely differences observed in performance are due to random chance alone under the assumption that plans are actually performing the same.

Surviving contract means the contact that will still exist under a consolidation, and all of the beneficiaries enrolled in the consumed contract(s) are moved to the surviving contracts.

Traditional rounding rules mean that the last digit in a value will be rounded. If rounding to a whole number, look at the digit in the first decimal place. If the digit in the first decimal place is 0, 1, 2, 3 or 4, then the value should be rounded down by deleting the digit in the first decimal place. If the digit in the first decimal place is 5 or greater, then the value should be rounded up by 1 and the digit in the first decimal place deleted.

(b) *Contract ratings*—(1) *General*. CMS calculates an overall Star Rating, Part C summary rating, and Part D summary rating for each MA–PD contract and a Part D summary rating for each PDP contract using the 5-star rating system described in this subpart. For PDP contracts, the Part D summary rating is the highest rating. Measures are assigned stars at the contract level and

weighted in accordance with § 423.186(a). Domain ratings are the average of the individual measure ratings under the topic area in accordance with § 423.186(b). Summary ratings are the weighted average of the individual measure ratings for Part C or Part D in accordance with § 423.186(c). Overall Star Ratings are calculated by using the weighted average of the individual measure ratings in accordance with § 423.186(d) with both the reward factor and CAI applied as applicable, as described in § 423.186(f).

(2) *Plan benefit packages*. All plan benefit packages (PBPs) offered under an MA contract or PDP plan sponsor have the same overall and/or summary Star Ratings as the contract under which the PBP is offered by the MA organization or PDP plan sponsor. Data from all the PBPs offered under a contract are used to calculate the measure and domain ratings for the contract. A contract level score is calculated using an enrollment-weighted mean of the PBP scores and enrollment reported as part of the measure specification in each PBP.

(3) *Contract consolidations*. (i) In the case of contract consolidations involving two or more contracts for health and/or drug services of the same plan type under the same parent organization, CMS assigns Star Ratings for the first and second years following the consolidation based on the enrollment-weighted mean of the measure scores of the surviving and consumed contract(s) as provided in paragraph (b)(3)(ii) of this section.

(ii) The Star Ratings posted on Medicare Plan Finder for contracts that consolidate are as follows:

(A) For the first year after consolidation, CMS will use enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts for all measures, except the survey-based 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.

(B) For the second year after consolidation, CMS will use 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 will ensure that the CAHPS survey sample will include enrollees in the sample frame from both the surviving and consumed contracts.

(c) *Data sources*. (1) Part D Star Ratings measures reflect structure, process, and outcome indices of quality. This includes information of the following types: Beneficiary experiences, benefit administration information, clinical data, and CMS administrative data. Data underlying Star Ratings measures may include survey data, data separately collected and used in oversight of Part D plans’ compliance with contract requirements, data submitted by plans, and CMS administrative data.

(2) Part D sponsors are required to collect, analyze, and report data that permit measurement of indices of quality. Part D sponsors must provide unbiased, accurate, and complete quality data described in paragraph (c)(1) to CMS on a timely basis as requested by CMS.

§ 423.184 Adding, updating, and removing measures.

(a) *General*. CMS adds, updates, and removes measures used to calculate the Star Ratings as provided in this section. CMS lists the measures used for a particular Star Rating each year in the Technical Notes or similar guidance document with publication of the Star Ratings.

(b) *Review of data quality*. CMS reviews the quality of the data on which performance, scoring and rating of a measure is based before using the data to score and rate performance or in calculating a Star Rating. This includes review of variation in scores among MA organizations and Part D plan sponsors, and the accuracy, reliability, and validity of measures and performance data before making a final determination about inclusion of measures in each year’s Star Ratings.

(c) *Adding measures*. (1) CMS will continue to review measures that are nationally endorsed and in alignment with the private sector, such as measures developed by National Committee for Quality Assurance and the Pharmacy Quality Alliance or endorsed by the National Quality Forum for adoption and use in the Part D Quality Ratings System. CMS may develop its own measures as well when appropriate to measure and reflect performance specific to the Medicare program.

(2) In advance of the measurement period, CMS will announce potential new measures and solicit feedback through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act and then subsequently will propose and finalize new measures through rulemaking.

(3) New measures added to the Part D Star Ratings program will be on the display page on *www.cms.gov* for a minimum of 2 years prior to becoming a Star Ratings measure.

(4) A measure will remain on the display page for longer than 2 years if CMS finds reliability or validity issues with the measure specification.

(d) *Updating measures*—(1) *Non-substantive updates*. For measures that are already used for Star Ratings, CMS will update measures so long as the changes in a measure are not substantive. CMS will announce non-substantive updates to measures that occur (or are announced by the measure steward) during or in advance of the measurement period through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Non-substantive measure specification updates include those that—

(i) Narrow the denominator or population covered by the measure;

(ii) Do not meaningfully impact the numerator or denominator of the measure;

(iii) Update the clinical codes with no change in the target population or the intent of the measure;

(iv) Provide additional clarifications:

(A) Adding additional qualifiers that would meet the numerator requirements;

(B) Clarifying documentation requirements;

(C) Adding additional instructions; or

(v) Add alternative data sources.

(2) *Substantive updates*. For measures that are already used for Star Ratings, in the case of measure specification updates that are substantive updates not subject to paragraph (d)(1), CMS will propose and finalize these measures through rulemaking similar to the process for adding new measures. CMS will initially solicit feedback on whether to make substantive measure updates through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. Once the update has been made to the measure specification by the measure steward, CMS may continue collection of the performance data for the legacy measure and include it in Star Ratings until the updated measure has been on display for 2 years. CMS will place the updated measure on the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings as specified in paragraph (c) of this section.

(e) *Removing measures*. (1) CMS will remove a measure from the Star Ratings program as follows:

(i) When the clinical guidelines associated with the specifications of the measure change such that the specifications are no longer believed to align with positive health outcomes, or

(ii) A measure shows low statistical reliability.

(2) CMS will announce in advance of the measurement period the removal of a measure based upon its application of this paragraph through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act in advance of the measurement period.

(f) *Improvement measure*. CMS will calculate improvement measure scores based on a comparison of the measure scores for the current year to the immediately preceding year as provided in this paragraph; the improvement measure score would be calculated for Parts C and D separately by taking a weighted sum of net improvement divided by the weighted sum of the number of eligible measures.

(1) *Identifying eligible measures*. Annually, the subset of measures to be included in the Part D improvement measure will be announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. CMS identifies measures to be used in the improvement measure if the measures meet all the following:

(i) CMS will include only measures available for the current and previous year in the improvement measures and that have numeric value scores in both the current and prior year.

(ii) CMS will exclude any measure for which there was a substantive specification change, from the previous year.

(iii) The Part D improvement measure will include only Part D measure scores.

(2) *Determining eligible contracts*. CMS will calculate an improvement score only for contracts that have numeric measure scores for both years in at least half of the measures identified for use applying the standards in paragraphs (f)(1)(i) through (iii) of this section.

(3) *Special rules for calculation of the improvement score*. For any measure used for the improvement measure for which a contract received 5 stars in each of the years examined, but for which the measure score demonstrates a statistically significant decline based on the results of the significance testing (at a level of significance of 0.05) on the change score, the measure will be categorized as having no significant

change and included in the count of measures used to determine eligibility for the measure (that is, for the denominator of the improvement measure score).

