DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 417, 422, 423, 460, and 498

[CMS–4182–F]

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: Final rule.

SUMMARY: This final rule will revise the Medicare Advantage (MA) program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Comprehensive Addiction and Recovery Act (CARA) to further reduce the number of beneficiaries who may potentially misuse or overdose on opioids while still having access to important treatment options; implement certain provisions of the 21st Century Cures Act; support innovative approaches to improve program quality, accessibility, and affordability; offer beneficiaries more choices and better care; improve the CMS customer experience and maintain high beneficiary satisfaction; address program integrity policies related to payments based on prescriber, provider and supplier status in MA, Medicare cost plan, Medicare Part D and the PACE programs; provide an 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:

Effective Date: This rule is effective June 15, 2018.

The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of June 15, 2018.

Applicability Dates: The applicability date of the provisions of this rule is January 1, 2019 except for the provisions in §§ 422.100(f)(4) and (5) and 422.101(d) (discussed in section II.A.4. of this final rule (Maximum Out-of-Pocket Limit for Medicare Parts A and B Services)) and § 422.100(f)(6) (discussed in section II.A.5. of this final rule (Cost Sharing Limits for Medicare Parts A and B Services)). Those provisions are applicable for contract year 2020 (January 1, 2020). E-Prescribing and the Part D Prescription Drug Program; Updating Part D E Prescribing Standards discussed in section II.D.8. of this final rule is applicable January 1, 2020 conditioned on The Office of the National Coordinator for Health Information Technology (ONC) adopting the same standard for use in its Electronic Health Record Certification Program by that date.

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SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this final 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 changes are necessary to—

- Support Innovative Approaches to Improving Quality, Accessibility, and Affordability;
- Improve the CMS Customer Experience; and
- Implement Other Changes.

In addition, this final rule makes technical changes related to treatment of Part A and Part B premium adjustments and updates the NCPDP SCRIPT standard used for Part D electronic prescribing. While the Part C and Part D programs have high satisfaction among enrollees, we continually evaluate program policies and regulations to remain responsive to current trends and newer technologies, and provide increased flexibility to serve patients. 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 patient's health care needs. These changes being finalized will empower MA and Part D plans to meet the needs of enrollees at the local level, and should result in more enrollee choice and more affordable options. 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.

2. Summary of the Major Provisions

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

In line with the agency's response to the President's call to end the scourge of the opioid epidemic, this final rule implements statutory provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA), which amended the Social Security Act and was enacted into law on July 22, 2016. CARA includes new authority for Medicare Part D plans to establish drug management programs effective on or after January 1, 2019. Through this final rule, CMS has established 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.'' Specifically, under drug management programs, Part D plans will engage in case management of potential at-risk beneficiaries, through contact with their prescribers, when such beneficiary is found to be taking a specific dosage of opioids and/or obtaining them from multiple prescribers and multiple pharmacies who may not know about each other. Sponsors may then 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) after case management with the prescribers for the safety of the enrollee. CMS also limits the use of the special enrollment period (SEP) for dually- or other low income subsidy (LIS)-eligible beneficiaries by those LIS-eligible beneficiaries who are identified as at-risk or potentially at-risk for prescription drug abuse under such a drug management program. Finally, these provisions will codify the current Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) by integrating this current policy with drug management program provisions.

Through the adoption of this policy, from 2011 through 2017, there was a 76 percent decrease (almost 22,500 beneficiaries) in the number of Part D beneficiaries identified as potential very high risk opioid overutilizers. Thus, drug management programs will expand 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, and will be an important next step in addressing the opioid epidemic and safeguarding the health and safety of our nation's seniors.

b. Revisions to Timing and Method of Disclosure Requirements

Consistent with agency efforts supporting innovative approaches to improve quality, accessibility, and affordability and reduce burden, we are finalizing changes to align the MA and Part D regulations in authorizing CMS to set the manner of delivery for mandatory disclosures in both the MA and Part D programs. CMS will use this authority to allow MA plans to meet the disclosure and delivery requirements for certain documents by relying on notice of electronic posting and provision of the documents in hard copy when requested, when previously the documents, such as the Evidence of Coverage (EOC), had to be provided in hard copy. Additionally, we are changing the timeframe for delivery of the MA and Part D EOC to the first day of the Annual Election Period (AEP), rather than 15 days prior to that date. Allowing Part C and Part D plans to provide the EOC electronically will alleviate plan burden related to printing and mailing and reduce the number of paper documents that enrollees receive from plans. Changing the date by which plans must provide the EOC to enrollees will allow plans more time to finalize the formatting and ensure the accuracy of the information in the EOC. Changing the date will also separate the mailing and receipt of the EOC from the Annual Notice of Change (ANOC), which describes the important changes in a patient's plan from one year to the next. The ANOC must be delivered 15 days prior to the AEP and will be received by enrollees ahead of the EOC, thus allowing enrollees to focus on materials that drive decision-making during the AEP. We see this final change as an overall reduction of burden that our regulations have on plans and enrollees. In aggregate, we estimate a savings (to plans for not producing and mailing hardcopy EOCs) of approximately $54.7 million each year, 2019 through 2023.

c. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE

This final rule will rescind current regulatory provisions that require prescribers of Part D drugs and providers of MA services and items to enroll in Medicare in order for the Part D drug or MA service or item to be covered. As a replacement, a Part D plan sponsor will be required to reject, or 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.'' Similarly, an MA service or item will not be covered if the provider that furnished the service or item is on the preclusion list. The preclusion list will consist of certain individuals and entities that are currently revoked from the Medicare program under 42 CFR 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 they 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 believe that this change from an enrollment requirement to a preclusion list requirement will reduce the burden on Part D prescribers and MA providers without compromising our program integrity efforts.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and benefits	Costs
Implementation of the Comprehensive Addiction and Recovery Act of 2016.	The purpose of this provision is to create a lock-in status for certain at-risk beneficiaries. In addition to the benefits of preventing opioid and benzodiazepine dependency in beneficiaries, we estimate, in 2019, a reduction of $19 million in Trust Fund expenditures because of reduced opioid scripts. This $19 million reduction modestly increases to a $20 million reduction in 2023.	The creation of lock in-status is a burden to plans. The cost to industry is estimated at about $2.8 million per year. This $2.8 million cost arises from (i) the uploading and preparing of additional notices to enrollees ($101,721), (ii) the re-negotiation of contracts between Part D sponsors and pharmacies ($547,415), (iii) the programming of edits about lock-ins into the systems of Part D sponsors ($2,152,332), and (iv) the right of enrollees to appeal a status of lock-in ($35,183).
Revisions to Timing and Method of Disclosure Requirements.	We estimate 67% of the current 47.8 million beneficiaries will prefer use of the internet versus hard copies. This will result in a savings to the industry of $54.7 million each year, 2019 through 2023. This is due to a reduction in printing and mailing costs.	
Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE.	For 2019, this provision saves providers $34.4 million. For 2020 and future years, there are no savings. The $34.4 million in savings to providers arises because of removal of the requirement of MA providers and suppliers and Part D prescribers to enroll in Medicare as a prerequisite for furnishing health care items and services. Part C providers and suppliers save $24.1 million in reduced costs while Part D providers save $10.3 million in reduced costs.	For 2019, this provision costs Part D sponsors or their PBMs $9.3 million. For 2020 and future years, costs are negligible (below $50,000). The $9.3 million cost arises because of programming and staff resources needed to produce and send required notifications to enrollees and prescribers.

Provision	Savings and benefits	Costs
Physician Incentive Plans—Update Stop-Loss Protection Requirements.	For 2019, this provision reduces required reinsurance resources by $204.6 million. The $204.6 million savings increases yearly because of expected enrollment increases and medical inflation; the savings is $281.8 million in 2023. The savings arise because we are replacing the current insurance schedule in the regulation with updated stop-loss insurance requirements that will allow insurance with higher deductibles. This updated schedule will 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. Through transfers, the 2019 $204.6 million savings results in $71.6 savings to the Medicare Trust Fund and $133 million savings (in the form of rebates) to Medicare Advantage (MA) organizations. It is likely that some of the savings to MA organizations will result in increased health care benefits to MA enrollees.	

B. Background

In the proposed rule titled ''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'' which appeared in the November 28, 2017 **Federal Register** (82 FR 56336), we proposed to 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; clarify program requirements; and make certain technical changes regarding treatment of Medicare Part A and Part B appeal rights related to premium adjustments.

We received approximately 1,669 timely pieces of correspondence containing multiple comments on the CY 2019 proposed rule. While we are finalizing several of the provisions from the proposed rule, there are a number of provisions from the proposed rule that we intend to address later and a few that we do not intend to finalize. We also note that some of the public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading. However, we note that in this final rule we are not addressing comments received with respect to the provisions of the proposed rule that we are not finalizing at this time. Rather, we will address them at a later time, in a subsequent rulemaking document, as appropriate.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

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 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. Thus, although drug management programs are voluntary, this rule codifies a framework that will place requirements upon such programs when established by Part D sponsors.

This final rule implements 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'').[1] This integration will mean that Part D plan sponsors implementing a drug management program could limit an at-risk beneficiary's access to coverage of frequently abused drugs beginning 2019 through a beneficiary-specific point-of-sale (POS) claim edit and/or by requiring the beneficiary to obtain frequently abused drugs from a selected

[1] 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 and case management. Please refer to the CMS website, ''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.

pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary. To do so, the beneficiary will have to meet clinical guidelines that factor in that the beneficiary is taking opioids over a sustained time period and that the beneficiary is obtaining them from multiple prescribers and/or multiple pharmacies. This final rule also implements 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 or at-risk beneficiaries.

We received the following general comments and our responses follow:

Comment: Commenters were overall supportive of our proposal. Some commenters found it to be a conservative and uniform approach to implementing the CARA drug management program provisions. Other commenters included specific suggestions for improvements with their overall supportive or neutral comments.

Response: We thank the commenters for their comments. We summarize and respond to specific recommendations later in this preamble.

Comment: We received a request that we confirm that nothing in the final rule impacts PACE organizations' waivers of Part D requirements in § 423.153. This commenter also asked that existing waivers of § 423.153 be extended to include § 423.153(f) unless such a waiver is not needed due to the voluntary nature of drug management programs.

Response: PACE organizations are not excluded from OMS reporting under the current policy. Additionally, because of the voluntary nature of the provisions under § 423.153(f), a waiver is not necessary for PACE organizations. However, to the extent that PACE organizations commence drug utilization management activities covered under § 423.153(f), PACE organizations must comply with the requirements of 423.153(f).

Comment: We received comments that expressed concern about the time needed for Part D plan sponsors to make the necessary systems changes to implement compliant drug management programs.

Response: Section 704(g)(1) of CARA states that the amendments made by this section shall apply to prescription drug plans (and MA–PD plans) for plan years beginning on or after January 1, 2019. However, given the current national opioid epidemic, we expect that Part D sponsors will diligently implement fully-functional drug management programs in 2019. Moreover, as the new requirements for drug management programs build from and are integrated with existing policy, we expect sponsors will be able to implement them expeditiously.

Comment: We received one suggestion that CMS pilot different approaches for implementing the CARA drug management program provisions, specifically the ''lock-in'' provisions, as we did before implementing our current policy.

Response: Because the CARA drug management provisions will be integrated with our current policy, albeit with some modifications to that policy, we are not persuaded that an additional pilot is necessary since plan sponsors already have experience with addressing potential opioid overutilization.

Comment: A commenter requested that CMS acknowledge the work it will take for Standard Development Organizations (SDOs) to implement the finalized CARA provisions. In particular, the commenter noted that development of any codes and messaging associated with the new CARA-related requirements will take time to implement.

Response: We understand that any modifications to existing standards to accurately achieve the desired functionalities to further the electronic exchange of information between healthcare stakeholders about the final CARA provisions may require time. We rely on SDOs to coordinate these efforts, and CMS is committed to working with the SDOs during this process, if needed.

Comment: A commenter requested clarification on how to handle concurrent DUR edits, such as formulary-level cumulative opioid MME safety edits, and the drug management program. Specifically, the comment sought clarification on whether the drug management program beneficiary-specific POS claim edits or lock-in limitations would take precedence over an approved exception to a cumulative opioid MME safety edit.

Response: A plan sponsor may implement formulary-level coverage rules for opioids (that is, prior authorization, quantity limits or step therapy) or safety edits, and implement a drug management program. The formulary and coverage rules would apply to all enrollees (unless they obtain an exception), and the drug management program would apply to potential at-risk and at-risk beneficiaries. A Part D sponsor's concurrent and retrospective DUR programs should be closely coordinated. In certain circumstances, it may be appropriate for a sponsor to make an at-risk determination through the drug management program for a beneficiary who received an approved exception to a cumulative opioid MME safety edit, and as part of the at-risk determination, may determine that continuing the approved exception is no longer appropriate.

For example, a plan implemented a hard formulary-level cumulative MME opioid edit at 200 MME with 2 or more opioid prescribers. A beneficiary received their opioids from 2 prescribers and has a cumulative MME that exceeds 200 MME. They trigger the edit and request a coverage determination. The prescriber attests to medical necessity and the exception request is approved. At a later time, the beneficiary seeks opioids from 3 additional prescribers, and meets the CARA/OMS criteria. Through case management, the prescriber verifies the beneficiary is at-risk and agrees to prescriber lock-in due to care coordination issues.

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

Our proposal was to integrate the CARA Part D drug management program provisions with our current policy and codify them both. Specifically, under this regulatory framework, we proposed that Part D plan sponsors may voluntarily adopt drug management programs through which they address potential overutilization of frequently abused drugs identified retrospectively through the application of clinical guidelines/OMS 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 through OMS and any beneficiary coverage limitations they have implemented through MARx, CMS' system for payment and enrollment transactions. Thus, although drug management programs are voluntary, our proposal was to codify a framework that will place requirements upon such programs when established by Part D sponsors.

We stated that 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; 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.

Comment: Commenters expressed strong support for integrating the drug management program provisions of CARA with the current policy. Commenters expressed that our proposal is reasonable, thoughtful, thorough, practical, and comprehensive; that it builds on a successful existing Medicare Part D program; that it will involve a common set of procedures and help ensure a streamlined and efficient process rather than creating a separate one that would require additional oversight and add administrative burden. We did not receive comments that opposed integrating the drug management program provisions of CARA with the current policy.

Response: We thank the commenters for their supportive comments and are finalizing this integration approach to our proposal.

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

We proposed the following definitions 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 proposed 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 refers to a beneficiary who is potentially at-risk in several subsections.

Accordingly, we proposed 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 recently enrolled, such identification had not been terminated upon disenrollment, and the new plan has adopted the identification. We noted that we included 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.

We received the following comments and our response follows:

Comment: A commenter did not believe that a definition for a ''potential at-risk beneficiary'' was needed, nor the additional prescriber verification the commenter associated with the definition.

Response: We disagree. Although as we noted above, section 1860D–4(c)(5) of the Act does not explicitly define a ''potential at-risk beneficiary,'' it refers to a beneficiary who is potentially at-risk in section 1860D–4(c)(5)(B)(ii), which addresses initial notices; in 1860D–4(c)(5)(H)(i) which addresses data disclosures; and in section 1860D–4(c)(5)(I) which addresses the sharing of information for subsequent plan enrollments. Therefore, we proposed to define a potential at-risk beneficiary in § 423.100, as the CARA drug management program provisions clearly contemplate this status for a beneficiary.

With respect to additional prescriber verification of a potential at-risk beneficiary, we believe this comment is based on a misunderstanding of our proposal, as we did not propose that a beneficiary's status as a potential at-risk beneficiary must be verified. Rather, we proposed and are finalizing a requirement, as we discuss later in this preamble, that a prescriber must verify that a beneficiary is at-risk, which serves as his or her professional opinion that a Part D plan sponsor takes into account during case management.

Comment: We received a question whether an individual who is subject to lock-in under his or her Medicaid program and then becomes dually-eligible constitutes a potential or at-risk beneficiary under our proposed definitions.

Response: Such a beneficiary would not automatically be considered to be a potential at-risk or an at-risk beneficiary under a Part D sponsor's drug management program. Rather, whether such a beneficiary is a potential at-risk or at-risk beneficiary would depend upon whether he or she meets the clinical guidelines and is determined to be an at-risk beneficiary under the process set forth in this rule. An automatic determination based on a beneficiary's inclusion and status in a Medicaid drug management program would not be appropriate because each Medicaid drug management program has its own criteria and requirements for reviewing and addressing recipients who may be at-risk for prescription drug abuse or misuse and its own interventions. We also note that Medicaid programs are not required to comply with section 1860D–4(c)(5) as Part D drug management programs are.

To the extent a Part D sponsor is aware or discovers based on reliable information that a beneficiary who meets the clinical guidelines was locked-in under a Medicaid drug management program, that sponsor may consider that information in deciding whether to determine that a beneficiary is an at-risk beneficiary under the requirements of this final rule. Also, any beneficiary entering the Part D program will be immediately subject to their plan's formulary-level controls to address opioid overutilization before they may be identified as potentially at-risk, so any opioid overutilization by the beneficiary in his or her new Part D plan may be addressed by these controls.

Comment: We received a comment requesting clarification with regard to a person who is locked-in under an employer plan and then becomes eligible for a Part D EGWP, if the EGWP can continue the lock-in in the Part D plan or at least consider the prior lock-in as part of a new determination.

Response: Beginning with plan year 2019, Part D sponsors, including sponsors of EGWPs, may adopt drug management programs that meet the requirements we are finalizing in this rule. Under a Part D prescription drug management program, sponsors may implement a prescriber and/or pharmacy lock-in or beneficiary-specific POS claim edit for frequently abused drugs with respect to an at-risk beneficiary. Similar to a Medicaid beneficiary who becomes newly eligible for Medicare and enrolls in Part D, a person who is locked-in under a

commercial plan does not automatically meet the definition of an at-risk beneficiary we are finalizing in § 423.100. Rather, such a person first must be determined to be an at-risk beneficiary in accordance with the requirements we are finalizing at § 423.153(f).

In other words, in order for a beneficiary to be eligible to be immediately locked-in to a prescriber or pharmacy in a Part D plan in which they are newly enrolled, the plan from which they most recently disenrolled must be a Part D plan in which he or she was determined to be an at-risk beneficiary under that plan's drug management program. When a new enrollee comes from a non-Part D plan in which the beneficiary was subject to lock-in, however, the sponsor can consider the prior lock-in if it learns or knows of it based upon reliable information which is legally available to the sponsor in conjunction with the information it gathers from the case management process, the beneficiary, and the sponsor's other relevant internal sources and data.

Comment: A commenter asked if a Part D sponsor may consider opioid utilization information from external sources during case management, such as a state prescription drug monitoring program (PDMP) in making the determination if a beneficiary is at-risk.

Response: As noted above with respect to beneficiaries who were locked-in under an employer or Medicaid plan before enrolling in Medicare Part D, we encourage sponsors to use all reliable sources legally available to them to obtain an accurate account of a potential at-risk or at-risk beneficiary's utilization of frequently abused drugs.

After considering the comments, we are finalizing the definition of potential at-risk beneficiary and at-risk beneficiary with minor modifications for clarity. First, we are removing the phrase ''and the new plan adopted the identification'' from paragraph (2) of both definitions. As we noted above, the purpose of this language was to indicate that the beneficiary's at-risk status in the subsequent plan is not automatic, which we meant for purposes of the limitation on the special enrollment period (SEP) for LIS beneficiaries with an at-risk status. However, as we discuss later in this preamble, this limitation will be triggered or continued by Part D sponsors sending the initial and second notices to such beneficiaries, as applicable, so we no longer believe this phrase is necessary in these definitions.

Second, we also are making a minor clarifying change in the definition of at-risk beneficiary to explicitly acknowledge that it is the Part D sponsor that determines which beneficiaries are at-risk beneficiaries under its drug management program.

The definition of potential at-risk beneficiary will read: 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 and such identification had not been terminated upon disenrollment. The definition of at-risk beneficiary will read: *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 by a Part D plan sponsor under its 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 and such identification had not been terminated upon disenrollment.

(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 proposed 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 proposed 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. Since we did not receive any specific comments to change this definition, we are finalizing it as proposed.

Comment: A commenter requested that CMS include the criteria, resources, and the evidence basis upon which it will rely to determine that a drug is a frequently abused drug for purposes of a drug management program.

Response: The definition of frequently abused drug that we are finalizing indicates that criteria, resources, and evidence basis will be the DEA schedule designation, government, and professional drug guidelines, and analyses of drug utilization or scientific data.

We did not receive any further comment on the definition of ''frequently abused drug'' and are therefore finalizing it as proposed.

Consistent with current policy, we proposed that opioids are frequently abused drugs, except buprenorphine for medication-assisted treatment (MAT) and injectables. As we stated in the preamble to the proposed rule, we plan to publish and update a list of frequently abused drugs for purposes of Part D drug management programs.

Comment: All commenters agreed that the Secretary should determine that opioids are frequently abused drugs, many referencing the national opioid overuse epidemic.

Response: We appreciate that stakeholders are focused on the opioid public health emergency.

Comment: Some of these commenters agreed with our proposal to determine only opioids, except buprenorphine for medication-assisted treatment (MAT) and injectables, as frequently abused drugs, at least in the initial implementation of Part D drug management programs, in order to allow CMS and stakeholders to focus on opioid overuse and gain experience with the use of lock-in as a tool to address overutilization in the Part D program, before potentially determining other controlled substances as

frequently abused drugs. These commenters urged CMS to wait until drug management programs were established, and testing and monitoring indicate that the program can be administered in a manner that does not limit beneficiary access to needed medications before expanding the programs further. Some of these commenters were concerned that an at-risk beneficiary would have to obtain all frequently abused drugs from one pharmacy or one prescriber and that this could disrupt patient care if the pharmacy did not carry all frequently abused drugs.

However, some commenters urged us to determine that all controlled substances are frequently abused drugs. These commenters were particularly focused on a determination as to benzodiazepines, and to a lesser extent, muscle relaxants. Due to this focus, these commenters referred to the CDC Guideline that specifically recommends that clinicians avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible due to increased risk for overdose. They also referred to CMS work in this area: (1) The fact that CMS added a concurrent benzodiazepine-opioid flag to OMS in October 2016 in response to the CDC Guideline and after our own research on the use of benzodiazepines among Medicare beneficiaries [2] to alert Part D sponsors that concurrent use may be an issue that should be addressed during case management; [3] and (2) the fact that we have stated that a sponsor may implement a beneficiary-specific claim edit at POS for non-opioid medications under the current policy.[4] They further referred to a statistic from the National Institute on Drug Abuse that 30 percent of overdoses involving opioids also involve benzodiazepines.[5] Finally, these commenters pointed out that the FDA has found that the growing combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system has resulted in serious side effects, including slowed or difficult breathing and deaths. These commenters further noted that in an effort to decrease the use of opioids and benzodiazepines, and opioids and other such depressants, the FDA added *Boxed Warnings*—its strongest warnings—to the drug labeling of prescription opioid pain and cough medicines, and benzodiazepines.[6] Given these developments, these commenters stressed the importance of Part D plan sponsors being able to use the tools that will be available to them under drug management programs to address the dangers of concurrent opioid and benzodiazepine use.

Response: In light of these comments, we are persuaded that it is appropriate that drug management programs are able to address concurrent opioid and benzodiazepine use. Such a determination is consistent with the definition of frequently abused drugs that we are finalizing. First, the Secretary determines benzodiazepines are frequently abused or diverted, taking into account that they are controlled substances under the Controlled Substances Act (CSA) and that prescription benzodiazepines are on Schedule IV, where the DEA places substances that have a potential for abuse. In addition, the Secretary takes into account that the FDA has issued a warning about the risks associated with using opioids and benzodiazepines concurrently. Further, the CDC included in its evidence-based opioid prescribing guideline a caution to co-prescribe opioids and benzodiazepines. Finally, CMS' own statistics reveal that 51 percent of Part D beneficiaries that will be identified as potentially at-risk under the 2019 clinical guidelines we are finalizing are using opioids and benzodiazepines concurrently compared to 24 percent across all Part D opioid users. This statistic is indicative that concurrent use is even more of a danger among potential at-risk beneficiaries than Medicare Part D beneficiaries generally. Therefore, the Secretary determines that benzodiazepines are a frequently abused drug for purposes of Part D drug management programs beginning in 2019. However, the clinical guidelines will still only consider a beneficiary's opioid use, as we explain just below.

Comment: A commenter agreed with our statement in the proposed rule that there is difficulty in establishing overuse guidelines for non-opioid substances. The commenter stated that this underscores the need for a robust evidence base to support determining that additional types of drugs are frequently abused drugs.

Response: We agree with the commenter's concern, and for this reason we are not modifying the clinical guidelines for 2019 to include benzodiazepine use, even though benzodiazepines will be considered a frequently abused drug for 2019. This means that a beneficiary who is determined to be at-risk based on clinical guidelines that look at the beneficiary's opioid use could have a coverage limitation applied under a drug management program to both opioids and benzodiazepines to manage current and future concurrent use. For example, a sponsor could require an at-risk beneficiary to obtain both opioids and benzodiazepines from one selected pharmacy.

We believe that this is appropriate based on the robust evidence that concurrent benzodiazepine use with opioids results in an even higher risk of an adverse health event than use of opioids alone. We will expect to rarely see a sponsor apply a limitation only to an at-risk beneficiary's access to coverage for benzodiazepines, since to do so, the beneficiary would have to have met the clinical guidelines which look at opioid use that is potentially risky. However, we acknowledge that prescriber agreement during case management could rarely lead to such an outcome. For example, no opioid prescriber agrees to a beneficiary-specific POS claim edit for opioids, but rather, all but one states they will no longer prescriber opioids to coordinate the beneficiary's use. However, the benzodiazepine prescriber agrees to such an edit for benzodiazepines. We discuss prescriber agreement in more detail later in this preamble.

Given that we are finalizing two categories of drugs as frequently abused drugs for 2019, depending upon what a plan sponsor learns during case management, we reiterate that the sponsor may have to permit a beneficiary to obtain frequently abused drugs from more than one pharmacy and/or more than one prescriber in order to provide reasonable access, if the sponsor applies lock-in as a coverage limitation, which we discuss later in this preamble.

Comment: A few commenters suggested that Part D sponsors be able to expand their drug management programs to include additional frequently abused drugs based on their experience with their enrollees. One suggested that a sponsor be required to submit such an expansion to CMS for approval.

Response: We disagree with this comment. Section 1860D–4(c)(5)(G) of the Act defines ''frequently abused

[2] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Concurrent-Use-of-Opioids-and-Benzodiazepines-in-a-Medicare-Part-D-Population-CY-2015.pdf.*

[3] 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.

[4] Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D'' September 6, 2012.

[5] *https://www.drugabuse.gov/drugs-abuse/opioids/benzodiazepines-opioids.*

[6] *https://www.fda.gov/Drugs/DrugSafety/ucm518473.htm.*

drug'' as a drug that is a controlled substance that the Secretary determines to be frequently abused or diverted. Consistent with this statutory provision, we believe it is appropriate that the determination of frequently abused drugs not be plan-specific, but rather be consistent across Part D plans, as this will permit better oversight and promote consistency across all Part D drug management programs.

We proposed that future determinations of frequently abused drugs by the Secretary primarily be included in the annual Medicare Parts C&D Call Letter or in similar guidance, if necessary, to address midyear entries to the drug market or evolving government or professional guidelines or relevant data analysis, which will be subject to public comment. We proposed that 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.

Comment: We received comments supportive of our proposal to apply the standards we are establishing in rulemaking to future determinations of frequently abused drugs through the annual Medicare Parts C&D Call Letter, or in similar guidance. We did not receive any comments that opposed this proposed approach.

Response: We appreciate the comments.

Comment: A commenter asked us to confirm that we would use the same process to determine that a drug is no longer a frequently abused drug.

Response: We will apply the same regulatory standards and use the same process that we use to determine that a drug is a frequently abused drug when determining that a drug no longer is a frequently abused drug for purposes of Part D drug management programs.

Comment: A few commenters urged CMS to exclude abuse-deterrent (AD) opioids from this definition of ''frequently abused drug'' as there is no evidentiary data to support the thesis that AD opioids are frequently abused and existing observation data supports their exclusion from this broad standard.

Response: The FDA requires a boxed warning on opioid abuse-deterrent formulations (ADFs), because even with these formulations there is still potential for addiction, abuse, misuse, and diversion. The FDA has also noted [7] that ''abuse-deterrent technologies have not yet proven successful at deterring the most common form of abuse—swallowing a number of intact capsules or tablets to achieve a feeling of euphoria. Moreover, the fact that a product has abuse-deterrent properties does not mean that there is no risk of abuse. It means, rather, that the risk of abuse is lower than it would be without such properties.'' Also, ADFs do not prevent patients who may be using opioids for therapeutic reasons from taking higher doses than prescribed or diverting the opioid. For these reasons, we disagree that abuse-deterrent formulations should be excluded from the determination of frequently abused drugs.

Comment: A few commenters asked CMS to clarify whether methadone, a Part D drug when indicated for pain, would be included in the definition of a frequently abused drug under the drug management program. Other commenters agreed with excluding buprenorphine for MAT from the definition of frequently abused drug as not to limit patient access to treatment and noted that removing buprenorphine as a frequently abused drug is consistent with the CDC's approach to exclude buprenorphine from the determination of a person's daily opioid MME.

Response: Yes, methadone for pain is included in the definition of a frequently abused drug for purposes of Part D drug management programs, consistent with current policy/OMS. Although buprenorphine is recognized by the DEA as a drug of abuse, we thank the commenters that agreed with excluding buprenorphine for MAT from the definition of frequently abused drug so that access to MAT, such as buprenorphine, is not impacted. However, the commenters' reference to the CDC's exclusion of buprenorphine from the determination of a person's daily opioid MME made us believe that commenters may be conflating the definition of a frequently abused drug with the clinical guidelines and associated opioid dosage thresholds. Therefore, we realize that we need to be more specific about what opioid use, opioid prescribers, and opioid dispensing pharmacies means in the clinical guidelines, which we also discuss later.

Since the publication of the proposed rule, the CDC removed the conversion factors for all formulations of buprenorphine, for pain and for MAT, from the most recent CDC MME conversion factor file (*https://www.cdc.gov/drugoverdose/data-files/CDC_Oral_Morphine_Milligram_Equivalents_Sept_2017.xlsx*). Therefore, CMS cannot determine the MME. As such, buprenorphine products are not used to determine the beneficiary's average daily MME. However, we will still use prescription opioids, including all formulations of buprenorphine for pain and MAT, to determine opioid prescribers and opioid dispensing pharmacies in the clinical guidelines.

- Clinical Guidelines & 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 by the Secretary in consultation with stakeholders. We proposed to include a definition of ''clinical guidelines'' that cross references standards that we proposed at § 423.153(f) for how the guidelines will be established and updated. Specifically, we proposed to define clinical guidelines for purposes of a Part D drug management program in § 423.100 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 standards in § 423.153(f)(16) and beginning with contract year 2020, will be published in guidance annually.

We also proposed to add § 423.153(f)(16) to state that potential at-risk beneficiaries and at-risk beneficiaries are identified by CMS or a 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 will determine the guidelines by identifying the standards we will apply in determining them.

This proposed approach also indicated that the program size will be determined as part of the process to develop the clinical guidelines—a process into which stakeholders will 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 proposed to define ''program size'' in

[7] ''Abuse-Deterrent Opioids—Evaluation and Labeling Guidance for Industry'', U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Clinical Medical, April 2015.

§ 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, as part of the process to develop clinical guidelines, can be effectively managed by such sponsors.

Comment: We did not receive any specific comments about the definition we proposed for clinical guidelines in § 423.100, nor the standards we proposed in § 423.153(f)(16).

Response: We are therefore finalizing the definition and standards as proposed, with one modification adding language so that the guidelines will be published in guidance annually beginning with contract year 2020 guidance, since we are publishing the 2019 clinical guidelines in this final rule.

Comment: We received comments supportive of our proposal to apply the standards we are establishing in rulemaking for clinical guidelines in § 423.153(f)(16) to develop future OMS criteria through the annual Medicare Parts C&D Call Letter process beginning with plan year 2020.

We did not receive comments that specifically opposed this proposed approach.

Response: We appreciate these comments.

Because Part D drug management programs will be integrated with the current policy/OMS beginning in 2019, there will be no separate OMS criteria in 2019 and beyond. For plan year 2019, we proposed the clinical guidelines to be the OMS criteria established for plan year 2018. The clinical guidelines for use in drug management programs we proposed 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 estimated that these criteria would identify approximately 33,053 potential at-risk beneficiaries in the Part D program based on 2015 data, whom we believe are at the highest risk of death or overdose due to their opioid use. Also, under our proposal, we stated that Part D plan sponsors will not be able to vary the criteria of the guidelines to include more or fewer beneficiaries in their drug management programs, as they may under the current policy, except that we proposed to continue to permit plan sponsors to apply the criteria more frequently than CMS will 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).

We also described other clinical guidelines that we considered in the Regulatory Impact Analysis section of the proposed rule. Stakeholders were invited to comment on those options and any others that would identify more or fewer potential at-risk beneficiaries.

Comment: We received comments that were overall supportive of the clinical guidelines/criteria we proposed for 2019 with the estimated program size of 33,053. However we did receive a few comments suggesting criteria for the clinical guidelines that were not among the alternate options we included in the RIA. Some of these supportive comments supported the guidelines without reservation, making statements such as noting the guidelines align with the CDC Guideline or that they understood or supported CMS' desire to gain experience with the use of lock-in as a drug management tool before adopting clinical guidelines with flexibility and/or that would identify more potential at-risk beneficiaries. These commenters want CMS to adopt a clear and universal set of guidelines which minimizes customer and provider confusion, as well as administrative burden when submitting and receiving OMS quarterly reports. These commenters assert that voluntary plan guidelines would increase confusion and fragmentation across the Medicare landscape. However, some commenters urged that Part D plan sponsors should have complete flexibility to identify potential at-risk beneficiaries, or at least some flexibility to identify additional ones consistent with our current policy. These commenters emphasized that sponsors should be able to establish and update targeting criteria and program features based on evolving clinical evidence and feedback and the specific needs of their members. Some of these commenters referred to the experience Part D sponsors and their PBMs have gained in identifying opioid overutilization among their plan members over the last several years and the need to be able to do more to address the opioid overuse crisis. Some commenters referred in particular to beneficiaries who do not have an average daily MME of greater or equal to 90 mg but who are filling opioids prescriptions from many different prescribers or pharmacies that they may currently address but would not be able to under our proposal. These commenters pointed out that such beneficiaries benefit from better coordination of care, which case management and coverage limitations on frequently abused drugs can support. Another commenter referred to beneficiaries with high dose utilization regardless of the number of prescribers as appropriate for review by drug management programs.

As to program size, a commenter stated that the proposed clinical guidelines would identify a reasonable number of potential at-risk beneficiaries. Another commenter proposed alternative criteria involving a lower MME level that it stated would identify more than 300,000 Part D beneficiaries as potentially at-risk, whereas the other commenters (including those commenters that requested increased flexibility) did not provide a program size estimate. On the other hand, we did not receive comments that the clinical guidelines we proposed would identify a potential at-risk beneficiary population that cannot be effectively managed by Part D plan sponsors, and because the proposed guidelines are the same as the OMS criteria for 2018 that were established through the 2018 Parts C&D Call Letter process, we did not expect such comments.

We received a few comments that the proposed clinical guidelines appear to be aimed at primarily limiting the program size arbitrarily rather than permitting scientific evidence and clinical research to dictate the most appropriate guidelines.

Response: We appreciate the commenters that provided a specific suggestion for criteria; however, these criteria were not among the alternate options we included in the RIA. Therefore, we decline to adopt these suggestions, as the clinical guidelines are to be developed by the Secretary in consultation with stakeholders.

We were persuaded by the commenters that Part D sponsors should have some flexibility in adopting targeting criteria for potential at-risk beneficiaries in order to be able to identify more such beneficiaries, which in turn enables sponsors to be able to do more to address the opioid overuse public health emergency. In addition, flexibility in adopting targeting criteria for potential at-risk beneficiaries is consistent with the current policy, and we wish to be more conservative in varying from that policy for the same reasons. However, we still believe it prudent to place certain parameters around the beneficiaries who may be identified as potentially at-risk by sponsors for their drug management programs, particularly as we gain

experience with the use of lock-in as a drug management tool.

Given that no other commenter recommended a specific program size, there is no discernible consensus that a population of more than 300,000 would be manageable for Part D sponsors. We therefore decline to adopt these criteria as the clinical guidelines for that reason, and also because we want sponsors to focus on the Part D population that is at the highest risk. Also, as we noted previously, the statute requires us to establish policies to ensure that the populations of enrollees in a prescription drug management program can be effectively managed by plans. Therefore, we disagree that the clinical guidelines arbitrarily limit the size of these programs.

After publication of the proposed rule, we conducted an analysis of the clinical guidelines/OMS criteria for 2019 that we proposed using 2017 PDE data, as the original estimates were based on 2015 data. We were pleased to confirm that the current policy, which will be integrated into Part D drug management programs, continues to make substantial progress in reducing potential opioid overutilization in the Part D program. The reduction in the number of beneficiaries meeting the OMS criteria between 2015 and 2017 far outpaced previous trends. We thank the Part D sponsors that have executed the current policy, the providers who have participated, and the various stakeholders who have provided helpful input over the years.

According to this analysis, the 2019 clinical guidelines/OMS criteria we proposed would identify an estimated 11,753 potential at-risk beneficiaries rather than the 33,053 we originally estimated. Given the incremental approach we have taken with the current policy over the years since its inception, this revised estimate provides an opportunity to adjust the clinical guidelines/OMS criteria downward in terms of prescriber and pharmacy thresholds which will incorporate more potential at-risk beneficiaries in 2019.

Therefore, after considering the comments and this updated data, we are doing two things with respect to our clinical guidelines proposal, which we will identify a similar program size as the one we proposed, as well as strike a balance between those commenters wanting complete flexibility to adopt criteria to identify potential at-risk beneficiaries and those urging no flexibility. First, we are finalizing alternative criteria that we considered in the RIA as Option 3 as minimum criteria. These minimum criteria 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: 3 or more opioid prescribers and 3 or more opioid dispensing pharmacies *OR* 5 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies.

This means that beneficiaries meeting these criteria will be reported to sponsors by OMS and sponsors with drug management programs must review each case and report their findings back to OMS as they do today consistent with how they have operated under the current policy. In addition, sponsors may not vary these minimum criteria. However, as we previously stated, sponsors will be permitted to apply the minimum criteria more frequently using their own prescription claims data than CMS will apply them through OMS quarterly. According to our analysis of 2017 PDE data, these minimum criteria would identify 44,332 potential at-risk beneficiaries and is the option based on 90 MME in the RIA that has a revised program size estimate which is closest to our original estimate of 33,053 but that would not identify fewer at-risk beneficiaries. Given the scope of the opioid crisis, and current data showing significant reduction in the number of beneficiaries meeting the OMS criteria, finalizing criteria that would have resulted in a smaller program size could undermine the increasing momentum in addressing opioid overutilization in the Medicare Part D program.

Second, we are finalizing supplemental criteria to provide sponsors with some flexibility in adopting criteria for their drug management programs. This means that sponsors may continue to report additional beneficiaries to OMS—as they do today under the current policy. However, unlike the current policy, such beneficiaries must meet the following supplemental criteria: Use of opioids (regardless of average daily MME) during the most recent 6 months with 7 or more opioid prescribers *OR* 7 or more opioid dispensing pharmacies.

These supplemental criteria were included in the additional criteria options that we considered and are included in a options chart in the Regulatory Impact Analysis (RIA) of the proposed rule; specifically, in Row 2 of option 6. Using 2017 data, we estimate that these supplemental criteria would identify an additional 22,841 potential at-risk beneficiaries. We believe these criteria would be responsive to the concern of the commenters who, in urging us to allow flexibility for sponsors to adopt targeting criteria, expressed concerns about not being able to continue to address plan members who are receiving opioids from a large number of prescribers or pharmacies but who do not meet a particular MME threshold.

We note that we do not anticipate that OMS will report beneficiaries meeting these supplemental criteria to sponsors; however, Part D sponsors may review beneficiaries who meet them—and must report them to OMS if they do—at a level that is manageable for their drug management programs in conjunction with the potential at-risk beneficiaries reported by OMS minimum criteria, whom they must address.

Thus, the final clinical guidelines for 2019 will result in an estimated program size of approximately 67,173 beneficiaries—44,332 of whom Part D sponsors with drug management programs must review and 22,841 of whom such sponsors may review. We believe this program size can be effectively managed by plans because we have already received feedback from Part D sponsors through the final 2018 Medicare Parts C&D Call Letter process that 33,000 beneficiaries are manageable. Thus, we conclude that 44,332 beneficiaries are associated with the option included in the RIA of the proposed rule that is the closest in number without identifying fewer potential at-risk beneficiaries and is consistent with historical program size under the current policy. Moreover, we received no comments that 33,053 beneficiaries is the largest program size Part D sponsors can manage. Finally, as we stated above, sponsors may review the additional 22,841 beneficiaries at a level that is manageable for their drug management programs.

These final criteria for 2019 meet the definition of clinical guidelines that we are finalizing. They are criteria to identify potential at-risk beneficiaries who may be determined to be at-risk beneficiaries under drug management programs, and they were developed in accordance with the standards we are finalizing in § 423.153(f)(16) and beginning for 2020, will be published in guidance annually. These criteria also adhere to the standards we proposed in § 423.153(f)(16) because: (1) They were developed with stakeholder consultation in that we solicited comment on them in the proposed rule; (2) they are based on the acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, and the level of frequently abused drugs in that they identify potential at-risk beneficiaries taking opioids and obtaining them from 7 or more prescribers or 7 or more pharmacies; (3)

they are derived from our and commenters' expert opinion that obtaining opioids from many prescribers or many pharmacies is a potentially dangerous utilization pattern of frequently abused drugs due to an apparent lack of coordination of care that warrants further review and this opinion is supported by the fact that this pattern is highly unusual in the Part D program as it represents 0.11 percent of beneficiaries; and (4) they include a program size estimate.

We have consolidated the clinical guidelines/OMS criteria in Table 1 for easier reference. We note that we were not persuaded by the commenter who urged us to adopt criteria that would address high opioid use regardless of the number of prescribers or pharmacies, as one purpose of drug management programs, and lock-in tools specifically, is to promote better care coordination among multiple providers.

Comment: Some commenters suggested that if we have concerns with allowing Part D sponsors flexibility in adopting targeting criteria for potential at-risk beneficiaries, that we establish a process through which a sponsor could submit their guidelines to CMS.

Response: We thank these commenters for their idea, but we prefer the approach we have taken as providing consistency across the entire Part D program and a program size, as required by CARA.

Comment: A few commenters urged caution in the use of policies determining access to medications based upon thresholds such as MME, which the commenters viewed as a potentially problematic type of one-size-fits all approach. These commenters noted that scientific literature does not support the establishment of a recommended maximum dose for opioids. These commenters also pointed out that the use of such thresholds may result in a false impression of a superior safety profile, which we interpreted to mean that referring to a specific MME level as potentially dangerous may give the impression that a level below that amount is universally safe.

Response: We agree with the commenter that the CDC Guideline—and our clinical guidelines for Part D drug management programs that refer to it—are not intended as a maximum threshold for prescribing, as we noted in the preamble to the proposed rule. In the absence of dosing limits in the FDA-approved labeling for opioids, we are using the CDC guideline to establish a threshold to identify potentially high-risk beneficiaries who may benefit from closer monitoring and to create alignment between Government programs.

Moreover, our implementation of the CARA drug management program provisions focuses on beneficiaries who are receiving opioids from multiple prescribers and/or multiple pharmacies, not just at a certain MME level. In addition, our finalized requirements for drug management programs require Part D sponsors to engage in case management with prescribers, obtain their verification that the beneficiary is at-risk and their agreement before implementing a prescriber lock-in or beneficiary-specific claim edit, as long as the prescribers are responsive to case management. This means that decisions about the amount of frequently abused drugs an at-risk beneficiary should receive are made by the beneficiary's prescriber(s) if they are responsive and not based on the targeting threshold for review of the beneficiary's utilization. Thus, this approach is aimed at addressing overutilization of frequently abused drugs while maintaining access to such drugs when medically necessary in the Part D program.

Comment: A commenter proposed modifying ''for any duration'' in the clinical guidelines to permit beneficiaries a reasonable overlap time to refill medications and suggested that CMS set a reasonable overlap period of no more than 3 days for the purposes of identifying potential at-risk beneficiaries.

Response: CMS performed an extensive analysis of the OMS criteria using 2015 data (*https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Revised-OMS-Criteria-Modification-Analysis.pdf*). Adjusting the clinical guideline MME calculation for each beneficiary to account for overlapping fills would be difficult to operationalize from a data analysis perspective since it would be dependent on the number of fills and the opioids dispensed, including strength each beneficiary received. For this reason, CMS chose to calculate the MME daily dose using the average daily dose during the opioid usage. We included ''for any duration'' in the clinical guidelines since this means that these beneficiaries reached or exceeded the MME level in a short period of time, and received their opioids from multiple prescribers and pharmacies. This indicates potential coordination of care issues or misuse. We found that the number of additional overutilizers with an episode length less than 90 days for any of the MME dose thresholds analyzed ranged from only 57 to 320 beneficiaries, or 1 to 2 percent of the 90+ day episode opioid overutilizer count. Therefore, we included these beneficiaries as potential opioid overutilizers under the current policy, and we will continue to utilize this methodology for OMS reporting of potential at-risk beneficiaries for drug management programs.

If a sponsor performs case management for a potential at-risk beneficiary who was reported through OMS and discovers that the high use was a result of appropriate prescription overlap and not misuse, we would expect the sponsor to stop conducting case management for that beneficiary, and to not send the initial notice to the beneficiary.

Comment: A commenter requested that CMS clarify that the language ''for any duration during the most recent 6 months'' means that the opioid use occurred during the most recent 6 months and not 6 months of consistent use.

Response: We confirm that this language means that the opioid use occurred during the most recent 6 months.

Comment: A commenter suggested that CMS apply path analysis to develop clinical guidelines to identify potential at-risk beneficiaries using the Integrated Data Repository (IDR), which is a data warehouse that integrates multiple data sources and supports analytics across CMS.

Response: We thank the commenter for suggesting an approach in the IDR to improve identification of potential at-risk beneficiaries for CMS to consider.

We proposed that under the clinical guidelines, prescribers associated with the same single Tax Identification Number (TIN) be counted as a single prescriber, because we have found under the current policy that such prescribers are typically in the same group practice that is coordinating the care of the patients served by it, and failing to do so would result in a high volume of false positives reported through OMS. Thus, it is appropriate to count such prescribers as one, so as not to identify beneficiaries through OMS who are not potentially at-risk.

In this regard, in applying the clinical guidelines criteria, CMS proposed to count prescribers with the same TIN as one prescriber, unless any of the prescribers are associated with multiple TINs. We also proposed that when 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. For example, under the criteria we are finalizing, a beneficiary who meets the 90 MME criterion and received opioid

prescriptions from 3 prescribers in the same group practice and 2 independent opioid prescribers (1 group practice + 2 prescribers = 3 prescribers) and filled the prescriptions at 4 opioid dispensing pharmacies that do not share real-time electronic data, will still meet the criteria, which is appropriate. However, a beneficiary who meets that 90 MME criterion and received opioid prescriptions from 3 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 that do not share real-time electronic data will not meet the criteria.

Comment: Several commenters supported the proposal conceptually to count prescribers associated with the same single TIN as a single prescriber, but many of these commenters noted that some Part D plans sponsors and PBMs do not have access to prescriber TIN information. A few commenters recommended that CMS count prescribers with the same National Provider Identifier (NPI) as a single prescriber, and a commenter suggested that CMS require prescribers to share real-time electronic data through an electronic health record (EHR).

Response: We appreciate the support for this proposal as well as the information on the operational challenges. After considering these comments, we are finalizing this aspect of the clinical guidelines for 2019. Part D plan sponsors without the ability to group prescribers using the TIN through data analysis will have to make these determinations during case management. If a sponsor finds that the multiple opioid prescribers for the beneficiary are from a single group practice, and therefore, the beneficiary does not meet the clinical guidelines, the sponsor could stop conducting case management for that beneficiary, and would not send the initial notice to the beneficiary. We will issue guidance and updated OMS technical user guides to plan sponsors at a later time, including data sources and standard responses used in OMS reporting, which may include providing such feedback to CMS.

In addition, this information may be discovered after the sponsor provided the beneficiary the initial notice. In such an event, the sponsor would send the beneficiary an alternate second notice that the beneficiary is not at-risk. To the comments about grouping by NPI, we clarify that under the current policy/OMS we use the NPI to first identify single prescribers, and then we further group single prescribers with the same single TIN. We will continue this methodology for the clinical guidelines under the drug management program. We appreciate the comment regarding real-time prescriber data, but we did not propose such a system for Part D prescribers.

Comment: We received several comments supporting our proposal that when 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. We also received many comments that Part D plan sponsors and their PBMs do not have the systems capabilities to account for pharmacies that have multiple locations that share real-time electronic data, in order to treat all locations of the pharmacy collectively as one pharmacy. We received one comment that they are able to, but that there are operational challenges to synthesizing the data to be useful for drug management programs.

Response: As we stated in the proposed rule, 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. Because of this statutory requirement, it makes sense to us to consider such multiple locations as one pharmacy for purposes of the clinical guidelines, similar to how we account for group practices, to reduce false positives, particularly because the purpose of the guidelines is to identify when a beneficiary may be at risk for overutilization because they use multiple pharmacies. Therefore, we are finalizing this aspect of the clinical guidelines for 2019.

We understand that we, and apparently most sponsors and their PBMs, do not have the systems capability to automatically determine when a pharmacy is part of a chain. Therefore, Part D plan sponsors without this capability will have to make these determinations during case management. If through such case management, a plan sponsor finds that multiple locations of a pharmacy used by the beneficiary share real-time electronic data, the sponsor will be required to treat those locations as one pharmacy. This may result in the sponsor not or no longer conducting case management for a beneficiary because the beneficiary does not meet the clinical guidelines, or in the sponsor sending the beneficiary an alternate second notice that the beneficiary is not at-risk if the sponsor discovers this information after it provided the beneficiary with the initial notice.

We note that group practices and chain pharmacies are discussed later in this preamble in the context 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).

As noted above, Table 1 shows that in 2017 approximately 44,332 beneficiaries would have met the minimum criteria of the 2019 clinical guidelines that we are finalizing, which is approximately 0.10 percent of the 45 million beneficiaries enrolled in Part D in 2017. Approximately, 22,841 additional beneficiaries will have met the supplemental criteria that we are finalizing, which is approximately 0.05 percent. To derive this estimated population of potential at-risk beneficiaries, we analyzed prescription drug event data (PDE) from 2017,[8] using the CDC opioid drug list and MME conversion factors, and applying the criteria we are finalizing as the clinical guidelines. This estimate is over-inclusive because we did not exclude beneficiaries in long-term care (LTC) facilities who will be exempted from drug management programs, as we discuss later in this section.

However, based on similar analyses we have conducted, this exclusion will 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 will 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.

[8] Unique count of beneficiaries who met the criteria in any 6 month measurement period (January 2017–June 2017; April 2017–September 2017; or July 2017–December 2017).

TABLE 1: 2019 CLINICAL GUIDELINES/OMS CRITERIA* FOR IDENTIFYING POTENTIAL AT-RISK BENEFICIARIES

Minimum Criteria Applied (Sponsors with Drug Management Programs Must Review)	**Impact to Part D Program**
≥ 90 MME and either: **3**+ opioid prescribers **AND** **3**+ opioid dispensing pharmacies **OR** **5+** opioid prescribers (regardless of the number of opioid dispensing pharmacies) Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber. Pharmacies with multiple locations that share real-time data are counted as one pharmacy.	44,332 beneficiaries in 2017 (69.9% were LIS) Represents 0.10% of 45,218,211 Part D beneficiaries in 2017 LTC beneficiaries included in estimate but are exempt. Estimate does not include pharmacies grouped as one pharmacy; CMS does not have system capability.
Supplemental Criteria Applied (Sponsors with Drug Management Programs May Review as Many as Manageable)	**Impact to Part D Program**
Any Level MME and: 7+ opioid prescribers **OR** 7+ opioid dispensing pharmacies Prescribers associated with the same single Tax Identification Numbers (TIN) are counted as a single prescriber. Pharmacies with multiple locations that share real-time data are counted as one pharmacy.	22,841** beneficiaries in 2017 (77.8% were LIS) Represents 0.05% of 45,218,211 Part D beneficiaries in 2017 LTC beneficiaries included in estimate but are exempt. Estimate does not include pharmacies grouped as one pharmacy; CMS does not have system capability.

*Benzodiazepines are a frequently abused drug for purposes of Part D drug management programs but are not a factor in the these clinical guidelines/MS criteria. Buprenorphine products are not used to determine the beneficiary's average daily MME. However, prescription opioids including all formulations of buprenorphine for pain and MAT, are used to determine opioid prescribers and opioid dispensing pharmacies under the minimum criteria. Similarly, sponsors must include all prescription opioids, including all buprenorphine products, to determine opioid prescribers and opioid dispensing pharmacies under the supplemental criteria.

**Note: A total of 25,480 beneficiaries met the supplemental criteria alone. The estimate is 22,841 beneficiaries after removing duplicate beneficiaries already identified by the minimum criteria.

As clarified above, since the CDC removed all formulations of buprenorphine, for pain and for MAT, from the most recent CDC MME conversion factor file, buprenorphine products are not used to determine the beneficiary's average daily MME. However, we will use prescription opioids, including all buprenorphine products for pain and MAT, to determine opioid prescribers and opioid dispensing pharmacies under the minimum criteria. Similarly, sponsors must include all prescription opioids, including all buprenorphine products, to determine opioid prescribers and opioid dispensing pharmacies under the supplemental criteria.

- Exempted Beneficiary

We proposed 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 through a contract with a single pharmacy; or (3) Has a cancer diagnosis. While the first two exceptions are required under CARA, we proposed 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. We did not propose to exempt additional categories of beneficiaries.

We received the following comments and our response follows:

Comment: Commenters were overall supportive of our proposal to exempt beneficiaries who have a cancer diagnosis. A few of the commenters noted that the CDC Guideline recommendations do not apply to active cancer treatment. Many of these commenters asked for more guidance on how this exemption, which is a feature of the current policy, would be operationalized. Others felt the exemption is too broad and could be applied to beneficiaries who have not been treated for cancer in years or who are being treated for non-terminal cancer but possibly do have an opioid overuse issue that needs to be addressed. A few commenters disagreed with the exemption as an inappropriate

one-size-fits-all approach. Even the commenters who did not support the exemption noted that the cancer population is unique and must be handled delicately.

Response: We thank the commenters for their supportive comments as to the exemption for cancer. Our intent is to exempt beneficiaries who are currently being treated for active cancer-related pain from Part D drug management programs and this is the exemption we are finalizing based on the comments. While our current policy generally excludes beneficiaries with cancer diagnoses from OMS reporting,[9] we believe it is appropriate to be more specific with respect to regulatory parameters for Part D prescription drug management programs. Therefore, the comments have persuaded us that we need to be more precise with this codified exemption.

As we noted in the proposed rule, there are some limitations around this exemption under the current policy due to our current data sources which will remain when implementing the drug management program clinical guidelines. For example, there may be a lag in current year diagnosis data in CMS systems and the RxHCC codes from the risk adjustment processing system are based on diagnosis data from the past year. Therefore, Part D plan sponsors will have to identify such exempted beneficiaries through the case management process if they are inadvertently reported through OMS or when the sponsor is reviewing cases pursuant to applying the minimum clinical guidelines more frequently than CMS and the supplemental criteria of the clinical guidelines. Plan sponsors may have more recent cancer diagnosis information or learn this information through clinical contact with prescribers. Plan sponsors may currently refer to the CDC Guideline as a reference which distinguishes active cancer treatment from cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only. We will monitor health care guidelines that address this topic and issue guidance as warranted to further refine the execution of the exemption for beneficiaries being treated for active cancer-related pain that we are finalizing.

While we understand the concerns of the commenters who did not support this exemption about potential inappropriate opioid use among this population, we note that this exemption is a feature of the current policy, which has reportedly been working well and we therefore believe it is appropriate to extend it to drug management programs. We agree that this population deserves heightened protection but we are finalizing an exemption that we believe is narrowly tailored to address the concerns of commenters who urged us to proceed with caution with respect to this exemption.

Comment: Many commenters supported the exemption for beneficiaries in the LTC setting. A few commenters recommended that we not exempt LTC beneficiaries from retrospective drug utilization review (DUR) processes. A commenter asked if it could still implement a beneficiary-specific claim edit at POS for frequently abused drugs if it independently determined an LTC resident to be at-risk.

Response: Section 1860D–4(c)(5)(C)(ii) exempts beneficiaries in the LTC setting, and we therefore do not have the authority to permit plans to include them in Part D drug management programs. We are finalizing this exemption as proposed. Because beneficiary-specific POS claim edits for frequently abused drugs are included in drug management programs through the integration approach we are finalizing, a sponsor may not implement such an edit for an exempt beneficiary.

However, while exempt beneficiaries are exempt from drug management programs, they are not exempt from retrospective DUR processes. Part D plan sponsors still must comply with its other utilization management obligations in § 423.153, and could implement a beneficiary-specific edit for drugs other than frequently abused drugs, for example, if necessary to comply with those obligations. In addition, sponsors may also still review the use of drugs that constitute frequently abused drugs by beneficiaries in LTC facilities and work with such facilities to identify patterns of inappropriate or medically unnecessary care among enrollees. However, as just stated, the sponsors cannot implement beneficiary-specific edits for drugs that constitute frequently abused drugs, nor prescriber or pharmacy lock-in for such drugs.

Comment: A commenter requested that CMS exempt any Part D claim submitted by a Network Long-Term Care Pharmacy (NLTCP), as defined in Chapter 5 of the Medicare Prescription Drug Benefit Manual, asserting that such pharmacies are required to meet minimum performance and service criteria, including performing drug utilization reviews and identifying inappropriate drug usage. Another asked for clarification on whether beneficiaries serviced by long-term care pharmacies are exempt or if the exemption is limited to beneficiaries in long-term care facilities.

Response: Section 1860D–4(c)(5)(C)(ii) of the Act exempts residents of a long-term care facility rather than pharmacy claims submitted by long-term care pharmacies. Therefore, we find it is appropriate to finalize an exemption that takes the same approach as the statute. However, we note that beneficiaries serviced by long-term care pharmacies may meet another exemption, such as the one for beneficiaries residing in facilities for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy.

Comment: A few commenters stated that they will need the Long-Term Institution (LTI) report to be released on a monthly basis rather than the current quarterly basis.

Response: We thank the commenters for their comment and will explore if more frequent reporting is feasible.

Comment: Many commenters supported the proposed exemption for beneficiaries who are residents of a facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy. Others urged us to propose one.

Response: We clarify for commenters that the proposed rule included an exemption for beneficiaries who are residents of a facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, as required by Section 1860D–4(c)(5)(C)(ii). Therefore, we are finalizing this exemption as proposed.

Comment: Many commenters urged us to extend an exemption to beneficiaries in assisted living facilities, asserting that such beneficiaries are at very low risk of substance abuse and that applying lock-in to them could be disruptive and undermine their care. Other commenters opposed such an exemption and urged us to proceed with caution in carving out multiple exemptions that could undermine the purpose of drug management programs. Other commenters referred to the difficulty in identifying such beneficiaries to exempt them.

[9] Currently, for OMS, the following beneficiaries are excluded from OMS reporting: Those with ICD–10–CM codes associated with American Medical Association (AMA) Physician Consortium for Performance Improvement (PCPI) ICD–10 cancer diagnoses in the Common Working File (CWF) data during the 12 months prior to the end of the measurement period or cancer RxHCCs in the latest Risk Adjustment Processing System (RAPS). Note, this is currently aligned with the Pharmacy Quality Alliance opioid overuse measure specifications.

Response: Based on the comments received, we are not persuaded that beneficiaries in assisted living facilities should be exempt from Part D drug management programs, because we do not believe that these facilities routinely dispense drugs to their residents through a contract with a single pharmacy, and therefore these beneficiaries could be identified by the clinical guidelines on this or another basis and be potentially at-risk. However, if a sponsor learned during case management that a beneficiary resides in an assisted living facility that does dispense drugs through a contract with a single pharmacy, then the sponsor must exempt such resident from its drug management program.

In addition, we are persuaded that many exemptions for certain group of beneficiaries or ones that are crafted too broadly would risk undermining the purpose of drug management programs. Therefore, we decline to establish a separate exemption for assisted living facility residents. We note that several required features of Part D drug management programs, such as case management, multiple written beneficiary notices, the right to appeal and our general oversight, will serve as beneficiary safeguards should a Part D sponsor inappropriately limit a beneficiary's coverage to frequently abused drugs through a drug management program.

Comment: A commenter questioned how a drug management program should handle at-risk beneficiaries who move in and out of an LTC facility.

Response: An at-risk beneficiary who moves into an LTC facility becomes an individual exempted from a drug management program and a sponsor must remove such beneficiary from such program as soon as it reliably learns that the beneficiary has moved into an LTC facility, whether that be via the beneficiary, the facility, a pharmacy, a prescriber, or an internal or external report. A beneficiary who moves out of an LTC facility is no longer exempted unless he or she meets another prong of the finalized definition of exempted beneficiary.

Comment: Several commenters suggested that an exemption for beneficiaries who are receiving non-hospice palliative and end-of-life care would be appropriate in light of the exemption for beneficiaries who have elected hospice care. A few of these commenters asserted that without an exemption in the regulation, beneficiaries could be included in a drug management program at a plan sponsor's discretion and experience restricted access to pain-control medication when they need them the most. Some commenters noted that the CDC Guideline exempts patients receiving palliative and end-of-life care. Others disagreed, asserting that we had put sufficient safeguards in place to protect such beneficiaries in drug management programs. Other commenters referred to the difficulty in identifying such beneficiaries in order to exempt them.

Response: We are persuaded that beneficiaries who are receiving non-hospice palliative and end-of-life care but have not elected hospice should be exempted from Part D drug management programs. While we wish to exercise caution and thoughtfulness in establishing regulatory exemptions versus clinical guidelines/criteria, as we noted above, we agree based on the multiple comments that such beneficiaries should be treated the same as beneficiaries who have elected hospice care for purposes of drug management programs, as they are very similar in their health care status, if not their health benefit plan status. While we expect that Part D plan sponsors and PBMs would not inappropriately place such beneficiaries in their drug management programs, an actual regulatory exemption from drug management programs would be more definitive. Furthermore, adding these exemptions would align the drug management programs with the CDC Guideline, which was developed by experts and specifically provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care. Therefore for consistency with the CDC Guideline, beneficiaries who are receiving non-hospice palliative and end-of-life care but who have not elected hospice will be exempted from Part D drug management programs as well.

As discussed in the proposed rule, the data challenges to identify these Part D beneficiaries will still exist for CMS and we anticipate for Part D sponsors also. Therefore, we will explore options for refining OMS reporting in this regard, and sponsors will have to identify these exempted beneficiaries through the case management process.

We also remind Part D sponsors that drugs and biologicals covered under the Medicare Part A per-diem payments to a Medicare hospice program are excluded from coverage under Part D. For a prescription drug to be covered under Part D for a beneficiary who has elected hospice, the drug must be for treatment unrelated to the terminal illness or related conditions. This is because drugs and biologicals covered under the Medicare Part A per-diem payments to a Medicare hospice program are excluded from coverage under Part D. Therefore, in 2014,[10] we strongly encouraged sponsors to place beneficiary-level PA requirements on only four categories of prescription drugs including analgesics. As a result, a small number of beneficiaries who elected hospice care have been identified and excluded from the current policy/OMS.

Comment: A few commenters requested clarification on the practical meaning of an exempted individual. Specifically, they asked if the beneficiary is exempted from only coverage limitations or from retrospective DUR processes. A commenter opposed our proposal that drug management programs would supersede the current policy in that beneficiary-specific edits would no longer be permitted on non-opioid medications. Another commenter requested clarification on the status of existing beneficiary-specific POS claim edits for opioids and benzodiazepines beginning January 1, 2019.

Response: Exempted beneficiaries are exempted from Part D drug management programs. Also, because we are integrating the ''lock-in'' component of the drug management programs with the current policy, going forward, beneficiary-specific POS edits and lock-in for frequently abused drugs will be permitted only in compliance with § 423.153(f). However, as we noted earlier, the prescription drug management program requirements that we are finalizing in this rule do not affect plan sponsors' obligation to comply with other requirements pertaining to coverage or utilization management. Part D plan sponsors are still obligated to conduct other drug utilization review and management consistent with existing DUR requirements, which includes reviewing utilization for any Part D drug and may include implementing beneficiary-specific POS claim edits on drugs that are not frequently abused drugs, if necessary. However, we do not have specific guidance in this area, but we would expect the sponsor to employ the same level of diligence and documentation with respect to beneficiary-level POS claim edits for non-frequently abused drugs that we

[10] Please see the most recent CMS guidance, ''Update on Part D Payment Responsibility for Drugs for Beneficiaries Enrolled in Medicare Hospice'', issued on November 15, 2016.

require for drug management programs, consistent with current policy.[11]

In addition, beneficiaries for whom Part D sponsors have implemented beneficiary-specific POS claim edits for opioids and/or benzodiazepines before January 1, 2019 can continue to be subject to those edits under the current policy after December 31, 2018, which means that they may remain in place unless removed under the current policy. For example, as the result of a coverage determination or appeal.[12] To the extent that such a beneficiary is reported through OMS on January 1, 2019 or later to a sponsor with a drug management program, that sponsor must comply with the requirements we are finalizing in this rule.

Comment: A commenter suggested that CMS develop a process by which additional categories of exempted individuals could be evaluated and added that are evidence-based and involve health care practitioners.

Response: We will evaluate the implementation of the drug management programs. Based on this experience or new or emerging relevant health care information, we will consider proposing additional exemptions through rulemaking as necessary.

Comment: A commenter asked how to handle retroactive notifications that would qualify a beneficiary for an exemption.

Response: As we stated in a previous response with regard to beneficiaries who move into LTC facilities, a sponsor must remove an exempted beneficiary from a drug management program as soon as it reliably learns that the beneficiary is exempt, whether that be via the beneficiary, the facility, a pharmacy, a prescriber, or an internal or external report.

Based on these comments, we are finalizing with modification the following definition for exempted beneficiary: An exempted beneficiary, with respect to a drug management program, will mean an enrollee who: (1) Has elected to receive hospice care or is receiving palliative or end-of-life 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) is being treated for active cancer-related pain. Given this exemption, CMS will report potential at-risk beneficiaries who meet the minimum criteria of the clinical guidelines to sponsors through the OMS. Currently, we have the ability to exempt beneficiaries in LTC facilities, in hospice, and with active cancer-related pain. Sponsors may have more current data or obtain information through the case management and notification processes to further exempt beneficiaries, including those receiving palliative or end-of-life care.

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

As noted previously, we proposed 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 proposed 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 proposed to revise § 423.153 by adding a new paragraph (f) about drug management programs for which the introductory sentence will 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 will be codified in various provisions under § 423.153(f).

We received the following comments and our response follows:

Comment: While CMS received many comments that were supportive of drug management programs as a whole, we did not receive comments specific to these provisions.

Response: We are therefore finalizing as proposed.

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

We proposed 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 proposed to require that these policies and procedures address the appropriate credentials of the personnel conducting case management and the necessary and appropriate contents of files for case management. We additionally proposed to require sponsors to monitor information about incoming enrollees who will 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.

To codify these requirements, we proposed the written policies and procedures specified at § 423.153(f)(1) (see 82 FR 56510).

We received the following comments and our response follows:

Comment: We received a comment strongly supportive of the requirements in this provision.

Response: We thank the commenter for the support.

Comment: We received a few comments inquiring what credentials are needed for clinical staff who conduct case management. The commenters were concerned that the clinical staff conducting case management be adequately qualified to perform it in terms of education and training. These commenters stated that unqualified case managers could significantly detract from the benefit of Part D drug management programs.

Response: We agree that the requirement that clinical staff conduct case management needs more detail. CMS expects that such clinical staff conducting case management as part of a Part D plan sponsor's drug management program would be a physician or other appropriate health care professional with sufficient expertise to conduct medical necessity reviews related to potential opioid overutilization. While we are not specifying particular credentials for clinical staff, in response to these comments, we are clarifying in the finalized version of § 423.153(f)(1)(i) that clinical staff must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

Comment: We received several comments that a dentist should be required to be included on the case management team when a prescriber of frequently abused drugs is a dentist.

Response: We decline to adopt this recommendation. We do not want to be overly prescriptive as to the specific background of licensed clinical staff conducting case management. We believe the plan should have some flexibility, beyond what is discussed in the preceding response and described in § 423.153(f)(1)(i), to determine appropriate credentials of the clinical

[11] See ''Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D,'' dated September 6, 2012.

[12] Patient Safety Analysis Overutilization Monitoring System User Guide. January 2018.

staff conducting case management based on the facts and circumstances of the case.

Comment: We received a question asking how prescriber agreement should be documented and shared with appropriate parties. We also received a few comments that a Part D sponsor must ensure that any records of contacts between the sponsors and prescribers under drug management programs must be easily accessible to at-risk beneficiaries who wish to appeal and that these records are easily able to be auto-forwarded to the Independent Review Entity (IRE).

Response: We agree that such information must be documented and available to appropriate parties including at-risk beneficiaries and the IRE, when applicable. To comply with § 423.153(f)(1)(ii), sponsors must document contact with prescribers during case management, for example, if a prescriber agreed with the plan sponsor to implement a limit on the beneficiary's access to coverage for frequently abused drugs pursuant to § 423.153(f)(4). Also, the sponsor must document if the beneficiary calls the sponsor to provide his or her pharmacy or prescriber preferences for lock-in. To make this clearer, we are adding language to § 423.153(f)(1)(ii) such that the necessary and appropriate contents of files for case management must include documentation of the substance of prescriber and beneficiary contacts.

Comment: We received a comment that we should require Part D plan sponsors' policies and procedures for clinical contact to include secure identity verification safeguards to protect prescribers from ''phishing'' communications that attempt to trick prescribers into disclosing patient information.

Response: We decline to make this a requirement specific to Part D drug management programs. We note that health care providers' offices and Part D sponsors are both covered entities under Health Insurance Portability and Accountability Act of 1996. We also encourage Part D sponsors to have written policies and procedures for their staff who contact providers to proactively identify themselves in a manner that should reasonably satisfy the providers of their identity and for providers to likewise have written practice policies and procedures to reasonably establish the identity of the staff of health benefit plans who contact them and do not proactively establish their identity.

Given these comments and our responses, we are finalizing § 423.153(f)(1) with modification to include the changes regarding the licensure of the clinical staff conducting case management and the required documentation of the substance of prescriber and beneficiary contacts.

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

To meet the requirements of section 1860D–4(c)(5)(C) and section 1860D–4(c)(5)(B)(i)(II) of the Act, we proposed in a new § 423.153(f)(2) to require Part D sponsors' clinical staff to engage in 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. Specifically, we proposed that a new § 423.153(f)(2) would state that 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:

- Send written information to the beneficiary's prescribers that the beneficiary meets the clinical guidelines and is a potential at-risk beneficiary;
- 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
- In cases where the prescribers have not responded to the inquiry described in (f)(2)(i)(B), make reasonable attempts to communicate telephonically with the prescribers within a reasonable period after sending the written information.

We proposed to add paragraph (ii) to § 423.153(f)(2) that would specify that the exception would be 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 because it has already been performed by a prior Part D sponsors for the beneficiary. 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 limitation on access to coverage for frequently abuse drugs is warranted for the safety of the beneficiary. Also, sponsors will use this information to choose standardized responses in OMS and provide information to MARx about any plan coverage limitations that the sponsors implement. We will address required reporting to OMS and MARx by sponsors again later.

Our proposed § 423.153(f)(2) used the terms ''reasonable attempts'' and ''reasonable period'' rather than specify a required number of attempts or a specific timeframe for plan sponsor to call prescribers. We explained that this was due to 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 further stated that we wished to leave flexibility in the regulation text for sponsors to balance these priorities on a case-by-case basis in their drug management programs. However, we note that we proposed 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.

We received the following comments and our response follows:

Comment: We received a comment requesting that a plan sponsor be able to communicate to CMS if no prescriber will verify that the beneficiary is at-risk.

Response: We plan to expand and modify OMS and the MARx system to accommodate the CARA drug management program provisions we are finalizing here. We will issue additional guidance and technical instructions as needed.

Comment: We received a comment asking that we recommend that Part D sponsors encourage prescribers during case management to discuss drug management programs with their patients. We also received a request that we issue guidance to plan sponsors directing them to encourage prescribers, as part of the required clinical contact,

to perform a comprehensive substance abuse disorder screening and/or assessment of the patient deemed to be a potential at-risk beneficiary, and if indicated, refer him or her for follow-up treatment with a pain specialist or addiction treatment provider.

Response: We encourage Part D plan sponsors to undertake both of these suggestions, but decline to require it at this time, as we believe prescribers, in their professional discretion by and large will undertake appropriate adjusted treatment plans with their patients and/or MA–PDs will negotiate such issues with their network providers. We also remind commenters that not all Part D prescription drug plans have network providers.

Comment: We received some comments that Part D sponsors should not be permitted to telephone prescribers in order to avoid disrupting their practices.

Response: We decline to adopt this suggestion. The clinical guidelines identify beneficiaries who are potentially at-risk for a serious adverse health event, including death, due to their opioid use and apparent lack of coordinated care. The requirements we are finalizing permit sponsors to escalate the steps they take during case management to engage in clinical contact with the beneficiary's prescribers of frequently abused drugs. We would expect such prescribers to understand such sponsors' attempts to make them aware of important information in this regard that they likely do not know.

Comment: We received a comment that integrated delivery systems use communication tools other than telephone calls to escalate matters to prescribers and that CMS should allow such systems to use such tools instead.

Response: Our intent is for Part D sponsors to use the most effective means designed to elicit a prescriber response to case management. Therefore, based on this comment, we are modifying the regulatory language in § 423.153(f)(2)(i)(C).

Comment: We received a question whether a gaining sponsor must immediately lock-in a new enrollee if the sponsor receives notice from the losing sponsor that the enrollee was locked-in by the losing sponsor.

Response: No. Part D sponsors are responsible for their own drug management programs. As such, a gaining sponsor is not required to but may do so under certain circumstances as we discuss later in this preamble. Also, we note that with respect to at-risk beneficiaries that are new to a plan, sponsors that do not take any action should be aware that such beneficiaries may later be reported through OMS if they meet the clinical guidelines. Also, we note that pursuant to § 423.153(f)(2)(i), the sponsor must conduct case management for every potential at-risk beneficiary, unless an exception applies.

After considering these comments, we are finalizing the proposed language in § 423.153(f)(2) with the modification described.

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

We proposed to describe all the tools that will be available to sponsors to limit an at-risk beneficiary's access to coverage for frequently abused drugs under a drug management program in § 423.153(f)(3). Our proposal specified that subject to the requirements of paragraph (f)(4) of this section, a Part D plan sponsor may do all of the following:

- Implement a point-of-sale claim edit for frequently abused drugs that is specific to an at-risk beneficiary.
- 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—

++ Prescribed for the beneficiary by one or more prescribers;

++ Dispensed to the beneficiary by one or more network pharmacies; or

++ Specified in both paragraphs (f)(3)(ii)(B)(1) and (2) of this section.

Paragraph (iii)(A) will 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) will 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.

We received the following comments and our response follows:

Comment: We received a question whether a Part D sponsor, under a drug management program, may implement a combination of a beneficiary-specific POS claim edit, prescriber and/or pharmacy lock-in for frequently abused drugs, and whether these limitations may be implemented at different times. Another comment recommended that plan sponsors be permitted to establish a prescriber lock-in concurrently with a beneficiary-specific POS claim edit and not require the plan to contact the prescribers separately for each limitation.

Response: We acknowledge that there may be cases where a plan may impose one or more coverage limitations for frequently abused drugs simultaneously on an at-risk beneficiary, and at a later time, add new limitations and/or terminate existing ones. Thus, a plan sponsor may choose to implement multiple limitations on access to coverage for frequently abused drugs for an at-risk beneficiary at one time.

For instance, after case management, a plan sponsor may decide to pursue implementation of a POS claim edit, prescriber lock-in, and pharmacy lock-in for an at-risk beneficiary simultaneously because of the circumstances of the particular case. In this instance, prescriber agreement would be necessary to implement the POS edit and the prescriber lock-in.

A plan sponsor may also implement additional coverage limitations over time (for example, start with a beneficiary-level POS edit, subsequently add a prescriber lock-in, and subsequently add a pharmacy lock-in) because the case has not resolved itself as expected after initial case management. We remind plan sponsors that when implementing additional coverage limitations, the plan sponsor must repeat the case management process including prescriber verification, prescriber agreement, if applicable, and notice requirements for each additional limitation, and that such actions would also confer a new 60 day appeal timeframe. We discuss this scenario further in the appeal section of this preamble.