(4) *Calculation of the improvement score*. The improvement measure will be calculated as follows:

(i) The improvement change score (the difference in the measure scores in the 2-year period) will be determined for each measure that has been designated an improvement measure and for which a contract has a numeric score for each of the 2 years examined.

(ii) Each contract's improvement change score per measure will be categorized as a significant change or not a significant change by employing a two-tailed t-test with a level of significance of 0.05.

(iii) The net improvement per measure category (outcome, access, patient experience, process) would be calculated by finding the difference between the weighted number of significantly improved measures and significantly declined measures, using the measure weights associated with each measure category.

(iv) The improvement measure score will then be determined by calculating the weighted sum of the net improvement per measure category divided by the weighted sum of the number of eligible measures.

(v) The improvement measure score will be converted to a measure-level Star Rating using hierarchical clustering algorithms.

(vi) The Part D improvement measure scores for MA-PDs and PDPs will be determined using cluster algorithms in accordance with § 423.186(a)(2)(ii). The Part D improvement measure thresholds for MA-PDs and PDPs would be reported separately.

(g) *Data integrity*. (1) CMS will reduce a contract's measure rating when CMS determines that a contract's measure data are inaccurate, incomplete, or biased; such determinations may be based on a number of reasons, including mishandling of data, inappropriate processing, or implementation of incorrect practices that have an impact on the accuracy, impartiality, or completeness of the data used for one or more specific measures.

(i) CMS will reduce measures based on Part D reporting requirements data to 1 star when a contract did not score at least 95 percent on data validation for the applicable reporting section or was not compliant with CMS data validation standards/sub-standards for data directly used to calculate the associated measure.

(ii) For the appeals measures, CMS will use statistical criteria to estimate the percentage of missing data for each contract using data from multiple sources such as a timeliness monitoring study or audit information to scale the star reductions to determine whether the data at the independent review entity (IRE) are complete.

(A) The criteria would allow CMS to use scaled reductions for the Star Ratings for the applicable appeals measures to account for the degree to which the IRE data are missing.

(B) The data submitted for the timeliness monitoring project (TMP) or audit that aligns with the Star Ratings year measurement period will be used to determine the scaled reduction.

(C) The determination of the Part C appeals measure IRE data reduction is done independently of the Part D appeals measure IRE data reduction.

(D) The reductions range from a one-star reduction to a four-star reduction; the most severe reduction for the degree of missing IRE data would be a four-star reduction.

(E) The thresholds used for determining the reduction and the associated appeals measure reduction are as follows:

- (1) 20 percent, 1 star reduction.
- (2) 40 percent, 2 star reduction.
- (3) 60 percent, 3 star reduction.
- (4) 80 percent, 4 star reduction.

(F) If a contract receives a reduction due to missing Part D IRE data, the reduction is applied to both of the contract's Part D appeals measures.

(G) The scaled reduction is applied after the calculation for the appeals measure-level star ratings. If the application of the scaled reduction results in a measure-level star rating less than one-star, the contract will be assigned one-star for the appeals measure.

(H) The Part D Calculated Error is determined by the quotient of the number of untimely cases not auto-forwarded to the IRE and the total number of untimely cases.

(I) The projected number of cases not forwarded to the IRE in a 3-month period is calculated by multiplying the number of cases found not to be forwarded to the IRE based on the TMP or audit data by a constant determined by the data collection or data sample time period. The value of the constant will be 1.0 for contracts that submitted 3 months of data; 1.5 for contracts that submitted 2 months of data; and 3.0 for contracts that submitted 1 month of data.

(J) Contracts would be subject to a possible reduction due to lack of IRE

data completeness if both of the following conditions are met:

(1) The calculated error rate is 20 percent or more; and

(2) The projected number of cases not forwarded to the IRE is at least 10 in a 3-month period.

(K) A confidence interval estimate for the true error rate for the contract is calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent and an associated z of 1.959964 for a contract that is subject to a possible reduction.

(1) A contract's lower bound is compared to the thresholds of the scaled reductions to determine the IRE data completeness reduction.

(2) The reduction is identified by the highest threshold that a contract's lower bound exceeds.

(2) CMS will reduce a measure rating to 1 star for additional concerns that data inaccuracy, incompleteness, or bias have an impact on measure scores and are not specified in paragraphs (g)(1)(i) and (ii) of this section, including a contract's failure to adhere to CAHPS reporting requirements.

§ 423.186 Calculation of Star Ratings.

(a) *Measure Star Ratings*—(1) *Cut points*. CMS will determine cut points for the assignment of a Star Rating for each numeric measure score by applying either a clustering or a relative distribution and significance testing methodology. For the Part D measures, we propose to determine MA-PD and PDP cut points separately.

(2) *Clustering algorithm for all measures except CAHPS measures*. (i) The method minimizes differences within star categories and maximizes differences across star categories using the hierarchical clustering method.

(ii) In cases where multiple clusters have the same measure score value range, those clusters would be combined, leading to fewer than 5 clusters.

(iii) The clustering algorithm for the improvement measure scores is done in two steps to determine the cut points for the measure-level Star Ratings. Clustering is conducted separately for improvement measure scores greater than or equal to zero and those with improvement measure scores less than zero.

(A) Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating.

(B) Improvement scores less than zero would be assigned either 1 or 2 stars for the improvement Star Rating.

(3) *Relative distribution and significance testing for CAHPS measures*. The method combines

evaluating the relative percentile distribution with significance testing and accounts for the reliability of scores produced from survey data; no measure Star Rating is produced if the reliability of a CAHPS measure is less than 0.60. Low reliability scores are those with at least 11 respondents, reliability greater than or equal to 0.60 but less than 0.75, and also in the lowest 12 percent of contracts ordered by reliability. The following rules apply:

(i) A contract is assigned 1 star if both of the following criteria in paragraphs (a)(3)(i)(A) and (B) of this section are met and the criterion in paragraph (a)(3)(i)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is lower than the 15th percentile; and
(B) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score.

(C) The reliability is not low.

(D) Its average CAHPS measure score is more than one standard error below the 15th percentile.

(ii) A contract is assigned two stars if it does not meet the 1 star criteria and meets at least one of the following criteria:

(A) Its average CAHPS measure score is lower than the 30th percentile and the measure does not have low reliability.

(B) Its average CAHPS measure score is lower than the 15th percentile and the measure has low reliability.

(C) Its average CAHPS measure score is statistically significantly lower than the national average CAHPS measure score and below the 60th percentile.

(iii) A contract is assigned three stars if it meets at least one of the following criteria:

(A) Its average CAHPS measure score is at or above the 30th percentile and lower than the 60th percentile, and it is not statistically significantly different from the national average CAHPS measure score.

(B)(1) Its average CAHPS measure score is at or above the 15th percentile and lower than the 30th percentile;

(2) The reliability is low; and

(3) The score is not statistically significantly lower than the national average CAHPS measure score.

(C)(1) Its average CAHPS measure score is at or above the 60th percentile and lower than the 80th percentile;

(2) The reliability is low; and

(3) The score is not statistically significantly higher than the national average CAHPS measure score.

(iv) A contract is assigned 4 stars if it does not meet the 5-star criteria and meets at least one of the following criteria:

(A) Its average CAHPS measure score is at or above the 60th percentile and

the measure does not have low reliability.