Furthermore, a plan sponsor might also terminate existing limitations on access to coverage over time (for example, an at-risk beneficiary may have a POS edit and pharmacy lock-in and the plan sponsor terminates the pharmacy lock-in and leaves in place the POS edit).

While we are allowing plan sponsors to make such additions/terminations to limitations to access to coverage for frequently abused drugs for an at-risk beneficiary, we recognize that such

changes might be disruptive and/or confusing for the beneficiary, and thus strongly discourage plans from making frequent changes to such limitations for a particular at-risk beneficiary. To minimize such disruption and ensure such actions are taken in the manner contemplated by the statute, we have added a provision at § 423.153(f)(5)(iv) to the regulation text which specifies that, if a plan intends to make changes to the limitations imposed on a beneficiary under their drug management program after the beneficiary has been identified as at-risk, the plan sponsor is required to provide the beneficiary notices under the rules established at § 423.153(f)(5) through (f)(8) and discussed later in this preamble. Additionally, we will closely monitor information submitted by sponsors to CMS in OMS and MARx and complaint data to make sure plans are not inappropriately disrupting beneficiary access to coverage for frequently abused drugs by making frequent changes to the limitations on access to coverage. While we are not currently imposing limitations on how many times the plan can make such changes, we will re-evaluate this policy in the future if it becomes problematic.

In response to this comment, we are finalizing this provision as proposed, except we are modifying § 423.153(f)(3) to state a Part D plan sponsor may do ''any or all of the following,'' and § 423.153(f)(3)(ii)(C) to simply state ''both.'' This will make clearer that read as a whole, § 423.153(f)(3) means that a Part D sponsor may use the tool of a beneficiary-specific point-of-sale edit, or prescriber or pharmacy lock-in, or any combination of these three tools to limit an at-risk beneficiary's access to coverage of frequently abused drugs under its drug management program.

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

We proposed in § 423.153(f)(4) that before a Part D plan sponsor could limit the access of at-risk beneficiary to coverage for frequently abused drugs, the sponsor would first be required to take certain actions. We proposed in paragraph § 423.153(f)(4)(i)(A) that a sponsor would be required to 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 that is required by section 1860D–4(c)(5)(C)(iv) of the Act and prescriber verification that the beneficiary is an at-risk beneficiary in accordance with Section 1860D–4(c)(5)(B)(i)(II).

We also proposed in paragraph § 423.153(f)(4)(i)(B) that the sponsor would be required to obtain the agreement of the prescribers of frequently abused drugs with the limitation, unless the prescribers were not responsive to the required case management. We invited stakeholders to comment on not requiring prescriber agreement to implement pharmacy lock-in.

We further proposed in paragraph § 423.153(f)(4)(i)(C) that the sponsor must first provide notices that complied with § 423.153(f)(5) and (f)(6) to the beneficiary in accordance with section 1860D–4(c)(5)(B)(i)(I) of the Act. We additionally proposed in paragraph § 423.153(f)(4)(ii) that a sponsor has complied with the requirement in § 423.153(f)(2)(i)(C) to make reasonable attempts to communicate telephonically with prescribers with a reasonable period if the prescribers were not responsive after 3 attempts to contact them within 10 business days. Finally, we proposed language in § 423.153(f)(4)(ii) that would provide an exception to the case management requirement in § 423.153(f)(2) in cases when a potential or an at-risk beneficiary was identified as such by the beneficiary's most recent prior prescription drug benefit plan and the sponsor had obtained the case management information from the sponsor and updated it as appropriate. We discussed such cases elsewhere in this section. We also discuss proposed § 423.153(f)(4)(iv) that would have imposed a 6-month delay before a sponsor could implement prescriber lock-in later in this preamble.

We received the following comments and our responses follow:

Comment: A commenter suggested that we allow a coverage limitation to be put in place through a drug management program if a prescriber requests one to assist in coordinating the care for his or her patient.

Response: If the beneficiary meets the clinical guidelines/OMS criteria we are finalizing, and a prescriber requests during case management that a coverage limitation be implemented for the beneficiary, the sponsor may implement it in accordance with the requirements we are finalizing for drug management programs in this rule.

Comment: Many commenters stated that Part D sponsors should not have to seek prescriber agreement to limit at-risk beneficiaries to a pharmacy(ies) for access to coverage for frequently abused drugs. These commenters argued that requiring prescriber agreement for pharmacy lock-in would create additional administrative burden and inefficiencies and thus prevent drug management programs from responding in a timely fashion to potentially dangerous overutilization of frequently abused drugs. These commenters also argued that sponsors of stand-alone Part D plans do not have contracts with most of the prescribers and, therefore, have limited opportunity to have clinical contact with these prescribers. Moreover, many commenters felt it was not appropriate to require that the prescriber agree to pharmacy lock-in when the pharmacy is not required to agree when a sponsor applies prescriber lock-in to an at-risk beneficiary.

Other commenters supported our proposal to require prescriber agreement for pharmacy lock-in. These commenters argued that provider discretion and clinical judgment is appropriate to prevent pharmacy lock-in from being implemented by Part D sponsors inappropriately and impeding legitimate patient access.

Response: CMS was persuaded by commenters' rationale that requiring prescriber agreement for pharmacy lock-in could undermine one purpose of drug management programs, which is to promptly address potentially dangerous overutilization of frequently abused drugs. While we recognize that prescriber agreement is an essential component of prescriber lock-in, and prescriber agreement is preferred in the case of a beneficiary-specific claim edit for frequently abused drugs, we are now persuaded that prescriber agreement to pharmacy lock-in is not essential, as pharmacy lock-in is primarily about where the drugs are dispensed and not who wrote the prescription or its dosage. Therefore, we are finalizing this provision with this modification. Plan sponsors will not be required to obtain the agreement of the prescribers of frequently abused drugs to implement a pharmacy lock-in. However, we do note that should a prescriber proactively alert the plan sponsor that they do not believe that pharmacy lock-in is appropriate for a particular at-risk beneficiary, we expect the plan sponsor to take such information into consideration.

On the point of prescriber agreement, we also wish to note that it was unclear in some of the statements if the commenters understood that section 1860D–4(c)(5)(C)(iv) and Section 1860D–4(c)(5)(B)(i)(II) of the Act require, respectively, that a Part D sponsor engage in clinical contact with prescribers regarding whether medications are appropriate for a beneficiary's medical condition and to

verify that a beneficiary is at-risk before limiting access to coverage for frequently abused drugs. Thus, eliminating the need to obtain prescriber agreement to a pharmacy lock-in does not eliminate the requirement to comply with § 423.153(f)(2) and (f)(4)(i)(A) with respect to pharmacy lock-in.

Comment: Several commenters asked CMS to provide additional details about what options Part D plan sponsors would have if a prescriber does not agree to a pharmacy lock-in.

Response: As mentioned above, we are not finalizing the proposal that sponsors must receive prescriber agreement before placing an at-risk beneficiary in pharmacy lock-in.

Comment: In general, commenters supported our proposal that a Part D sponsor would have to obtain prescriber agreement before implementing prescriber lock-in or a beneficiary-specific claim edit at POS for frequently abused drugs to limit an at-risk beneficiary's access to coverage for frequently abused drugs, in cases when a prescriber is responsive to case management. These commenters maintained that the prescribers are in the best position to understand the beneficiary's background and know additional relevant considerations.

However, many commenters voiced their recommendation that the Part D sponsor be able to implement prescriber lock-in without obtaining agreement from all prescribers. Several commenters expressed that it would be difficult to get all prescribers to agree to any limitation, and suggested that as long as at least one prescriber of frequently abused drugs agreed to the limitation, sponsors should be able to proceed with a prescriber lock-in. Commenters suggested that plan sponsors will have already coordinated with the prescribers during case management, at which time the sponsor will have confirmed the appropriateness of the medication and verified with a prescriber that the beneficiary is at risk. Thus, these commenters further suggested that obtaining formal approval of the lock-in will only serve to delay initiating the lock-in.

Commenters also raised the point that a given prescriber may be contributing to the overutilization, in which case his or her approval may not be obtained and requested clarification how a sponsor should act in a beneficiary's best interest if prescribers disagree with each other about the implementation of a claim edit or lock-in. Some commenters recommended that CMS require approval only from the primary prescriber of frequently abused drugs, as determined by case management.

Response: We agree that in order for drug management programs to operate effectively, and prevent the resource-intensive process of obtaining agreement from multiple prescribers, a Part D sponsor should not have to obtain the agreement to prescriber lock-in of all the at-risk beneficiary's prescribers of frequently abused drugs. Therefore, we are changing the language of § 423.153(f)(4)(i)(B) to refer to at least one prescriber, which means that only one prescriber has to agree to prescriber lock-in or a beneficiary-specific POS edit.

In addition, we believe the language of § 423.153(f)(4)(ii)(B) needs to be clearer that prescribers must be responsive in the case of a prescriber lock-in, meaning that non-responsive prescribers cannot constitute agreement as they can in the case of a beneficiary-specific POS edit. Therefore, we are finalizing the § 423.153(f)(4) with this modification in paragraph (ii)(A) and a new (B).

Comment: We received a comment suggesting that a better approach to prescriber agreement would be for at-risk beneficiaries to identify a primary prescriber to help drug management and increase beneficiary safety.

Response: As noted above, we have modified our proposal and are finalizing that all prescribers do not have to agree to prescriber lock-in in order for a plan to implement prescriber lock-in for an at-risk beneficiary; rather, at least one prescriber has to agree. However, we believe that the prescriber who agrees to prescriber lock-in for a beneficiary should be identified through the plan sponsor as a result of case management, and not the at-risk beneficiary. There may be a conflict of interest in having an at-risk beneficiary select whom they consider to be their ''primary'' prescriber for purposes of prescriber agreement, given they might be motivated to select a ''primary'' prescriber that they feel would not agree to prescriber lock-in, such that they can continue receiving inappropriate amounts of frequently abused drugs. We reiterate that the requirement that at least one prescriber agree is for agreement to lock-in is different from the beneficiary's preferences for the prescriber to which they will be locked into, which we discuss later in this preamble.

Comment: We received comments that a prescriber should be able to agree, disagree or neither agree nor disagree with a limitation on a beneficiary's access to coverage for frequently abused drugs.

Response: A prescriber is of course free to have any of these reactions to case management. A plan sponsor cannot implement prescriber lock-in for the beneficiary, unless at least one prescriber agrees to prescriber lock-in, as discussed earlier. Typically, we would expect the one prescriber to agree to prescriber lock-in and agree to serve as the prescriber. A sponsor cannot lock-in a beneficiary to a prescriber who disagrees, unless the prescriber changes their mind, which must be documented in the case file.

We foresee a situation when a prescriber initially disagrees with prescriber lock-in and asserts that he or she must be able to continue to prescribe frequently abused drugs for the beneficiary. In such a case, if another prescriber has agreed to serve as the prescriber to which the beneficiary is locked into, a plan sponsor may need to again ask the first prescriber if he or she would agree to be a prescriber the beneficiary is locked into, and the beneficiary is ultimately locked into two prescribers to ensure reasonable access pursuant to § 423.153(f)(12), which we discuss further below. This could happen, for example, when a beneficiary has been obtaining opioids from multiple prescribers and benzodiazepines from one psychiatrist. A sponsor may have to permit an at-risk beneficiary to obtain opioids from the prescriber who agreed to the lock-in limitation and benzodiazepines from the psychiatrist, who initially did not agree to prescriber lock-in, but ultimately does agree to serve that beneficiary in a lock-in capacity.

With respect to a beneficiary-specific POS claim edit for frequently abused drugs, however, a plan sponsor may not implement one at a dosage that is lower than the highest dosage a prescriber asserts is medically necessary, which is consistent with our current policy.[13]

If a prescriber neither agrees nor disagrees with a limitation on access to coverage for frequently abused drugs, such a prescriber may be considered by the sponsor to be non-responsive, and an at-risk beneficiary could not be locked into that prescriber.

Comment: We received a comment suggesting that 30 days be the time period during which a Part D sponsors must attempt to reach an unresponsive prescriber.

Response: We believe 30 days is too long considering that drug management programs involve frequently abused drugs and multiple prescribers and

[13] Supplemental Guidance Related to Improving Drug Utilization Review Controls in Part D, September 6, 2012.

pharmacies; that the clinical guidelines identify beneficiaries who are at potentially at high risk for an adverse health event due to the amount of such drugs they are taking; and that there is an apparent lack of coordinated care.

Comment: We received a comment that a sponsor should only be required to attempt to reach a prescriber twice in 10 business days rather than 3 times in order to establish that the prescriber is unresponsive.

Response: We decline to make this change as this is our current policy and we received minimal comment on this proposed requirement. The purpose of the policy is to ensure that sponsors have diligently tried to involve prescribers in the case management process.

We wish to note that we believe the language we proposed in § 423.153(f)(4)(iii) which provides an exception to case management is duplicative of the language we discussed above that we are finalizing in § 423.153(f)(2)(ii). Therefore, we are deleting the language in § 423.153(f)(4)(iii).

Given the foregoing, we are finalizing § 423.153(f)(4) with modification, including ones to assist the reader in more easily understanding the cross-references.

We will also state in paragraph (ii)(A) that, except as provided in paragraph (ii)(B) which regards a prescriber limitation, if the sponsor complied with the requirement of paragraph (f)(2)(i)(C) of this section about attempts to reach prescribers, and the prescribers were not responsive after 3 attempts by the sponsor to contact them within 10 business days, then the sponsor has met the requirement of paragraph (f)(4)(i)(B) of this section which regards eliciting information from the prescribers. Paragraph (i)(B) will state that the sponsor may not implement a prescriber limitation pursuant to § 423.153(f)(3)(ii)(A) if no prescriber was responsive.

(vii) Beneficiary Notices and Limitation of Special Enrollment Period (§§ 423.153(f)(5), 423.153(f)(6), 423.153(f)(7), 423.153(f)(8), 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 proposed 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 will be required to provide an initial written notice to the potential at-risk beneficiary. We also proposed 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, as well as additional detail specified in the proposed regulation text.

In proposed paragraph (f)(5)(ii)(C)(2)—which will require a description of public health resources that are designed to address prescription drug abuse—we proposed 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 will have 30 days to provide information to the sponsor, which is a timeframe we discuss later in this preamble. We proposed 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 noted that our proposed implementation of the statutory requirements for the initial notice will permit the notice also to be used when the sponsor intends to implement a beneficiary-specific POS claim edit for frequently abused drugs.

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 proposed to implement these requirements such that they will occur in the following order: first, the plan sponsor will conduct the case management which encompasses clinical contact and prescriber verification required by § 423.153(f)(2) and obtain prescriber agreement if required by § 423.153(f)(4), and subsequently, if applicable, the plan sponsor will provide the initial notice indicating the sponsor's intent to limit the beneficiary's access to frequently abused drugs. 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 will 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 proposed that 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 as part of case management, so as to avoid unnecessarily alarming the beneficiary. This is because the result of case management may be that the sponsors takes a ''wait and see'' approach to observe if the prescribers adjust their management of, and opioid prescriptions they are writing for, the beneficiary. We noted that while this approach is acceptable, we still expect sponsors to address the most egregious cases of apparent opioid overutilization without unreasonable delay.

Under our proposed approach, a sponsor will 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 will provide a second notice to an at-risk beneficiary when it actually imposes a limit on the beneficiary's access to coverage for frequently abused drugs. Alternatively, the sponsor will provide an alternate second notice if it decides not to limit the beneficiary's access to coverage for frequently abused drugs. The second notice and alternate second notice are discussed later in this final rule.

Finally, we proposed 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).

We received the following comments related to the initial notice, and general comments applicable to all the proposed notices, and our responses follow:

Comment: We received many comments related to our proposal to require written beneficiary notice both when a plan identifies the beneficiary as potentially at risk for prescription drug abuse, and again when the plan determines the beneficiary is at risk and implements a beneficiary-level POS edit

and/or a pharmacy or prescriber lock-in for frequently abused drugs. Some commenters disagreed with our proposal to require two notices, stating that a second notice would be unnecessary, confusing, or overly burdensome.

Several other commenters strongly supported our proposal to require the two notifications, including the proposed change to the existing OMS process that would require the initial and second notices before a plan imposes a beneficiary-specific edit at POS. Commenters stated that requiring multiple notices will increase the likelihood that affected beneficiaries will be notified of their status and aware of how they could dispute it. A commenter wanted CMS to require more than two notices, because CMS did not propose to require acknowledgement of receipt from the beneficiary.

Response: We thank those commenters who agreed with our proposals to require two notices and to integrate existing OMS process into a uniform process for all drug management program restrictions. While we appreciate the concerns expressed by commenters who do not agree with our proposal, as we noted in the proposed rule, the statute at § 1860D–4(c)(5)(B) clearly requires written beneficiary notification both upon identification as a potential at-risk beneficiary and again when the plan determines the beneficiary is at risk. We do not agree that additional notices beyond what we proposed should be required, as it would be overly burdensome on plans and provide little value to beneficiaries.

Comment: Several commenters asked if stakeholders will have an opportunity to comment on the beneficiary notices and for more information on whether they can be modified by plans and when they will be released. A commenter requested that CMS conduct focus-group testing with beneficiaries to ensure the notice is understandable.

Response: As discussed in section III.B.14 of this final rule, these notices are subject to approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The notices will be posted in the **Federal Register** to give stakeholders an opportunity to review and comment before final versions of the notices are posted. CMS will consider testing through beneficiary focus groups, time permitting. The notices and accompanying instructions will contain detailed information about permissible modifications by plans. CMS intends to release the notices with sufficient time for plan sponsors to implement them into their drug management programs.

Comment: We received some comments related to requirements to translate these beneficiary notices. Some of the commenters stated that these notices should be designated to be among materials subject to translation requirements in proposed §§ 422.2268 and 423.2268. A commenter asked for clarification on whether plans are required to include section 1557 taglines with these notices.

Response: While CMS is still developing instructions related to translation requirements to provide guidance on the requirements at §§ 422.2268 and 423.2268, we note that, 423.128(d)(1)(iii) requires Part D plan sponsors' call centers to have interpreter services available to call center personnel to answer questions from limited-English proficient beneficiaries. These obligations are based on Medicare regulations and other civil rights laws, such as Title VI of the Civil Rights Act of 1964, that apply to Medicare health and drug plans. Applicability of Section 1557, and the scope of requirements for access for limited English proficient beneficiaries, and what is a significant communication are determined by the Office for Civil Rights (OCR).

Comment: A commenter urged CMS to consider implementing additional requirements for beneficiary notification, including establishing requirements stipulating information that must be written on envelopes containing written notices, adding requirements for telephonic or email notification in addition to written notices, and requirements for prescribers to contact beneficiaries to confirm receipt of the required notices.

Response: We agree with the commenter that detailed beneficiary notification is important, both upon identification as a potential at-risk beneficiary and again either confirming the at-risk identification or that the plan has determined the beneficiary is not at-risk. However, we disagree with this commenter that additional notice requirements are necessary or advisable. We believe it would be overly burdensome to require plans to include specific information on the outside of mailing envelopes and there is no such precedent for similar beneficiary notices in the Part D program, such as notices of coverage denials or transition letters. While CMS expects that prescribers of frequently abused drugs will communicate regularly with their patients, we do not believe it is necessary to require prescribers to confirm that beneficiaries received the required plan notices. Finally, we note that, while CMS does not require telephonic or email notification in addition to the required written notices, plans are not precluded from doing so.

Comment: A commenter asked why CMS proposed to require that the initial notice contain contact information for other organizations that can provide assistance to beneficiaries regarding the sponsor's drug management program.

Response: Such information is statutorily required under § 1860D–4(c)(5)(B)(ii)(VII) to be included in the initial notice. As specified in the statute, it should be similar to the information provided in other standardized Part D beneficiary notices. We expect the notice may include, for example, contact information for the enrollee's State Health Insurance Program (SHIP), 1–800–MEDICARE, the Medicare Rights Center, and/or other organizations as appropriate.

Comment: We received some comments that supported our proposal to require plan sponsors to make reasonable efforts to provide copies of notices to the potentially at-risk and at-risk beneficiary's prescriber(s).

Response: We thank these commenters for their support.

Comment: A few commenters opined that Part D plan sponsors and third party administrators do not have access to a list of all State and Federal public health resources designed to address prescription drug abuse. These commenters stated that requiring plans operating in multiple states to compile such a list would be overly burdensome, and requested that CMS provide templates containing such information as required under proposed § 423.153(f)(5)(ii)(C)(*2*). Another commenter asked if MA–PD plans will be allowed to include information about plan-specific mental health benefits in addition to State and Federal resources.

Response: CMS appreciates the input provided by these commenters. While the notice templates and instructions are still under development, CMS expects to provide information on Federal and State public health resources to assist plans in meeting the statutory requirement at § 1860D–4(c)(5)(B)(ii)(II) to include such information in the initial notice. Under the existing regulations at § 423.505(i), Part D plan sponsors are ultimately responsible for adhering to all terms and conditions of their contract with CMS, including compliance with all Federal laws, regulations and CMS instructions related to activities or responsibilities delegated to a third party. Pursuant to the regulation at § 423.153(f)(5)(ii)(C)(*2*), which we are finalizing as proposed, plans will be also required to include

information about relevant benefits and services covered by the plan, such as medical, mental health and MAT benefits.

Comment: Some commenters stated that CMS should specify in regulation text that initial notices must not be sent to potential at-risk beneficiaries until the plan has communicated with and received clinical information from the beneficiary's prescribers. These commenters noted that failure to conduct case management prior to sending the initial notice would interfere with doctor-patient relationships and unnecessarily alarm beneficiaries who may be determined not to be at-risk.

Response: We agree with these commenters that initial notices should not be sent to beneficiaries before the plan has engaged in case management and attempted to communicate with the beneficiary's prescriber(s), and this is specified in the regulation text at § 423.153(f)(2)(i). However, we know from experience with the OMS process that prescribers are not always responsive to the plan's attempts to make clinical contact; therefore, we proposed at § 423.153(f)(2)(i)(C) that plans must make additional attempts to contact such prescribers. Additionally, we proposed at § 423.153(f)(4) that plans cannot limit access to frequently abused drugs unless the plan has conducted case management and obtained agreement from prescribers (or made certain attempts to contact prescribers). We believe this approach strikes an appropriate balance between ensuring sufficient access to frequently abused drugs and protecting at-risk beneficiaries from potential harm in the absence of improved care coordination.

After consideration of the comments received on this section, we are finalizing our proposal with modification to clearly codify the policy that a sponsor should not provide the initial notice to the beneficiary until after the sponsor has engaged in the required case management by adding the phrase ''after conducting the case management required by § 423.153(f)(2)'' at the beginning of § 423.153(f)(5)(i).

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

Section 704(a)(3) of CARA gave the Secretary the discretion to limit the SEP for full benefit dually eligible (FBDE) beneficiaries outlined in section 1860D–1(b)(3)(D) of the Act. In addition to providing relevant information to a potential at-risk beneficiary, we proposed that the initial notice will notify dually- and other low income subsidy (LIS)-eligible beneficiaries that they would be unable to use the special enrollment period (SEP) for LIS beneficiaries due to their potential at-risk status. (Hereafter, this SEP is referred to as the ''duals' SEP''). This limitation is related to, but distinct from, other changes to the duals' SEP discussed in the proposed rule.

We proposed that once a dually- or other LIS-eligible 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 will 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.

We proposed 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 of the limitation, as specified in the second notice provided under § 423.153(f)(6), whichever is sooner.

We noted 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. Furthermore, we noted 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, including when an individual has a gain, loss, or change in Medicaid or LIS eligibility. We proposed that the ability to use the duals' SEP 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 under § 423.100 of this final rule. (See section II.A.10 for a more detailed discussion of Part D SEP changes.)

We received the following comments and our response follows:

Comment: We received many comments supporting the limitation of the duals' SEP for those individuals identified as potential at-risk or at-risk for overutilizing frequently abused drugs. Commenters noted that this limitation would support care coordination for this population, ensure that these beneficiaries are effectively managed, and prevent those that do abuse drugs from frequent plan switching, and either changing to a Part D plan without a drug management program, or accessing opioids because of a gap in information sharing across plans. Several commenters stated that this move would support their state's efforts in curbing the opioid epidemic.

Response: We appreciate the support for our proposal to limit the SEP for individuals identified as potential at-risk or at-risk for overutilizing frequently abused drugs.

Comment: A commenter requested that CMS confirm that any limitations on Part D LIS-eligible individuals would not impact the ability of such individuals to make an enrollment or disenrollment during other enrollment periods for which he or she is eligible. Commenters specifically asked about the AEP and the SEPs available for individuals to enroll in or disenroll from Program for All-inclusive Care (PACE) or enroll in a 5-Star plan.

Response: We note that the enrollment limitation for a potential at-risk or an at-risk individual will not apply to other Part D enrollment periods, including the AEP or other SEPs, including new SEPs that will be established at § 423.38(c)(9) and (c)(10) and are discussed in more detail in section II.A.10. of this final rule. In the event that an individual is subject to this limitation, but is eligible for another enrollment period, he or she may use that enrollment period to make a change. For example, a potential at-risk or at-risk dually- or other LIS-eligible individual who is subject to the duals' SEP limitation may use the PACE SEP to enroll in or disenroll from PACE, or they may use the 5-Star Rating SEP to enroll in an MA plan, PDP, or cost plan with a Star Rating of 5 stars during the year in which that plan has the 5-star overall rating, provided the enrollee meets the other requirements to enroll in that plan.

Comment: A commenter asked for clarification as to whether the SEP limitation for potential at-risk or at-risk individuals would apply when a

beneficiary loses Medicaid eligibility and goes through the deeming process permitted in capitated models under Financial Alignment Initiative demonstrations. The commenter stated that, in their state, a beneficiary is allowed to remain in the demonstration Medicare-Medicaid Plan (MMP) for up to 3 months while he or she tries to regain Medicaid eligibility. If the beneficiary regains Medicaid eligibility within this 3 month window, would the state be required to allow the beneficiary to change his or her enrollment? The commenter stated, that, now, they automatically re-enroll the beneficiary back into the MMP.

Response: The period of deemed continued eligibility provides an opportunity for individuals in Dual Special Needs Plans (D–SNPs) or MMPs who lose Medicaid eligibility to stay enrolled in their plan for a short time,[14] while they try to regain Medicaid eligibility. However, should an individual be eligible to leave the plan, and takes an action to leave the plan, using any valid SEP, the plan must honor the disenrollment request. It is our view that a change in Medicaid status, especially loss of Medicaid eligibility, is an important event with potentially significant financial impacts to the beneficiary. As a result, the SEP outlined in § 423.38(c)(9) will remain available to a potential at-risk or at-risk individual, even if the person is provided a deeming period by an MMP or D–SNP. This will permit individuals in a capitated model under the Financial Alignment Initiative demonstrations to change plans using the duals' SEP, within 3 months of a gain, loss, or change to Medicaid or LIS eligibility, or notification of such.

Comment: We received several comments relating to the operational aspects of implementing this limitation on the duals' SEP. Commenters requested clarification on how a plan sponsor would know if a potential at-risk or at-risk beneficiary was not eligible to use the duals' SEP, and how the MARx system would be operationalized to effectuate this change. A commenter requested clarification on how these individuals would be prevented from utilizing the duals' SEP.

Response: Information related to an individual's at-risk status, including the beginning and end dates for any limitation imposed, will be stored in MARx and available to plans for enrollment processing via the User Interface (UI) and the beneficiary eligibility query (BEQ). CMS will reject a submitted enrollment for a beneficiary who is subject to the SEP limitation and the plan will be notified with a unique transaction reply code (TRC). We will also notify plans via a TRC if a member has a change in their at-risk status period. We will provide further subregulatory guidance on system and operational changes that will occur to effectuate this limitation, as well as the larger drug management program.

Comment: To further assist in these efforts to curb opioid misuse, a commenter requested that CMS share data about any members in Part D plans who are subject to this SEP limitation to target Medicaid wrap services, including supplemental behavioral health and substance use treatment services.

Response: We thank the commenter for their suggestion and we will explore data sharing for states to provide additional services to these individuals.

Comment: A commenter recommended that CMS allow potential at-risk or at-risk individuals to use the duals' SEP to change to another plan if that plan has an established drug management program in place.

Response: We appreciate the comment; however, we disagree with allowing individuals identified as potentially at risk or at risk to use the duals' SEP. Even if an at-risk individual 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 the timing of information sharing between the plans and possible difference in provider networks.

Comment: A commenter stated that because the ''at-risk'' status is transferable from one plan to another, an individual will not avoid the implications of the lock-in by utilizing the SEP. As such, the commenter believed that the dual SEP should not be limited.

Response: We disagree. First, for general clarification purposes, the at-risk determination will not automatically transfer and be applied by a new Part D plan in the event a potentially at-risk or at-risk beneficiary changes plans. Even though a gaining plan will be able to see if a new member had an at-risk determination with their prior plan, the new plan will still have to make their own determination regarding the individual's status and send the individual the appropriate notice, which will trigger the SEP limitation, as we have explained elsewhere in this preamble. Although the beneficiary's prior at-risk designation is an indicator that the new plan will have to initiate case management and may even allow them to bypass the first notice and go straight to issuing the second notice, the at-risk determination is not directly transferable.

In addition, while we assume that all Part D sponsors will have drug management programs in place, it is not a requirement.

With respect to the need for the SEP limitation, this policy is still needed to prevent potential and at-risk beneficiaries from making frequent plan changes after they receive the initial and second notices, as applicable, and thus, avoid the care coordination that drug management plans are intended to provide.

We note that the SEP limitation—whether it is a first time designation or one that is being applied after enrollment into a new plan—will be effective as of the date on the initial notice that the Part D plan sponsor provides to an individual identified to be potentially at-risk. We are revising that language in § 423.38(c)(4) to state that beneficiaries that have been notified that they are potentially at-risk or at-risk, and such identification has not been terminated in accordance with § 423.153(f)), will not be able to use the duals' SEP.

Comment: A commenter encouraged CMS to offer increased resources to SHIPs to provide targeted outreach to the dual eligible and LIS populations who will be impacted by these changes. The commenter stated that CMS should also conduct outreach and education to providers and pharmacies, including mental health and substance use providers, as well as community based organizations (such as recovery learning communities), as these changes have a specific impact on beneficiaries with substance use disorders. The commenter stated that these efforts will help ensure that beneficiaries most likely to be impacted by these changes, and their providers, are made aware well in advance of implementation. Also, the commenter encouraged CMS and the Administration for Community Living (ACL) to provide continued funding for state Ombudsman programs that serve dual eligible populations enrolled in demonstration products, and to allow states to use this funding to serve dual

[14] Under the capitated model of the Financial Alignment Initiative demonstration, MMPs may provide up to 3 months of deemed continued eligibility for individuals who lose MMP eligibility due to short-term loss of Medicaid. As outlined in Chapter 2 of the Medicare Managed Care Manual, D–SNPs must provide at least 1 month and up to 6 months of deemed continued eligibility for individuals who lose eligibility due to loss of Medicaid, but are reasonably expected to regain Medicaid within that timeframe.

eligible beneficiaries enrolled in any integrated care product, including, for example FIDE SNPs.

Response: CMS appreciates the comment, and we will continue to explore avenues for beneficiary and provider outreach and education; however, provisions for addressing cost and funding resources is outside of the scope of this rule.

Comment: Several commenters opposed the limitation of the duals' SEP for at-risk beneficiaries. Commenters cited issues, such as limited access to prescription drugs and the possible risks of medical complications and increased costs resulting from such access barriers. They also noted the vulnerability and special needs of this population. A commenter stated that this limitation is unnecessary, as the current OMS program in Part D typically resolves cases of potential misuse without resorting to any beneficiary-specific tactic and would result in beneficiaries losing access to an important patient protection.

Response: We appreciate the comments. As we stated in the proposed rule, 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. It is our view that the SEP limitation will be an important tool to reduce the opportunities for dual and LIS-eligible beneficiaries designated as at-risk to switch plans, and circumvent the care coordination that a drug management program is designed to provide for this vulnerable population, especially as our nation faces an opioid epidemic. As stated previously, the enrollment limitation for a potential at-risk or an at-risk individual would not apply to other Part D enrollment periods, including the AEP or other SEPs. In the event that a potential at-risk or at-risk dually- or other LIS-eligible individual is subject to this limitation, but that individual is eligible to make an enrollment change using a different and valid election period, he or she may do so.

In the case where an individual is prescribed a specific drug that is not on the sponsor's formulary, the individual always has the right to request a coverage determination for the drug. Each Part D sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a formulary must establish and maintain exceptions procedures for receipt of an off formulary drug. A Part D sponsor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's or other prescriber's statement, and that the drug would be covered but for the fact that it is an off formulary drug. Since these protections apply to all beneficiaries, they also protect dually-eligible and other LIS-eligible beneficiaries.

Comment: A couple of commenters stated that maintaining maximum flexibility regarding enrollment in Medicare Part D and the ability to change PDPs best serves the interests of low-income beneficiaries, especially American Indian and Alaskan Native (A/I and A/N) beneficiaries. The commenters further stated that a decision to change plans is often made in order to access a specific prescription drug. The commenters further requested that, if the proposed regulation is retained, CMS specify an exemption for Indian Health Service (IHS)-eligible individuals as inserting the Medicare Part D drug plans into the relationship between Medicare/IHS beneficiaries and their IHS/Tribal providers would not be helpful. We discuss IHS beneficiaries again further below.

Response: CMS disagrees with establishing population-based exceptions to the duals' SEP limitation. In our view, all potential at-risk and at-risk beneficiaries should be afforded the opportunity to benefit from the care coordination that the drug management program is designed to provide. We do not believe it is prudent at this time to carve out a subset of at-risk beneficiaries to which special rules apply. As previously mentioned, there are opportunities for potential at-risk and at-risk individuals to make enrollment choices during other election periods. Also, an individual always has the right to request a coverage determination, including an exception request for an off-formulary drug.

Comment: A couple of commenters expressed concern about this SEP limitation not being appealable. A commenter urged CMS to make the loss of the duals' SEP for potential at-risk beneficiaries appealable, as an at-risk beneficiary's other non-opioid-related conditions may justify the using of an SEP. A commenter noted that the proposal stipulated an appeals process for beneficiaries wishing to appeal their at-risk status, but encouraged CMS in its final rule to clarify whether the loss of a duals' SEP would be appealable in any way, and urge CMS to make a provision for beneficiaries who may need access to this SEP despite their at-risk status.

Response: Similar to all other enrollment decisions, the limitation on the duals' SEP for potential at-risk or at-risk individuals is not appealable. However, after an individual is determined to be at-risk, he or she may appeal that determination. We intend to provide maximum transparency to the beneficiary by ensuring, consistent with the statutory requirements, that the beneficiary has information about appeal rights during the at-risk determination process.

Comment: A commenter stated that nothing in the law would make a dual-eligible at- risk or potentially at-risk beneficiary ineligible for an SEP.

Response: We disagree with the commenter. 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 Social Security Act (the Act). As discussed previously, the duals' SEP was extended to all other subsidy-eligible beneficiaries by regulation so that all LIS-eligible beneficiaries are treated uniformly.

Comment: A commenter is concerned that dually- and other LIS-eligible individuals inappropriately identified as potentially at-risk may not understand the process for correcting a determination that was made in error or may otherwise be inappropriate. The commenter further stated that some beneficiaries will be erroneously identified and not confirmed as at-risk and they should not be subject to the SEP limitation as a result of poor data, plan error, or some other reason unrelated to the beneficiary's action.

Response: We appreciate the comments. We believe that there will be sufficient safeguards in the design and implementation of prescription drug management programs to prevent errors and provide beneficiaries with an opportunity to make corrections. CMS expects that exempt individuals will be identified through OMS. For those that are not excluded based on this data, they should be excluded by their plans during case management, as clinical contact and prescriber verification and agreement should occur before an initial notice of potential at-risk status is sent to the individual and the SEP limitation is imposed. Thereafter, if a beneficiary believes he or she has been identified in error, the beneficiary has a chance to submit relevant information in response to the initial notice. If a determination is made that a beneficiary is an at-risk beneficiary, a Part D sponsor must also provide a second written notice to the beneficiary which is required to provide clear instruction on how a beneficiary may submit further applicable information to the sponsor. A beneficiary is also provided a right to redetermination of the at-risk status. CMS expects these measures will provide adequate protections for all beneficiaries.

Comment: Another commenter requested clarification that the SEP is only removed for LIS beneficiaries once the plan sponsor has completed case management activities, including prescriber agreement.

Response: We appreciate the question regarding when the duals' SEP limitation goes into effect. The duals' SEP limitation can go into effect without prescriber agreement; however, before the initial notice is sent, which informs the beneficiary of the limitation, the sponsor is required to engage in case management and attempt to communicate with the beneficiary's prescriber(s).

Comment: A commenter urged CMS to make a provision for LIS beneficiaries who lose access to their SEP, but need access to non-opioid drugs. For example, if an LIS beneficiary is determined to be at-risk and loses an SEP, and is later diagnosed with a different chronic condition that requires medication not on the beneficiary's current formulary. The commenter requested that CMS specify in the final rule that such a beneficiary would be given special consideration when submitting an appeal to their current plan to gain coverage of necessary non-opioid drugs.

Response: We do not believe any ''special consideration'' is necessary. An enrollee—regardless of LIS eligibility—always has the right to request a coverage determination for a drug. In all cases, the standard is that the plan must notify the enrollee of its coverage determination decision as expeditiously as the enrollee's health condition requires, but no later than the applicable adjudication timeframe (24 hours for an expedited coverage determination, 72 hours for a standard coverage determination).

Comment: A commenter noted that, while they agree with the proposal to implement the SEP provision, there may be an increase in complaints and grievances against the sponsor. The commenter encourages CMS to exclude beneficiaries identified as potentially at-risk and at-risk from Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys and not count complaints related to the duals' SEP limitation in the Complaint Tracking Module (CTM) numbers for star-rating purposes.

Response: Thank you for the comment. Our Star Ratings proposal did not address this topic, and we plan to take this comment under advisement.

After consideration of these comments, we are finalizing the provision on the CARA duals' SEP limitation at § 423.38(c)(4) with a modification to specify that beneficiaries that have been notified that they are potentially at-risk or at-risk as defined in § 423.100, and such identification has not been terminated in accordance with § 423.153(f)), will not be able to use the duals' SEP.

The duals' SEP limitation will align with the revised timeframes for the potential-at-risk and at-risk status as addressed in section 423.153(f) of this final rule. That is, if the Part D plan sponsor takes no additional action to identify the individual as an at-risk beneficiary within 60 days from the date on the initial notice, the ''potentially at-risk'' designation and the duals' SEP limitation will expire. At-risk determinations will be for an initial 12 month period, with the option to extend for a maximum of 24 months in total (that is, an additional 12 month period) upon reassessment of the beneficiary's at-risk status at the completion of the initial 12 month period.

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

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. We proposed to codify this requirement in § 423.153(f)(6)(i). As with the initial notice, our proposed implementation of the statutory requirement for the second notice will also permit it to be used when the sponsor implements a beneficiary-specific POS claim edit for frequently abused drugs. Specifically, we proposed 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 proposed to require the second notice to include the effective and end date of the limitation. Thus, this second notice will 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 proposed 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 proposed to add detail in the regulation text. The second notice must also 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 the notice. In paragraph (2), we proposed language that will require a sponsor to include the limitation the sponsor 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 proposed 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). In § 423.153(f)(6)(iii), we proposed 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. 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.

Also, the sponsor will 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 will 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.

We received the following comments and our responses follow:

Comment: We received many comments related to our proposal requiring plans to provide a second written notice to beneficiaries before implementing a restriction under the plan's drug management program, most of which supported the proposal. Other commenters opposed it, expressing a belief that only one notice would be sufficient. Some of these commenters offered ideas for various alternative approaches for CMS to consider, such as including information in the plan's Evidence of Coverage that would replace the notices described in the proposed rule, or using a single notice similar to the current OMS requirement. Other commenters stated that the two notices required for lock-in should be limited to lock-in and plans should continue to be permitted to send a single notice when implementing a beneficiary-level POS edit.

Response: We disagree with the comments recommending requiring a single beneficiary notice or replacing one or both notices with general information in other documents. Section

1860D–4(c)(5)(B) requires two written notices before a beneficiary can be locked-in to a prescriber or pharmacy, and includes a high level of specificity about the content of the notices. Moreover, the required initial and second notices contain important information about access restrictions that may be or will be placed on potentially at-risk and at-risk beneficiaries, resources such beneficiaries may need to treat potential drug dependency issues, and notification of important beneficiary rights.

We also disagree with comments stating that the proposed notice requirements for the lock-in program should be limited to lock-in, and that CMS should retain existing beneficiary notice policies, including sending only one notice, when implementing beneficiary-level POS edits. Currently, the application of a beneficiary-level POS claim edit is not considered a coverage determination and does not trigger appeal rights under Subpart M. As we explained in the proposed rule, 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) will be an aspect of an at-risk determination (a type of initial determination that will confer appeal rights on the beneficiary, consistent with section 1860D–4(c)(5)(E) of the Act) under our proposal establishing the Part D drug management program. As discussed in subsection (c) of this preamble, we are finalizing the proposal to integrate the current OMS process with lock-in to create a uniform drug management program for Part D. Under this final rule, since the application of a beneficiary-level POS edit for frequently abused drugs can only be applied upon the plan's at-risk determination and is subject to appeal, it is necessary to treat those edits the same as limitations on selected pharmacy(ies) or prescriber(s). Furthermore, we believe that establishing an inconsistency with respect to notice requirements would be confusing for beneficiaries and plans. For these reasons, and because we believe the second notice, which identifies the action taken by the plan and instructs the beneficiary how to exercise their statutory appeal rights, is an important beneficiary protection, the notice is required both for lock-in and for POS edits for frequently abused drugs.

Comment: A commenter suggested that CMS require that the second notice, in addition to the initial notice, include a description of all State and Federal public health resources addressing prescription drug abuse that are available to the beneficiary.

Response: While we agree that this information is important to communicate to affected beneficiaries, we recognize the potential burden that multiple notices may place on plan sponsors as well as beneficiaries. We note that such information is required in the initial notice, and the statute does not require it in the second notice. While CMS will not preclude plans from providing this information again, for example, if requested by the enrollee, we do not believe it is necessary to require that it be included in both notices.

After consideration of comments received, we are finalizing our proposal without modification to require plans to send both the initial and second notice before implementing a beneficiary-level POS edit or a pharmacy or prescriber lock-in under a 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))

Although not explicitly required by the statute, we proposed at § 423.153(f)(7) that if a sponsor determines that a potential at-risk beneficiary is not an at-risk beneficiary and 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 will be required to provide the beneficiary with an alternate second notice. Specifically, we proposed that such alternate second notice use language approved by the Secretary in a readable and understandable form, and contain the following information: The sponsor has determined that the beneficiary is not an at-risk beneficiary; the sponsor will not limit the beneficiary's access to coverage for frequently abused drugs; if applicable, the SEP limitation no longer applies; clear instructions that explain how the beneficiary may contact the sponsor; and other content that CMS determines is necessary for the beneficiary to understand the information required in this notice.

As with the other notices, we proposed 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 this notice.

We received the following comments and our response follows:

Comment: We received a few comments on this proposal. Some of these commenters supported the proposal and agreed that such notice is necessary to minimize beneficiary confusion and limit unneeded appeals when a plan decides not to implement any restrictions on frequently abused drugs. A commenter disagreed with our proposal to require an alternate second notice, stating such notice is not necessary.

Response: As we stated in the proposed rule, we believe that this alternate notice is necessary to ensure beneficiaries who received the initial notice of an intended limitation on access to frequently abused drugs under the plan's drug management program are informed of the outcome of the plan's decision not to take such action. We are finalizing § 423.153(f)(7) without modification.

(E) Timing of Notices and Exceptions to Timing (§ 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. Although not specifically required by CARA, we believe it is also important to establish a maximum timeframe by which the plan must send the second notice or the alternate second notice, to ensure that plans do not leave a case open indefinitely. We proposed to specify at § 423.153(f)(8)(i) that a Part D sponsor must provide the second notice described in paragraph (f)(6) or the alternate second notice described in paragraph (f)(7), 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).

Section 1860D–4(c)(5)(B)(iv)(II) of the Act explicitly provides for an exception to the required 30 day minimum 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 will necessitate that a Part D sponsor provide the second written notice to the beneficiary before the minimum 30 day time period normally required has elapsed.

As we explained in the proposed rule, because this provision also allows an at-risk identification to carry forward to the next plan, we believe it is appropriate to permit a gaining plan to provide the second notice to an at-risk beneficiary so identified by the most

recent prior plan without having to wait the minimum 30 days, if certain conditions are met. This is consistent with our current policy under which a gaining sponsor may immediately implement a beneficiary-specific 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.[15]

As such, at § 423.153(f)(8)(ii), we proposed one exception to the timing of the notices, applicable to at-risk beneficiaries who switch plans. The exception allows a gaining plan sponsor to immediately provide the 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 the prior plan and such identification had not been terminated. The exception is only permissible if the gaining sponsor is implementing either a beneficiary-specific POS edit as described in paragraph (f)(3)(i) under the same terms as the prior plan, or a limitation on access to coverage as described in paragraph (f)(3)(ii), if such limitation will require the beneficiary to obtain frequently abused drugs from the same pharmacy location and/or the same prescriber, as applicable, that was selected under the immediately prior plan under (f)(9).

We received the following comments and our responses follow:

Comment: Some commenters recommended that the timeframe between the first and second notices be shortened to within 15 days, which the commenters believe would provide sufficient time for beneficiaries to submit preferences. A commenter noted that there is no added value in waiting 30 days after the initial notice to provide the second notice because it contains similar information.

Response: We disagree with these commenters. Outside of circumstances identified by the Secretary through rulemaking, section 1860D–4(c)(5)(B)(iv) requires that the second notice be provided ''on a date that is not less than 30 days'' after the initial notice. Moreover, because the statute gives significant deference to beneficiary preferences, CMS does not believe that 15 days is sufficient for beneficiaries to receive the initial notice, identify their preferences for prescribers and/or pharmacies, potentially confer with the preferred prescribers and/or pharmacies, communicate preferences to their plan, and give the plan sufficient time to implement the limitation in their systems, including situations where the plan determines that an exception to preferences under § 423.153(f)(10) is warranted.

Comment: We received several comments supporting our proposal to establish a maximum timeframe by which sponsors must send the second or alternate second notice. However, most of these commenters expressed concerns that 90 days is too long because potentially at-risk beneficiaries would be subject to a limitation on their SEP without appeal rights during that 90 day timeframe. Commenters stated that, if those beneficiaries identified as potentially at-risk did not lose access to the SEP, 90 days would be acceptable. Other commenters expressed a belief that plans would not need 90 days to obtain beneficiary preferences and implement relevant access limitations upon receipt of those preferences.

Response: We appreciate the commenters' feedback about the proposed 90 day maximum timeframe. As we noted in the preamble to the proposed rule, while section 1860D–4(c)(5)(B)(iv) of the Act requires plans to wait a minimum of 30 days from the initial notice before providing the second notice, Congress did not establish a maximum timeframe. Because case management, clinical contact and prescriber verification requirements would be met before the plan sends the initial notice, we agree with the commenters that our proposed 90 day maximum timeframe between notices could be shortened. Therefore, we are modifying § 423.153(f)(8)(i) to require the notice required under (f)(6) or alternate notice required under (f)(7) to be provided to the beneficiary no more than the earlier of the date the sponsor makes the relevant determination or 60 days after the date of the initial notice required under (f)(5).

Given the comments received, many of which stated that the 90 day maximum timeframe we proposed is too long, we believe 60 days strikes the right balance. We do not believe the maximum timeframe should be shorter than 60 days, because sponsors may need this time to process information from beneficiaries that is received at the end of the minimum 30 day timeframe, or to communicate with prescribers who may have been unresponsive prior to receiving a copy of the initial notice the plan provided to the beneficiary. This revised timeframe is still sufficient to limit any potential compliance issues for sponsors related to timeliness and unnecessary appeals where such information is still being processed. However, we do not expect sponsors to routinely take the maximum amount of time to issue the second notice, and note that they must send it sooner if they make the relevant determination sooner. We note that the SEP is addressed in an earlier section of this preamble.

Comment: We received several comments related to our proposal at § 423.153(f)(8)(ii) to, under certain circumstances, permit a gaining plan to immediately send a second notice without waiting 30 days to a beneficiary who is already subject to a drug management program coverage limitation (a beneficiary-specific POS claim edit or pharmacy or prescriber lock-in) in their immediately prior plan. Most commenters supported our proposal to establish an exception to the 30-day notice for at-risk beneficiaries, as identified by the losing plan, when such beneficiaries switch plans and the gaining plan decides to continue the same limitation(s). Some of these commenters agreed that exceptions to the 30 day notice should be limited to circumstances where the beneficiary was already given notice by the previous plan. Some commenters noted that because a beneficiary may be changing plans due to dissatisfaction with their current providers, these beneficiaries must also have an opportunity to change their preferences with respect to pharmacies and prescribers when they change plans. Other commenters supported the exception that we proposed but stated that the statute allows exceptions under additional circumstances based on the health and safety of the beneficiary or significant drug diversion activity. A commenter recommended that CMS should specify that when a beneficiary who moves to a new plan offered by the same parent organization as their prior plan, the plan is not required to send any notice to the beneficiary to continue the restriction because such notice would only serve to confuse the beneficiary.

Response: As we explained in the proposed rule, we believe that exceptions to the statutory requirement to wait at least 30 days before sending the second notice and implementing a coverage limitation under a drug management program should be very limited. Since the drug management program is focused on improved care coordination for beneficiaries who are utilizing high doses of frequently abused drugs and/or have multiple providers, and the statute specifies that such exceptions be identified through rulemaking regarding the health or

[15] See ''Beneficiary-Level Point-of-Sale Claim Edits and Other Overutilization Issues,'' August 25, 2014.

safety of the beneficiary or regarding significant drug diversion activities, we do not believe that it is appropriate to permit such an exception based on a sponsor's concerns about the health and safety of a particular beneficiary because that is too subjective and could adversely impact such beneficiaries, who could be subject to a coverage limitation without notice. Rather, we are finalizing the exception we proposed related to at-risk beneficiaries who switch plans and the gaining plan decides to continue a limitation(s) under the same terms as the losing plan, because we believe, in this instance, the coverage limitation(s) can safely be immediately implemented—namely, when the beneficiary already has been identified as at-risk by his or her prior plan, and the coverage limitations would continue in the same manner under his or her new plan. We have not at this time identified additional circumstances under which an exception to the 30-day minimum between the first and second notices is warranted. We note that this final rule does not change existing requirements that Part D plan sponsors cannot pay fraudulent claims. With respect to a beneficiary who changes plans within the same parent organization, we are clarifying that the gaining plan must still meet the requirements set forth at § 423.153(f)(8)(ii). We do not believe it is advisable to apply a different standard to a gaining plan just because it has the same parent organization as the losing plan.

While we are finalizing our proposed exception to the timing of the notices, we agree with the commenters who stated that beneficiaries who change plans should still have an opportunity to change their preferences for prescribers and pharmacies. Therefore, we are clarifying that an at-risk beneficiary's right to submit new preferences we are finalizing at (f)(9) also applies to beneficiaries who switch plans. While a gaining plan could still implement the restriction without providing 30 day advance notice, they must comply with the statutory and regulatory requirements to accept beneficiary preferences. Under the exception to the notice requirements that we are finalizing in this rule, a gaining plan choosing to immediately impose the restriction(s) of the prior plan is not required to resend the initial notice described at (f)(5) that was sent by the prior plan, but must issue a new version of the second notice described at (f)(6). This notice, which is being developed by CMS, will allow the gaining plan to include updated information from the initial notice that changes with the change to the new plan (for example, plan contact information or relevant medical benefits available to such beneficiary under the new plan).

After consideration of all comments received on § 423.153(f)(8), we are finalizing our proposal at paragraph (f)(8)(i) to retain the minimum 30 day timeframe between the initial and second or alternate second beneficiary notices (except as provided in subparagraph (ii)), with a modification establishing a maximum timeframe of 60 days between the notices.

Additionally, we are finalizing the proposed exception to the minimum 30 day timeframe at § 423.153(f)(8)(ii), which permits a gaining plan to immediately issue the second beneficiary notice required by (f)(6) and implement a continuation of the same claim edit and/or pharmacy or prescriber lock-in for an at-risk beneficiary who was already provided the initial and second notice for such limitation(s) from the losing plan. As discussed above, we believe the circumstances under which a limitation can be safely implemented without advance beneficiary notice and are consistent with the requirements for such exceptions at section 1860D–4(c)(5)(iv)(II) are limited in scope. While, at this time, we have not identified additional circumstances under which we believe an exception to the 30 day beneficiary notice is warranted under section 1860D–4(c)(5)(B)(iv)(II), we will continue to evaluate this issue, and may establish additional exceptions through future rulemaking.

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

Some of the drug management program provisions in CARA are only relevant to ''lock-in.'' We proposed 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))

In the proposed rule, we noted that, at that time, we viewed prescriber lock-in as 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 after case management or the implementation of a beneficiary specific POS claim edit or a pharmacy lock-in. We also were concerned about impacting an at-risk beneficiary's relationship with their provider, and we sought comment on whether a 6-month delay before a sponsor could implement prescriber lock-in would lessen burden on prescribers.

As a result, we proposed in § 423.153(f)(4)(iv) 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 specifically sought 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 later believed a beneficiary's access to coverage of frequently abused drugs should be limited to a selected prescriber(s).

We received the following comments and our response follows:

Comment: Many commenters expressed significant concerns with the proposal to require a Part D plan sponsor to wait at least six months from the date the beneficiary is first identified as a potential at-risk beneficiary before limiting that beneficiary to a prescriber for frequently abused drugs, noting that it works against the goal of CARA and defeats the purpose of the lock-in program. Moreover, many commenters also expressed that a 6 month delay to prescriber lock-in was not in the spirit of a national public health emergency, and may actually place at-risk beneficiaries at even greater risk for adverse health outcomes. A commenter expressed support for the 6 month delay, noting that it would allow time for alternative interventions to be implemented so as to not burden the prescriber unnecessarily. A commenter offered a lengthy legal argument against the 6-month delay for prescriber lock-in.

Response: In light of these comments, we have been persuaded not to finalize require a 6 month waiting period before a plan may limit an at-risk beneficiary to a prescriber for frequently abused drugs. We agree with the majority of commenters that CMS should not impose a waiting period for plan sponsors to implement a prescriber lock-in for at-risk beneficiaries, and that once a beneficiary is deemed at-risk, a plan sponsor should have the full range of limitations on access to coverage for frequently abused drugs to employ for such beneficiaries. We are persuaded

that our initial concern about the beneficiary's relationship with a provider is significantly outweighed by the more immediate concerns for the beneficiary's safety.

In addition, we are unpersuaded that our proposal would reduce burden on providers. This is because a sponsor, in conducting the case management is required under § 423.153(f)(2), to contact prescribers and the sponsor may seek a prescriber's agreement to a beneficiary-specific POS claim edit pursuant to § 423.153(f)(4). Thus, we now believe that requiring a sponsor to wait 6 months to contact the prescriber again to assist with additional case management for the prescriber lock-in, and to possibly obtain the prescriber's agreement to such lock-in, will actually increase provider burden.

For these reasons, we are not finalizing the proposal 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. Therefore, we have removed the language from § 423.153(f)(4) relevant to this 6-month waiting period for prescriber lock-in.

(B) Selection of Pharmacies and Prescribers (§§ 423.153(f)(9) Through (13))

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

Section 1860D–4(c)(5)(D)(iii) 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 network 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, for example, the beneficiary's preferred provider would contribute to the beneficiary's abuse of prescription drugs. We address exceptions to beneficiary's preferences later in the preamble.

In light of this language, we proposed a Part D plan sponsor must accept an at-risk beneficiary's preferences for in-network prescribers and pharmacies from which to obtain frequently abused drugs unless an exception applies. In cases that involve stand-alone PDPs, we proposed that a sponsor must accept the beneficiary's selection of prescriber, unless an exception applies, because such PDPs do not have provider networks. We further proposed that a stand-alone PDP or MA–PD does not have to accept a beneficiary's selection of a non-network pharmacy, except as necessary to provide reasonable access, which we discuss later in this section. Our rationale for this proposal was that the selection of network prescribers and pharmacies puts the plan sponsor 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.

Also, we did not propose to place a limit on how many times beneficiaries can submit their preferences, but we did solicit additional comments on this topic. Finally, under our proposal, the sponsor would be required to confirm the selection of pharmacy and/or prescriber in writing to the beneficiary either in the second notice, if feasible, or within 14 days of receipt of the beneficiary's submission.

We received the following comments and our response follows:

Comment: Commenters widely supported CMS's proposal that the pharmacy or prescriber in which an at-risk beneficiary is locked-into must be in-network for a plan, except to provide reasonable access or when the plan does not have a relevant network. Specifically, commenters noted that allowing selection of out of network pharmacies or prescribers would undermine keeping beneficiary costs low, and efforts to combat pharmacy-based fraud and abuse.

Response: We thank commenters for their support.

Comment: CMS received a handful of comments that disagreed that a prescriber should have to be in-network, given some Medicare Advantage beneficiaries may receive out-of-network treatment from providers due to their relationships with the prescriber and the high quality of care that they provide. These commenters requested that CMS eliminate the requirement that a prescriber generally must be in-network if the plan sponsor imposes a limit on a beneficiary's access to coverage for frequently abused drugs to a selected prescriber or prescribers.

Response: We were not persuaded that sponsors should have to accept a beneficiary's selection of an out-of-network prescriber or pharmacy, unless needed to maintain reasonable access or if the plan does not have a relevant network. Our rationale for this is that Section 1860D–4(c)(5)(D)(iii) refers specifically to the beneficiary selecting a network prescriber(s) and/or pharmacy(ies) and the plan sponsor accepting such selections based on the beneficiary's preference. We therefore believe that the statute does not contemplate requiring Part D plan sponsors to select a beneficiary's preference of an out-of-network prescriber or pharmacy in all instances.

However, because our requirements for drug management programs—as proposed and finalized—permit stand-alone PDPs to use prescriber lock-in, the requirement for a sponsor to accept the beneficiary's selection of a network prescriber is inapplicable, and the sponsor must accept the beneficiary's selection of a prescriber, unless an exception applies, such as if the selection would contribute to the beneficiary's abuse of prescription drugs. With regard to this exception, we note that when there is a prescriber or pharmacy network, and the plan sponsor asserts it would accept a beneficiary's in-network pharmacy or prescriber preference(s) but such selection would contribute to prescription drug abuse or drug diversion by the beneficiary, we would question why such pharmacy or prescriber is in the sponsor's network.

We realize that in the case of at-risk beneficiaries enrolled in MA plans that provide out-of-network coverage of services and are designed and specifically authorized for that purpose (that is, PPO, PFFS, and cost plans), these beneficiaries have access to supplemental services out of network. However, as we stated above, Section 1860D–4(c)(5)(D)(iii) states that if an at-risk beneficiary submits preferences for which in-network prescribers and pharmacies the beneficiary would prefer, the PDP sponsor shall select them. The requirement, discussed later, that Part D prescription drug management programs ensure reasonable access addresses the sponsor's selection out-of-network prescribers and pharmacies when necessary and therefore accommodate our regulations at § 422.105; § 422.112 that permit out-of-network coverage.

We note that by requiring a plan sponsor to accept an at-risk beneficiary's selection of an out-of-network prescriber, we would in effect have a blanket requirement that a coordinated health plan to manage an at-risk beneficiary out-of-network, which would be difficult to achieve. For those at-risk beneficiaries locked into a particular prescriber(s) and/or pharmacy(ies), prescriptions for frequently abused drugs would need to be obtained from an in-network prescriber (when such a network exists), even in the case of at-risk beneficiaries who are enrolled in MA plan that provide for out-of-network coverage.

Therefore, we are finalizing our provision as proposed.

We wish to make a point of clarification regarding at-risk beneficiaries who are entitled to fill prescriptions or receive services from IHS, Tribal, and Urban Indian (ITU) organization pharmacies and providers. An IHS I/T/U pharmacy or provider may be the selected pharmacy or prescriber for such beneficiaries and they may go to such a pharmacy or prescriber pursuant to our reasonable access requirement, even if they are not in-network which we discuss again later.

Comment: Regarding a limitation on how many times beneficiaries can submit their preferences, many commenters suggested that we allow an at-risk beneficiary to submit his or her preferences anywhere from 1 to 3 times per year, noting that it was important to cap the number of times preferences can be submitted. A commenter noted that the beneficiary's unlimited opportunity to change preferences for prescribers and pharmacies will be problematic and burdensome, and recommended that CMS place a limit on the number of times a beneficiary may change preferences on an annual basis, unless they can provide good cause for requesting the change. Suggested examples of good cause would include moving beyond easy access to the prescriber or pharmacy; the prescriber has discharged the beneficiary from his/her practice; or the pharmacy is unable to provide the requested drugs.

Response: While commenters raised concerns that at-risk beneficiaries should have some parameters around changing their preferences for a selected pharmacy or prescriber, CMS must balance curbing opioid overuse and misuse with ensuring reasonable access to selected pharmacies and prescribers. Therefore, we will allow at-risk beneficiaries to submit their preferences to plan sponsors without a numerical restriction during the plan year. We note that the sponsor does not have to make changes to the selection of pharmacy(ies) and prescriber(s) based on the at-risk beneficiaries preferences if the plan sponsor believes such changes are contributing to abuse or diversion of frequently abused drugs, pursuant to § 423.153(f)(10), discussed above. Also, CMS will monitor for these issues and act accordingly to ensure efficient operation of the program and prevention of excessive administrative burden.

Comment: A commenter stated that an at-risk beneficiary should not be locked-into pharmacies in which the plan sponsor or PBM overseeing the drug management program has a financial interest.

Response: Since the selection of the pharmacy in which an at-risk beneficiary is locked into is largely a beneficiary choice, and one they are provided specifically in the statute with little exception, CMS does not find this comment persuasive, and will finalize this provision as proposed.

Comment: A commenter stated that plan sponsors should be able to implement the change in a beneficiary's preference within 14 days after the beneficiary has submitted the preference.

Response: We note that our proposal, which we are finalizing, requires the sponsor to inform the beneficiary of the selection in the second notice or if not feasible due to the timing of the beneficiary's submission of preference, in a subsequent written notice issue no later than 14 days after receipt of the submission.

Accordingly, we are finalizing § 423.153(f)(9), as proposed. We note that we added the words ''or change'' in paragraph (iii) for consistency with the rest of the regulation text in this section.

(*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 will contribute to prescription drug abuse or drug diversion by the at-risk beneficiary. Section 1860–D–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 accepting his or her allowable preference for pharmacy or prescriber from which the beneficiary must obtain frequently abused drugs under the plan.

We received the following comments and our response follows:

Comment: Commenters generally agreed with our proposal that plan sponsors may disallow a beneficiary's selection of a prescriber or pharmacy that may contribute to prescription drug abuse or drug diversion.

Response: We appreciate the commenters support.

Comment: A commenter suggested that CMS require plans/PBMs to report the percentage of times when beneficiary preference is/is not considered and to track which pharmacy the plan/PBM utilizes to override patient preference.

Response: While we are not currently requiring that plans or PBMs report to CMS the percentage of times when beneficiary preference is/is not considered and to track which pharmacy the plan/PBM utilizes to override patient preference, we will re-evaluate this policy in the future if it becomes problematic. Therefore, we will closely monitor to make sure plans are not inappropriately choosing to not accept beneficiary preferences, in order to ensure efficient operation of the program and prevention of excessive administrative burden.

While we received no comments specific to beneficiary appeal rights when the plan's selection of pharmacies or prescribers for lock-in are not aligned with the beneficiary's submitted preferences, we remind plans that the statute at § 1860D–2(c)(5)(E) specifically states that the selection of pharmacy or prescriber for lock-in is subject to appeal. If a beneficiary complains about being locked into a pharmacy or prescriber that is not the one they selected, such complaint must be treated as an appeal. We address beneficiary appeals rights later in this preamble.

We are finalizing the following at § 423.153(f)(10) Exception to Beneficiary Preferences, as proposed.

(*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 1860–D–4(c)(5)(D)(i) of the Act provides that the Part D sponsor shall make the selection. Section 1860–D–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, the beneficiary's predominant usage of prescriber or pharmacy or both, impact on cost-sharing, and reasonable travel time. We proposed § 423.153(f)(11) to codify these statutory provisions.

Since the statute explicitly allows the beneficiary to submit preferences, we interpreted 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 plan recognition that the beneficiary's selection will contribute to prescription drug abuse or drug diversion, we proposed that the sponsor must ensure reasonable access by choosing the network pharmacy or prescriber that the beneficiary uses most frequently 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 proposed 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. We stated that 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. Sections 1860D–4(c)(5)(D)(ii)(I) and (II) address 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, which we proposed to codify at § 423.153(f)(12). To address chain pharmacies and group practices, we proposed that in the case of a group practice, all prescribers of the group practice shall be treated as one prescriber and all locations of a pharmacy that share real-time electronic data should be treated as one pharmacy.

We proposed to interpret these provisions to mean that a sponsor will 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 received the following comments and our response follows:

Comment: A commenter noted that the reasonable access provisions did not allow for situations where a patient who is locked-in is hospitalized or develops a new medical condition that requires they see a new physician, and that CMS should consider providing additional flexibility in such unexpected or unplanned situations.

Response: We note that drugs dispensed during a hospitalization are covered under the Medicare Part A benefit. Aside from that, plans are required to provide reasonable access to at-risk beneficiaries in their drug management programs under proposed § 423.153(f)(11). Proposed § 423.153(f)(12) requires a Part D plan sponsor to select more than one prescriber to prescribe frequently abused drugs when it reasonably determines it is necessary to do so to provide the at-risk beneficiary with reasonable access. To the extent that a new health condition necessitates an at-risk beneficiary to change providers who prescribe frequently abused drugs rather than see more than one, the beneficiary can submit a new prescriber preference, as discussed earlier.

With respect to a hospital emergency room visit, for example, we stated that in urgent circumstances, proposed § 423.153(f)(11) requires a Part D sponsor to ensure an at-risk beneficiary has reasonable access in the case of emergency services, which we stated means that 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. Thus, we believe § 423.153(f)(11) and (12) address the commenter's concerns.

Comment: We received a comment requesting that group practices be permitted to designate one or more prescribers when a plan sponsor intends to limit a beneficiary's access to coverage of frequently abused drugs to a selected prescriber or prescribers at a group practice, and permit the group practice to modify such designation from time to time. The commenter stated that this requirement should apply whether or not the prescribers at the group practice are all associated with the same single Tax Identification Number (TIN).

Response: Under the provision we proposed and are finalizing, all prescribers of a group practice are treated as one prescriber. A TIN is a mechanism that can assist Part D sponsors in identifying group practices, but as discussed earlier in the preamble, case management can also reveal the existence of a group practice that is prescribing frequently abused drugs to a beneficiary.

Comment: We received several comments that recommended that CMS re-evaluate its policy for determining chain pharmacies, as identification of which pharmacies share real-time data may be difficult in many situations, noting that sponsors do not have an effective way to manage such arrangements, and PBMs do not have the systems capabilities to discern if their systems are integrated and interchangeable. A commenter stated support for CMS' proposal as it relates to chain pharmacies, but noted that managing this option will be challenging absent additional instructions from CMS.

Response: Section 1860D–4(c)(5)(D)(ii) of the Act states that with respect to 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 for purposes of an at-risk beneficiary's selection of pharmacies. Until such pharmacies can be determined through data, sponsors with drug management programs will have to ascertain such pharmacies through the case management and beneficiary notification processes. We therefore are finalizing this provision as proposed.

Earlier in the preamble in responding to comments about prescriber agreement, we stated that in the case of prescriber lock-in, if a prescriber who has not agreed to this limitation insists that he or she must be able to continue to prescribe frequently abused drugs for the beneficiary, a plan sponsor may need to offer to lock-in the at-risk beneficiary to more than one prescriber to ensure reasonable access pursuant to § 423.153(f)(12), for example, if the beneficiary has been obtaining opioids from one prescriber and benzodiazepines from another. Thus, we point out that in finalizing the drug management program regulations, we are not interpreting the reasonable access provisions to require a sponsor to select more than one prescriber, 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 but only to consider it in the context of the requirement to provide reasonable access. This should also be the sponsor's approach when a beneficiary submits a preference for more than one prescriber and/or more than one pharmacy as his or her preference.

Also earlier in this preamble, we stated that an IHS pharmacy or provider may be the selected pharmacy or

prescriber for at-risk beneficiaries who are entitled to fill prescriptions from IHS, tribal, or Urban Indian (I/T/U) organization pharmacies and receive services through the IHS health system, and that they may go to such a pharmacy or prescriber pursuant to our reasonable access requirement, even if they are not in-network. Therefore, we are adding language to § 423.153(f)(12) to address situations when the sponsor reasonably determines that the selection of an out-of-network prescriber or pharmacy is necessary to provide the beneficiary with reasonable access. This language also addresses our earlier comment that a stand-alone PDP or MA–PD does not have to accept a beneficiary's selection of a non-network pharmacy or prescriber, except as necessary to provide reasonable access.

Given the foregoing, we therefore finalize as proposed the following at § 423.153(f)(11), with a modification to include language that the sponsor must ensure reasonable access by taking into account ''all relevant factors, including but not limited to'' and to renumber for better clarity: Reasonable access. In making the selections under paragraph (f)(12) of this section, a Part D plan sponsor must ensure that the beneficiary continues to have reasonable access to frequently abused drugs, taking into account all relevant factors, including but not limited to: (i) Geographic location; (ii) Beneficiary preference; (iii) The beneficiary's predominant usage of a prescriber or pharmacy or both; (iv) The impact on cost-sharing; (v) Reasonable travel time; (vi) Whether the beneficiary has multiple residences; (vii) Natural disasters and similar situations; and (viii) The provision of emergency services.

We are also finalizing with modification for the addition of language requiring the selection of an out-of-network prescriber or pharmacy if necessary at § 423.153(f)(12). Paragraphs (f)(12)(i) and (ii) will specify the following:

- A Part D plan sponsor must select, as applicable—

++ 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, or the selection of an out-of-network provider is necessary; and

++ 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, unless the selection of an out-of-network pharmacy is necessary.

- For purposes of paragraph (f)(12) of § 423.153, 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

++ Group practice, all prescribers of the group practice shall be treated as one prescriber.

(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 proposed § 423.153(f)(13) to codify this statutory requirement.

We also proposed that plan sponsors must obtain the network prescriber's or pharmacy's confirmation that the selection is accepted before conveying this information to the at-risk beneficiary, unless the prescriber or pharmacy agreed in advance in its network agreement to accept all such selections and the agreement specifies how the prescriber and pharmacy will be notified of its selection. In these cases, the network provider would agree to forgo specific notification if selected under a drug management program to serve an at-risk beneficiary.

We received the following comments and our responses follow:

Comment: We received a comment that CMS should prohibit plan sponsors from including in their provider agreements any requirement that would require a prescriber to confirm in advance and forego specific confirmation, if selected under a drug management program to serve an at-risk beneficiary.

Response: In light of this comment, and given the fact that we are finalizing a requirement for prescriber agreement for prescriber lock-in, as discussed earlier in the preamble, we believe the appropriate approach is that the required prescriber agreement during case management satisfies the requirement that the plan sponsor notify the prescriber that the at-risk beneficiary has been identified for inclusion in a drug management program and the prescriber has been selected as a prescriber that the beneficiary will be locked into for purposes of frequently abused drugs. In our view, the process of obtaining the prescriber agreement to prescriber lock-in also serves as the receipt of confirmation from the prescriber, not to mention our requirement that the sponsor make reasonable efforts to provide the prescriber with a copy of the beneficiary notices that the sponsor must provide, discussed earlier. Such an approach reduces unnecessary repetition of communication with prescribers.

For network pharmacies, this approach means that the notification that the at-risk beneficiary has been identified for inclusion in a drug management program and the pharmacy has been selected as a pharmacy that the beneficiary will be locked into for purposes of frequently abused drugs and the pharmacy's confirmation can be negotiated between the plan sponsor and the pharmacy, and if not, the plan sponsor must do so on a case-by-case basis, which is also the case for out-of-network prescribers and pharmacies.

Comment: A commenter proposed an additional exception to the confirmation requirement for plan sponsors that own or operate their own pharmacies, arguing that such confirmation would be unnecessary given that the pharmacy would already be confirmed, as part of their integrated system.

Response: We are not persuaded that an exception is needed in these situations. If the pharmacy is a separate legal entity from the plan sponsor, then the contract could contain a blanket agreement stating that the pharmacy agrees to accept at-risk beneficiaries that the plan sponsors locks into that pharmacy, as we mentioned in the proposed rule. If the pharmacy is the same legal entity as the plan sponsor, then notification is automatic, and no further notification or contract language would be necessary.

Based on the comments and our responses, we are finalizing this provision with modifications to state the following regarding confirmation of selections(s):

- 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. For prescribers, this notification occurs during case management as described in

paragraph (f)(2) or when the prescriber provides agreement pursuant to paragraph (f)(4)(i)(B).

- The sponsor must receive confirmation from the prescriber(s) or pharmacy(ies) or both, as applicable, that the selection is accepted before conveying this information to the at-risk beneficiary, unless the pharmacy has agreed in advance in a network agreement with the sponsor to accept all such selections and the agreement specifies how the pharmacy will be notified by the sponsor of its selection.
- A sponsor complies with paragraphs (i) and (ii) as it pertains to a prescriber by obtaining the prescriber's agreement pursuant to § 423.153(f)(4)(i)(B).

(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 proposed to integrate the lock-in provisions with existing Part D Opioid DUR Policy/OMS. Determinations made in accordance with any of those processes, at § 423.153(f), and discussed previously, are interrelated issues that we collectively refer to as an ''at-risk determination.'' In this final rule, we are adding a definition of at-risk determination at § 423.560 to describe a decision made under a plan sponsor's drug management program in accordance with § 423.153(f) that involves the identification of an individual as an at-risk beneficiary for prescription drug abuse; a limitation, or the continuation of a limitation, on an at-risk beneficiary's access to coverage of frequently abused drugs (that is, a beneficiary specific point-of-sale edit the selection of a prescriber and/or pharmacy and implementation of lock-in); and information sharing for subsequent plan enrollments.

We proposed 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. Consistent with the existing Part D benefit appeals process, we proposed 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. We also proposed 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 an at-risk determination made under a drug management program. While we did not propose to adopt auto-escalation, the 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 proposed 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 also proposed 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 § 423.153(f).

In addition to the changes related to the implementation of drug management program appeals, we also proposed 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).''

We received the following comments and our responses follow:

Comment: A few commenters strongly objected to beneficiaries not having appeal rights during their designation as ''potential'' at-risk beneficiaries at the time the initial notice is received from the plan sponsor.

Response: As we noted in the proposed rule, when a beneficiary is identified as being potentially at-risk, but has not yet been definitively identified as at-risk, the plan is not taking any action to limit such beneficiary's access to frequently abused drugs. Because the plan sponsor has not taken any action to limit a beneficiary's access at this point in the process, the situation is not ripe for appeal. We proposed that a beneficiary will have the right to appeal a determination made under a plan sponsor's drug management program when the beneficiary receives the second notice explaining that access to coverage for frequently abused drugs will be limited. We believe the intent of the statute is to confer appeal rights to beneficiaries at the point in the process at which a beneficiary is notified that access will be limited and provide an explanation of the restrictions that will be applied under the drug management program.

As discussed earlier in this preamble, the proposed 90 day maximum timeframe for the plan sponsor to send the second or alternate second notice is being reduced to 60 days under this final rule. Specifically, the second or alternate second notice is to be provided to the beneficiary no more than the earlier of the date the sponsor makes the relevant determination or 60 days after the date of the initial notice. This 60 day period may be used by a plan sponsor to process information received from beneficiaries or communicate with prescribers who may have been unresponsive prior to receiving a copy of the initial notice the plan provided to the beneficiary. As we also previously noted in this preamble, we do not expect plans to routinely take the maximum amount of time to issue the second notice, and note that the plan must send it sooner if they make the relevant determination sooner. Reducing this period between the initial notice and the second or alternate second notice to a maximum of 60 days balances plan sponsors' need for time to process information from beneficiaries and prescribers, if applicable, with providing timely notice to beneficiaries.

Comment: Several commenters encouraged CMS to make the appeals process regarding lock-in as simple as possible for beneficiaries to ensure that those who need particular drugs are able to access them. These commenters suggested that CMS implement all of the protections of CARA, including automatic escalation to independent review. Several commenters do not agree with CMS' interpretation of the CARA language on appealing lock-in and believe automatic escalation to the IRE would ensure beneficiary due process and access to needed prescription drugs. These commenters strongly oppose the use of the existing Part D appeals process for appeals of at-risk status or other consequences of drug management, and view the process as a significant barrier that will increase the timeframe for the lock-in appeals process. Commenters expressed concerns regarding case management and physician agreement as additional hurdles for beneficiaries who are not at-

risk, in addition to plan compliance with the current requirements for timely appeals. A few commenters stated that CARA contemplates a more streamlined process that is easier for beneficiaries to navigate and that automatic escalation would allow for improved tracking and monitoring of the scope and impact of the lock-in program, in addition to providing more uniform decision making across various plan programs. A commenter suggested that CMS conduct analysis to determine which option would prevent or reduce bias against beneficiaries, as well as minimize the timeframe by which the review process occurs, and upon implementation closely monitor the decisions of at-risk status to ensure decisions are made in the best interest of the beneficiary. A commenter recommended a separate appeals process that is similar to the grievance process.