(B) Its average CAHPS measure score is at or above the 80th percentile and the measure has low reliability.

(C) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score and above the 30th percentile.

(v) A contract is assigned five stars if both of the following criteria in paragraphs (a)(3)(v)(A) and (B) of this section are met and the criterion in paragraph (a)(3)(v)(C) or (D) of this section is met:

(A) Its average CAHPS measure score is at or above the 80th percentile.

(B) Its average CAHPS measure score is statistically significantly higher than the national average CAHPS measure score.

(C) The reliability is not low.

(D) Its average CAHPS measure score is more than one standard error above the 80th percentile.

(4) Measure scores are converted to a 5-star scale ranging from 1 (worst rating) to 5 (best rating), with whole star increments for the cut points.

(b) *Domain Star Ratings.* (1)(i) CMS groups measures by domains solely for purposes of public reporting the data on Medicare Plan Finder. They are not used in the calculation of the summary or overall ratings. Domains are used to group measures by dimensions of care that together represent a unique and important aspect of quality and performance.

(ii) The 4 domains for the Part D Star Ratings are: Drug Plan Customer Service; Member Complaints and Changes in the Drug Plan's Performance; Member Experience with the Drug Plan; and Drug Safety and Accuracy of Drug Pricing.

(2) CMS calculates the domain ratings as the unweighted mean of the Star Ratings of the included measures.

(i) A contract must have scores for at least 50 percent of the measures required to be reported for that contract type for that domain to have a domain rating calculated.

(ii) The domain ratings are on a 1 to 5 star scale ranging from 1 (worst rating) to 5 (best rating) in whole star increments using traditional rounding rules.

(c) *Part D summary ratings.* (1) CMS will calculate the Part D summary ratings using the weighted mean of the measure-level Star Ratings for Part D, weighted in accordance with paragraph (e) with an adjustment to reward consistently high performance described and the application of the CAI, under paragraph (f) of this section.

(2)(i) A contract must have scores for at least 50 percent of the measures required to be reported for the contract type to have a summary rating calculated.

(ii) The Part D improvement measure is not included in the count of the minimum number of rated measures.

(3) The summary ratings are on a 1 to 5 star scale ranging from 1 (worst rating) to 5 (best rating) in half-star increments using traditional rounding rules.

(d) *Overall MA-PD rating.* (1) The overall rating for a MA-PD contract will be calculated using a weighted mean of the Part C and Part D measure-level Star Ratings, weighted in accordance with paragraph (e) of this section and with an adjustment to reward consistently high performance described and the application of the CAI, under paragraph (f).

(2)(i) An MA-PD must have both Part C and Part D summary ratings and scores for at least 50 percent of the measures required to be reported for the contract type to have the overall rating calculated.

(ii) The Part C and D improvement measures are not included in the count of measures needed for the overall rating.

(iii) Any measures that share the same data and are included in both the Part C and Part D summary ratings will be included only once in the calculation for the overall rating.

(iv) The overall rating is on a 1 to 5 star scale ranging from 1 (worst rating) to 5 (best rating) in half-increments using traditional rounding rules.

(e) *Measure weights*—(1) *General rules.* Subject to paragraphs (e)(2) and (3) of this section, CMS will assign weights to measures based on their categorization as follows.

(i) Improvement measures receive the highest weight of 5.

(ii) Outcome and Intermediate outcome measures receive a weight of 3.

(iii) Patient experience and complaint measures receive a weight of 1.5.

(iv) Access measures receive a weight of 1.5.

(v) Process measures receive a weight of 1.

(2) *Rules for new measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. In subsequent years, the measure will be assigned the weight associated with its category.

(3) *Special rule for Puerto Rico.* Contracts that have service areas that are wholly located in Puerto Rico will receive a weight of zero for the Part D adherence measures for the summary and overall rating calculations and will

have a weight of 3 for the adherence measures for the improvement measure calculations.

(f) *Completing the Part D summary and overall rating calculations.* CMS will adjust the summary and overall rating calculations to take into account the reward factor (if applicable) and the categorical adjustment index (CAI) as provided in this paragraph.

(1) *Reward factor.* This rating-specific factor is added to both the summary and overall ratings of contracts that qualify for the reward factor based on both high and stable relative performance for the rating level.

(i) The contract's performance will be assessed using its weighted mean and its ranking relative to all rated contracts in the rating level (overall for MA-PDs and Part D summary for MA-PDs and PDPs) for the same Star Ratings year. The contract's stability of performance will be assessed using the weighted variance and its ranking relative to all rated contracts in the rating type (overall for MA-PDs and Part D summary for MA-PDs and PDPs). The weighted mean and weighted variance are compared separately for MA-PD and standalone Part D contracts (PDPs). The measure weights are specified in paragraph (e) of this section. Since highly-rated contracts may have the improvement measure(s) excluded in the determination of their final highest rating, each contract's weighted variance and weighted mean will be calculated both with and without the improvement measures. For an MA-PD's Part C and D summary ratings, its ranking is relative to all other contracts' weighted variance and weighted mean for the rating type (Part C summary, Part D summary) with the improvement measure.

(ii) Relative performance of the weighted variance (or weighted variance ranking) will be categorized as being high (at or above 70th percentile), medium (between the 30th and 69th percentile) or low (below the 30th percentile). Relative performance of the weighted mean (or weighted mean ranking) will be categorized as being high (at or above the 85th percentile), relatively high (between the 65th and 84th percentiles), or other (below the 65th percentile).

(iii) The combination of the relative variance and relative mean is used to determine the reward factor to be added to the contract's summary and overall ratings as follows:

(A) A contract with low variance and a high mean will have a reward factor equal to 0.4.

(B) A contract with medium variance and a high mean will have a reward factor equal to 0.3.

(C) A contract with low variance and a relatively high mean will have a reward factor equal to 0.2.

(D) A contract with medium variance and a relatively high mean will have a reward factor equal to 0.1.

(E) A contract with all other combinations of variance and relative mean will have a reward factor equal to 0.0.

(iv) The reward factor is determined and applied before application of the CAI adjustment under paragraph (f)(2) of this section; the reward factor is based on unadjusted scores.

(2) *Categorical adjustment index.* CMS applies the categorical adjustment index (CAI) as provided in this paragraph to adjust for the average within-contract disparity in performance associated with the percentages of beneficiaries who receive a low income subsidy or are dual eligible (LIS/DE)/or have disability status. The factor is calculated as the mean difference in the adjusted and unadjusted ratings (overall, Part D for MA-PDs, Part D for PDPs) of the contracts that lie within each final adjustment category for each rating type.

(i) The CAI is added to or subtracted from the contract's overall and summary ratings and is applied after the reward factor adjustment (if applicable).

(A) The adjustment factor is monotonic (that is, as the proportion of LIS/DE and disabled increases in a contract, the adjustment factor increases in at least one of the dimensions) and varies by a contract's categorization into a final adjustment category that is determined by a contract's proportion of LIS/DE and disabled beneficiaries.

(B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year. The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year. A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period. Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

(C) A MA-PD contract may be adjusted up to three times with the CAI:

one for the overall Star Rating and one for each of the summary ratings (Part C and Part D).

(D) A PDP contract may be adjusted only once for the CAI: For the Part D summary rating.

(E) The CAI values are rounded and displayed with 6 decimal places.

(ii) In determining the CAI values, a measure will be excluded as a candidate for inclusion for adjustment if the measure meets any of the following:

(A) The measure is already case-mix adjusted for socioeconomic status.

(B) The focus of the measurement is not a beneficiary-level issue but rather a plan or provider-level issue.

(C) The measure is scheduled to be retired or revised.

(D) The measure is applicable only to SNPs.

(iii) CMS will announce the measures identified for inclusion in the calculations of the CAI in accordance with this paragraph through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. The measures for inclusion in the calculations of the CAI values will be selected based on the analysis of the dispersion of the LIS/DE within contract differences using all reportable numeric scores for contracts receiving a rating in the previous rating year. CMS calculates the results of each contract's estimated difference between the LIS/DE and non-LIS/DE performance rates per contract using logistic mixed effects model that includes LIS/DE as a predictor, random effects for contract and an interaction term of contract. For each contract, the proportion of beneficiaries receiving the measured clinical process or outcome for LIS/DE and non-LIS/DE beneficiaries would be estimated separately. The following decision criteria is used to determine the measures for adjustment:

(A) A median absolute difference between LIS/DE and non-LIS/DE beneficiaries for all contracts analyzed is 5 percentage points or more.

(B) The LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts.

(C) The Part D measures for MA-PDs and PDPs will be analyzed independently, but the Part D measures selected for adjustment will include measures that meet the selection criteria for either delivery system.

(iv) The adjusted measures scores for the selected measures are determined using the results from regression models of beneficiary level measure scores that adjust for the average within contract difference in measure scores for MA or PDP contracts.

(A) A logistic regression model with contract fixed effects and beneficiary level indicators of LIS/DE and disability status is used for the adjustment.

(B) The adjusted measure scores are converted to a measure-level Star Rating using the measure thresholds for the Star Ratings year that corresponds to the measurement period of the data employed for the CAI determination.

(v) The rating-specific CAI values will be determined using the mean differences between the adjusted and unadjusted Star Ratings (overall, Part D summary for MA-PDs and Part D summary for PDPs) in each final adjustment category.

(A) For the annual development of the CAI, the distribution of the percentages for LIS/DE and disabled (using the enrollment data that parallels the previous Star Ratings year's data) would be examined to determine the number of equal-sized initial groups for each attribute (LIS/DE and disabled).

(B) The initial categories are created using all groups formed by the initial LIS/DE and disabled groups.

(C) The mean difference between the adjusted and unadjusted summary or overall ratings per initial category would be calculated and examined. The initial categories would then be collapsed to form the final adjustment categories. The collapsing of the initial categories to form the final adjustment categories would be done to enforce monotonicity in at least one dimension (LIS/DE or disabled).

(D) The mean difference within each final adjustment category by rating-type (Part D for MA-PD, Part D for PDPs or overall) would be the CAI values for the next Star Ratings year.

(vi) CMS develops the model for the modified contract-level LIS/DE percentage for Puerto Rico using the following sources of information:

(A) The most recent data available at the time of the development of the model of both 1-year American Community Survey (ACS) estimates for the percentage of people living below the Federal Poverty Level (FPL) and the ACS 5-year estimates for the percentage of people living below 150 percent of the FPL. The data to develop the model will be limited to the 10 states, drawn from the 50 states plus the District of Columbia with the highest proportion of people living below the FPL, as identified by the 1-year ACS estimates.

(B) The Medicare enrollment data from the same measurement period as the Star Rating's year. The Medicare enrollment data would be aggregated from MA contracts that had at least 90 percent of their enrolled beneficiaries

with mailing addresses in the 10 highest poverty states.

(vii) A linear regression model is developed to estimate the percentage of LIS/DE for a contacts that solely serve the population of beneficiaries in Puerto Rico.

(A) The maximum value for the modified LIS/DE indicator value per contract would be capped at 100 percent.

(B) All estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.

(C) The model's coefficient and intercept are updated annually and published in the Technical Notes.

(g) *Applying the improvement measure scores.* (1) CMS runs the calculations twice for each highest rating for each contract-type (overall rating for MA-PD contracts and Part D summary rating for PDPs), with all applicable adjustments (CAI and the reward factor), once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's highest rating, CMS applies the following rules:

(i) Contracts with 2 or fewer stars for their highest rating when calculated without improvement and with all applicable adjustments (CAI and the reward factor) will not have their rating calculated with the improvement measure(s).

(ii) If the highest rating for each contract-type is 4 stars or more without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), a comparison of the highest rating with and without the improvement measure(s) is done. The higher rating is used for the rating.

(iii) If the highest rating is between 2 stars and 4 stars with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s).

(2) The Part D summary rating for MA-PDs will include the Part D improvement measure.

(h) *Posting and display of ratings.* For all ratings at the measure, domain, summary and overall level, posting and display of the ratings is based on there being sufficient data to calculate and assign ratings. If a contract does not have sufficient data to calculate a rating, the posting and display would be the flag "Not enough data available." If the measurement period is prior to one year past the contract's effective date, the posting and display would be the flag "Plan too new to be measured".

(i) *Medicare Plan Finder performance icons.* Icons are displayed on Medicare Plan Finder to note performance as provided in this paragraph:

(1) *High-performing icon.* The high performing icon is assigned to a Part D plan sponsor for achieving a 5-star Part D summary rating and an MA-PD contract for a 5-star overall rating.

(2) *Low-performing icon.* (i) A contract receives a low performing icon as a result of its performance on the Part C or Part D summary ratings. The low performing icon is calculated by evaluating the Part C and Part D summary ratings for the current year and the past 2 years. If the contract had any combination of Part C or Part D summary ratings of 2.5 or lower in all 3 years of data, it is marked with a low performing icon. A contract must have a rating in either Part C or Part D for all 3 years to be considered for this icon.

(ii) CMS may disable the Medicare Plan Finder online enrollment function (in Medicare Plan Finder) for Medicare health and prescription drug plans with the low performing icon; beneficiaries will be directed to contact the plan directly to enroll in the low-performing plan.

(3) *Plan preview of the Star Ratings.* CMS will have plan preview periods before each Star Ratings release during which Part D plan sponsors can preview their Star Ratings data in HPMS prior to display on the Medicare Plan Finder.

■ 67. Section 423.265 is amended by revising paragraph (b)(2) to read as follows.

§ 423.265 Submission of bids and related information.

* * * * *

(b) * * *

(2) *Substantial differences between bids*—(i) *General rule.* Except as provided in paragraph (b)(2)(ii) of this section, potential Part D sponsors' bid submissions must reflect differences in benefit packages or plan costs that CMS determines to represent substantial differences relative to a sponsor's other bid submissions. In order to be considered "substantially different," each bid must be significantly different from the sponsor's other bids with respect to beneficiary out-of-pocket costs or formulary structures.

(ii) *Exception.* A potential Part D sponsor's enhanced bid submission does not have to reflect the substantial differences as required in paragraph (b)(2)(i) of this section relative to any of its other enhanced bid submissions.

* * * * *

§ 423.503 [Amended]

■ 68. Section 423.503 is amended in paragraphs (b)(1) and (2) by removing the phrase "14 months" and adding in its place "12 months" each time it appears.

■ 69. Section 423.504 is amended by revising paragraphs (b)(4)(ii) and (b)(4)(vi)(C) to read as follows.