Response: We agree with commenters that the appeals process for enrollees identified as at-risk should be as easy to navigate as possible. As we noted in the proposed rule, 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 is not only required by statute, but will allow at-risk beneficiaries to be more familiar with, and more easily access, the appeals process as opposed to creating a new process specific to appeals related to a drug management program. Since the statute specifically refers to section 1860D–4(h) of the Act and the process we proposed is consistent with the existing appeals process, we disagree with the comment that further analysis of options is necessary to ''prevent or reduce bias against beneficiaries.'' As we noted in the proposed rule, affording a plan sponsor the opportunity to review its initial determination may result in resolution of the disputed issues at a lower level of review and obviate the need for further appeal of the issues to the Part D IRE which, in turn, will minimize the time for reviewing and resolving disputes. With respect to the monitoring of plan sponsors' at-risk decisions, appeal decisions involving at-risk status will be subject to review under existing plan sponsor audit processes. We do not believe that a process similar to the existing grievance process, as recommended by a commenter, would comport with the statute, which requires the use of the existing appeals process. However, potential at-risk and at-risk beneficiaries retain their existing right to file a grievance with the plan if they have complaints about the prescription drug management program.

With respect to the comment on case management and physician involvement, these are key components to drug management programs and we disagree that these components create additional hurdles for beneficiaries within the appeals process. In fact, we believe that the extensive case management we expect to be performed under plan sponsors' drug management programs, including ongoing communications among the plan sponsor, enrollee, prescriber(s) and pharmacy, will result in a relatively low volume of appeals under these programs. In addition, the appeals that are processed will be informed by the case management conducted by the plan sponsor and the involvement of the physician.

Comment: Many commenters agreed with the proposal to utilize the existing Part D appeals process for at-risk beneficiaries, including not requiring automatic escalation for external review. These commenters believed that use of the existing process is the simplest and most administratively efficient approach, as it is familiar to beneficiaries, plan sponsors, and other stakeholders. These commenters also believed that plan sponsors should have the opportunity to review additional information and potentially adjust their initial decision before the case is reviewed by the IRE.

Response: We thank the commenters for expressing support for use of the existing Part D benefit appeals process for beneficiaries identified as at-risk under a plan sponsor's drug management program. In addition to comporting with the statutory requirement, we agree with the commenters that use of the existing appeals process is the most administratively efficient approach and will result in better outcomes for at-risk beneficiaries. Not only is the existing appeals process familiar to enrollees, plans, and the IRE, but it allows a plan sponsor the opportunity to review information it used to make an at-risk determination under its drug management program (and any additional relevant information submitted as part of the appeal), promotes the resolution of issues at a lower level of administrative review and potentially reduces the need for the beneficiary to further appeal the issues in dispute. However, if the matter is not resolved by the plan sponsor at the redetermination level, an at-risk beneficiary will have the right to seek review by the Part D IRE.

Comment: With respect to the calculation of the amount in controversy (AIC) for an ALJ hearing or judicial review, a commenter expressed support for using a formula based on the value of any refills for frequently abused drugs to calculate the AIC, noting that it will provide a greater probability for higher review, benefiting both the plan and the beneficiary.

Response: We thank the commenter for expressing support for the proposal related to calculation of the AIC at § 423.1970(b)(2) for disputes related to identification as an at-risk beneficiary under a plan sponsor's drug management program.

Comment: A few commenters requested clarification as to whether the beneficiary Notice of Appeal Rights (reject code 569), which triggers a pharmacy to provide the beneficiary with the standardized pharmacy notice, Prescription Drug Coverage and Your Rights (CMS–10147), should accompany any POS claim rejections regarding prescriber or pharmacy lock-in or beneficiary-specific POS edits. Commenters recommended that the CMS–10147 not be provided to beneficiaries when a claim rejects at POS due to issues under a plan sponsor's drug management program.

Response: We agree with the commenters that a POS claim rejection as a result of a restriction imposed under a plan sponsor's drug management program should not trigger delivery of the standardized pharmacy notice (CMS–10147). The pharmacy notice informs a beneficiary to contact his or her Part D plan to request a coverage determination. As discussed above in this final rule, a determination under a plan sponsor's drug management program is not a coverage determination as defined at § 423.566. Instead, a determination made under a drug management program is governed by the provisions proposed at § 423.153(f) related to at-risk determinations. If a beneficiary disagrees with a decision made under § 423.153(f), the beneficiary has the right to appeal such decision. The at-risk beneficiary will be notified of this appeal right pursuant to the notice described at § 423.153(f)(6).

Comment: Several commenters requested clarification that when a beneficiary appeals their coverage limitation under the drug management program, that the request should be processed as a redetermination and not as a coverage determination. A few commenters requested clarification as to whether or not the POS edit or a lock-

in would be a coverage determination. Commenters asked if Chapter 18 of the Prescription Drug Benefit Manual would apply, and if so, noted that CMS should release proposed changes to the guidance for comment. Commenters inquired about how the CARA provisions would impact the coverage determination and redetermination processes, including approval and denial language used by plan sponsors. A commenter stated that they do not believe that these are coverage determinations because they involve access issues and being treated as such would pose system, policy, and process challenges. This commenter also asked for clarification on how this process would impact the appeals auto-forward star measure if treated as a coverage determination.

Response: We did not propose to change the current definition of a coverage determination at § 423.566. As we stated in the proposed rule, 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. 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 appeals provisions in Subpart M and Subpart U. The 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) will be subject to the processes proposed at § 423.153(f).

What we did propose is 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. Thus, we agree with these commenters that a determination made under a drug sponsor's drug management program should not be considered a coverage determination as defined at § 423.566. If a beneficiary has a dispute related to a determination under the processes set forth at § 423.153(f), the beneficiary has the right to request a redetermination and potentially higher levels of appeal. Therefore, drug management program disputes are subject to the appeals provisions in Subpart M and Subpart U of the regulations and the guidance in Chapter 18 of the Prescription Drug Benefit Manual also applies. Disputes under a plan sponsor's drug management program will be adjudicated under the existing appeals process and the regulatory timeframes will apply. The manual guidance will be updated, as necessary, to reflect any changes relevant to drug management program disputes. With respect to the redetermination notice, plan sponsors may use CMS' model redetermination notice (with modifications) or develop their own notice for informing an enrollee of the outcome of the appeal.

Comment: A few commenters suggested that these appeals be limited to the beneficiary-level edit, the selected pharmacy or the prescriber, and not the underlying criteria for identification and guidance. Commenters noted that the appeal should be limited to the issue of whether the beneficiary is an appropriate candidate for lock-in, and not have any other scope. A commenter stated that the appeal should not relate to whether the plan may impose prior authorization or other utilization management restrictions on certain prescriptions. Rather, according to the commenter, beneficiary appeals should be limited to compliance with internal program criteria and CMS guidance, rather than allowing beneficiaries to challenge the underlying criteria. A commenter asked that CMS clarify how to effectuate a redetermination that requires the reversal of one limit, but other limits remain (for example, a formulary restriction and lock-in), and which limit takes priority. This commenter stated that beneficiaries would have to receive decision notices explaining that because of the remaining limits, their drug access will continue to be limited. Another commenter requested guidance on whether to handle a dispute involving beneficiary-specific POS claim edit and a dispute about a pharmacy or prescriber selection under the same appeal, or the POS edit as a coverage determination and the lock-in as an appeal.

Response: As explained above, the statute explicitly states that one of the issues that can be appealed is the identification as an at-risk beneficiary for prescription drug abuse under a Part D drug management program. With respect to the comment that an enrollee not be permitted to challenge the ''underlying criteria,'' we interpret this to mean a plan sponsor's clinical guidelines used to identify potential at-risk beneficiaries. We believe that a beneficiary disputing his or her at-risk determination will inherently be arguing that the plan's criteria for identifying at-risk beneficiaries do not apply to his or her particular circumstances. In addition to the at-risk determination, an enrollee has the right under the statute to appeal the selection of a prescriber or pharmacy as well as a coverage determination made under a plan sponsor's drug management program. As previously noted, determinations made under the processes at § 423.153(f) will be adjudicated under the existing Part D benefit appeals process. Such determinations include limitation on access to coverage for frequently abused drugs, including a POS claim edit for frequently abused drugs that is specific to an at-risk beneficiary and a limit on an at-risk beneficiary's access to coverage for frequently abused drugs to those that are prescribed by one or more prescribers or dispensed to the beneficiary by one or more network pharmacies. As also previously noted, we did not propose to revise the existing definition of a coverage determination. In addition to a determination made under the processes at § 423.153(f), a coverage determination, including an exception, is also subject to appeal. For example, if an enrollee does not dispute a POS edit for a quantity limit on a drug within 60 days of the date of the second notice pursuant to § 423.153(f)(6) but later requests an exception to the quantity limit and that request is denied by the plan sponsor, the enrollee has the right to appeal the denial of the exception request. While the enrollee always has the right to request a coverage determination, changes to previously imposed limitations can also be implemented through ongoing case management and a new determination under the processes at § 423.153(f).

As noted earlier, a commenter asked whether a dispute regarding pharmacy or prescriber selection for purposes of lock-in and a dispute related to a beneficiary specific POS claim edit should be processed as the same appeal. If a beneficiary's request for an appeal raises multiple issues related to the limitations imposed on the beneficiary under a drug management program, the plan sponsor must address each issue as part of the appeal. For example, if the beneficiary's appeal request includes a dispute related to pharmacy selection and a POS edit, the adjudication and disposition of the appeal would involve both issues. All disputes raised in the enrollee's appeal request that arise under a plan's drug management program will be adjudicated as a single case. Assuming the request is filed timely, an enrollee could later appeal another limitation imposed under the drug management program, such as the selection of a prescriber, and the adjudication and disposition of that appeal would relate to prescriber selection for purposes of lock-in and be considered separate and distinct from any previous or pending appeal

requests. An appeal request must be filed within 60 calendar days from the date of the notice that explains the limitations imposed under the drug management program (unless there is good cause for late filing of the appeal). In addition to appealing determinations made under the processes at § 423.153(f) that limit a beneficiary's access, 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.

With respect to effectuation of a redetermination of an at-risk determination, we agree with the commenter that the redetermination notice should clearly explain which aspect of the program is changing (for example, change in pharmacy lock-in) and which restrictions remain unchanged and will continue to apply to the beneficiary. We would like to clarify that all changes must be effectuated pursuant to the effectuation rules at § 423.636 and § 423.638; in other words, one change does not take ''priority'' over another applicable change with respect to effectuation. For example, if the outcome of a standard redetermination related to pharmacy and prescriber lock-in is a change to the pharmacy and the prescriber(s) an at-risk enrollee must use, the plan sponsor must implement both of those changes concurrently and as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date the plan sponsor receives the redetermination request.

Comment: A few commenters suggested that CMS confirm that a beneficiary should not continue to receive inappropriate fills of opioids during the appeals process.

Response: We thank the commenters for their request for confirmation that a beneficiary who has been identified as at-risk, has received the second notice, and has requested an appeal should not continue to receive ''inappropriate fills'' of opioids during the appeals process. We are interpreting ''inappropriate fills'' to mean a fill that does not comport with the specific restrictions placed on the at-risk beneficiary (for example, pharmacy lock-in). Once the beneficiary has been notified via the second notice of applicable restrictions, there should be no additional fills of any of the drug(s) subject to the drug management program that do not satisfy the parameters of the program established for the at-risk beneficiary, unless those restrictions are later modified through the appeals process.

Comment: A commenter asked that CMS clarify whether these appeals are required to be handled based on the timeframes for a request for benefit or a request for payment, and whether or not these are subject to the expedited timeframes.

Response: As noted in the proposed rule, at-risk determinations made under the processes at § 423.153(f) would be adjudicated under the existing Part D benefit appeals process and timeframes set forth in Subpart M and Subpart U. As such, at-risk determinations will be subject to the benefit request timeframes set forth at § 423.590(a). We also proposed 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. Consistent with existing rules, the beneficiary must meet the requirements set forth in regulation in order to obtain an expedited review of their at-risk determination.

Comment: In the case of a beneficiary appealing the Part D plan sponsor's initial selection of a prescriber or pharmacy, a commenter requested clarification whether the plan sponsor must obtain confirmation of acceptance from the new prescriber and/or pharmacy the beneficiary has selected as part of the appeal and whether this confirmation needs to be made within the appeals timeframes. This commenter expressed concern with obtaining such confirmation within the short window for adjudicating the case.

Response: While we appreciate the commenter's concern regarding the timeframe for making a decision, we believe that the current timeframes afford the plan sponsor sufficient time to obtain confirmation from a prescriber and/or pharmacy that they have accepted the beneficiary's selection for lock-in. Under the current Part D benefit appeals process, plan sponsors are required to obtain similar information from prescribers and we believe that appeals of at-risk determinations should not be materially different from the outreach plans conduct as part of the coverage determination, exceptions, and benefits appeals process. Please refer to the discussion regarding confirmation of pharmacy and prescriber selection earlier in this preamble.

Comment: A few commenters requested clarification as to whether or not plans would be permitted to terminate exceptions or implement temporary exceptions, in consultation with the prescriber, prior to the end of a plan year due to opioid case management and, if so, what prior notice requirements will apply.

Response: Consistent with existing rules for the exceptions process at § 423.578(c), if a drug is found to no longer be safe for the enrollee, then a previously approved exception request could be terminated prior to the end of the plan year. This would include if the plan determines that the previously approved exception is no longer safe as part of an at-risk determination or ongoing case management under its drug management program. A determination made by a plan sponsor under the processes at § 423.153(f) is subject to appeal. For example, if a determination is made under a plan sponsor's drug management program to implement a beneficiary-specific *POS* claim edit for a drug, the beneficiary will be notified of that decision per the provisions at § 423.153(f)(6) and the decision may be appealed. If the beneficiary does not appeal the decision within 60 calendar days from the date of the notice that explains the limitations the plan sponsor is placing on the beneficiary's access to coverage for frequently abused drugs, the beneficiary retains the right to request a coverage determination related to a beneficiary-specific POS edit at any time. And, as stated above, changes to previously imposed limitations can also be implemented through ongoing case management and a new determination under the processes at § 423.153(f).

Comment: A few commenters expressed concern regarding the lack of any proposed review criteria that would be used by plans to evaluate these appeals based on the at-risk determination. Commenters stated that appeal requests for opioid restrictions do not fit in any existing utilization management criteria (for example formulary and tiering exceptions criteria) and request additional guidance from CMS. These commenters are concerned that if the beneficiary appeals the limitation beyond the plan, the IRE or ALJ/attorney adjudicator will likely review these restrictions similar to a formulary or tiering exception and not based on the at-risk determination. A commenter indicated that this type of review may have an adverse impact on plans' D03 STARS Ratings, and if approved, an exception must be effectuated through the end of the plan year, which could remove the enrollee from case management for the rest of the year even if they meet the criteria for such.

Response: We appreciate the commenters' concerns. If the case goes to the IRE, or higher levels of appeal, the administrative case file assembled by

the plan sponsor will contain the relevant information needed by the adjudicator to make an informed decision, such as information used by the plan sponsor to determine at-risk status, a description of the case management the plan has performed and the beneficiary's preference with respect to prescriber or pharmacy lock-in. We believe the regulations, applicable manual guidance, the plan sponsor's review criteria and case management notes on the access limitations that apply to the enrollee (which would be included in the administrative case file) will be sufficient for an adjudicator to review an appeal. With respect to the comment on an approved exception, please refer to the introductory section on drug management programs earlier in this preamble for a discussion of determinations where continuing an approved exception is no longer appropriate.

Comment: With respect to the handling and reporting of appeals, a few commenters expressed concerns regarding the negative impact choosing to implement the lock-in procedures could potentially have on a plan. A commenter noted that opioid restriction reviews are not represented in their reporting and there are no allowable values in the audit universes that would designate a case as an opioid restriction. As a result, the commenter believes that if an approved exception is terminated prior to the end of the plan year, this could be detected on audit and the plan sponsor may be found to be non-compliant with exception processing requirements.

Response: If a plan sponsor makes a determination under its drug management program per the processes at § 423.153(f) that results in a finding that a drug previously approved through the exception process is found to no longer be safe for treating the beneficiary's disease or medical condition, the previously approved exception can be terminated prior to the end of the plan year. With respect to the commenter's concern about such a case being reviewed on audit, the plan sponsor would not be subject to a finding of non-compliance for having terminated a previously authorized exception if such termination is consistent with a clinically appropriate determination made under the plan sponsor's drug management program.

Comment: A few commenters encourage CMS to communicate appeal-related information and requirements in a clear, concise, and consistent manner to beneficiaries, the IRE, and plan sponsors to support a uniform understanding of the agency's rules and related expectations. A commenter stated that beneficiaries are not always aware of their exceptions and appeal rights and many do not understand how the process works. This commenter expressed concern that there may be a lack of transparency in the appeals process or excessive administrative burden for the beneficiary and provider, which may extend to those who may be inappropriately identified as at-risk and subject to unnecessary access restrictions to needed medications.

Response: We agree with the commenters that appeals-related information and requirements should be communicated in a clear, concise, and consistent manner to beneficiaries, Part D plan sponsors, and the IRE. We will continue to update existing materials and develop new CARA related communications, such as the first and second notices described elsewhere in this final rule, with these goals in mind.

After consideration of these comments, we are finalizing with modifications the provisions on CARA appeals with two clarifying changes. First, in this final rule, we are including a definition of at-risk determination to § 423.560 to clarify the types of actions made under the processes at § 423.153(f) that are subject to appeal. In addition to coverage determinations made under a drug management program, an enrollee has the right to appeal the identification as an at-risk beneficiary for prescription drug abuse; a beneficiary specific point-of-sale (POS) edit; the selection of a prescriber or pharmacy for purposes of lock-in; and information sharing for subsequent plan enrollments. Second, proposed new paragraph (a)(1)(v) at § 423.562 has been revised to clarify that determinations made in accordance with the processes at § 423.153(f) are collectively referred to as an at-risk determination as defined at § 423.560.

Finally, we did not receive comments on the technical changes to § 423.562(a)(1)(ii) and we are finalizing those changes as proposed.

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

Section 1860–D–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.

We proposed 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. However, we also noted that 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 their 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, termination of an at-risk determination will not prevent an at-risk beneficiary from being subsequently identified as a potential at-risk beneficiary and an 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.

We received the following comments and our response follows:

Comment: We received widespread comments that suggested that a maximum 12-month lock-in period was arbitrary, and that automatic termination of a beneficiary's at-risk status after 12 months threatens beneficiary safety. Commenters suggested that termination of such programs should be based on the needs of the beneficiary following a clinical assessment, and that an arbitrary time limit assumes without any clinical justification that he or she is no longer at-risk for drug abuse after 12 months. Following this period, many commenters also recommended plan sponsors should be permitted to conduct a review of the beneficiary's at-risk status at the expiration of the first 12 months whether a beneficiary is determined at-risk, and if so, implement a termination after an additional 12 months, for 24 months total. While very few commenters supported the 12-month limitation timeframe, they did not provide rationale for their support.

Response: We disagree with commenters that the 12-month period lock-in period we proposed is arbitrary. As we noted in the proposed rule, during the Stakeholder Listening Session on CARA held in November

2016, most commenters recommended a maximum 12-month period for lock-in. We also noted that a 12-month lock-in period is common in Medicaid lock-in programs.[16] Additionally, Section 1860D–4(c)(5)(F) grants the Secretary the authority to establish a maximum limitation period, and we choose to exercise said authority.

CMS was, however, persuaded that a 12-month limitation maximum might be too short to ensure for beneficiary safety in some instances, and a longer limitation on access to coverage for frequently abuse drugs might be needed in such cases. We also re-reviewed limitation periods in Medicaid lock-in programs, and found that another very common lock-in period is 24 months. An additional prevalent trend for Medicaid lock-in periods is the ability to extend the lock-in period based on a review of appropriateness of continuance of lock-in.[17] This trend aligned very closely with the many commenters who suggested a 24-month limitation period, and/or the ability of the plan sponsor to extend the limitation as a result of a clinical assessment. As a compromise between these two options, CMS is finalizing an initial 12-month limitation period as proposed, but with ability modification allowing for the sponsor to extend the limitation for up to an additional 12 months. This extension will be dependent upon a clinical assessment whether the beneficiary demonstrates that they are no longer likely, in the absence of the limitation(s) the plan sponsor has placed on their access to coverage for frequently abused drugs, to be an at-risk beneficiary for prescription drug abuse at the conclusion of the initial 12 months of the limitation. Thus, the maximum limitation period will be 24 months.

Based on the provisions discussed earlier regarding when prescriber agreement is required, we believe the plan sponsor must, as part of the required clinical assessment, obtain prescriber agreement to extend a prescriber lock-in beyond the initial 12 months. Prescriber agreement will also be required with respect to extending beneficiary-specific POS edits. However, as with the initial POS edit, one can be extended without prescriber agreement if no prescriber is responsive. Also, the plan sponsor will be required to send the at-risk beneficiary another second notice, indicating that the limitation is being extended, and that they continue to be considered as an at-risk beneficiary. Aside from the required prescriber agreement just described, a plan sponsor will have discretion as to how they clinically assess whether an at-risk beneficiary's demonstrates whether they are no longer likely to be an at-risk beneficiary for prescription drug abuse in the absence of limitation at the conclusion of the initial 12 months of the limitation. This assessment might include a review of medical records or prescription drug monitoring program data, if available to the sponsor. Given that the plan sponsor will not be required to obtain prescriber agreement to extend pharmacy lock-in past the initial 12 month period, we expect the plan sponsor to have a clinical basis to extend the limitation, such as, the plan sponsor has recently rejected claims for frequently abused drugs from non-selected pharmacies to an extent that indicates the beneficiary may abuse frequently abused drugs without the limitation.

Comment: A handful of commenters suggested that a limitation to coverage for frequently abused drugs only be terminated as a result of a clinical assessment by the at-risk beneficiary's prescriber with no maximum limitation period.

Response: CMS believes it advisable to place a time limit on the duration of a limitation on access to coverage for frequently abused drugs that a plan sponsor can place on an at-risk beneficiary in order to balance the beneficiary's right to utilize their Part D benefit without encumbrance against with the sponsor's responsibility to manage the Part D benefit and promote the safety of its enrollees.

Comment: A commenter suggested that CMS could consider requiring Part D sponsors to send annual notifications to beneficiaries who are subjected to a lock-in and their approving prescribers to let them know the lock-in will be extended another 12 months. This would afford beneficiaries and prescribers an annual opportunity to request that the lock-in be reconsidered or raise any concerns.

Response: We decline to adopt this suggestion, as it does not suggest a basis upon which the limitation would be extended. Under the provision we are finalizing, a clinical assessment is required and, if the limitation on access to coverage is extended beyond the initial 12 month period, the plan sponsor would be required to send the at-risk beneficiary an additional second notice pursuant to § 423.153(f)(6) explaining that the limitation is being extended and for how long.

Also, a beneficiary, their representative, or their prescriber on behalf of the beneficiary, is not precluded from requesting that the plan revisit its determination that the beneficiary is an at-risk beneficiary as defined at § 423.100, or the terms of any limitation imposed on the beneficiary under the plan's drug management program.

Based on these comments and our responses, we are therefore finalizing additional language at § 423.153(f)(14). The revised language will specify that the identification of an at-risk beneficiary as such must terminate as of the earlier of the following:

- 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 limitation under this paragraph, to be an at-risk beneficiary; or
- The end of a—

++ One year period calculated from the effective date of the limitation, as specified in the notice provided under paragraph (f)(6) of this section, unless the limitation was extended pursuant to paragraph (f)(14)(ii)(B) of this section.

++ Two year period calculated from the effective date of the limitation, as specified in a notice provided under paragraph (f)(6) of this section, subject to the following requirements:

—The plan sponsor determines at the end of the one year period that there is a clinical basis to extend the limitation.

—Except in the case of a pharmacy limitation imposed pursuant to paragraph (f)(3)(ii)(B) of this section, the plan sponsor has obtained the agreement of a prescriber of frequently abused drugs for the beneficiary that the limitation should be extended.

—The plan sponsor has provided another notice to the beneficiary in compliance with paragraph (f)(6) of this section.

—If the prescribers were not responsive after 3 attempts by the sponsor to contact them within 10 business days, then the sponsor has met the requirement of paragraph (f)(14)((ii)(B)(2) of this section.

—The sponsor may not extend a prescriber limitation implemented pursuant to paragraph (f)(3)(ii)(A) of this section if no prescriber was responsive.

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

[17] Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2016 Annual Report: Prescription Drug Fee-For Service Program (October 2017).

(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 pursuant to § 423.153(f)(2), certain data disclosure and sharing of information must happen. First, CMS must identify potential at-risk beneficiaries to sponsors who are in the sponsors' Part D prescription drug benefit plans. In addition, a new sponsor 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 (that is, applying the minimum clinical guidelines more frequently or in applying the supplemental clinical guidelines). 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.

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. We plan to expand and modify the scope of OMS and the MARx system as appropriate to accommodate the data disclosures necessary to oversee and facilitate Part D drug management programs.

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 proposed to codify the data disclosure and information sharing process under the current policy, with the expansion just described, by adding data disclosure requirements in § 423.153.

We received the following comments and our response follows:

Comment: We received comments supportive of our proposal regarding data disclosures and sharing of information. We did not receive comments opposed to our proposal.

Response: We thank the commenters for their support.

Comment: A commenter recommended that we clarify sponsors must conduct case management with respect to potential at-risk beneficiaries who are current utilizers under the Part D sponsor and not such beneficiaries who are identified by the prior sponsor. This commenter stated further that if sponsors are required to conduct case management on potential at-risk beneficiaries identified by the prior sponsor, then the response due date should be extended for such cases (that is, to next OMS quarter), as sponsors may need to contact the prior sponsor for case details to conduct case management for the prior claims data. In extending the outlier response due date, this commenter urged us to consider that the volume of such cases may differ based on the size of the prior sponsor.

Response: Pursuant to § 423.153(f)(2)(i), sponsors are required to conduct case management with respect to all potential at-risk beneficiaries who are identified by CMS or the sponsor applying the clinical guidelines, regardless of whether the beneficiary meets the clinical guidelines based on PDE data from the beneficiary's current Part D contract alone or across multiple contracts (including contracts the beneficiary was previously enrolled in during the measurement period).

§ 423.153(f)(2)(ii) does provide an exception to the case management requirements with respect to potential at-risk beneficiaries identified as such by their most recent prior plan, if the identification has not been terminated and the sponsor obtains case management information from the previous sponsor, which is clinically adequate and up to date. Under the current policy, a sponsor may report in OMS that a beneficiary's case is under review. We plan to keep this response. However, because of this comment, we realize that there may be some instances in which a sponsor receives notice about a potential at-risk beneficiary who has just enrolled in its plan, but the deadline to provide information to CMS within 30 days from the date of the most recent prior CMS report identifying potential at-risk beneficiaries pursuant to proposed § 423.153(f)(15) might be very short. Therefore, we are modifying § 423.153(f)(15) such that the sponsor would have to provide the information within 30 days from the date of the most recent CMS report received after receiving such a notice.

Comment: We received a comment requesting clarity on the issue of patient consent in the sharing of the patient personal health information related to implementation of these finalized provisions.

Response: While the commenter's concerns about sharing personal health information are not entirely clear, we note that Part D plan sponsors are required under § 423.136 to establish procedures for maintenance and sharing of medical records and other health information about enrollees in accordance with all applicable Federal and State confidentiality laws.

Comment: We received a question asking what data sources we will use to identify LIS beneficiaries who are potentially at-risk.

Response: We plan to use OMS to identify all potential at-risk beneficiaries who meet the minimum criteria of the clinical guidelines, discussed earlier, to report to Part D plan sponsors. We will modify the OMS as appropriate to implement the Part drug management program requirements. We will issue guidance and updated OMS technical user guides to plan sponsors at a later time, including data sources used in OMS reporting.

Comment: We received a question whether the original plan that identified the beneficiary's at-risk status has a duty to inform the new plan of individual's status.

Response: Plan sponsors will be required to communicate beneficiaries' potential and at-risk statuses to each other through the data disclosures and information sharing we are finalizing in this section.

Comment: We received a question whether we will be providing new response codes for pharmacy and prescriber lock-in in OMS, specifically whether we will eliminate the response code ''BSC'' which stands for ''Beneficiary did not meet sponsor's internal criteria.'' We also received some specific suggestions to: (1) Include responses to OMS that differentiate between lock-in and a claim edit at POS;

(2) add a sponsor summary page to OMS; (3) make enhancements to MARx to recognize internal and external contract changes; and (4) allow for more complete case management information to be shared to obviate the needs for sponsors to contact each other.

Response: We appreciate these suggestions. We plan to expand and modify the scope of OMS and MARx as appropriate and technically possible in light of the final requirements in this rule to accommodate the data disclosures necessary to oversee and facilitate Part D drug management programs. We plan to issue guidance about this expansion and details on the modifications. Based on these comments, we are finalizing § 423.153(f)(15) with modifications to specify the following regarding data disclosure:

- CMS identifies potential at-risk beneficiaries to the sponsor of the prescription drug plan in which the beneficiary is enrolled.
- 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:

++ Provide information to CMS within 30 days of receiving a report about a potential at-risk beneficiary from CMS.

++ Provide information to CMS about any potential at-risk beneficiary that meets paragraph (1) of the definition in § 423.100 that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries.

++ Provide information to CMS about any potential at-risk beneficiary that meets paragraph (2) of the definition in § 423.100 within 30 days of the date after which the sponsor referred to in paragraph (2).

++ Provide information to CMS as soon as possible but no later than 7 days of the date of the initial notice or second notice that the sponsor provided to a beneficiary, or as soon as possible but no later than 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.

++ 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—

—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

—The edit or limitation that the sponsor had implemented for the beneficiary had not terminated before disenrollment.

We note that this final provision contains a technical correction to refer to 7 days instead of 7 business days the first instance this timeframe is used for consistency and added ''as soon as possible'' in § 423.153(f)(15(D). It also substitutes ''provide information'' for ''respond'' in one place for consistent terminology in this section.

(xii) Out of Scope Comments and Summary

We received comments on the following topics which were out of scope of our proposal and to which we are therefore not responding: (1) CMS oversight of Part D drug management programs; (2) Education of Part D enrollees and providers regarding prescription drug management programs; (3) A seven day limit on opioids for acute pain; (4) Additional ideas about how to address the national opioid overuse crisis; (5) Opioid use standards in Medicare Set Aside arrangement (MSAs).

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 are tied to health status or disease state in a manner that ensures that similarly situated individuals are treated uniformly is consistent with the uniformity requirement in the Medicare Advantage (MA) regulations at § 422.100(d). We solicited comments on this reinterpretation in the proposed rule. In response to those comments and our further consideration of this issue, we are providing guidance here to MA organizations. As discussed in more detail below, the Bipartisan Budget Act of 2018 (Pub. L. 115–123) amends section 1853 of the Act to authorize waiver of the uniformity requirement beginning in 2020 for MA plans that provide additional supplemental benefits (which are not required to be health care benefits) to chronically ill enrollees. It also amends section 1859 of the Act to require a nationwide revision of the Medicare Advantage Value-Based Insurance Design test model currently administered by the Center for Medicare and Medicaid Innovation, which provides similar flexibility to participating MA plans to offer targeted supplemental benefits. Our reinterpretation of the uniformity requirements is not identical to these statutory changes, but does provide a comparable flexibility for MA plans that is consistent with the requirement that MA plans offer uniform benefits, with uniform premium and uniform cost-sharing to all enrollees.

This regulatory requirement that MA plans provide uniform benefits implements both section 1852(d) of the Act, which requires that benefits under the MA plan are available and accessible to each enrollee in the plan, and section 1854(c) of the Act, which requires uniform premiums for each enrollee in the plan. Previously, we required MA plans to offer all enrollees access to the same benefits at the same level of cost sharing. 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 medical criteria identified by the MA plan for the benefits) are treated the same. In addition, there must be some nexus between the health status or disease state and the specific benefit package designed for enrollees meeting that health status or disease state. As examples, uniformity flexibility will allow an MA plan to offer an enrollee with diabetes any or all of the following:

- Reduced cost sharing for endocrinologist visits;
- More frequent foot exams as a tailored, supplemental benefit;
- A lower deductible.

In these examples, non-diabetic enrollees will not have access to these tailored cost sharing or supplemental benefits; however, any enrollee that develops diabetes will then have access to these benefits.

We believe that our reinterpretation of the uniformity requirement is consistent with the underlying Part C statutory requirements because targeted supplemental benefits and cost sharing reductions must be offered uniformly to all enrollees with a specified health status or disease state. By tying specific supplemental benefits to specific medical conditions, MA plans would be building upon the concept of medical necessity and developing targeted benefits designed to treat the illnesses of enrollees who meet specific medical criteria. Further, treating similarly situated enrollees equally preserves the uniformity of the benefits package. This

flexibility is similar to our policy over the past several years of permitting MA plans to adopt tiered cost-sharing, that is, allowing plans to have different cost sharing for contracted providers of the same type (for example, hospitals) provided that enrollees are equally able to access the lower cost-sharing providers.

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.[18] 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, potentially 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.

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 criteria. Objective criteria that are contained in written policies and that are clearly and adequately communicated to enrollees (such as in the EOC and other plan documents) are necessary to ensure that these tailored benefits are not provided in a discriminatory fashion and that the overall package of benefits is uniform among similarly situated individuals. We view this flexibility as an extension of the concept that as an enrollee in good health without cardiac problems would not receive cardiac rehabilitation services, an enrollee who does not meet the medical criteria would not receive the targeted benefits offered by an MA plan.

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), and we note that Bipartisan Budget Act of 2018 expands the testing of the model under section 1115A(b) to all 50 states by 2020. This demonstration includes some of the elements that are a part of our reinterpretation of the uniformity requirements. However, there are also features of the VBID demonstration that are unique to the demonstration test, such as the ability for participating plans to target Part D benefits, the restriction to certain medical conditions, and the requirement that plans apply to participate. We expect the VBID demonstration to provide CMS with insights into future VBID innovations for the MA program.

After the publication of the proposed rule, Congress passed the Bipartisan Budget Act of 2018 (Pub. L. 115–123). Section 50322 of the law expanded supplemental benefits in Section 1852(a)(3) of the Act and also authorized waiver of the uniformity requirements to permit MA plans to offer targeted supplemental benefits for the chronically ill through new provisions, effective in plan year 2020.

Specifically, the Bipartisan Budget Act of 2018 expands supplemental benefits available to chronically ill enrollees by adding a new subparagraph (D) to Section 1852(a)(3). This subparagraph expands supplemental benefits for the chronically ill to include benefits that ''have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee and may not be limited to being primarily health related benefits.'' These additional supplemental benefits will be qualitatively different than the supplemental health care benefits that MA plans may currently offer and may continue to offer to enrollees who are not chronically ill. In addition, it provides authority for the waiver of uniformity requirements ''only with respect to supplemental benefits provided to a chronically ill enrollee.''

We have evaluated how this new authority for the Secretary to waive uniformity requirements relates to our concurrent reinterpretation of uniformity requirements. We believe that a waiver of uniformity requirements was authorized in this new provision to allow for the delivery of different, non-uniform benefits to a subset of enrollees that meet a specific definition: Chronically ill enrollee.[19] We do not believe that our reinterpretation, which also allows for targeted benefits based on the disease state or health status, can only be accomplished through a waiver of uniformity requirements.

We believe that the waiver authorized under the Bipartisan Budget Act is necessary in order to allow MA plans the flexibility to offer chronically ill enrollees supplemental benefits that are not uniform across the entire population of the chronically ill. The Bipartisan Budget Act states that supplemental benefits must ''have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.'' This means that MA plans do not have to offer uniform supplemental benefits to all chronically ill enrollees, and instead, may vary supplemental benefits offered to the chronically ill as it relates to the *individual enrollee's* specific medical condition and needs. In other words, a supplemental benefit adopted under the new statutory provision may not be provided to a chronically ill enrollee if that benefit does not have a reasonable likelihood of improving that enrollee's health condition. Therefore, we have determined that the waiver of uniformity requirements and the enactment of section 1852(a)(3)(D) of the Act does not limit our authority to interpret sections 1851(d) and 1854(c) of the Act as permitting uniform benefits to include specific services targeted for groups of similarly situated specific enrollees based on medical criteria.

Our reinterpretation of uniformity requirements maintains the spirit of the MA regulations at § 422.100(d), which aims for equal treatment across all similarly situated enrollees. A specific health status or disease state—or meeting a specific group of medical criteria—is merely a means of ''grouping'' similarly situated enrollees for equal access to and treatment in connection with coverage of benefits.

[18] 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, section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

[19] The Bipartisan Budget Act specifically identifies the chronically ill as individuals with (1) one or more morbidities that is life threatening and limits overall function (2) has a high risk of hospitalization and adverse outcomes, and (3) requires intensive care coordination.

All enrollees in that group must have access to the same targeted benefits. The new expansion of supplemental benefits for the chronically ill breaks that construct because the needs of one chronically enrollee may be very different from those of another within the same health status or disease state. As such, a waiver was authorized to provide for differences in supplemental benefits across chronically ill enrollees in order for MA organization to craft specific supplemental benefit offerings for each vulnerable plan member so that individual needs are met.

Further, our reinterpretation of uniformity requirements is compatible with the new legislation in Bipartisan Budget Act. Beginning in 2020, MA plans may offer three forms of supplemental benefits: ''standard'' supplemental benefits offered to all enrollees; ''targeted'' supplemental benefits offered to qualifying enrollees by health status or disease state; and ''chronic'' supplemental benefits offered to the chronically ill. The first two (standard and targeted) will be allowable in 2019. Only ''chronic'' supplemental benefits will be evaluated under the new expansive definition in the Bipartisan Budget Act and be eligible for a waiver of the uniformity requirements. Standard and targeted supplemental benefits will be evaluated under our existing interpretation of whether the benefit is ''primarily health related.'' It is possible that an enrollee qualifies for a ''targeted'' supplemental benefits as well as ''chronic'' supplemental benefits. In that circumstance, the MA plan must provide the targeted supplemental benefits as long as the enrollee establishes the required health status or disease state and the benefits are medically appropriate. However, the MA plan must only provide ''chronic'' supplemental benefits if the benefit has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.