§ 423.504 General provisions.

* * * * *

(b) * * *

(4) * * *

(ii) Personnel and systems sufficient for the Part D plan sponsor to organize, implement, control, and evaluate financial and communication activities, the furnishing of prescription drug services, the quality assurance, medical therapy management, and drug and or utilization management programs, and the administrative and management aspects of the organization.

* * * * *

(vi) * * *

(C)(1) Each Part D plan sponsor must establish and implement effective training and education for its compliance officer and organization employees, the Part D sponsor's chief executive and other senior administrators, managers and governing body members.

(2) Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee, and new appointment to a chief executive, manager, or governing body member.

* * * * *

■ 70. Section 423.505 is amended—

- a. By revising paragraph (b)(18);
- b. In paragraph (b)(25), by removing the word "marketing" and adding in its place the word "communication"; and
- c. By revising paragraph (b)(26).

The revisions read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(18) To agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy including all of the following:

(i) Making standard contracts available upon request from interested pharmacies no later than September 15 of each year for contracts effective January 1 of the following year.

(ii) Providing a copy of a standard contract to a requesting pharmacy within 2 business days after receiving such a request from the pharmacy.

* * * * *

(26) Maintain a Part D summary plan rating score of at least 3 stars under the 5-star rating system specified in subpart 186 of this part 423. A Part D summary plan rating is calculated as provided in § 423.186.

* * * * *

§ 423.507 [Amended]

■ 71. Section 423.507 is amended by removing and reserving paragraph (b).

■ 72. Section 423.508 is amended by revising paragraph (a) to read as follows:

§ 423.508 Modification or termination of contract by mutual consent.

(a) *General rule.* A contract may be modified or terminated at any time by written mutual consent. If the PDP sponsor submits a request to end the term of its contract after the deadline provided in § 423.507(a)(2)(i), the contract may be terminated by mutual consent in accordance with paragraphs (b) through (f) of this section. CMS may mutually consent to the contract termination if the contract termination does not negatively affect the administration of the Medicare Part D program.

* * * * *

■ 73. Section 423.509 is amended by revising paragraph (a)(4)(v)(A) and adding paragraphs (a)(4)(xiii) and (xiv) and (b)(2)(v) to read as follows:

§ 423.509 Termination of contract by CMS.

- (a) * * *
- (4) * * *
- (v) * * *

(A) Requirements in subpart V of this part.

* * * * *

(xiii) The Part D plan sponsor has committed any of the acts in § 423.752 that support the imposition of intermediate sanctions or civil money penalties under § 423.750.

(xiv) Following the issuance of a notice to the sponsor no later than August 1, CMS must terminate, effective December 31 of the same year, an individual PDP if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

- (b) * * *
- (2) * * *

(v) In the event that CMS issues a termination notice to a Part D plan sponsor on or before August 1 with an effective date of the following December 31, the Part D plan sponsor must issue notification to its Medicare enrollees at least 90 days prior to the effective date of the termination.

* * * * *

■ 74. Section 423.558 is amended by adding paragraph (a)(4) to read as follows:

§ 423.558 Scope.

(a) * * *

(4) Review of at-risk determinations made under a drug management program in accordance with § 423.153(f).

* * * * *

■ 75. Section 423.560 is amended by revising the definitions of “Appeal”, “Grievance”, “Reconsideration”, and “Redetermination” and adding in alphabetical order a definition for “Specialty tier” to read as follows:

§ 423.560 Definitions.

* * * * *

Appeal means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in § 423.566(b). Appeal also includes the review of at-risk determinations made under a drug management program in accordance with § 423.153(f). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (Council), and judicial reviews.

* * * * *

Grievance means any complaint or dispute, other than one that involves a coverage determination or at-risk determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.

* * * * *

Reconsideration means a review of an adverse coverage determination or at-risk determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits or the IRE obtains.

Redetermination means a review of an adverse coverage determination or at-risk determination by a Part D plan sponsor, the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor obtains.

Specialty tier means 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.

■ 76. Section 423.562 is amended by revising paragraph (a)(1)(ii), adding paragraph (a)(1)(v), and revising paragraph (b)(4) to read as follows:

§ 423.562 General provisions.

- (a) * * *
- (1) * * *

(ii) Use a single, uniform exceptions and appeals process which includes procedures for accepting oral and written requests for coverage determinations and redeterminations that are in accordance with § 423.128(b)(7) and (d)(1)(iv).

* * * * *

(v) If the Part D plan sponsor has established a drug management program under § 423.153(f), appeal procedures that meet the requirements of this subpart for issues that involve at-risk determinations.

* * * * *

- (b) * * *

(4) If dissatisfied with any part of a coverage determination or an at-risk determination under a drug management program in accordance with § 423.153(f), all of the following appeal rights:

(i) The right to a redetermination of the adverse coverage determination or at-risk determination by the Part D plan sponsor, as specified in § 423.580.

(ii) The right to request an expedited redetermination, as provided under § 423.584.

(iii) If, as a result of the redetermination, a Part D plan sponsor affirms, in whole or in part, its adverse coverage determination or at-risk determination, the right to a reconsideration or expedited reconsideration by an independent review entity (IRE) contracted by CMS, as specified in § 423.600.

(iv) If the IRE affirms the plan’s adverse coverage determination or at-risk determination, in whole or in part, the right to an ALJ hearing if the amount in controversy meets the requirements in § 423.1970.

(v) If the ALJ or attorney adjudicator affirms the IRE’s adverse coverage determination or at-risk determination, in whole or in part, the right to request Council review of the ALJ’s or attorney adjudicator’s decision, as specified in § 423.1974.

(vi) If the Council affirms the ALJ’s or attorney adjudicator’s adverse coverage determination or at-risk determination, in whole or in part, the right to judicial review of the decision if the amount in

controversy meets the requirements in § 423.1976.

* * * * *

■ 77. Section 423.564 is amended by revising paragraph (b) to read as follows:

§ 423.564 **Grievance procedures.**

* * * * *

(b) *Distinguished from appeals.*

Grievance procedures are separate and distinct from appeal procedures, which address coverage determinations as defined in § 423.566(b) and at-risk determinations made under a drug management program in accordance with § 423.153(f). Upon receiving a complaint, a Part D plan sponsor must promptly determine and inform the enrollee whether the complaint is subject to its grievance procedures or its appeal procedures.

* * * * *

■ 78. Section 423.578 is amended by—

- a. Revising paragraphs (a) introductory text, (a)(1) and (2), (a)(4) introductory text, and (a)(5) and (6);
- b. Removing paragraph (a)(7); and
- c. Revising paragraph (c)(3).

The revisions read as follows:

§ 423.578 **Exceptions process.**

(a) *Requests for exceptions to a plan's tiered cost-sharing structure.* Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the requested non-preferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (a)(4) of this section.

(1) The tiering exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.

(2) Part D plan sponsors must establish criteria that provide for a tiering exception, consistent with paragraphs (a)(3) through (6) of this section.

* * * * *

(4) A prescribing physician or other prescriber must provide an oral or written supporting statement that the preferred drug(s) for the treatment of the enrollee's condition—

* * * * *

(5) If the physician or other prescriber provides an oral supporting statement,

the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up.

(6) Limitations on tiering exceptions: A Part D plan sponsor is permitted to design its tiering exceptions procedures such that an exception is not approvable in the following circumstances:

(i) To cover a brand name drug, as defined in § 423.4, at a preferred cost-sharing level that applies only to alternative drugs that are—

(A) Generic drugs, for which an application is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or

(B) Authorized generic drugs as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act.

(ii) To cover a biological product licensed under section 351 of the Public Health Service Act at a preferred cost-sharing level that does not contain any alternative drug(s) that are biological products.

(iii) If a Part D plan sponsor maintains a specialty tier, as defined in § 423.560, the 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.

* * * * *

(c) * * *

(3) *When a tiering exceptions request is approved.* Whenever an exceptions request made under paragraph (a) of this section is approved—

(i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—

(A) The enrollee's prescribing physician or other prescriber continues to prescribe the drug;

(B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and

(C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.

(ii) The Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies to preferred alternative drugs. If the plan's formulary contains alternative drugs on multiple tiers, cost-sharing must be assigned at

the lowest applicable tier, under the requirements in paragraph (a) of this section.

* * * * *

■ 79. Section 423.580 is revised to read as follows:

§ 423.580 **Right to a redetermination.**

An enrollee who has received a coverage determination (including one that is reopened and revised as described in § 423.1978) or an at-risk determination under a drug management program in accordance with § 423.153(f) may request that it be redetermined under the procedures described in § 423.582, which address requests for a standard redetermination. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request a standard redetermination under the procedures described in § 423.582. An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of an enrollee) may request an expedited redetermination as specified in § 423.584.

■ 80. Section 423.582 is amended by revising paragraphs (a) and (b) to read as follows:

§ 423.582 **Request for a standard redetermination.**

(a) *Method and place for filing a request.* An enrollee or an enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must ask for a redetermination by making a written request with the Part D plan sponsor that made the coverage determination or the at-risk determination under a drug management program in accordance with § 423.153(f). The Part D plan sponsor may adopt a policy for accepting oral requests.

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for a redetermination must be filed within 60 calendar days from the date of the notice of the coverage determination or the at-risk determination under a drug management program in accordance with § 423.153(f).

* * * * *

■ 81. Section 423.584 is amended by revising paragraph (a) to read as follows:

§ 423.584 **Expediting certain redeterminations.**

(a) *Who may request an expedited redetermination.* An enrollee or an enrollee's prescribing physician or other prescriber may request that a Part D plan sponsor expedite a redetermination that involves the issues specified in

§ 423.566(b) or an at-risk determination made under a drug management program in accordance with § 423.153(f). (This does not include requests for payment of drugs already furnished.)

* * * * *

■ 82. Section 423.590 is amended by revising paragraphs (a), (b)(1) and (2), the paragraph (f) subject heading, and paragraphs (f)(1) and (g)(3)(i) to read as follows:

§ 423.590 Timeframes and responsibility for making redeterminations.

(a) *Standard redetermination—request for covered drug benefits or review of an at-risk determination.* (1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must notify the enrollee in writing of its redetermination (and effectuate it in accordance with § 423.636(a)(1) or (3) as expeditiously as the enrollee’s health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(2) If the Part D plan sponsor makes a redetermination that affirms, in whole or in part, its adverse coverage determination or at-risk determination, it must notify the enrollee in writing of its redetermination as expeditiously as the enrollee’s health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

(b) * * *

(1) If the Part D plan sponsor makes a redetermination that is completely favorable to the enrollee, the Part D plan sponsor must issue its redetermination (and effectuate it in accordance with § 423.636(a)(2)) no later than 14 calendar days from the date it receives the request for redetermination.

(2) If the Part D plan sponsor affirms, in whole or in part, its adverse coverage determination, it must notify the enrollee in writing of its redetermination no later than 14 calendar days from the date it receives the request for redetermination.

* * * * *

(f) *Who must conduct the review of an adverse coverage determination or at-risk determination.* (1) A person or persons who were not involved in making the coverage determination or an at-risk determination under a drug management program in accordance with § 423.153(f) must conduct the redetermination.

* * * * *

(g) * * *

(3) * * *

(i) For adverse drug coverage redeterminations, or redeterminations related to a drug management program in accordance with § 423.153(f), describe both the standard and expedited reconsideration processes, including the enrollee’s right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process;

* * * * *

■ 83. Section 423.602 is amended by revising paragraph (b)(2) to read as follows:

§ 423.602 Notice of reconsideration determination by the independent review entity.

* * * * *

(b) * * *

(2) If the reconsideration determination is adverse (that is, does not completely reverse the adverse coverage determination or redetermination by the Part D plan sponsor), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the threshold requirement under § 423.1970;

* * * * *

■ 84. Section 423.636 is amended by revising paragraph (a)(2) and adding paragraphs (a)(3) and (b)(3) to read as follows:.

§ 423.636 How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.

(a) * * *

(2) *Requests for payment.* If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 14 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

(3) *Review of an at-risk determination.* If, on redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f), the Part D plan sponsor reverses its at-risk determination, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee’s health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(b) * * *

(3) *Review of an at-risk determination.* If, on appeal of an at-risk determination made under a drug management program in accordance with § 423.153(f), the determination by the

Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must implement the change to the at-risk determination within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

■ 85. Section 423.638 is revised to read as follows:

§ 423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.

(a) Reversals by the Part D plan sponsor—

(1) *Requests for benefits.* If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee’s health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(2) *Review of an at-risk determination.* If, on an expedited redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f), the Part D plan sponsor reverses its at-risk determination, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee’s health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(b) Reversals other than by the Part D plan sponsor—

(1) *Requests for benefits.* If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee’s health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Review of an at-risk determination.* If the expedited redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f) by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan

sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

§ 423.652 [Amended]

■ 86. Section 423.652 is amended paragraph (b)(1) by removing the phrase "July 15" and adding in its place "September 1".

■ 87. Section 423.750 is amended by revising paragraph (a)(3) to read as follows:

§ 423.750 Types of intermediate sanctions and civil money penalties.

(a) * * *

(3) Suspension of communication activities to Medicare beneficiaries by a Part D plan sponsor, as defined by CMS.

* * * * *

■ 88. Section 423.752 is amended by revising paragraphs (a)(9) and (b) to read as follows:

§ 423.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) * * *

(9) Fails to comply with communication restrictions described in subpart V or applicable implementing guidance.

* * * * *

(b) Suspension of enrollment and communications. If CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may impose the intermediate sanctions at § 423.750(a)(1) and (3).

* * * * *

■ 89. Section 423.756 is amended by revising paragraph (c)(3)(ii) introductory text to read as follows:

§ 423.756 Procedures for imposing intermediate sanctions and civil money penalties.

(c) * * *

(3) * * *

(ii) In instances where intermediate sanctions have been imposed, CMS may require a Part D plan sponsor to market or to accept enrollments or both for a limited period of time in order to assist CMS in making a determination as to whether the deficiencies that are the bases for the intermediate sanctions have been corrected and are not likely to recur.

* * * * *

■ 90. Section 423.1970 is amended by revising paragraph (b) to read as follows:

§ 423.1970 Right to an ALJ hearing.

* * * * *

(b) *Calculating the amount in controversy in specific circumstances.*

(1) If the basis for the appeal is the refusal by the Part D plan sponsor to provide drug benefits, CMS uses the projected value of those benefits to compute the amount remaining in controversy. The projected value of a Part D drug or drugs must include any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year.