Based on these differences, it will be important for MA plans to identify in their bids and in their Evidence of Coverage documents which supplemental benefits are offered as ''standard'', ''targeted'', or ''chronic'' benefits. CMS will evaluate the acceptability of the supplemental benefit offering based on this designation and the standards identified in section 1852(a)(3) of the Act. We believe that both the new uniformity interpretation and the new statutory provision will succeed in increasing MA plans' flexibility and plan options and ultimately allow for better health outcomes.

We received the following comments, and our response follows:

Comment: A number of commenters supported CMS' implementation of this reinterpretation. These commenters stated that their ability to lower cost sharing will help beneficiaries seek high value and effective care.

Response: We thank commentators for their support of this reinterpretation.

Comment: Commenters suggested that CMS include regulatory text in the final rule that confirms that the flexibility that will be allowed in the MA uniformity requirements.

Response: In this final rule, we are reinterpreting existing statutory and regulatory authority to allow MA organizations the ability to reduce cost sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer different lower deductibles for enrollees that meet specific medical criteria. Thus, it is unnecessary to provide additional regulation language.

Comment: A number of commenters requested that CMS provide additional sub-regulatory guidance surrounding this policy.

Response: We will provide additional guidance and update all corresponding guidance documents (that is, bid guidance and operational guidance) to reflect the new interpretation. This guidance will be available before contract year 2019 bids are due.

Comment: We received a number of comments asking that CMS issue sub-regulatory guidance with examples for permissible and impermissible actions, as well as examples of what would be considered discriminatory. In addition, others suggested that CMS specify the medical criteria that MA plans should use to determine enrollee eligibility as well as clear guidelines for eligible tailored supplemental benefits and/or reduced cost sharing.

Response: CMS will provide additional operational guidance before CY 2019 bids are due.

Comment: A commenter recommended that CMS open its implementing guidance to public comment prior to issuance.

Response: We appreciate this comment. We will not be able to solicit industry comment in time for CY 2019 bids. However, we will take this suggestion under consideration as we develop future guidance and will reach out for input as needed.

Comment: A number of commenters requested that CMS to provide certain technical clarifications. For instance, commenters questioned whether the plan-level deductible could be eliminated, or just reduced, and if lower cost sharing means a zero-dollar copay.

Response: Yes, under this reinterpretation, a plan may reduce or eliminate a deductible, co-pay, or cost sharing for Part C services. We remind all organizations that this is reinterpretation is about MA benefits only and does not permit changes in Part D cost sharing or Part D benefits, which must be consistent with Part D applicable law and CMS policy. In addition, additional operational guidance will be provided before CY 2019 bids are due.

Comment: We also received comments asking CMS to clarify whether a plan may reduce or eliminate certain cost sharing based on participation in a disease management program.

Response: Yes, under this reinterpretation, a plan may restrict cost sharing reductions based on participation in a disease management program so long as there is equal access to the disease management program based on objective criteria related to a health status or disease state.

Comment: We received comments asking CMS to clarify whether a plan may offer different co-pays to a subset of the population for some visits, but not all.

Response: We appreciate the comment and are still considering how our new interpretation of the uniformity requirement would apply to such situations. We intend to provide clarifying guidance on this issue through HPMS memoranda and updates to the Medicare Managed Care Manual.

Comment: A commenter requested that CMS clarify whether reduced cost sharing can be extended to premiums.

Response: No, this flexibility does not extend to premiums; beneficiaries in the same plan must have the same premium. Allowing different premiums would violate section 1854(c) of the Act, which explicitly requires uniform premiums. Our reinterpretation of section 1854(c), section 1852(d) regarding access to benefits for all enrollees, and the regulations implementing those statutes permits only reductions in Part C cost sharing and deductibles, and in targeting Part C supplemental benefits. As noted elsewhere, these specific benefits must be tied to health status or disease state and must be applied to health care services that are medically related to each disease condition. Additionally, targeted benefits and reduced cost sharing must be offered 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).

Comment: We received a comment asking CMS to confirm if MA plans may choose to apply these flexibilities to out-of-network benefits.

Response: CMS will provide additional guidance and update all corresponding guidance documents to reflect the new interpretation. This guidance will be available before CY 2019 bids are due.

Comment: We received comments requesting that CMS encourage plans to offer such flexibilities to beneficiaries with specific conditions (for example, dementia), stating that such flexibilities could help the ongoing treatment.

Response: In the proposed rule, we stated that an MA plan may offer reduced cost sharing, deductibles, and or targeted supplemental benefits to enrollees diagnosed with specific diseases. 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. We do not have the authority to restrict or mandate which diagnoses or health conditions a plan chooses for this flexibility. Plans may determine which diagnoses or health conditions they choose to offer these flexibilities. CMS encourages plans to consider the population of their plan when making these decisions.

Comment: We received a number of comments requesting that CMS allow reduced cost sharing and targeting supplemental benefits based on conditions unrelated to medical conditions, such as living situation and income. A commenter suggested CMS allow plans to reduced premiums for beneficiaries who sign up for automated premium payments.

Response: The revised uniformity interpretation does not allow plans to reduce cost sharing and offer targeted supplemental benefits based on criteria unrelated to a diagnosis or health condition. We have determined that a plan may only provide access to targeted supplemental benefits (or specific cost sharing for certain services or items) based on health status or disease state. In identifying eligible enrollees, the MA plan must use medical criteria that are objective and measurable. In addition, 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 diagnosis or health condition. Note that, effective CY 2020, the Bipartisan Budget Act of 2018 calls for a new category of supplemental benefits to be made available to chronically ill enrollees that are not limited to being primarily health related. Because the new benefits will not be limited to the primarily health related standard, it is possible for certain offerings to address issues beyond a specific medical condition, such as social supports. However, the basis for offering the new benefits will be based solely on an enrollees' qualification as ''chronically ill'' and may not be based on conditions unrelated to medical conditions, such as living situation and income.

Comment: We received a comment urging CMS to include an affirmation that C–SNPs would automatically be permitted to adjust benefits and cost sharing based on the eligibility groupings that CMS has approved for each C–SNP.

Response: CMS will update sub-regulatory guidance to clarify the impact of both this reinterpretation and the Bipartisan Budget Act on SNP policy.

Comment: A commenter suggested that CMS should also provide clarification on how the additional benefit flexibility for highly integrated dual eligible special needs plans (D–SNPs), as outlined in Chapter 16b of the Medicare Managed Care Manual, is retained and/or modified under these provisions.

Response: Chapter 16b and any corresponding guidance will be updated to clarify any impact this reinterpretation has on D–SNP policy.

Comment: A commenter asked CMS to allow plans to provide certain supplemental benefits only to fully integrated D–SNP (FIDE SNP) enrollees who do not meet nursing home level of care requirements that would otherwise make them eligible for home and community-based services under an Elderly Waiver.

Response: CMS will update sub-regulatory guidance to clarify the impact of both this reinterpretation and the Bipartisan Budget Act on D–SNP policy.

Comment: We received some comments suggesting that CMS allow plans to reduce cost sharing and offer targeting supplemental benefits based on functional status, in addition to a medical condition.

Response: There must be an underlying disease condition that is diagnosed, such as Alzheimer's disease or Parkinson's disease, in order for the plan to reduce cost sharing and offer targeted supplemental benefits. As stated in the proposed rule, 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. Specifically, MA plans offering targeted benefits will be responsible for developing the criteria to identify enrollees who fall within each of the clinical categories selected by an organization. Furthermore, cost sharing reductions and targeted supplemental benefits must be for health care services that are medically related to each disease condition.

Note that, effective CY 2020, the Bipartisan Budget Act of 2018 calls for a new category of supplemental benefits to be made available to chronically ill enrollees that are not limited to being primarily health related. Because the new benefits will not be limited to the primarily health related standard, it is possible for certain offerings to address issues beyond a specific medical condition, such as social supports. However, the basis for offering the new benefits will be based solely on an enrollees' qualification as ''chronically ill'' and may not be based on conditions unrelated to medical conditions, such as living situation and income.

Comment: We received a comment asking CMS to expand our definition of health status or disease state to include ''medically complex patients.''

Response: We have determined that a plan may only provide access to targeted supplemental benefits (or specific cost sharing for certain services or items) based on health status or disease state. In identifying eligible enrollees, the MA plan must use medical criteria that are objective and measurable. MA plans offering targeted benefits are responsible for developing the criteria to identify enrollees who fall within each of the clinical categories selected by an organization.

Comment: We received comments requesting that CMS clarify whether a plan may reduce cost sharing only for a subset of high-quality network providers as long as all members with the same health status or disease state receive the same lower cost sharing for using these providers.

Response: Yes, under this flexibility, a plan may reduce cost sharing for certain high-quality providers to members with a specified health status or disease state. MA plans may identify high-value providers across all Medicare provider types. This can include physicians and practices, hospitals,

skilled-nursing facilities, home health agencies, ambulatory surgical centers, etc.

Comment: Some commenters suggested CMS delay implementation, stating that plans need time to enhance their existing internal tools and systems to accommodate varying benefit structures for different sub-populations within a single plan. Some commented that this may be administratively burdensome to implement, and therefore, may not be equal adoption across all MA organizations.

Response: CMS will permit this flexibility beginning in CY 2019. MA organizations that need additional time to consider whether and how to take advantage of this new flexibility are not required to offer targeted supplemental benefits or reductions in cost sharing or deductibles. We believe it is important to allow plans the flexibility to target and better provide for the needs of their enrollees. Our reinterpretation of the uniformity requirements offers flexibility to MA organizations in designing their coverage and is not a mandate.

Comment: Some commenters recommended that only high-performing plans be permitted to provide flexibility in the MA Uniformity Requirements.

Response: CMS appreciates these comments and believes this flexibility will help enrollees seek higher value care. Therefore, CMS will permit all plans to use this flexibility beginning in CY 2019. CMS appreciates these comments and believes this flexibility will help enrollees seek higher value care. This flexibility is not a change to the regulation; it is a reinterpretation of an existing regulation. Therefore, all MAOs must comply with uniformity requirements regardless of individual plan performance. CMS will permit all plans to use this flexibility beginning in CY 2019.

Comment: We received a number of comments suggesting that this reinterpretation is premature. Some commenters suggested that CMS wait until the VBID demonstration has concluded.

Response: The existing VBID demonstration will continue. Information regarding this demonstration can be found at *https://innovation.cms.gov/initiatives/vbid/.* While we have adopted features of the VBID demonstration, the VBID demonstration and the new uniformity flexibilities are distinct. CMS will permit this flexibility beginning in CY 2019, as we believe it is important to allow plans the flexibility to target and better provide for the needs of their enrollees. We hope that the VBID demonstration will provide CMS with insights into future innovations for the MA program.

Comment: Some commenters suggested that CMS take a measured approach by setting initial limits on the number of targeted conditions and tailored benefit packages that an MA plan can offer.

Response: The existing uniformity flexibility regulatory authority does not allow CMS to limit the number of targeted conditions without additional rulemaking.

Comment: Some suggested that CMS adopt the oversight requirements in the VBID demonstration in allowing plans to use this flexibility under the new reinterpretation.

Response: Currently, the VBID demonstration has a number of oversight requirements, including some marketing restrictions, monitoring to ensure compliance with demonstration rules, data reporting to help CMS evaluate outcomes, and restricting low performing plans from participation. CMS has no plans to adopt these additional demonstration requirements. First, CMS has a robust compliance and auditing program to oversee MA plans and all benefit packages are reviewed by CMS. Therefore, we do not believe any additional monitoring or compliance is needed. Second, MA rules require that this benefit be available in marketing materials and transparent to enrollees. Therefore, we cannot restrict marketing this benefit. Third, we believe we do not need to introduce any additional uniformity reporting as the VBID reporting is designed to aide demonstration evaluation. However, CMS will monitor the implementation of this flexibility and make appropriate adjustments as needed.

Comment: Commenters asked that CMS clarify how this flexibility impacts the VBID demonstration.

Response: The existing VBID demonstration will continue. We note that Bipartisan Budget Act of 2018 expands the testing authority under section 1115A(b) to all 50 states. This flexibility will not impact the VBID demonstration, which is separate from this rulemaking. The new flexibilities discussed here will have no impact on current VBID operations. Information regarding this demonstration can be found at *https://innovation.cms.gov/initiatives/vbid/.* The VBID demonstration will provide CMS with insights into future innovations for the MA program.

Comment: A commenter asked if CMS planned to implement reporting requirements related to this flexibility, noting that such requirements are in the VBID demonstration.

Response: CMS has no plans to add any reporting requirements related to uniformity flexibility at this time. We do note that MA plans must explain the targeted supplemental benefits and reductions in cost sharing and deductibles in their bids (OMB 0938–0763), including information necessary for CMS to evaluate if there is any discrimination involved. In addition, MA plans must include descriptions of these benefits in benefit disclosures required under § 422.111.

Comment: We received a number of comments expressing concern that this policy could increase beneficiary confusion, particularly as it relates to marketing materials provided during the annual election process.

Response: To mitigate beneficiary confusion, CMS will require MA plans that take advantage of this flexibility to include benefit flexibility information in their CY 2019 EOC. Also, indication of additional benefits and/or reduced cost sharing for enrollees with certain health conditions will be displayed in Medicare Plan Finder.

Comment: We received several comments asking CMS to clarify whether plans will be permitted to market this flexibility to potential enrollees. Some suggested CMS permit marketing. Others suggested CMS prohibit marketing.

Response: Plans will be allowed to market the additional benefits and/or reduced cost sharing to potential enrollees to give beneficiaries the information necessary to choose the best plan for their health care needs. Plans will be required to follow the same CMS marketing rules for this benefit, as they are required to follow when marketing any other benefit. This includes ensuring that materials are not materially inaccurate or misleading or otherwise make material misrepresentations. Specifically, CMS will require that plans include comprehensive benefit flexibility information in their CY 2019 EOC and indicate the additional benefits and/or reduced cost sharing in Medicare Plan Finder.

Comment: A number of commenters expressed concern that this policy may lead to discrimination. For example, some commenters expressed concern that a plan may balance the reduction of cost sharing for one group by increasing cost sharing for others. Further, some commenters expressed concern that this could lead to lead to ''cherry-picking'' by plans for beneficiaries with low-cost conditions while discriminating against

those with higher-cost chronic conditions.

Response: As noted in the preamble language, the implementation of this flexibility must not violate existing anti-discrimination rules (for example, service category cost sharing and per member per month actuarial equivalence standards communicated by CMS annually in the Call Letter). Organizations that exercise this flexibility must ensure that the cost sharing reductions and targeted supplemental benefits only apply to healthcare services that are medically related to each health status or disease state. CMS will not permit cost sharing reductions across all benefits for an enrollee; cost sharing reductions must be for specific benefits related to a specific health status or disease state. Specifically, plans must not target cost sharing reductions and additional supplemental benefits for a large number of disease conditions, while excluding other higher-cost conditions. CMS will review benefit designs to make sure that targeted disease state(s) and/or clinical condition(s) included in the benefit design are non-discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations.

Comment: A commenter recommended that plan members should have full appeal rights with respect to denial of access to supplemental benefits.

Response: All negative coverage decisions are subject to appeal rights. CMS is reinterpreting existing statutory language at section 1854(c) and 1852(d) of the Act, and the implementing regulation at § 422.100(d), to allow 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. We have reviewed and considered all comments on this clarification and will begin implementing this additional flexibility in CY 2019. In addition, we will provide additional operational guidance before CY 2019 bids are due.

3. Segment Benefits Flexibility

In reviewing section 1854(h) of the 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 so long as the supplemental 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. As county-level areas, these are separate rating setting areas within the plan's service area; no further subdivision is permitted. We are proposed to revise our interpretation of the existing statute and regulations to allow MA plan segments to vary by supplemental benefits in addition to premium and cost sharing, consistent with the MA regulatory requirements defining segments at § 422.262(c)(2).

We received the following comments, and our response follows:

Comment: We received a number of comments supporting the implementation of this reinterpretation.

Response: We thank commentators for their support of this reinterpretation.

Comment: Many commenters requested that CMS clarify if this segmentation can be offered to a sub-set of the network providers.

Response: The MA regulations at § 422.2 define a provider network as occurring at the MA plan level: ''. . . the providers with which an MA organization contracts or makes arrangements to furnish to furnish covered health care services to Medicare enrollees under a MA coordinated care plan or network PFFS plan''. In implementing its network adequacy standard CMS allows for networks at the MA plan level (a provider specific plan) or at the contract level. In addition to being inconsistent with the regulations we believe that allowing networks to be established at the MA plan segment level would introduce an unnecessary level of complexity to the MA program.

Comment: A commenter asked if there are any restrictions to the benefits that may vary and if all supplemental benefits and services are eligible, or is this specific to a set of supplemental benefits?

Response: Plans may vary supplemental benefits by plan segment consistent with the bid submitted for the segment. All basic benefits (that is, Part A and B benefits) must be offered by all MA plans in all segments.

Comment: A commenter asked if the maximum out-of-pocket (MOOP) amount was one of the elements that may vary.

Response: Yes, because the MOOP is an element of the cost-sharing structure of the plan, each segment may have its own MOOP. This flexibility already exists in MA.

Comment: Commenters asked CMS to clarify if in sub-regulatory guidance that plans are allowed to display multiple segments in the Evidence of Coverage (EOC), Summary of Benefits, and other coverage documents.

Response: Plans will be required to follow the same CMS communication, disclosure and marketing guidelines for each segment In addition, as noted in section II.B, CMS will require plans to include comprehensive benefit flexibility information in their CY 2019 (EOC).

Comment: A commenter noted that CMS uses both ''supplemental benefits'' and ''benefits'' in the preamble language and asked CMS explicitly clarify if this new segment benefit flexibility applies only to supplemental benefits and not to the core MA benefit package to which beneficiaries are entitled.

Response: Thank you for the comment. All MA plans must provide basic benefits—meaning Part A and Part B benefits consistent with the cost-sharing limits identified in section 1854(e)(4)(A) [20] and § 422.100(j) and (k)—in all 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. Supplemental benefits include cost-sharing reductions from the actuarial equivalent on average of original Medicare for basic benefits and coverage of additional services and items not covered by original Medicare.

Comment: Some commenters expressed concern that CMS is moving too quickly in implementing this reinterpretation and that such flexibility should be tested on a small scale first.

Response: We believe this flexibility will allow plans to better target and provide for the needs of their populations. CMS will monitor the implementation of this flexibility and make appropriate adjustments as needed. In addition, we note that MA organizations are not required to use this flexibility to vary benefits, cost-sharing and premium at the segment level.

[20] Beginning in 2006, an MA plan may reduce cost sharing below the actuarial value specified in section 1854(e)(4)(A) of the Act only as a mandatory supplemental benefit. The actuarial value of the deductibles, coinsurance, and copayments applicable to the basic benefits on average to enrollees in an MA plan must be equal to the actuarial value of the deductibles, coinsurance, and copayments that would be applicable with respect to such benefits on average to individuals enrolled in original Medicare.

Comment: We received many comments related to concern about benefit transparency and that this flexibility to offer segments with varied benefits, cost-sharing, or premiums, may lead to beneficiary confusion. Commenters expressed concern that this flexibility will result in beneficiary confusion regarding the differences between plans, which may create a confusing environment for Medicare beneficiaries trying to make informed decisions when choosing plans.

Response: Plans will be required to follow existing rules governing mandatory disclosures (for example, § 422.111), communications and marketing. In addition, CMS will require plans to include comprehensive benefit flexibility information in their CY 2019 EOC.

In this final rule, CMS is adopting a reinterpretation of section 1854(h) of the Act and §§ 422.100(d)(2) and 422.262 to allow MA organizations the ability 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. We have reviewed comments on our proposal and have considered these comments as we finalize the policy. Plans will be permitted to begin implementing this flexibility in CY 2019.

4. Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100(f)(4) and (5) and 422.101(d))

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 basic benefits (meaning Parts A and B services) that do not exceed the annual limits established by CMS. CMS added § 422.100(f)(4) and (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 stated in the CY 2018 final Call Letter [21] 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.

CMS proposed to amend §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to clarify that CMS may use Medicare FFS data to establish the annual MOOP limits, which have historically been linked to values that approximate the 85th and 95th percentile of out-of-pocket expenditures for beneficiaries in original Medicare. The proposal included that CMS 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. CMS also proposed that it have authority to increase the number of service categories that have higher cost sharing in return for offering a lower (voluntary) MOOP amount. To codify these various authorities, CMS proposed regulation text permitting CMS to set the annual MOOP limits 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. CMS intends to use the annual Call Letter process to communicate its application of the regulation and to transition changes to MOOP limits over time, beginning no earlier than in CY 2020, to avoid disruption to benefit designs and minimize potential beneficiary confusion.

As noted in the proposed rule, CMS discussed in the 2010 rulemaking (75 FR 19709) that it provides greater flexibility in establishing cost sharing for basic benefits to MA plans that adopt a lower, voluntary MOOP limit than is available to plans that adopt the higher, mandatory MOOP limit. The number of beneficiaries with access to a voluntary MOOP limit plan and the proportion of total enrollees in a voluntary MOOP limit plan has decreased significantly from CY 2011 to CY 2017.

Currently, CMS sets the mandatory MOOP amount at 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. CMS sets the voluntary MOOP amount of $3,400 to represent 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 these MOOP limits. Since the MOOP requirements for local and regional MA plans were finalized in regulation, a strict application of the 95th and 85th percentiles would have resulted in MOOP limits for local and regional MA plans fluctuating from year-to-year. To avoid enrollee confusion, allow plans to provide stable benefit packages year over year, and minimize disincentives to the adoption of the lower voluntary MOOP amount because of fluctuations in the amount, CMS has exercised discretion in order to maintain stable MOOP limits from year-to-year that approximate but are not exactly at the 85th and 95th percentile of, beneficiary cost sharing in Medicare FFS.

In the proposed rule, CMS explained that it would want to change the MOOP limits if a consistent pattern of increasing or decreasing costs emerges over time. CMS also summarized how stakeholders have suggested changes to how CMS establishes MOOP limits, including suggestions to use the most appropriate data to inform its decision-making, increase the MOOP limits and the number of service categories that have higher cost sharing in return for a plan offering a lower MOOP limit, and implement different levels of MOOP and service category cost sharing standards to encourage plan offerings with lower MOOP limits.

CMS explained in the proposed rule its goal 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 MA benefit stability over time. Medicare FFS data currently represents the most relevant and available data at this time so the proposal included codifying use of Medicare FFS data in §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3).

CMS also explained in the proposed rule that it wished to have flexibility to

[21] The CY 2018 final Call Letter may be accessed at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

change its existing methodology (of using the 85th and 95th percentiles of projected beneficiary out-of-pocket Medicare FFS spending) in the future. The proposed rule was explicitly based on a policy objective of 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, the proposed amendments to §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) were to incorporate authority to balance these factors to set the MOOPs. The flexibility contemplated by the proposed rule would 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 rule also explained how CMS would, in advance of each plan year, use the annual Call Letter and other guidance documents to explain its application of the regulations and the data used to identify MOOP limits. In addition, CMS committed to transitioning any significant changes adopted using the new proposed authority over time to avoid disruption to benefit designs and minimize potential beneficiary confusion.

In conclusion, CMS proposed to amend §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to clarify that CMS may use Medicare FFS data to establish annual MOOP limits and to adopt a flexible standard for setting the MOOPs. This flexible standard would authorize CMS to increase the voluntary MOOP limit to another percentile level of Medicare FFS beneficiary spending; 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 (as a means to encourage plan offerings with lower MOOP limits).

We received the following comments on this proposal, and our response follows,

Nearly all commenters who provided feedback on this provision (Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100(f)(4) and (5) and 422.101(d))) also provided feedback on the proposal at section II.B.5 (Cost Sharing Limits for Medicare Parts A and B Services (§ 422.100(f)(6))). In this section, we address comments that focus on either this section or both sections, while we address comments that focus on cost sharing limits in section II.B.5.

Comment: The majority of commenters supported this proposal, stating that CMS should primarily use Medicare FFS and MA encounter data to inform its decision-making, and that CMS should consider authorizing more than two levels of MOOP and associated cost sharing standards to encourage plan offerings with lower MOOP limits. Some commenters also made suggestions for levels of MOOP limits and cost sharing service category adjustments that could be especially beneficial.

Response: We thank commenters for their support. 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. This final rule limits that data to the FFS Medicare data, but as other data sources become accessible, relevant, and of the quality necessary to make these determinations, we will engage in rulemaking to change the rule.

Comment: Many commenters expressed concern with MA encounter data being used at this time to establish MOOP levels based on data quality issues. Commenters also encouraged CMS to continue working with MA organizations to improve the validity and reliability of MA encounter data. A commenter suggested CMS consider other data such as of Marketplace Qualified Health Plan review data.

Response: Medicare FFS data is the most relevant and available data at this time. CMS will consider future rulemaking to use MA encounter cost data as well as Medicare FFS data to establish MOOP limits. In determining completeness and accuracy of MA encounter data CMS does consider the various managed care payment arrangements and payment policies that may exist between organizations, as compared to Medicare FFS data (which are based on relatively consistent payment schedules and payment policies). At this time we cannot commit to a timeline for use of MA encounter data or other data sources to establish MOOP limits. As we learn more and are able to establish standards for the completeness and sufficiency of alternate data sources, we will revisit this issue.

Comment: Some commenters noted concern with the specific methodology that CMS would use other than the 85th or 95th percentile of Medicare FFS beneficiary costs to establish MOOP limits and how abrupt changes may impact cost sharing and the levels of MOOP limits. A commenter also stated concern about what level of change to MOOP limits would be considered ''significant'' and necessitate a multi-year transition. Some commenters suggested CMS maintain the current voluntary and mandatory MOOP limits (that is, $3,400 and $6,700) and establish additional MOOP limits between these levels with prorated cost sharing standards to minimize any impact to benefit design and beneficiaries. Some commenters suggested CMS further change the regulatory cost sharing standards for inpatient, skilled nursing facility, emergency care, and other professional services as an incentive for plans to adopt lower MOOP limits, while other commenters cautioned CMS to limit changes to these categories to prevent discrimination.

Response: We appreciate the feedback and will take these suggestions and concerns under consideration. CMS plans to transition changes under the finalized regulations over time, beginning no earlier than CY 2020, to avoid disruption to benefit designs and minimize potential beneficiary confusion. The regulation standard adopted in this final rule for §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) (that the MOOP be set 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) will apply to determinations regarding a transition period from one particular MOOP to another MOOP. We anticipate that sudden and significant shifts in the MOOP would cause sudden changes in premiums, benefits and cost sharing, which are identified under the new regulation text as something to be minimized. Consistent with past practice, CMS will continue to publish the expected changes for the next year and a description of how the regulation standard is applied (that is, the methodology used) in the annual Call Letter prior to bid submission so that MA plans can submit bids consistent with MA standards. CMS has historically provided prior notice and an opportunity to comment on the Call Letter guidance document and does not expect that to change. This will provide MA organizations adequate time to comment and prepare for changes. We anticipate potential changes in MOOP limits or cost sharing based on MA benefit design strategies will be

conveyed through existing enrollee communication materials.

Comment: Several commenters were concerned about CMS's strategy to promote plan adoption of lower MOOP limits by increasing the cost sharing flexibility for those plans. They suggested that allowing this flexibility may result in discriminatory benefit designs as plans may raise cost sharing limits for certain service categories more likely to be utilized by vulnerable beneficiaries, and that such beneficiaries would be especially disadvantaged if they do not reach the lower, voluntary MOOP limit. Some commenters identified concern for specific service categories if their cost sharing limits were raised (for example, inpatient and professional services) and requested CMS be especially thoughtful when considering changes to these categories. A few commenters proposed that CMS consider lowering cost sharing limits for mandatory MOOP plans as another method to encourage adoption of a lower MOOP limit.

Response: CMS agrees that while increasing flexibility for MA plans that voluntarily offer lower MOOP limits can allow for improved plan design, it will be important to make sure that vulnerable patient populations are not discriminated against and that plan designs are not confusing to beneficiaries. Other existing regulations governing cost sharing designs of MA plans—such as the prohibition on discrimination (§ 422.100(f)(2)), requirement that certain services have cost sharing that is no higher than FFS Medicare limits (§ 422.100(j)), and requirement that overall plan cost-sharing for coverage of basic benefits must be actuarially equivalent to the level of cost sharing (deductible, copayments, or coinsurance) charged to beneficiaries under the original Medicare program option (§ 422.254(b)(4))—remain in place and are unchanged by this final rule. CMS will manage the flexibility plans have in setting cost sharing limits to make sure that plan designs are not discriminatory. For example, CMS does not intend to significantly increase cost sharing limits as a percentage of Medicare FFS above current levels for inpatient, primary, and specialty care based on cost sharing standards that CMS publishes in its annual Call Letter. 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.

Comment: Some commenters reported concern with the proposal to amend § 422.100(f)(6) and implement it as described in the proposed rule strategy because of unintended consequences, such as beneficiaries having to choose between plans offering different levels of MOOP limits and variability in cost sharing across services. A commenter suggested that CMS update plan selection resources such as Medicare Plan Finder (MPF) to simplify the plan selection process and assist beneficiaries choose the plan that best fits their unique health care needs.

Response: We agree that cost sharing must not be discriminatory and that it is important to make sure that beneficiaries have adequate information to support their plan enrollment decision-making. Beneficiaries typically make decisions based on plan characteristics that are important to their needs (for example, benefits, cost sharing, MOOP limit, plan premium, and providers) and are not familiar with the complexities associated with bidding guidance and cost sharing standards that plans use to prepare bids. To minimize beneficiary confusion, CMS will continue evaluations and enforcement of the current authority prohibiting plans from misleading beneficiaries in their communication materials. In addition, we will disapprove a plan bid if its proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals. In addition, CMS will continue efforts to improve plan offerings and plan comparison tools and resources (for example, MPF and 1–800–MEDICARE).

Comment: We received a comment that noted the importance of MOOP limits as part of a benefit offering for beneficiary protection and that there are MA plans being marketed that do not have a MOOP for out-of-network services.

Response: CMS notes that all Medicare LPPOs and RPPOs are required to have a combined in- and out-of-network MOOP limit. HMO–POS plans may offer out-of-network benefits as supplemental benefits, but are not required to have these services contribute to the in-network MOOP limit or a combined in- and out-of-network MOOP limit.

We received over 40 comments pertaining to the proposal, with the majority reflecting support to amend §§ 422.100(f)(4) and (5) and 422.101(d)(2) and (3) to clarify that CMS may use Medicare FFS data to establish annual MOOP limits. The majority of comments also supported the regulation amendment to add a standard governing CMS establishment of MOOP limits (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). As noted in the proposed rule, CMS will interpret and implement these amendment to give CMS the authority to change MOOP limits; increase the number of service categories that have higher cost sharing in return for offering lower MOOP limits; and implement more than two levels of MOOP limits. Consistent with past practice, CMS will continue to publish the expected changes for the next year and a description of how the regulation standard is applied in the annual Call Letter prior to bid submission so that MA plans can submit bids consistent with MA standards. CMS plans to transition changes under the finalized regulations over time, beginning no earlier than CY 2020, to avoid disruption to benefit designs and minimize potential beneficiary confusion. After careful consideration of all of the comments we received, we are finalizing the proposal to amend §§ 422.100(f)(4) and (5) and § 422.101(d)(2) and (3) as described with an applicability date of January 1, 2020; this applicability date is consistent with our intent that these new standards apply to cost sharing limits set for plans years after 2019. We are also finalizing minor revisions as follows:

(1) In § 422.100(f)(5), we are finalizing the regulation text without the phrase ''annually determined by CMS using Medicare Fee for Service and to establish appropriate'' in the introductory text; we believe that the regulation text finalized in the paragraph (f)(5)(ii) is sufficiently clear on this point.

(2) In § 422.100(f)(5)(ii), we will finalize the text with ''CMS sets'' in place of ''CMS will set'' for clarity.

5. Cost Sharing Limits for Medicare Parts A and B Services (§ 422.100(f)(6))

In addition to MOOP Limits, MA plan cost sharing for Parts A and B services is subject to additional regulatory requirements and limits in §§ 417.454(e), 422.100(f)(6), and 422.100(j). 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) 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 the cost sharing levels in Medicare Fee-for-Service (FFS); under the statute and the regulations, CMS may add to that list of services. CMS identifies Parts A and B services that are more likely to be used by enrollees in establishing its cost sharing parameters for review and evaluation. 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 or designing 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 proposed to amend § 422.100(f)(6) to clarify that it may use Medicare FFS data to establish appropriate cost sharing limits for certain services that are not discriminatory. In addition, CMS proposed to amend the regulation to reflect that CMS would use FFS data and MA encounter data to inform patient utilization scenarios to help identify MA plan cost sharing standards and thresholds that are not discriminatory. We specifically solicited comment on whether to codify that use of MA encounter data for this purpose in § 422.100(f)(6). In this final rule, we reiterate our intent to use the annual Call Letter process to communicate its application of the regulation and announce our intent to transition changes to cost sharing standards over time, beginning no earlier than in CY 2020, to avoid disruption to benefit designs and minimize potential beneficiary confusion. This proposal is not related to a statutory change.

In the proposed rule, CMS explained that it sought to codify authorization 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. In addition, CMS stated its intent 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. We referenced soliciting comments before finalizing guidance as necessary and appropriate. We expect this process will allow MA organizations to prepare plan bids consistent with parameters that CMS have determined to be non-discriminatory. In addition, and as appropriate, CMS noted that we may also issue guidance using Health Plan Management System (HPMS) memoranda.

CMS noted in the proposed rule that while it 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 (Medicare Managed Care Manual, Chapter 4, Section 50.1 at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS019326.html*). We stated our belief 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 an MA 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 without CMS seriously questioning and reviewing the cost-sharing as discriminatory. CMS does not believe that cost sharing at such high levels can legitimately serve any purpose other than discriminating against the enrollees who need and frequently use those services. Some service categories may identify specific benefits for which a unique copayment will apply, while others are grouped, such as durable medical equipment or outpatient diagnostic and radiological services, which contain a variety of services with different levels of cost which may reasonably have a range of copayments.

As discussed in section II.A/B.4 in the proposed rule and this final rule, CMS uses (and will continue to use under revisions finalized for §§ 422.100 and 422.101) Medicare FFS data in setting limits and thresholds for MA cost sharing for the basic benefits (that is, the Part A and Part B services that MA plans must cover). Medicare FFS data currently represents the most relevant and available data at this time. CMS uses it as well to evaluate the cost sharing for specific services, apply the anti-discrimination standard currently at § 422.100(f)(6), and consider whether to exercise 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 may consider future rulemaking regarding the use of MA encounter data to understand program health care costs and compare to Medicare FFS data in establishing cost sharing limits. Therefore, in addition to proposing to codify use of the FFS data, CMS proposed to include in § 422.100(f)(6) that CMS would use MA encounter data to inform utilization scenarios used to identify discriminatory cost sharing.

CMS explained that its proposal to amend § 422.100(f) would allow use of 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 solicited 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.

We received the following comments on this proposal, and our response follows,

Nearly all commenters who provided feedback on this provision (Cost Sharing Limits for Medicare Parts A and B Services (§ 422.100(f)(6))) also provided feedback on section II.B. 4 (Maximum Out-of-Pocket Limit for Medicare Parts A and B Services (§§ 422.100(f)(4) and (5) and 422.101(d))). In this section, we address commenters that primarily focus on cost sharing limits, while section II.B.4 addresses commenters that focus on MOOP limits or both of these provisions.

Comment: The majority of commenters supported the proposal, stating that CMS should use Medicare FFS data to establish non-discriminatory cost sharing limits as it is currently the most relevant and appropriate information in determining cost sharing standards and thresholds. Commenters also supported providing guidance through the annual Call Letter to achieve CMS's goal of setting and announcing each year presumptively discriminatory levels of cost sharing that will not be considered discriminatory or in violation of other applicable standards.

Response: We thank the commenters for their support. 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. We will also continue to solicit comments before finalizing guidance as necessary and appropriate. Addressing changes in these vehicles that solicit comments provides for more timely and effective changes to protect beneficiaries. We expect this process will allow MA organizations to prepare plan bids consistent with parameters that CMS have determined to be non-discriminatory. In addition, and as appropriate, CMS will announce and issue guidance using HPMS memoranda.

Comment: Many commenters were concerned about the quality of MA encounter data and questioned whether such data should be used to establish cost sharing limits. A few commenters were concerned about using MA encounter data to inform utilization scenarios, as proposed, based on data quality issues. A commenter proposed that CMS consider using a phased in approach over multiple years by blending Medicare FFS and MA encounter data for utilization analyses to address data quality concerns.

Response: We understand the concerns expressed by commenters about using MA encounter data to estimate costs associated with specific health care services. However, we believe MA encounter data can be used to understand utilization trends in establishing the utilization scenarios selected for cost sharing standards (for example, 6-day and 10-day inpatient cost sharing standards). Medicare FFS data currently represents the most relevant and available data at this time but we believe adding MA encounter data to FFS data will improve our utilization scenarios for the MA population. CMS may consider future rulemaking to incorporate MA encounter data with Medicare FFS data to establish cost sharing limits as well. Under this final rule, CMS will use Medicare FFS data along with MA encounter data to help inform utilization scenarios (for example, inpatient lengths of stay) in establishing cost sharing standards as we continue to rely on Medicare FFS data to determine cost sharing dollar limits. We believe the use of MA encounter data to inform utilization scenarios is reasonable as we are using it in conjunction with Medicare FFS data, which mitigates concerns about the completeness and quality of the MA encounter data.

Comment: Several commenters were concerned about CMS's strategy to promote plan adoption of lower MOOP limits by increasing the cost sharing flexibility for those plans. Commenters expressed concern that allowing this flexibility may result in discriminatory benefit designs as plans may raise cost sharing limits for certain service categories more likely to be utilized by vulnerable beneficiaries. Some commenters referenced specific service categories of concern if cost sharing limits were raised (for example, inpatient and professional services) and requested CMS be especially thoughtful when considering changes to these categories.

Response: CMS agrees that while increasing flexibility in cost sharing standards for plans that voluntarily offer lower MOOP limits can allow for improved plan design, it will be important to make sure that vulnerable patient populations are not discriminated against and that plan designs are not confusing to beneficiaries. CMS will manage the flexibility plans have in setting cost sharing limits to make sure that plan designs are not discriminatory.

Comment: Some commenters noted concern with the specific methodology that CMS would use to establish cost sharing limits and how abrupt any changes may be from one contract year to the next. A few commenters requested CMS provide additional guidance on its implementation of the proposed changes to § 422.100(f)(6).

Response: CMS intends to use the annual Call Letter process to communicate its application of the regulation and to transition changes to cost sharing standards over time, beginning no earlier than CY 2020, to avoid disruption to benefit designs and minimize potential beneficiary confusion. Consistent with past practice, CMS will continue to publish annual limits, expected changes for the next year, and a description of how the regulation standard is applied (that is, the methodology used) in the annual Call Letter prior to bid submission so that MA plans can submit bids consistent with CMS standards. This will provide MA organizations adequate time to comment and prepare for changes.

We received over 40 comments pertaining to the proposal, with the majority reflecting support to amend § 422.100(f)(6) to permit use of Medicare FFS data to establish cost sharing limits that will not be considered discriminatory for Part A and B services in MA plans. Commenters also generally supported continued use of the annual Call Letter process for explaining our application and implementation of the revised § 422.100(f)(6). After careful consideration of all the comments, we are finalizing our proposal to use Medicare FFS data along with MA encounter data to inform utilization scenarios (for example, inpatient lengths of stay) and rely on Medicare FFS data to determine cost sharing standards and thresholds. We are finalizing these amendments with an applicability date of January 1, 2020; this applicability date is consistent with our intent that these new standards apply to cost sharing limits set for plans years after 2019. As MA encounter cost data quality improves, CMS will consider future rulemaking to incorporate with Medicare FFS data to establish cost sharing limits. CMS intends to use the annual Call Letter process to communicate its application of the regulation and plans to transition changes under the finalized regulations over time, beginning no earlier than CY 2020, to avoid disruption to benefit designs and minimize potential beneficiary confusion. We are also finalizing a minor revision to paragraph (f)(6) to improve the flow of the text. Specifically, we are separating the last sentence into two sentences divided by a semicolon with minor grammatical edits.

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 (PBP) is substantially different from those of other plans offered by the organization in the same 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. CMS proposed to eliminate the 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 was limited to the meaningful difference provision related to the MA program. A proposal related to the Part D meaningful difference regulation is addressed at section III. II.A.16. of this final rule.

In the proposed rule, CMS explained the goal of eliminating the meaningful difference requirement: 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. Other regulations 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)). Therefore, CMS explained in the proposed rule, MA organizations could be expected to continue designing PBPs that, within a service area, are different from one another with respect to key benefit design characteristics. CMS stated its belief that any potential beneficiary confusion would be minimized when comparing multiple plans offered by the MA 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). In addition, CMS stated its intent to continue the practice of furnishing information to MA organizations about the 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.

As stated in the proposed rule, 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.[22] CMS noted that more sophisticated approaches to consumer engagement and decision-making should help beneficiaries, caregivers, and family members make informed plan choices. CMS cited supporting 1–800–MEDICARE and enhancements to MPF that have improved the customer experience, such as including MA and Part D benefits and a new consumer friendly tool for the CY 2018 Medicare open enrollment period. This new tool assists beneficiaries in choosing a plan that meets their unique health and financial needs based on a set of 10 quick questions.

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 (OOPC) and other factors currently integrated in the evaluation's methodology. 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.* 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, LPPO), SNP sub-type, and inclusion of Part D coverage are considered meaningful differences, which align with beneficiary decision-making. As noted in the proposed rule, premiums, risk scores, actual plan utilization, and enrollment are not included in the evaluation because these factors will introduce risk selection, costs, and margin into the evaluation, resulting in a negation of the evaluation's objectivity. CMS clarified that the 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.

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 status or disease state 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 the PBP.

CMS restated its commitment to ensuring transparency in plan offerings so that beneficiaries can make informed decisions about their health care plan choices while also noting the importance of encouraging competition, innovation, and providing access to affordable health care approaches that address individual needs. CMS recognized that 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, CMS noted the meaningful difference evaluation will 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. CMS noted the challenges with trying to capture differences in provider network, more tailored benefit and cost sharing designs, or other innovations. In addition, we are concerned that plans may be forced to potentially develop more complicated and confusing benefit designs to achieve differences between plans.

CMS recognized 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 stated concern that the meaningful difference requirement

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

results in organizations potentially reducing the value of benefit offerings. These are unintended consequences of the existing meaningful difference evaluation and may restrict innovative benefit designs that address individual beneficiary needs and affordability.

As discussed in the proposed rule, 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. Annual guidance and model materials are provided to MA organizations to assist them in providing resources, such as the plan's Annual Notice of Change (ANOC) and Evidence of Coverage (EOC), which contain valuable information for the enrollee to evaluate and select the best plan for their needs. 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 noted that MA organizations may be able to offer a portfolio of plan options with clear differences between benefits, providers, and premiums which will 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 also noted additional beneficiary protections including: Plans are required to not mislead beneficiaries in communication materials; CMS may disapprove a bid if CMS finds that a plan's proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals; and CMS may terminate 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)). For these reasons, CMS proposed to remove §§ 422.254(a)(4) and 422.256(b)(4) to eliminate the meaningful difference requirement for MA bid submissions. CMS also solicited comments and suggestions on making sure beneficiaries have access to innovative plans that meet their unique needs.

We received the following comments on this proposal, and our response follows:

Comment: Some commenters fully supported the proposal, stating that eliminating the meaningful difference requirement will support plan innovation and provide Medicare beneficiaries access to plans that meet their unique needs. Several commenters noted that eliminating the current meaningful difference requirement that established arbitrary differences between plans will allow MA organizations to put the beneficiary at the center of benefit design. This will result in MA organizations being able to offer a portfolio of plan options with clear differences between benefits, providers, and premiums that are easily understood by beneficiaries. Commenters also noted that CMS's efforts to support beneficiaries make informed choices by maintaining existing requirements for marketing materials and nondiscriminatory benefit designs will sufficiently safeguard beneficiaries if the meaningful difference requirement is eliminated.

Response: We thank the commenters for supporting the proposal. We believe this proposed change could result in more innovative products that are more competitive and market-driven within a less restrictive regulatory framework.

Comment: A commenter supported the proposal and questioned how the agency will ensure potential savings from eliminating the meaningful difference requirement will be passed on to beneficiaries in the form of lower premiums, while also maintaining coverage of essential and appropriate benefits.

Response: CMS expects that the elimination of the meaningful difference evaluation, in conjunction with the expansion of benefit flexibilities, will allow organizations to provide benefit offerings that satisfy the unique needs of beneficiaries, increase enrollee satisfaction, reduce overall plan expenditures, and result in more affordable plans. All MA plans must provide enrollees in that plan with all Parts A and B services so beneficiaries are assured a minimum package of covered services; many plans also provide supplemental benefits, at the MA organization's option. While CMS reviews and approves MA PBPs and premiums for actuarial soundness and satisfying CMS standards, we do not have the legal authority to dictate MA organizations' business decisions to establish premiums at a specific level. MA organizations can adjust their plan offerings to reflect annual changes in medical costs and payment rates and may do so in a variety of ways, such as adjustments to cost sharing amounts, adding or subtracting supplemental benefits, or making changes to the monthly premium(s). Plans face competition in their defined market areas and must also comply with Part C standards related to changes in benefits, cost sharing, and premium. In addition, all beneficiaries are made aware of plan changes including premium for the upcoming year and can choose to switch plans during the annual election period.

Comment: Several commenters disagreed with the proposal to eliminate the meaningful difference requirement because they believe it is a beneficiary protection. Reasons for maintaining the meaningful difference requirement included: Concerns about the ability of Medicare beneficiaries to make the nuanced comparisons among various plan types and benefit packages, limited resources to assist beneficiaries with complicated decisions, expectation that older people and people with disabilities do not use technology to the same extent as non-Medicare beneficiary populations (thereby limiting the usefulness of MPF, a primary means of CMS assistance to beneficiaries in comparing plans), and unknown resource availability to support call centers to assist beneficiaries who do not have access to or use the internet. Several comments were concerned that narrower networks could be potentially discriminatory or a means of limiting benefit access for enrollees. Another commenter had concerns that eliminating the meaningful difference requirement may encourage plan risk segmentation based on benefit design but did not include any rationale for their concern. Some commenters referenced plan selection research, such as National Institutes of Health, and Brookings studies,[23] noting Consumers Union findings that indicate beneficiaries face challenges in navigating the Medicare market due to not using available tools (such as MPF),

[23] Bertko J, Ginsburg PB, Lieberman S, Trish E, Antos J. Medicare Advantage: Better information tools, better beneficiary choices, better competition. U.S.C.-Brookings Schaeffer Initiative for Health Policy. Nov. 2017. Retrieved from *https://www.brookings.edu/wp-content/uploads/2017/11/ma-consumer-reforms.pdf.*

Cognitive Functioning and Choice between Traditional Medicare and Medicare Advantage; J. Michael McWilliams, Christopher C. Afendulis, Thomas G. McGuire, and Bruce E. Landon; Health Affairs, September 2011 (*http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3513347/*).

The Evidence is Clear: Too Many Health Insurance Choices Can Impair, Not Help Consumer Decision Making; Lynn Quincy and Julie Silas; Consumers Union, November 2012 (*http://consumersunion.org/pdf/Too_Much_Choice_Nov_2012.pdf*).

confusion when using MPF, and high rates of individuals not making an active health plan selection because of choice anxiety. Several commenters also noted their general concern that the net effect of eliminating the meaningful difference requirement and other proposals pursued in the proposed rule may have unintended consequences regarding beneficiary confusion that will negate the value of market innovation, especially for people with lower income and educational levels.

Response: We acknowledge the commenters' concerns about beneficiary confusion. We believe that the tools CMS provides for beneficiaries to make decisions and our enforcement of communication and marketing requirements (such as the prohibition on misleading beneficiaries) mitigate and address these concerns. Under our existing authority at § 422.110, CMS will monitor to ensure organizations are not engaging in activities that are discriminatory or potentially misleading or confusing to Medicare beneficiaries. We note that CMS has authority, clarified in this final rule, to review marketing (review in advance of use) and communication (review after use) materials to ensure compliance with MA program requirements. CMS will conduct outreach with organizations that appear to offer a large number of similar plans in the same county following bid submissions and communicate any general concerns through the annual Call Letter process and/or HPMS memoranda. CMS network adequacy requirements apply to all Part C provider networks to ensure adequate network provider access for enrollees. With regard to concerns about risk segmentation, CMS believes risk segmentation is not beneficial to MA organizations or enrollees who want to maintain stable benefits and premiums, but if an organization wanted to purposely create risk segmentation within its plan offerings, it could do so with or without the meaningful difference evaluation. The agency will continue to monitor and address potential concerns as part of our existing authority to review and approve bids. We expect eliminating the meaningful difference requirement will improve plan choices for beneficiaries by driving provider network and benefit package innovation and affordable health care coverage. MA organizations also consider beneficiary choice anxiety when developing their own portfolio of plan offerings, so that sales and broker personnel and marketing materials can highlight key differences between plan offerings and support informed choice. Beneficiaries also rely on established health plan characteristics to guide their decision making, such as preferences for plan type (for example, HMO or PPO), providers (for example, established primary care physician being in network), presence of Part D benefits, cost sharing, plan premium, and brand.[24] In addition, dually eligible beneficiaries may choose D–SNPs that provide more standardized plan options with little or no cost sharing responsibilities instead of a non-D–SNP plan without these benefits. This allows beneficiaries to reduce the number of health plan options of interest (for example, focus on MA organizations offering SNP options) and simplify the process to choose their health plan. After taking into account specific preferences, such as plan type, beneficiaries may choose from a limited subset of available plan options with the assistance of plan communication materials and existing CMS resources such as MPF and 1–800–MEDICARE. In addition, CMS will continue to prohibit plans from misleading beneficiaries in their communication materials, disapprove a plan's bid if its proposed benefit design substantially discourages enrollment in that plan by certain Medicare-eligible individuals, and allow CMS to terminate a plan that fails to attract a sufficient number of enrollees over a sustained period of time so that any potential beneficiary confusion is minimized when comparing multiple plans offered by the organization (§§ 422.100(f)(2), 422.510(a)(4)(xiv), 422.2264, and 422.2260(e)).

Comment: Several commenters had concern that eliminating the meaningful difference requirement would promote ''gaming'' among plan sponsors (for example, offering a large number of plan options in a service area) which may challenge or complicate beneficiary decision-making because of the potential increase in plan options; these commenters questioned if elimination of the requirement provides enough benefits to outweigh the risks. A few commenters questioned whether there is evidence that innovation is or will be inhibited by the meaningful difference evaluation. A commenter recommended CMS formally survey MA organizations about the impact of meaningful difference standards as well as survey beneficiaries regarding their satisfaction with MA plan offerings. Some commenters suggested CMS first pursue adjusting the meaningful difference requirement before eliminating it by either waiving the requirement if MA organizations can provide alternative evidence to CMS that their plan offerings are substantively different, significantly reducing the current $20 meaningful difference threshold between similar plans to provide more flexibility, accounting for differences in premiums, and providing broader consideration of provider network differences in the evaluation. A commenter requested that instead of eliminating the meaningful difference requirement, CMS revise the evaluation and require plan actuaries to attest to actuarial value differences among plans using a utilization profile that is representative of the plan population. A few comments stated that if CMS was to place a limit on the number of plans an organization could offer that CMS take into consideration the appropriate level within an organizational structure to establish the limit (for example, parent, legal entity, or contract organization), mergers and acquisitions, and that CMS treat full-provider networks separately from more limited provider networks.

Response: As discussed in the proposed rule, CMS is concerned the meaningful difference requirement may force MA organizations to design benefit packages to meet CMS standards rather than address beneficiary needs. CMS has been made aware of these concerns through comments submitted in response to recent Call Letters and the Request for Information (April 2017), that highlighted how MA organizations may be forced to meet arbitrary limits between their plans to comply with CMS meaningful difference standards. Based on this information CMS does not believe formal surveys are necessary to determine the unintended consequences of the meaningful difference evaluation. Our proposal to eliminate the meaningful difference requirement aimed to improve competition, innovation, available benefit offerings, and provide beneficiaries with

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

Atherly, A., Dowd, B., Feldman, R. The Effect of Benefits, Premiums, and Health Risk on Health Plan Choice in the Medicare Program. Health Services Research. 2004. Retrieved from *https://onlinelibrary.wiley.com/doi/full/10.1111/j.1475-6773.2004.00261.x.*

McCormack LA, Garfinkel SA, Hibbard JH, Norton EC, Bayen UJ. Health plan decision making with new medicare information materials. Health Services Research. 2001;36(3):531–554.

Abaluck, Jason, and Jonathan Gruber. 2011. ''Choice Inconsistencies among the Elderly: Evidence from Plan Choice in the Medicare Part D Program.'' American Economic Review, 101(4): 1180–1210.

Uhrig, J., Harris-Kojetin, L., Bann, C., Kuo, T. Do Content and Format Affect Older Consumers' Use of Comparative Information in a Medicare Health Plan Choice? Results from a Controlled Experiment. 2006. Retrieved from *http://journals.sagepub.com/doi/pdf/10.1177/1077558706293636.*

affordable plans that are tailored for their unique health care needs and financial situation. The number of MA plan bids may increase because of a variety of factors, that are not related to the elimination of the meaningful difference requirement, 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 plan choice for beneficiaries by driving provider network and benefit package innovation and affordable health care coverage. CMS believes that eliminating the current meaningful difference requirement will allow MA organizations to put the beneficiary at the center of benefit design as MA organizations will not be pressured to make benefit changes to comply with an arbitrary requirement that may ultimately result in higher premiums and/or cost sharing for beneficiaries. This will result in MA organizations being able to offer a portfolio of plan options with clear differences between benefits, providers, and premiums that are more easily understood by beneficiaries. In order to capture differences in provider networks, 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 and would require investment of greater administrative resources for MA organizations and CMS, while not producing results that are useful to beneficiaries. CMS expects that eliminating the meaningful difference requirement will improve the plan options available for beneficiaries. As it is unknown how many organizations will choose to add plan options as a result of this provision, we are unable to estimate the impact to beneficiaries should this lead to more competition. CMS expects increased competition will lead to potentially lower premiums and/or cost-sharing for Medicare beneficiaries. CMS does not anticipate beneficiaries will need additional time to compare differences between plans related to the elimination of the meaningful difference requirement. This particular change is expected to help MA organizations differentiate plan offerings more effectively so that beneficiaries can make decisions more efficiently. We believe that the tools and information CMS provides for beneficiaries to make decisions (for example, Medicare Plan Finder, Medicare and You Handbook, 1–800–MEDICARE), in addition to our enforcement of communication and marketing requirements, aim to mitigate any potential choice overload. We are not pursuing adjustments to the meaningful difference requirement (for example, waivers) because the use of a waiver or justification process introduces subjectivity into the benefit review and we believe the goal of increasing flexibility is better served by eliminating the requirement. With this final rule, organizations will have more flexibility to design MA plans in a manner that is more focused on beneficiary needs. Finally, we do not intend to establish a specific number of plans that any one organization could offer. The MA program has a different market structure than standalone PDPs, that is, PDPs serve entire regions while MA organizations may serve different service areas based on county. The same MA organization may have multiple plans but those plans may only overlap in a limited number of counties. Depending on the market structure (for example, makeup of providers and consumers) it may be helpful for MA organizations to provide offerings from multiple plan types so that beneficiaries have valuable options. In addition, it may be helpful for MA organizations to offer SNP plans to meet the needs of different beneficiary populations. CMS will monitor and address potential concerns as part of our existing authority to review and approve bids.

Comment: A few commenters requested that CMS conduct an evaluation to estimate whether eliminating the meaningful difference requirement would create choice anxiety among beneficiaries and its potential effect on future enrollment. A few commenters also questioned if CMS had presented sufficient reasons to justify eliminating the meaningful difference requirement.

Response: In the proposed rule (82 FR 56363 through 56365) and in the responses in this section, we have discussed our supporting rationale to eliminate the meaningful difference requirement. After carefully considering the commenters' concerns, we believe our proposal will result in improved options—both in terms of innovative plans and affordability—for beneficiaries and that existing safeguards, along with beneficiary decision making education and tools, will be successful in managing beneficiary choice anxiety concerns.

Comment: A commenter requested clarification on how this proposal, in conjunction with others, affects expectations for state Medicaid agencies and SNPs.

Response: CMS does not anticipate that eliminating the meaningful difference requirement, in conjunction with other proposals, would affect state Medicaid agencies. To the extent that clarification of state Medicaid or SNP issues is required as a result of the regulation changes in this final rule, CMS would communicate this guidance through the annual Call Letter process, HPMS memoranda, and Medicare Managed Care Manual updates. In addition, the CMS Medicare-Medicaid Coordination Office (MMCO) may provide assistance for states and D–SNPs. The Center for Medicare is working collaboratively with MMCO in the regulations drafting process and implementation steps related to this rule. Separately, MMCO is re-examining the potential need for resources related to implementing the provisions of section 50311 of the Bipartisan Budget Act of 2018.

Comment: Several commenters requested that CMS issue guidance regarding the distinctions in plan options that would be permissible and operational guidance on the implementation of this proposal in the annual Call Letter to support CY 2019 bid development and submission.

Response: MA organizations can use the information contained in this final rule about the elimination of the meaningful difference requirements and CMS expectations to prepare CY 2019 bid submissions. CMS intends to continue using the annual Call Letter process in future years for releasing draft versions of bid-related guidance for comment and to provide additional guidance regarding general concerns we may have with organizations' portfolio of plan offerings. In addition, we will provide information about potential concerns regarding activities that are potentially discriminatory or potentially misleading or confusing to Medicare beneficiaries.

Comment: Several commenters noted concern about resources to support beneficiaries choose a health plan and navigate their benefits (for example, 1–800–MEDICARE, MPF, SHIP counselors, and the Medicare Ombudsman program) and supported improvements to MPF that allow beneficiaries to more easily narrow down their choices based on personalized information (for example, more filters and pre-selection criteria to identify important plan characteristics that limit plan options to evaluate). Several commenters offered to provide

input to MPF changes, while others encouraged CMS to establish a group of representatives (for example, MA organizations, advocacy organizations, provider groups, and other stakeholders) to help develop MPF improvements, health plan decision-making education materials, and other information to improve the health plan selection process and overall experience for beneficiaries. Some comments indicated that changes to the MPF should occur prior to eliminating the meaningful difference evaluation. Commenters also had an interest in CMS establishing communications and marketing guidance so that MA organizations can describe how an organization's plan offerings are different in situations where multiple plan options are compared (for example, providing additional information in the Summary of Benefits). In addition, other comments noted the need for CMS to solicit input from multiple stakeholders to improve communication materials (for example, ANOC and EOC).

Response: These recommendations are not strictly within the scope of this final rule provision. We do however appreciate the many comments and suggestions related to improving the health plan decision making process and overall experience for beneficiaries. We agree with the need for clear and complete information and intend to continue improving the MPF to make it as user friendly as possible. We are sharing these comments and suggestions with the CMS Office of Communications. Additionally, we would encourage third party organizations that support beneficiaries in their decision-making to take advantage of existing resources 1–800–MEDICARE, MPF, SHIP counselors, and the Medicare Ombudsman program. CMS will take commenter suggestions under careful consideration and will continue to include stakeholders and beneficiaries in the planning, preparation, testing, and execution process for MPF; CMS subjects some model enrollee communication materials to periodic consumer testing and also considers comments submitted from MA organizations and stakeholders on an ongoing basis. In addition, CMS will look for ways to incorporate the suggestions from commenters about how the health plan selection process can be simplified for beneficiaries through existing and possibly new Medicare materials. MA organizations have and are encouraged to use existing flexibilities to highlight differences between their own plan offerings for beneficiaries in marketing and communications materials (for example, summary of benefits).

We received over 65 comments pertaining to the proposal; the great majority reflected mixed support for eliminating the meaningful difference requirement. After careful consideration of all of the comments we received, we are finalizing the elimination of the meaningful difference requirement from §§ 422.254 and 422.256 as proposed. Under our existing authority at § 422.2268, CMS will monitor to ensure organizations are not engaging in activities that are discriminatory or potentially misleading or confusing to Medicare beneficiaries. CMS will communicate and work with organizations that appear to offer a large number of similar plans in the same county, raising and discussing with such MA organizations any concerns. CMS plan checks would include plans offered under each contract, unique plan type, and county. Plan types currently include: (1) HMO and HMO–POS not offering all Parts A and B services out-of-network, (2) HMO POS offering all Parts A and B services out-of-network, (3) LPPO, (4) RPPO, (5) PFFS, and (6) unique SNP types (that is, different chronic diseases, institutional categories, and dual-eligible sub-types). From a beneficiary's perspective, CMS would expect plans within the same contract, plan type, and county to be distinguishable by beneficiaries using such factors as the inclusion or exclusion of Part D coverage, provider network, plan premium, Part B premium buy-down, estimated out-of-pocket costs, and benefit design so that MA organizations can market their plans clearly. CMS intends to issue guidance through the annual Call Letter process and HPMS memoranda to help organizations design plan options that avoid potential beneficiary confusion prior to bid submission.

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

In addition to general authority for the Secretary to establish the process through which MA plan election is made by Medicare beneficiaries, section 1851(c)(3)(A)(ii) of the Act authorizes the Secretary to implement default enrollment rules for the Medicare Advantage (MA) program. This default enrollment is in addition to the statutory direction that beneficiaries who do not elect an MA plan are defaulted to original (fee-for-service) Medicare. Section 1851(c)(3)(A)(ii) 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 proposed new regulation text to establish limits and requirements for these types of default enrollments to address our administrative experience with and concerns raised about these types of default enrollments under our existing practice. Based on our experience with the seamless conversion process thus far, we proposed to codify at § 422.66(c)(2) requirements for seamless default enrollments upon initial eligibility for Medicare. As proposed, such default enrollments would be into dual eligible special needs plans (D–SNPs) and would be subject to five substantive conditions: (1) The state has approved use of this default enrollment process and provided Medicare eligibility information to the MA organization; (2) CMS has approved the MA organization to use the default enrollment process before any enrollments are processed; (3) the individual is enrolled in an affiliated Medicaid managed care plan and is dually eligible for Medicare and Medicaid; (4) the MA organization provides a notice that meets CMS requirements to the individual; and (5) the individual does not opt out of the default enrollment. We proposed 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 also proposed changes to §§ 422.66(d)(1) and (d)(5) and 422.68 that coordinate with the proposal for § 422.66.

As noted in the proposed rule, we initially addressed default enrollment upon conversion to Medicare in a 2005 rulemaking (70 FR 4606 through 4607) and released subregulatory guidance [25] to provide an optional enrollment mechanism in 2006. This mechanism permitted MA organizations to 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

[25] *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/CY_2018_MA_Enrollment_and_Disenrollment_Guidance_6-15-17.pdf.*

that approved MA organizations not limit seamless continuation of coverage to situations in which an enrollee becomes eligible for Medicare by virtue of age, and directed MA organizations to implement seamless conversions to include all newly eligible Medicare beneficiaries, including those whose Medicare eligibility is based on disability. From its inception, the guidance 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, but we encountered complaints and heard concerns about the practice.

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 discussed the opportunity to integrate Medicare and Medicaid benefits via seamless continuation of coverage into D–SNPs, and we received positive comments from state Medicaid agencies supporting this enrollment mechanism and requesting clarification of the approval process. We also received comments from beneficiary advocates asking for additional consumer protections (for example, requiring written beneficiary confirmation and a special enrollment period for those enrolled using this optional mechanism).

On October 21, 2016,[26] 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. We discovered, based on our subsequent discussions with beneficiary advocates and MA organizations approved for this enrollment mechanism, that MA organizations find it difficult to comply with our current guidance and approval parameters, especially the requirement to identify commercial members who are approaching Medicare eligibility based on disability when the other plan offered by the MA organization is a commercial insurance plan. MA organizations also outlined challenges in confirming entitlement to Medicare Parts A and B within necessary timeframes and obtaining the individual's Medicare number—which in 2018 will become a random and unique number instead of the Social Security Number-based identifier used today. As discussed in more detail below, we anticipate that the switch from the SSN-based identifier will exacerbate this difficulty.

We noted in the proposed rule how organizations operating Medicaid managed care plans are better able to meet these requirements when states provide data, including the individual's Medicare number, to identify individuals about to become Medicare eligible; MA organizations with state contracts to offer D–SNPs will be able to obtain (under their agreements with state Medicaid agencies) the data necessary to process and submit default enrollments to CMS without needing to collect information from the Medicare beneficiaries. Therefore, we proposed 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 with the same parent organization as the organization that operates the Medicaid managed care plan in which the individual remains enrolled. At § 422.66(c)(2)(i)(B), we also proposed 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 and by providing necessary identifying information to the MA organization.

The proposal was designed to support state efforts to increase enrollment of dually eligible individuals into fully integrated systems of care There is evidence [27] that such systems improve health outcomes so supporting efforts to increase use those systems is consistent with overall CMS policy. Further, we believe then, and now, that the proposal provided states with additional flexibility and control.

To ensure individuals are aware of the default MA enrollment and of the changes to their Medicare and Medicaid coverage, we also proposed, at § 422.66(c)(2)(i)(C) and (c)(2)(iv), a requirement for MA organizations to issue a notice no fewer than 60 days before the default enrollment effective date to the enrollee. The notice [28] 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.

We also proposed, in paragraph (c)(2)(i)(E) and (2)(ii), that MA organizations must obtain approval from CMS before implementing default enrollment. We explained that 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. We also noted that 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 members of the affiliated Medicaid plan who were identified as eligible for default enrollment. Lastly, we proposed authority for CMS to suspend or rescind approval at any time it determined that the MA organization is not in compliance with the requirements. We requested comment on whether this authority to rescind approval should be broader. We also explained that we continued to consider 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 in order to assure that the regulation requirements are still being followed. We were particularly interested in comment on this point in conjunction with our alternative proposal (discussed later in this section) 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.

[26] *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/HPMS_Memo_Seamless_Moratorium.pdf.*

[27] 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) 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.*

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

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 also proposed 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. We further proposed 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 their commercial, Medicaid or other non-Medicare plan members. To reflect this proposal for a simplified election process, we proposed to add text in § 422.66(d)(5) authorizing a simplified election for purposes of converting existing non-Medicare coverage to MA coverage offered by the same organization. This new simplified enrollment process aimed to lessen burden for MA organizations, make enrollment easier for the newly-eligible beneficiary to complete, and provide opportunity for beneficiary choice, so that beneficiaries could remain with the organization that offers their non-Medicare coverage or select another MA plan that meets their individual needs with respect to provider network, prescription drug formularies, and cost and benefit structures. We explained that our 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 simplified enrollments throughout the individual's Initial Coverage Election Period (ICEP), provided he or she enrolled in both Medicare Parts A and B when first eligible. We proposed to use existing authority to create this new enrollment mechanism, which would be available to MA organizations in the 2019 contract year. We solicited comments on the proposed changes to § 422.66(d)(5) and the form and manner of the simplified enrollments.

In addition to these proposals and solicitations for comment related to default and seamless enrollments for newly eligible Medicare beneficiaries, we proposed 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 enrollment requests from an individual who is enrolled in a non-Medicare health plan offered by the MA organization during the month immediately preceding the month in which he or she is entitled to both Part A and Part B and who meets MA eligibility requirements. We are concerned that in some instances, this regulation has been interpreted as meaning that the enrollment request must be filed during the month before Medicare entitlement occurs. To clarify the requirement and be more consistent with section 1851(c)(3)(A)(ii), we proposed to amend § 422.66(d)(1) to add text clarifying that seamless continuation of coverage is available to an individual who requests enrollment during his or her Initial Coverage Election Period. We also proposed 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 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 solicited comment on these related proposals.

In conclusion, we proposed 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 proposed 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 will be available to all MA organizations and their members who enroll in an MA plan offered by the same entity that offers the individual's pre-Medicare coverage. Lastly, we proposed 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 solicited comments on all these proposals.

In addition, we presented an alternative for consideration and comment. Because we recognized that our proposal narrowed the scope of default enrollments compared to what CMS approved under section 1851(c)(3)(A) of the Act in the past, we discussed in the proposed rule that we continued to consider retaining processes similar to the pre-moratorium seamless conversion process. That 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. As an alternative 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 additional beneficiary protections, including the issuance of an additional notice to ensure that individuals understood the implication of taking no action when notified of the default enrollment. While this alternative would lead to increased use of the seamless conversion enrollment mechanism than what had been used in the past, we expressed concern that the operational challenges, particularly in relation to the new Medicare Beneficiary Identification number, could be significant for MA organizations to overcome at this time.

We also explained how we considered proposing regulations to limit the use of default enrollment to only beneficiaries who are eligible for Medicare based on age. While this alternative would simplify an MA organization's ability to identify eligible individuals, we noted concerns about disparate treatment among newly eligible beneficiaries based on their reason for obtaining Medicare entitlement.

We invited comments on our proposal and the alternate approaches we identified, 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 already covered by 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 to be limited to only the aged population.

We also asked for solutions to address the concerns we identified in the proposed rule, particularly related to

how MA organizations could 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.

We received the following comments and our responses follow:

Comment: We received significant support for our proposal to permit default MA enrollments, especially for dually-eligible beneficiaries who are newly eligible for Medicare. Most commenters supported the proposal to permit only D–SNPs to receive defaulted enrollments for dually-eligible beneficiaries. Some commenters who supported our proposal also supported the alternative we noted for consideration that would permit default enrollment of newly Medicare-eligible individuals enrolled in a non-Medicare health plan offered by the same organization.

Response: We appreciate the widespread support we received for the proposal. In our view, this proposal and our final rule support state efforts to increase enrollment of dually eligible individuals in fully integrated systems of care.

We appreciate the responses to our solicitation of feedback on expanding default enrollment to include individuals enrolled in commercial health plans offered by an MA organization. As noted in the proposed rule (82 FR 56366) and above, our experience with the current seamless conversion enrollment mechanism makes it clear that organizations attempting to seamlessly convert individuals from commercial coverage (that is, private coverage and Marketplace coverage) are, for the most part, unable to comply with our current guidance and approval parameters, especially the expectation that organizations have the means to identify their commercial members who are approaching Medicare eligibility based on disability. Given these challenges, we did not specifically propose to codify default enrollment from commercial coverage. We also solicited feedback on how MA organizations might overcome the challenges in confirming entitlement to Medicare Parts A and B within necessary timeframes and obtaining the individual's Medicare number, given that in 2018 this will become a random and unique number instead of a Social Security Number-based identifier. We received only a few responses to our solicitation of ideas on how to resolve these issues; commenters generally deferred to CMS to find a way to identify non-MA members when those members approach Medicare eligibility and for CMS to convey this information to plans well in advance of the Medicare eligibility date. In light of these comments, CMS may consider expanding default enrollment to occur from commercial or other coverage arrangements in future rulemaking. We are not finalizing the alternate proposal on which we solicited comment.

Comment: A commenter asked that we expand default enrollment to those enrolled in other ''state innovated models'' and delivery systems other than Medicaid managed care, such as ACOs. The same commenter asked that we allow the default enrollment provisions to be applied to individuals enrolled in coverage other than comprehensive Medicaid managed care, including prepaid inpatient health plans, prepaid ambulatory health plans, and primary care case management. Another commenter asked that we consider expanding our proposal for default enrollment and/or changing the current parameters for passive enrollment to allow a State to enroll any dually-eligible individual (whether in a Medicaid managed care plan or in a Medicaid Fee-for-Service program) into a D–SNP at any time.

Response: We appreciate the comments. As proposed, default enrollment would be subject to several substantive conditions, one of which required that anyone being considered for default enrollment be enrolled in a Medicaid managed care plan affiliated with the MA organization. Our proposal was specific to allowing default enrollment of individuals enrolled in comprehensive Medicaid managed care plans—rather than limited-benefit plans or case management arrangements—into D–SNPs when these Medicaid managed care plan enrollees first become eligible for Medicare. We believe that our overall goals of encouraging integrated care are best met by limiting the default enrollment to the context of comprehensive Medicaid managed care plans at this point and may revisit an expansion of this regulation in future rulemaking. We plan to further clarify allowable scenarios in subsequent guidance. However, given the parameters of section 1851(c)(3)(A)(ii) of the Act, we are unable to finalize a regulation that so substantially expands the population of beneficiaries subject to this default enrollment to include Medicaid beneficiaries who are not enrolled in a health plan offered by an MA organization.

Comment: Several commenters who support our proposal for default enrollment recommend that, if finalized, we ensure that beneficiaries who do not speak English as a primary language receive outreach in their language, preferably by both mail and telephone.

Response: We appreciate these comments and agree that clear communication with individuals identified for default enrollment is an important protection, especially with regard to the potential impact of MA plan enrollment on an individual's access to care. We note that existing law, such as Title VI of the Civil Rights Act of 1964 (applicable to MA organizations in connection with Medicare coverage) and 42 CFR 438.10 (applicable to Medicaid managed care plans) address requirements for providing access to enrollees who have limited English proficiency (LEP). Guidance on the Civil Rights Act of 1964 and authorities that are not limited to Medicare or Medicare is issued by the HHS Office for Civil Rights (OCR). We refer the commenter to section II.B.5 of this final rule on marketing and communications requirements. We believe, therefore, that revisions to our proposed rule are not necessary.

Comment: Several commenters stated that the network for the MA plan should be substantially identical and should not be substantially narrower than the network of the Medicaid plan from which default enrollment would occur.

Response: Although we did not include specific provider network criteria in our proposal for default MA enrollment, we note that CMS currently has in place network adequacy requirements that would apply to any MA plan into which default enrollment occurs. States also have the opportunity to use their State Medicaid agency contracts with D–SNPs to create additional provider network continuity requirements. Therefore, we do not believe that additional criteria are warranted.

Comment: Several of the commenters who opposed our proposal for default enrollment asked that in the event that our proposal for default enrollment is finalized, we consider additional beneficiary protections, such as a minimum star rating for the MA plan into which default enrollment would occur and the exclusion of MA plans that have been assessed a civil monetary penalty or have been sanctioned within the previous 18 months. Another commenter expressed concern about the potential for individuals to be default enrolled into an MA plan with a low star rating when there are MA plans with higher star ratings offered by other organizations in the same area. These commenters note that organizations with high star ratings that do not offer

a Medicaid plan would not be permitted to conduct default enrollment.

Response: We appreciate the comments we received regarding the significance of the compliance history of an MA organization that wishes to conduct default MA enrollment and the suggestion of a minimum star rating. We agree with these commenters that standards governing the quality of the MA D–SNP are appropriate to adopt as well. We believe that default enrollment should not be permitted into an MA plan offered by an MA organization with a low star rating and/or recent issues of significant noncompliance with our regulatory requirements such that CMS has imposed a suspension on new enrollments. Since default MA enrollment is based on an opt-out, rather than opt-in, approach, we believe it is important to ensure that individuals are not enrolled by default into MA plans offered by poor performing organizations. Therefore, we are finalizing the regulation with additional paragraphs ((c)(2)(i)(F) and (G)) that limit default enrollment authority to MA plans that have an overall rating of 3 Stars (or are low enrollment or new contracts) and that are not under a prohibition on new enrollments.

Comment: Most commenters expressed support for limiting CMS approval of an organization's request to conduct default enrollment to a specific time frame. Those who mentioned a specific time frame suggested a period of 2 to 5 years. A commenter suggested that CMS conduct a review after initial approval only if there is an indication of disruption in care.

Response: CMS oversight of plans' implementation of the default enrollment process is an important beneficiary protection. We agree with the suggestions of a 5 year timeframe, as it provides a reasonable amount of time for MA organizations to implement and then assess the approved process, limits administrative burden for MA organizations to request continued approval, and provides them the opportunity to update their processes as operational enhancement or new technologies emerge. However, in our view, should beneficiary complaints or allegations of noncompliance come to our attention, we need to be able to conduct a review of an organization's default enrollment process prior to the expiration of the five year period. Therefore, we will include in the final rule an approval time period of 5 years with a provision that permits CMS to suspend or rescind approval if CMS determines that the MA organization is not in compliance with the requirements or § 422.66(c)(2) or other MA program standards.

Comment: A commenter suggested that we share with states the criteria we will use to review plan proposals to offer default enrollment, adding that this may promote uniformity with implementation across the various states.

Response: The requirements for default enrollment are outlined in this regulation. In addition, we will consider additional guidance, which is available to states, industry, advocates, and the general public, as necessary.

Comment: Most commenters expressed support for our proposal to permit simplified elections for seamless continuation of commercial coverage into a MA plan offered by the same organization. A commenter expressed opposition to the offering of a simplified (opt-in) enrollment mechanism to anyone enrolled in a Medicaid managed care plan. Another commenter asked that we consider making the simplified (opt-in) enrollment mechanism available to all beneficiaries, including those who are not in their ICEP and those who are not enrolled in a non-Medicare plan offered by the same organization.