(2) If the basis for the appeal is an at-risk determination made under a drug management program in accordance with § 423.153(f), CMS uses the projected value of the drugs subject to the drug management program to compute the amount remaining in controversy. The projected value of the drugs subject to the drug management program shall include the value of any refills prescribed for the drug(s) in dispute during the plan year.

* * * * *

§ 423.2018 [Amended]

■ 91. Section 423.2018 is amended—

■ a. In paragraph (a)(1), by removing the phrase "appealed coverage determination was made" and adding in its place the phrase "appealed coverage determination or at-risk determination was made"; and

■ b. In paragraph (a)(2), by removing the phrase "after the coverage determination to be considered" and adding in its place the phrase "after the coverage determination or at-risk determination to be considered".

§ 423.2020 [Amended]

■ 92. Section 423.2020 is amended in paragraph (c)(1) by removing the phrase "the coverage determination, and" and adding in its place the phrase "the coverage determination or at-risk determination, and".

§ 423.2022 [Amended]

■ 93. Section 423.2022 is amended by—

■ a. Removing the first appearance of paragraph (b) subject heading and paragraph (b)(1) introductory text; and.

■ b. In paragraph (b)(1)(i) by removing the phrase "the coverage determination, redetermination," and adding in its place the phrase "the coverage determination or at-risk determination, redetermination,".

§ 423.2032 [Amended]

■ 94. Section 423.2032 is amended in paragraph (a) by removing the phrase "the coverage determination, redetermination," and adding in its

place the phrase "the coverage determination or at-risk determination, redetermination,".

§ 423.2036 [Amended]

■ 95. Section 423.2036 is amended in paragraph (e) by removing the phrase "a coverage determination" and adding in its place the phrase "a coverage determination or at-risk determination".

§ 423.2038 [Amended]

■ 96. Section 423.2038 is amended in paragraph (c) by removing the phrase "may be made, and" and adding in its place the phrase "may be made, or an enrollee's at-risk determination should be reversed, and".

§ 423.2046 [Amended]

■ 97. Section 423.2046 is amended in paragraph (a)(1)(iii) by removing the phrase "the coverage determination." and adding in its place the phrase "the coverage determination or at-risk determination.

§ 423.2056 [Amended]

■ 98. Section 423.2056 is amended—

■ a. In paragraph (a)(1) by removing the phrase "appealed coverage determination" and adding in its place the phrase "appealed coverage determination or at-risk determination", and

■ b. In paragraph (e) by removing the phrase "the coverage determination to be considered in the appeal." and adding in its place "the coverage determination or at-risk determination to be considered in the appeal."

§ 423.2062 [Amended]

■ 99. Section 423.2062 is amended in paragraph (b) by removing the phrase "coverage determination being considered and does not have precedential effect" and adding in its place the phrase "coverage determination or at-risk determination being considered and does not have precedential effect".

§ 423.2122 [Amended]

■ 100. Section 423.2122 is amended—

■ a. In paragraph (a)(1) by removing the phrase "the coverage determination." and adding in its place the phrase "the coverage determination or at-risk determination";

■ b. In paragraph (a)(3) by removing the phrase "a coverage determination is made" and adding in its place "a coverage determination or at-risk determination is made" and by removing the phrase "after the coverage determination considered" and adding in its place "after the coverage determination or at-risk determination considered".

§ 423.2126 [Amended]

■ 101. Section 423.2126 is amended in paragraph (b) by removing the phrase “coverage determination to be considered in the appeal.” and adding in its place the phrase “coverage determination or at-risk determination to be considered in the appeal.”

Subpart V—Part D Communication Requirements

■ 102. The subpart V heading is amended to read as set forth above.

■ 103. Section 423.2260 is amended by—

- a. Revising the section heading;
- b. Adding in alphabetical order definitions for “Communications”, “Communications materials”, and “Marketing”; and
- c. Revising the definition of “Marketing materials”.

The revisions and additions read as follows:

§ 423.2260 Definitions.

* * * * *

Communications means activities and use of materials to provide information to current and prospective enrollees.

Communication materials means all information provided to current and prospective enrollees. Marketing materials are a subset of communication materials.

Marketing means the use of materials or activities that meet the following:

- (1) By the Part D sponsor or downstream entities.
- (2) Intended to draw a beneficiary’s attention to a Part D plan or plans.
- (3) Influence a beneficiary’s decision making process when making a Part D plan selection or influence a beneficiary’s decision to stay enrolled in a plan (that is, retention-based marketing).

Marketing materials—

(1) Include, but are not limited to following:

(i) Materials such as brochures; posters; advertisements in media such as newspapers, magazines, television, radio, billboards, or the Internet; and social media content.

(ii) Marketing representative materials such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(2) Exclude the following materials:

- (i) Information about the plan’s benefit structure or cost sharing;
- (ii) Information about measuring or ranking standards (for example, star ratings);
- (iii) Mention benefits or cost sharing, but do not meet the definition of marketing in this section; or

(3) Unless otherwise specified by CMS because of their use or purpose, are required under § 423.128.

■ 104. Section 422.2262 is amended by revising paragraph (d) to read as follows:

§ 422.2262 Review and distribution of marketing materials.

* * * * *

(d) *Enrollee communication materials*. Enrollee communication materials may be reviewed by CMS, which may upon review determine that such materials must be modified, or may no longer be used.

■ 105. Section 423.2264 is revised to read as follows:

§ 423.2264 Guidelines for CMS review.

In reviewing marketing material or election forms under § 423.2262 of this part, CMS determines that the materials—

(a) Provide to Medicare beneficiaries interested in enrolling, adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges in a format (and, where appropriate, print size) and using standard terminology that may be specified by CMS.

(b) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(c) Include in written materials notice that the Part D sponsor is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary’s enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(d) Ensure that materials are not materially inaccurate or misleading or otherwise make material misrepresentations.

■ 106. Section 423.2268 is revised to read as follows:

§ 423.2268 Standards for Part D Sponsor communications and marketing.

(a) In conducting communication activities, Part D sponsors may not do any of the following:

- (1) Provide information that is inaccurate or misleading.
- (2) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor.
- (3) Claim the Part D sponsor is recommended or endorsed by CMS or

Medicare or that CMS or Medicare recommends that the beneficiary enroll in the Part D plan. It may explain that the organization is approved for participation in Medicare.

(4) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(5) Display the names and/or logos of co-branded network providers or pharmacies on the sponsor’s member identification card, unless the names, and/or logos are related to the member selection of specific provider organizations (for example, physicians, hospitals).

(6) Use a plan name that does not include the plan type. The plan type should be included at the end of the plan name.

(7) For markets with a significant non-English speaking population, provide materials, as defined by CMS, unless in the language of these individuals. Specifically, MA organizations must translate 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.

(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 (as defined in the CMS Marketing Guidelines) value, 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) Market non-health care/non-prescription drug plan related products to prospective enrollees during any Part D sales activity or presentation. This is considered cross-selling and is prohibited.

(4) 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.

(5) 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.

(6) Distribute marketing materials for which, before expiration of the 45-day period, the Part D sponsor receives from CMS written notice of disapproval because it is inaccurate or misleading, or misrepresents the Part D sponsor, its marketing representatives, or CMS.

(7) Conduct sales presentations or distribute and accept Part D plan enrollment forms in provider offices or other areas where health care is delivered to individuals, except in the case where such activities are conducted in common areas in health care settings.

(8) Conduct sales presentations or distribute and accept plan applications at educational events.

(9) Display the names and/or logos of provider co-branding partners on marketing materials, unless the materials clearly indicate that other providers are available in the network.

(10) Knowingly target or send marketing materials to any Part D enrollee, whose prior year enrollment was in an MA plan, during the Open Enrollment Period.

(11) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(12) 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.

(13) Solicit door-to-door for Medicare beneficiaries or through other unsolicited means of direct contact, including calling a beneficiary without the beneficiary initiating the contact.

(14) Use providers or provider groups to distribute printed information comparing the benefits of different health plans unless the providers, provider groups, or pharmacies accept and display materials from all health plans with which the providers, provider groups, or pharmacies contract. The use of publicly available comparison information is permitted if approved by CMS in accordance with the Medicare marketing guidance.

(15) Provide meals to potential enrollees, which is prohibited, regardless of value.

§ 423.2272 [Amended]

■ 107. Section 423.2272 is amended by removing paragraph (e).

§ 423.2274 [Amended]

■ 108. Section 423.2274 is amended—

- a. By redesignating paragraph (b)(1)(iii) as paragraph (b)(1)(iv);
- b. By redesignating paragraph (b)(2)(iii) as paragraph (b)(1)(iii);
- c. By removing paragraph (b)(2);
- d. By redesignating paragraph (b)(3) as paragraph (b)(2); and
- e. In newly redesignated paragraph (b)(2)(iii), by removing the phrase “from an MA plan,” and adding the phrase “from a Part D sponsor,” in its place.

§ 423.2410 [Amended]

■ 109. Section 423.2410 is amended in paragraph (a) by removing the phrase “an MLR” and adding in its place the phrase “the information required under § 423.2460”.

§ 423.2420 [Amended]

■ 110. Section 423.2420 is amended by—

- a. Removing and reserving paragraph (b)(2)(viii);
- b. Revising paragraph (d)(2)(i); and
- c. Removing the first paragraph designated as (d)(2)(ii).

The revision reads as follows:

§ 423.2420 Calculation of medical loss ratio.

* * * * *

(d) * * *

(2)

(i) Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results. Specific identification of an expense with an activity that is represented by one of the categories in paragraph (b) or (c) of this section will generally be the most accurate method.

* * * * *

■ 111. Section 423.2430 is amended by—

- a. Redesignating paragraphs (a) introductory text and paragraphs (a)(1) and (2) as paragraphs (a)(1), (2), and (3), respectively;
- b. Revising newly redesignated paragraph (a)(1);
- c. Adding paragraph (a)(4); and
- d. Removing and reserving paragraph (b)(8).

The revisions and additions read as follows:

§ 423.2430 Activities that improve health care quality.

(a) *Activity requirements.* (1) Activities conducted by a Part D sponsor to improve quality must either—

(i) Fall into one of the categories in paragraph (a)(2) of this section and meet all of the requirements in paragraph (a)(3) of this section; or

(ii) Be listed in paragraph (a)(4) of this section.

* * * * *

(4)(i) Medication Therapy Management Programs meeting the requirements of § 423.153(d).

(ii) Fraud reduction activities, including fraud prevention, fraud detection, and fraud recovery.

* * * * *

■ 112. Section 423.2460 is revised to read as follows:

§ 423.2460 Reporting requirements.

(a) For each contract year, from 2014 through 2017, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, a report that includes but is not limited to the data needed by the Part D sponsor to calculate and verify the MLR and remittance amount, if any, for each contract, under this part, such as incurred claims, total revenue, expenditures on quality improving activities, non-claims costs, taxes, licensing and regulatory fees, and any remittance owed to CMS under § 423.2410.

(b) For contract year 2018 and for each subsequent contract year, each Part D sponsor must submit to CMS, in a timeframe and manner specified by CMS, the following information:

(1) *Fully credible and partially credible contracts.* For each contract under this part that has fully credible or partially credible experience, as determined in accordance with § 423.2440(d), the Part D sponsor must report to CMS the MLR for the contract and the amount of any remittance owed to CMS under § 423.2410.

(2) *Non-credible contracts.* For each contract under this part that has non-credible experience, as determined in accordance with § 423.2440(d), the Part D sponsor must report to CMS that the contract is non-credible.

(c) Total revenue included as part of the MLR calculation must be net of all projected reconciliations.

(d) The MLR is reported once, and is not reopened as a result of any payment reconciliation processes.

§ 423.2480 [Amended]

■ 113. Section 423.2480 is amended—

- a. In the introductory text by removing the phrase “reviews of reports submitted” and adding in its place “review of data submitted”; and
- b. In paragraph (d) introductory text by removing the phrase “Reports submitted under” and adding in its place the phrase “Data submitted under”.

§ 423.2490 [Amended]

■ 114. Section 423.2490 is amended in paragraph (a) by removing the phrase “information contained in reports submitted” and adding in its place the phrase “information submitted”.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 115. The authority citation for part 460 continues to read as follows:

Authority: Secs. 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u-4(f)).

■ 116. Section 460.40 is amended by revising paragraph (j) to read as follows:

§ 460.40 Violations for which CMS may impose sanctions.

* * * * *

(j) Makes payment to any individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.

■ 117. Section 460.50 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 460.50 Termination of PACE program agreement.

* * * * *

(b) * * *

(1) * * *

(ii) The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement, including making payment to an individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.

* * * * *

§ 460.68 [Amended]

■ 118. Section 460.68 is amended by removing paragraph (a)(4).

§ 460.70 [Amended]

■ 119. Section 460.70 is amended by removing paragraph (b)(1)(iv).

§ 460.71 [Amended]

■ 120. Section 460.71 is amended by removing paragraph (b)(7).

■ 121. Section 460.86 is revised to read as follows:

§ 460.86 Payment to individuals and entities excluded by the OIG or included on the preclusion list.

(a) A PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in § 460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the OIG or is included on the preclusion list, defined in § 422.2 of this chapter.

(b) If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list, defined in § 422.2 of this chapter, the PACE organization must notify the enrollee and the excluded individual or entity or the individual or entity that is included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 122. The authority for part 498 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a-7j, and 1395hh).

■ 123. Section 498.3 is amended by adding paragraph (b)(20) to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) * * *

(20) An individual or entity is to be included on the preclusion list as defined in § 422.2 or § 423.100 of this chapter.

* * * * *

■ 124. Section 498.5 is amended by adding paragraph (n) to read as follows:

§ 498.5 Appeal rights.

* * * * *

(n) *Appeal rights of individuals and entities on preclusion list.* (1) Any individual or entity that is dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list (as defined in § 422.2 or § 423.100 of this chapter) may request a reconsideration in accordance with § 498.22(a).

(2) If CMS or the individual or entity under paragraph (n)(1) of this section is dissatisfied with a reconsidered determination under paragraph (n)(1) of this section, or a revised reconsidered determination under § 498.30, CMS or the individual or entity is entitled to a hearing before an ALJ.

(3) If CMS or the individual or entity under paragraph (n)(2) of this section is dissatisfied with a hearing decision as described in paragraph (n)(2) of this section, CMS or the individual or entity may request Board review and the individual or entity has a right to seek judicial review of the Board's decision.

Dated: October 27, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 30, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

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