Response: We appreciate the support for our proposal to promote beneficiary choice and simplify the enrollment process for all MA organizations that offer non-Medicare coverage. However, we disagree with the suggestion to prohibit use of the simplified enrollment mechanism by those enrolled in Medicaid managed care plans. In our view, an eligible individual always has the option to make an active choice into an MA plan that meets their needs when in an election period. Further, as not all individuals in Medicaid managed care plans will be automatically enrolled into a D–SNP (such as those individuals enrolled in Medicaid managed care plans whose parent organizations have opted not to use the default enrollment mechanism or those individuals whose Medicaid managed care enrollment is in a Medicaid prepaid health plan that covers a limited scope of benefits), the simplified enrollment mechanism will lessen burdens on the enrollee and MA organizations that offer such plans. We believe that a simplified election process for beneficiaries who wish to convert from their non-Medicare coverage to MA coverage offered by the same entity will facilitate a more efficient enrollment process overall.

As described in the proposed rule, this mechanism will be available to any MA organization that chooses to offer it. It will be potentially available to any beneficiary who wishes to join an MA plan offered by the same MA organization that offers his or her non-Medicare coverage at the time of his or her initial Medicare eligibility. The simplified enrollment mechanism aims to lessen the amount of information that an MA organization needs to collect from the beneficiary and to use information the MA organization already has. MA organizations that do not already have an existing relationship with an individual must collect all the necessary information in which to determine eligibility and process the enrollment request under § 422.60.

We appreciate the feedback to finalize use of a simplified enrollment mechanism authorized under § 422.66(d)(5) as amended in this final rule. We will permit individuals who are in their ICEP and enrolled in any type of non-Medicare plan to use the simplified (opt-in) enrollment mechanism to request enrollment in any type of MA plan offered by the same MA organization that offers the non-Medicare coverage.

Comment: A few commenters responded to our solicitation of feedback on limiting default enrollment to only the aged. Most of these commenters opposed this limitation; a commenter supported it. Those who oppose limiting default enrollment to only the aged believe that allowing default enrollment to be offered only to those whose Medicare eligibility is based on age, instead of to all beneficiaries, would be discriminatory on its face because the exclusion is based on having a disability or ESRD. Another commenter believes that states and plans should be allowed to determine whether including all individuals approaching Medicare eligibility is feasible and, if not feasible, include only those whose Medicare eligibility is based on age.

Response: We thank the commenters and agree that it would be inappropriate to exclude individuals whose Medicare eligibility is based on disability from default enrollment. We believe that an individual's eligibility to be included in default enrollment should be based on his or her projected Medicare eligibility in general and not on the specific reason for Medicare eligibility. We are, therefore, finalizing this aspect of our proposal as described in the notice of proposed rulemaking and are not including any authority to limit default enrollment (under paragraph (c)) or seamless conversions (under paragraph (d)) to beneficiaries whose eligibility is based on age.

Comment: In the event that our proposal for default enrollment is finalized, several commenters who opposed our proposal for default enrollment ask that default-enrolled beneficiaries be provided transition coverage, allowing use of an off-formulary drug, and allowing a beneficiary to maintain an out-of-network provider for 12 months, similar to the Medicare-Medicaid financial alignment demonstration.

Response: We appreciate these comments and note that several of the concerns expressed are addressed in other areas of current regulation and guidance. With regard to formulary concerns, we note that all plans offering Part D coverage must meet CMS' formulary adequacy requirements and, in addition, must offer a transition period upon a member's enrollment in a new plan. Specifically, under § 423.120(b)(3), new enrollees must be provided a temporary supply of non-formulary Part D drugs, as well as Part D drugs with utilization management restrictions, and can work with their new plan and provider to switch to a different formulary drug or request an exception during their first 90 days of enrollment in the new MA plan. States may also use their State Medicaid Agency contracts with D–SNPs to create additional continuity requirements. With regard to the commenters' suggestion that we require MA organizations to allow new members to receive care from out-of-network providers for 12 months, similar to the Medicare-Medicaid financial alignment demonstration, we note that a 6 month continuity of care period is more common for demonstration plans. In addition, we note that this period can be offered by demonstration plans due to the demonstration authority itself; we do not have similar authority to impose a similar requirement on MA organizations that choose to implement the default enrollment process.

Comment: The few commenters who opposed default enrollment cite as the basis for their position the lack of beneficiary choice and the potential for disruption in care resulting from default enrollment into a plan with different benefits, cost-sharing, provider network and formulary.

Response: In response to these comments, we note that an important feature of this enrollment process is clear and timely advance notice to the individual regarding default MA enrollment and the opportunity to decline the enrollment up to and including the day prior to the enrollment effective date. We, therefore, disagree with these commenters that the default MA enrollment process, as proposed and as finalized in this rule, does not involve beneficiary choice. The notice requirements in the final rule will provide the beneficiary a least a 2 month period in which to review his or her Medicare options and make an informed choice. Further, the new MA Open Enrollment Period, discussed at section II.B.1 of this final rule, would be available to any beneficiary who was default enrolled in an MA plan pursuant to § 422.66(c)(2). Upon an individual's new enrollment in an MA plan during the individual's ICEP, he or she would have 3 months, under the MA Open Enrollment Period discussed in § 422.62(a)(5), to make a change to another MA plan or select Original Medicare for health coverage. Additionally, as individuals eligible for default enrollment would only be those dually-eligible, they would also be eligible to use their quarterly opportunity under the duals SEP, as outlined in II.A.10 of this final rule, to make a Part D election, as well as any other election periods for which they may qualify, to make a change. In this context, a Part D election would include enrollment into an MA plan that includes a Part D benefit. We believe that there are adequate protections in place, as finalized with these amendments to § 422.66(c)(2) and elsewhere in this final rule, for beneficiary choice in connection with the initial election period when someone is first entitled to or eligible for Medicare.

The regulation we proposed requires the MA organization conducting default enrollment to provide notice that describes the costs and benefits of the MA plan into which the default enrollment would occur, as well as the process for accessing care under the plan. We agree with the commenters that information on the differences between an individual's current non-Medicare coverage and the new MA plan, including a statement as to whether the individual's current primary care provider will continue to be available to the individual upon enrollment in the MA plan, should be included in the advance notification of default enrollment. We also agree that information on other types of Medicare plans should be included in the notice to ensure an individual who is notified of default enrollment has sufficient information and can make an informed choice with regard to the coverage option that best meets his or her needs. Therefore, we are finalizing additional paragraphs, at (c)(2)(iv), that specific information be included in the notice describing the default enrollment and the ability to opt-out:

(A) Information on the differences in premium, benefits and cost sharing between the individual's current Medicaid managed care plan and the dual eligible MA special needs plan and the process for accessing care under the MA plan;

(B) 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 MA plan; and

(C) A general description of alternative Medicare health and drug coverage options available to an individual in his or her Initial Coverage Election Period.

In addition, we are including in the regulation that this information and the notice about the default enrollment is in addition to any mandatory disclosures required under § 422.111.

Comment: Several commenters who opposed our proposal for default enrollment expressed support for our proposal to develop a simplified (opt-in) enrollment mechanism, as long as differences between an individual's current and new plan are clearly communicated and that he or she is made aware of all options available to newly Medicare-eligible individuals. These commenters note that an individual's initial eligibility for Medicare is a critical decision point and that information on the full range of Medicare coverage options is important to help ensure that those approaching Medicare eligibility are aware of the resources available to them and of any time-limited enrollment opportunities, such as the option to obtain Medigap on a guaranteed issue basis.

Response: With respect to the new simplified (opt-in) election mechanism that would be available to all MA organizations for MA enrollments of their commercial, Medicaid or other non-Medicare members, we note that MA organizations that choose to implement this optional election mechanism will be required to follow existing rules governing mandatory disclosures (for example, § 422.111), communications and marketing that are applicable to other beneficiary-initiated enrollment requests. Required disclosures include a description of the MA plan benefits, including applicable conditions and limitations, premiums and cost-sharing (such as copayments, deductibles, and coinsurance), any other conditions associated with accessing benefits and for purposes of comparison, a description of the benefits offered under original

Medicare. Also included under § 422.111 is the requirement to disclose the number, mix, and distribution (addresses) of providers from whom enrollees may reasonably be expected to obtain services. We will provide additional information on this optional enrollment mechanism in subregulatory guidance.

Given these substantial existing disclosure requirements that will be applicable to the new simplified (opt-in) election mechanism, as well as our ongoing public outreach and education activities for individuals new to Medicare, we do not believe that additional notice or disclosure requirements are warranted.

Comment: A few commenters asked that we reduce the requirement to identify newly-eligible Medicare beneficiaries from 90 to 60 days.

Response: We believe the commenters' reference to a 90 day requirement for advance notification of newly-eligible Medicare beneficiaries is based on the current subregulatory guidance applicable to the seamless conversion enrollment mechanism. This guidance will be revised as a result of this final rule to account for default enrollment and the new simplified (opt-in) enrollment mechanism. The rule we are finalizing requires notice to the affected beneficiary at least 60 days in advance of the enrollment effective date (the month in which the individual is first entitled to both Part A and Part B). This reflects a change from the current seamless conversion process, which requires identification of beneficiaries that will be seamlessly enrolled 90 days in advance. While we believe that timely identification of individuals approaching Medicare eligibility is an important beneficiary protection that helps to ensure that plans are able to provide timely advance notification and submission of enrollment transactions to CMS, we also believe that for default enrollment this shorter timeframe does not have an adverse beneficiary impact. MA plans that are authorized to use this default enrollment process must identify all eligible enrollees in time to provide the required advance notification to individuals eligible for default enrollment no fewer than 60 days before the default enrollment effective date.

Comment: Several commenters suggested that CMS consider allowing default enrollment from Medicaid managed care plans into fully integrated dual eligible special needs plans (FIDE SNPs), which are a type of special needs plan designed to promote the full integration and coordination of Medicaid and Medicare benefits for dual eligible beneficiaries by a single managed care organization.

Response: We thank the commenters for their feedback and agree that allowing default enrollment from Medicaid managed care plans into FIDE SNPs is consistent with the proposed rule. FIDE SNPs are a specific type of approved MA–PD dual eligible special needs plan. We will finalize revised text to clarify that FIDE SNPs are permitted to use the default enrollment mechanism, subject to the other requirements in the rule.

Comment: A commenter stated that Congress should revisit default enrollment in traditional Medicare. This commenter believes that to the extent that MA quality is superior, enrollment should default to the highest quality option, rather than to traditional Medicare.

Response: As acknowledged by the commenter, this comment is outside of the scope of this regulation and our authority under section 1851. CMS's authority is circumscribed by the Medicare statute, particularly section 1851(c)(3)(A)(ii) of the Act with regard to default enrollments.

Comment: A commenter suggests that plans conducting default enrollment be allowed to send the notification of default enrollment up to 90 days after an individual's initial Medicare eligibility, adding that this would increase enrollment into integrated plans.

Response: We appreciate the suggestion; however we disagree with permitting notification of default enrollment after enrollment or, as implied by the commenter, effectuating the default enrollment up to 90 days after the initial date of Medicare eligibility. As described in our proposal, states have the information to identify newly eligible Medicare beneficiaries before the actual first date of Medicare eligibility; therefore, they have the information necessary to provide to their contracted MA organizations so that the integrated coverage can begin at the earliest possible date—the date the individual first has both Medicare Parts A and B. As such, the effective date for default enrollment will always coincide with the date of an individual's entitlement to and eligibility for Medicare Parts A and B, which would not allow the commenter's suggested change. We note as well that the commenter's suggestion would result in notification of the default enrollment well after the enrollment effective date, resulting in a period of time during which the individual is not aware of his or her enrollment in an MA plan, does not have the information necessary to access benefits and would be financially liable for healthcare services received from providers not contracted with the MA plan. To ensure that individuals receive timely advance notification of the default enrollment, we are declining the commenter's suggestion. We note that individuals who are enrolled into a MA plan through default enrollment continue to have a three-month opportunity to change their enrollment using the MA Open Enrollment Period, as outlined in § 422.62(a)(5). Further, an individual who chooses to opt out of default enrollment into an MA plan is still able to make an election during his or her Initial Coverage Election Period, which begins 3 months before and lasts 3 months after the month of initial Medicare eligibility.

Comment: A commenter suggested that default enrollment not be allowed where Medicare-Medicaid financial alignment demonstration plans are available.

Response: We are committed to partnership with state Medicaid agencies to pursue integrated care approaches that work for each state. We believe that the proposed regulatory language requiring state approval for default enrollment into D–SNPs provides an appropriate safeguard that ensures any default enrollments are consistent with the state's Medicare-Medicaid integration goals.

Comment: A commenter who opposes default enrollment into D–SNPs stated that it will lead to reduced competition and fewer D–SNP offerings for beneficiaries, resulting in higher costs and fewer benefits over time.

Response: We appreciate the comment but disagree with the commenter's assessment and conclusion regarding the impact of default MA enrollment on competition in the market and the number of D–SNP offerings. As default enrollment accounts only for those newly eligible for Medicare, it is our view that D–SNPs provide a valuable service to all beneficiaries—those currently and newly in the Medicare program.

After review of the comments, and as discussed earlier, we are finalizing the proposed changes to §§ 422.66(c) and 422.68(d)(1) and (5) with the following modifications:

- Paragraph 422.66(c)(2)(i) will be revised to clarify that we will allow default enrollment into a FIDE–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.
- Paragraph 422.66(c)(2)(i) will be revised to require a minimum star rating

on the contract receiving default enrollments for an MA organization to be approved for default enrollment. We are revising the paragraph to require that, for an organization to be approved for default enrollment, it must have an overall quality rating, from the most recently issued ratings, under the rating system described in §§ 422.160 through 422.166, of at least 3 stars or is a low enrollment contract or new MA plan as defined in § 422.252. In addition, the MA organization must not be under an enrollment suspension.

- Paragraph 422.66(c)(2)(ii) will be revised to include an approval period not to exceed 5 years, subject to CMS authority to rescind or suspend approval if the plan is non-compliant.
- Paragraph 422.66(c)(2)(iv) will be revised to require that the notice issued by the MA organization include information on the differences in premium, benefits and cost sharing between the individual's current Medicaid managed care plan and the dual eligible MA special needs plan and the process for accessing care under the MA plan; an explanation of 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 MA plan; and a general description of alternative Medicare health and drug coverage options available to an individual in his or her Initial Coverage Election Period.
- Paragraph 422.66(c)(2)(iv) will be revised to clarify that the mandatory notice is in addition to the information and documents required to be provided to new enrollees under § 422.111.

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, and care coordination, and reducing administrative burden.

In the proposed rule, we proposed a limited expansion of CMS' regulatory authority to initiate passive enrollment for certain dually eligible beneficiaries who are currently enrolled in an integrated D–SNP into another integrated D–SNP in instances where integrated care coverage would otherwise be disrupted, such as during a state re-procurement of Medicaid managed care contracts that results in current Medicaid managed care plans not being renewed, or when beneficiaries are enrolled in an integrated D–SNP that non-renews its MA contract at the end of the contract year. The intent of CMS' proposal was to improve care coordination and minimize disruption in care by promoting enrollment in integrated care arrangements for dually eligible beneficiaries currently enrolled in an integrated D–SNP.

Specifically, we proposed authorizing 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, when CMS determines that the passive enrollment will promote continuity of care and integrated care under § 422.60(g)(1)(iii). We also proposed, under § 422.60(g)(2), a number of requirements an MA plan would have to meet in order to qualify to receive passive enrollments under paragraph (g)(1)(iii). These proposed requirements are detailed below.

- MA plans receiving the passive enrollments must be highly integrated D–SNPs, 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 promote continuity of care, receiving MA plans must 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.
- D–SNP contracts must have a minimum overall MA Star Rating of at least 3 stars for the year prior to receipt of passive enrollment or be a low enrollment or new MA contract (which do not have a Star Rating because of the insufficient data available).
- Receiving MA plans must not have any prohibition on new enrollment imposed by CMS.
- Receiving MA plans must have appropriate limits on premium and cost-sharing for beneficiaries.

We solicited comments on our proposal to identify plans for receiving passive enrollments, particularly on the minimum quality standards relevant to dually eligible beneficiaries. We also solicited comments on whether to limit passive enrollment authority to circumstances that would not raise total cost to the Medicare and Medicaid programs. Additionally, we requested feedback on how to calculate the projected impact on Medicare and Medicaid costs from exercise of this authority.

In the proposed rule, we noted that we had also considered proposing new (or additional) beneficiary notification requirements for passive enrollments that occur under proposed paragraph (g)(1)(iii), including the provision of two notifications to enrollees prior to the effective date. Citing the existing beneficiary notifications that are currently required under Medicare regulations and concerns regarding the quantity of notifications sent to beneficiaries, we did not propose to modify the existing notification requirements under paragraph (g)(4) of the proposed rule. However, we solicited comment on alternatives regarding beneficiary notices, including comments about the content and timing of such notices.

We received the following comments and our responses follow.

Comment: Many commenters expressed support for CMS' proposal for a limited expansion of the current passive enrollment authority in order to promote continued enrollment of dually eligible beneficiaries in integrated D–SNPs, preserve and promote care integration, and limit disruptions in care under certain circumstances. Several commenters supported CMS' goal of care continuity while expressing their belief that the best way to empower beneficiaries is through mechanisms where beneficiaries opt in to integrated care. A commenter requested that CMS consider how passive enrollment of beneficiaries from an existing integrated D–SNP into another integrated D–SNP could create disruptions in care. A few commenters opposed our passive enrollment proposal due to concerns that passive enrollment limits beneficiary choice and erodes the role of competition in the marketplace. A commenter suggested that a better alternative for beneficiaries in integrated D–SNPs that are non-renewing is for them to revert to FFS Medicare. Another commenter noted that passive enrollment in other

circumstances has proven to be too confusing for dually eligible beneficiaries.

Response: We appreciate the support by most commenters of our goals of promoting continuity and quality of care for dually eligible beneficiaries currently enrolled in integrated D–SNPs in situations where they would otherwise experience an involuntary disruption in either Medicare or Medicaid coverage. As we stated in the proposed rule (82 FR 56369–56370), we anticipate using this new authority exclusively in limited situations related to market disruptions related to D–SNP non-renewal or changes in state Medicaid managed care organization procurements; therefore, we anticipate that this authority, as finalized, will have no significant impact on competition in the Medicare Advantage marketplace. We also proposed that D–SNPs meet certain requirements related to integration, quality, performance, and provider network and benefits comparability relative to the enrollees' previous coverage. We believe these safeguards will ensure continuity of care and limit any disruption associated with a plan change for affected enrollees. In addition, we believe the beneficiary notice requirements for passively enrolled individuals described in § 422.60(g)(4) ensure that beneficiaries will receive appropriate advance notice regarding the costs and benefits of their new coverage, the process for accessing care under the new plan, and an explanation of the beneficiary's ability to decline the enrollment or choose another plan. As described elsewhere in this final rule, we are strengthening the notice requirements associated with passive enrollment under this new limited expansion of CMS' passive enrollment authority. Finally, we note that all individuals enrolled into an integrated D–SNP under CMS' passive enrollment authority will have a special election period (SEP) under § 422.60(g)(5), which as finalized in this rule refers to the new SEP established in this final rule at § 423.38(c)(10). This SEP will allow individuals to opt out of the passive enrollment within 3 months of notification of a CMS or state-initiated enrollment action or that enrollment action's effective date (whichever is later). This SEP is in addition to any other election periods for which they qualify. During the SEP, a beneficiary would be able choose FFS Medicare or other coverage based on their personal preferences. Therefore, we are finalizing the proposed limited expansion of CMS' passive enrollment authority at § 422.60(g)(1)(iii). However, we note that we are making a technical revision to paragraph (g)(1)(iii) to clarify that a plan must meet all the requirements under paragraph (g)(2) to be eligible to receive passive enrollment.

Comment: A commenter stated that any beneficiary who has chosen FFS Medicare should not be passively enrolled. Several commenters suggested that passive enrollment be extended to existing and new dually eligible beneficiaries in FFS Medicare and stand-alone Part D plans. A few commenters recommended passively enrolling dually eligible beneficiaries into a D–SNP when states enroll beneficiaries into a mandatory Medicaid long-term services and supports (LTSS) program.

Response: While we appreciate commenters' support for coordinated care options for individuals who are not currently enrolled in an MA plan, we note that our intent in proposing an expansion of CMS' passive enrollment authority was to promote continuity of integrated care for those beneficiaries enrolled in an integrated D–SNP but who would experience an involuntary disruption in their Medicare or Medicaid coverage in the absence of passive enrollment into a comparable integrated D–SNP. This authority could not be used to transition enrollees currently in FFS Medicare to an MA plan.

Comment: Some commenters agreed that passive enrollment eligibility should be limited to highly integrated D–SNPs. A commenter recommended limiting eligibility for passive enrollment to integrated D–SNPs with the experience and size to meet the unique needs of the dual eligible population. A few commenters expressed concern that the scope of our proposal was too limited because only Fully Integrated Dual Eligible (FIDE) SNPs and other MA plans that meet the integration standard for a highly-integrated D–SNP, as defined in § 422.2 and described in § 422.102(e), respectively, would be qualified to receive the passive enrollments. These commenters noted the limited number of highly integrated D–SNPs and FIDE SNPs currently in the market. A few commenters recommended extending eligibility to include all D–SNPs that meet minimum quality standards and can demonstrate appropriate levels of integrated benefits. Another commenter recommended that CMS allow states the flexibility to determine which D–SNPs are eligible to participate in passive enrollment.

Response: We appreciate the commenters' perspectives on this issue. We may re-examine this issue as we gain experience, but we have concluded that it is more prudent to focus this form of passive enrollment on a narrow set of circumstances that offer the highest levels of integration between Medicare and Medicaid. This will allow us to better monitor implementation and will promote integration, which has been associated with better outcomes.[29] We also note that our proposed criteria are minimum standards only; states can establish additional criteria to determine which D–SNPs may be eligible for passive enrollment. As such, we are finalizing the scope of the proposed passive enrollment authority for dually eligible beneficiaries enrolled in an integrated D–SNP, without modification.

Comment: Several commenters encouraged CMS to consider further expanding our proposed passive enrollment authority to transition enrollees of non-renewing Medicare-Medicaid Plans (MMPs) into an integrated D–SNP.

Response: We clarify that under the Financial Alignment Initiative capitated model demonstrations, MA regulations—including those governing passive enrollments—apply to MMPs unless waived. As has been the case to date under the demonstrations, we will continue to use our demonstration authority to waive applicable MA regulatory requirements in three-way contracts as necessary, and in partnership with each state, to achieve each individual demonstration's objectives.

Comment: Several commenters supported the requirement for consultation with the state Medicaid agency that contracts with an eligible D–SNP, as proposed in § 422.60(g)(1)(iii). Some commenters noted that this consultation would ensure both the proper utilization of CMS' passive enrollment authority and consistency

[29] 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) 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.*

with states' integration goals and priorities. A commenter noted that this consultation would result in a more seamless process for states, integrated D–SNPs, and dually eligible beneficiaries. A few commenters noted that passive enrollment should occur at state discretion and pursuant to the State Medicaid Agency Contract with the D–SNP required under § 422.107.

Response: We appreciate the support for the proposed requirement that CMS consult with state Medicaid agencies to make a determination that D–SNPs meet the passive enrollment eligibility criteria and that the use of passive enrollment will promote integrated care and continuity of care for full-benefit dual eligible beneficiaries currently enrolled in an integrated D–SNP. We are committed to working with states to ensure that any passive enrollments under this authority meet CMS requirements as well as state priorities.

Comment: A commenter requested that CMS clearly communicate the criteria for an integrated D–SNP to be eligible to accept passive enrollees in subregulatory guidance.

Response: We anticipate issuing subregulatory guidance about the criteria for the passive enrollment authority finalized in this rule. We believe that the amendments to § 422.60(g) as finalized here are sufficiently clear, particularly in light of the detailed discussion in the proposed rule and these various responses to comment, that implementation in CY2019 will not be confusing for D–SNPs that are qualified to receive enrollments.

Comment: A commenter expressed concern that passive enrollment authority would be delegated to states. Another commenter recommended that CMS provide more clarification on whether CMS or state Medicaid agencies would be managing passive enrollment into integrated D–SNPs under our proposal, as well as on the implementation process for such passive enrollments.

Response: When circumstances arise in which passive enrollment into an integrated D–SNP could potentially be applied, CMS will consult with the applicable state Medicaid agency, consistent with § 422.60(g)(1)(iii) as finalized. We anticipate that such consultation would include collaboration between CMS and the state Medicaid agency on issues such as identifying plans that meet the requirements in § 422.60(g)(2), decisions about enrollee assignment, and communications with impacted plans. We clarify that, as is the case today with respect to other passive enrollments into MA plans, affected D–SNPs will submit enrollment transactions to CMS' MARx system.

Comment: Several commenters supported our proposed requirement in § 422.60(g)(2)(ii) that a receiving integrated D–SNP have substantially similar provider and facility networks to the other MA integrated D–SNP plan (or plans) from which the passively enrolled beneficiaries are enrolled. A few commenters suggested that CMS limit the application of provider network and benefit similarity in order not to further narrow the scope of permissible passive enrollments into D–SNPs.

Response: We appreciate the support of our proposed requirement for provider network comparability as a minimum requirement for an integrated D–SNP's eligibility for passive enrollment. We disagree with the commenters' suggestion that we limit our eligibility analysis on provider network comparability given our emphasis on continuity of care in the application of this limited expansion of CMS' passive enrollment authority. We believe that this comparability analysis will minimize the number of enrollees whose provider relationships are disrupted as a result of passive enrollment and will encourage retention following enrollees' transition to a new integrated D–SNP. We are therefore finalizing the requirements for assessing network comparability as a condition for eligibility for passive enrollment under § 422.60(g)(1)(iii) as proposed.

Comment: Several commenters requested clarification on how CMS will determine that the receiving integrated D–SNP has substantially similar provider and facility networks and Medicare- and Medicaid-covered benefits as the D–SNP from which the beneficiaries were passively enrolled.

Response: We appreciate the commenters' request for clarification and anticipate issuing clarifications through subregulatory guidance. The subregulatory guidance will articulate the process and timing for the losing and receiving D–SNPs to submit networks through the CMS Health Plan Management System. CMS will also review plan benefit packages submitted by the impacted D–SNPs as well as engage the State Medicaid agency to ensure covered services are similar to services currently being received by impacted dual eligible beneficiaries.

Comment: In addition to our proposed network comparability requirement, several commenters recommended the use of an ''intelligent assignment'' process for passively enrolling beneficiaries into a D–SNP based on the providers and prescription drugs associated with each individual beneficiary. Several commenters also recommended that, in our analysis of benefits comparability, CMS consider the comparability of the receiving D–SNP's formulary.

Response: We agree that intelligent assignment processes would be helpful for ensuring care continuity and minimizing enrollee disruption. We will consider the availability of intelligent assignment processes when effectuating passive enrollments under this authority and will also consider intelligent assignment options in the future. However, we note that all plans offering Part D coverage must meet CMS' formulary adequacy requirements and, in addition, must offer a transition period upon a member's enrollment in a new plan. Specifically, under § 423.120(b)(3), new enrollees must be provided a temporary supply of non-formulary Part D drugs, as well as Part D drugs with utilization management restrictions, and can work with their new plan and provider to switch to a different formulary drug or request an exception during their first 90 days of enrollment in their new plan.

Comment: A commenter expressed concern that passive enrollment could further limit enrollee choice in states in which biologic medications are reimbursed at low rates under Medicaid.

Response: We appreciate the commenter's concern about access to medically necessary drugs. We note that Medicare covers nearly all prescription drugs for dually eligible individuals under Parts A, B, and D. Medicaid coverage of drugs for dually eligible individuals is generally limited to over-the-counter drugs and products and prescription drugs that are otherwise excluded from the definition of a Part D drug. For dually eligible beneficiaries, the drugs referenced by this commenter would be covered under Medicare Part B rather than Medicaid.

Comment: Several commenters recommended a transition period during which passively enrolled beneficiaries can see current providers that are not in their new plan's network. A few commenters also suggested that care plans and authorized services be continued for a period of time following passive enrollment.

Response: We appreciate the commenters' suggestion that we incorporate continuity of care requirements into our proposed passive enrollment processes. We believe our finalization of the requirement for substantially similar provider and facility networks under § 422.60(g)(2)(ii) will facilitate continuity of care in most

cases. In addition, as previously discussed, the Part D transition requirements provide continuity of prescription drug benefits during a beneficiary's first 90 days of coverage in a new plan, including in cases where passive enrollment has been effectuated. We encourage states to consider using their State Medicaid Agency Contracts with D–SNPs as a vehicle for requiring that any passive enrollments into integrated D–SNPs apply transition rules that align with those applicable to Medicaid managed care organizations under § 438.62(b). As previously noted, we are finalizing our provider and benefits comparability requirements at § 422.60(g)(2)(ii) without further modification.

Comment: Several commenters responded to our request for comment on CMS' proposal that an integrated D–SNP meet certain quality criteria to qualify for passive enrollment, particularly with respect to the proposed requirement that a D–SNP have an overall quality rating of at least 3 stars based on the MA Star Ratings system. Several commenters expressed support for our proposed application of a minimum overall MA Star Rating of at least 3 stars. A commenter noted that CMS' consultation with the state Medicaid agency would ensure that an integrated D–SNP's Medicaid performance is considered in addition to the Medicare performance captured by the MA Star Ratings. Several commenters recommended raising the minimum required MA Star Rating level. A commenter noted concerns with the MA Star Ratings as a basis for our proposed quality requirement because star ratings may be affected more by the percentage of dually eligible members enrolled in an MA plan than other factors and suggested requiring state approval instead of a minimum MA Star Rating. Some commenters expressed concern that use of MA Star Ratings does not capture plans' performance related to services covered under Medicaid or other factors affecting plan capacity to ensure access to care for passively enrolled individuals.

Response: We appreciate commenters' support for establishing minimum quality criteria as part of our assessment of an integrated D–SNP's eligibility for passive enrollment under this provision. We call attention to our revision to § 422.60(g)(2)(iii), clarifying that the minimum star rating of at least 3 stars for a D–SNP to be eligible to receive passive enrollment from the most recently issued MA Star Rating for the D–SNP under the rating system described in §§ 422.160 through 422.166. While we acknowledge the limitations commenters identified with the MA Star Ratings, especially with respect to assessing the quality of Medicaid services provided under an integrated D–SNP, we believe the MA Star Ratings system is CMS' most effective and methodologically sound tool for measuring plan performance and quality and ensuring that passive enrollments are limited to MA plans that have demonstrated a commitment to quality. With regard to the methodological concerns related to the impact of enrollees' socioeconomic status on MA contract performance, we direct the commenter's attention to the discussion in this final rule about the MA and Part D Quality Rating System about adjustments to the ratings to address those and similar concerns in section II.A.11.t. We note that the additional required consultation with states in § 422.60(g)(1)(iii) as part of the process of determining that an integrated D–SNP meets the criteria for receipt of passive enrollment will provide valuable information regarding the performance and quality of the organization's Medicaid product. We are therefore finalizing the quality requirements under § 422.60(g)(2)(iii) with a clarification that the most recently issued overall MA Star Rating is the applicable rating for determining eligibility to receive passive enrollment. We note as well that new and low enrollment plans are generally not assigned an overall Star Rating because of the lack of data from a prior performance period (new plans) or insufficient number of enrollees for reliable sampling (low enrollment); therefore, the regulation text as proposed and as finalized, permits new and low enrollment plans that meet the other requirements to also receive these passive enrollments. However, we will consider revisiting the minimum MA Star Rating level in future rulemaking once we gain additional experience with implementing passive enrollments into integrated D–SNPs.

Comment: Several commenters made additional recommendations for specific minimum quality measures and other criteria relevant to dually eligible beneficiaries that CMS should consider as part of our determination of integrated D–SNPs' eligibility for passive enrollment under proposed § 422.60(g)(1)(iii). A few commenters recommended that CMS require integrated D–SNPs to have additional accreditation, such as the National Committee for Quality Assurance (NCQA) Medicaid plan accreditation and long-term services and supports (LTSS) accreditation. A commenter recommended using measures developed by the multi-stakeholder Core Quality Measures Collaborative. Another commenter suggested evaluating an integrated D–SNP's behavioral health services by number of days on waiting list and availability of a behavioral health expert. This commenter also suggested several methods for assessing LTSS.

Response: We appreciate the additional information these commenters provided regarding accreditation and measures relevant to dually eligible beneficiaries. Since the number of plans eligible to receive passive enrollment under our proposed limited expansion of passive enrollment authority is projected to be small, we believe it is important to consider minimizing burden to eligible plans and ensuring that there are an adequate number of plans to receive enrollments. MA Star Ratings are based on currently reported plan data and do not impose additional reporting or specific accreditation requirements on integrated D–SNPs. As stated previously, we are finalizing the quality requirements for receipt of passive enrollment under § 422.60(g)(1)(iii) as proposed.

Comment: We received no comments supporting a limitation of our proposed expansion of CMS' passive enrollment authority to circumstances that would not raise total cost to the Medicare and Medicaid programs. A few commenters stated they would not support a cost-effectiveness test as a standalone requirement for determining a D–SNP's eligibility to receive passive enrollments under our proposed rule. In addition, several commenters expressed concerns about establishing such a limitation for a variety of reasons. A commenter stated that a cost-effectiveness test would limit CMS' ability to align enrollment and preserve continuity of care. Another commenter believed that this approach did not consider long-term savings resulting from better integration. A few commenters also noted that the added cost and administrative burden involved in identifying these circumstances and measuring the cost-effectiveness of passive enrollment would potentially offset any cost-savings. Another commenter believed that choosing integrated D–SNPs for passive enrollment based on an artificial cost estimate would be inconsistent with the MA bid process and good faith contracting efforts.

Response: We thank commenters for their comments on this issue. We are not adding a cost-effectiveness test for passive enrollments under paragraph (g)(1)(iii) in this final rule.

Comment: In response to our request for comments on beneficiary notices for passive enrollments that would occur under proposed paragraph (g)(1)(iii), a few commenters supported maintaining the current requirement that receiving plans send one enrollee notice requirement when passive enrollment is applied, arguing that states or receiving plans could voluntarily choose to add more notifications as necessary, and that additional notices added to plan burden. A commenter noted that, because the Medicaid Managed Care Rule under § 438.54(c)(3) requires the State to notice beneficiaries regarding passive enrollment into a Medicaid managed care plan but does not specify the number of notices required, a requirement of one notice under our proposed passive authority resulted in better alignment between Medicare and Medicaid requirements. However, many commenters recommended a more robust noticing process, including increasing the number of required notices to two for these passive enrollments. Some commenters also recommended that impacted plans provide the notices in beneficiaries' primary language and identify for each enrollee any providers or prescription drugs not included under their new plan. A few commenters recommended additional telephonic outreach for beneficiaries whose notices are returned by the postal service as undeliverable and for those whose primary language is not English.

Response: We agree with most commenters on this issue that, on balance, two notices may be more beneficial than one notice when enrollees are being passively enrolled from one integrated D–SNP into another under paragraph (g)(1)(iii). A second notice provides an additional opportunity for the receiving D–SNP to connect with new members and to ensure they receive information about their benefits, rights, and options. We believe the benefits from an additional notice outweigh the additional burden. In contrast, passive enrollments effectuated under paragraphs (g)(1)(i) and (ii)—in other words, when an immediate termination as provided in § 422.510(b)(2)(i)(B) occurs or when CMS determines a plan poses a potential risk of harm to enrollees—are typically performed under time constraints which may make the provision of two notices impracticable.

We are therefore finalizing the notice requirements associated with passive enrollments under paragraph (g)(1)(iii) to require two notices and to establish parameters around the timing of such notices. Accordingly, we are adding new paragraph (g)(4)(ii) to require that plans receiving passive enrollments under paragraph (g)(1)(iii) send two notices to enrollees that describe the costs and benefits of the plan and the process for accessing care under the plan and clearly explain the beneficiary's ability to decline the enrollment or choose another plan. In addition, we are adding new paragraph (ii)(A) to specify that the first notice provided under paragraph (ii) must be provided, in a form and manner determined by CMS, no fewer than 60 days prior to the enrollment effective date. We are also adding a new paragraph (ii)(B) to specify that the second notice must be provided—again, in a form and manner determined by CMS—no fewer than 30 days prior to the enrollment effective date.

We clarify that for passive enrollments under paragraphs (g)(1)(i) and (ii), only one notice will be required. This requirement is now reflected in new paragraph (4)(i), which also specifies that the notice must describe the costs and benefits of the plan and the process for accessing care under the plan, as well as the beneficiary's ability to decline enrollment or choose another plan, and be provided prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical).

We appreciate commenters' suggestions about the importance of telephonic outreach and will encourage affected plans to conduct this additional telephonic outreach. We will also encourage the D–SNPs losing members to passive enrollment into another plan to share information about their enrollees' language preferences to facilitate the provision of information in non-English languages and alternate formats as applicable. As we gain additional experience using this passive enrollment authority, we will consider the development of additional guidance or further rulemaking about beneficiary notice requirements as necessary.

Comment: We received a number of comments about the content of beneficiary notices sent to passively enrolled individuals. Some commenters recommended that notices used as part of this process be consumer tested. Several commenters recommended that notices include alternative options for Medicare coverage, such as available PACE organizations. A few commenters suggested that the notices include information on the Special Election Period (SEP) and opt-out process. A few commenters also recommended that beneficiaries have access to individual counseling regarding their benefit options. A commenter recommended that notices be designed to ensure informed consent by affected enrollees.

Response: We appreciate the suggestions commenters provided about the content of beneficiary notices for passive enrollment under paragraph (g)(1)(iii). We note that CMS currently requires notices sent to passively enrolled individuals to clearly explain the beneficiary's ability to decline the enrollment or choose another plan. We are therefore finalizing the requirements related to notice content without modification at § 422.60(g)(4)(i) and (ii), as described elsewhere in this preamble. We agree with commenters who emphasized the importance of providing additional information and counseling to inform beneficiary choice. As we move forward with implementation of this limited expansion of CMS' passive enrollment authority, we will consider developing a notice template that includes information about the availability of resources for additional information and choice counseling in the impacted service area, including SHIP programs, as well as 1–800–Medicare and Medicare Plan Finder. We will consider opportunities for consumer testing notice language, though we note that each instance of passive enrollment under this authority will be unique and require tailoring to the specific circumstances. As noted previously, we believe that the addition of a second notice will help increase beneficiaries' awareness of the change to their coverage and ensure individuals have the information to make decisions about whether to remain in the new integrated D–SNP or select other coverage that better serves their needs.

Comment: A few commenters recommended any beneficiary who is unable to be contacted should not be passively enrolled and should instead be defaulted into FFS Medicare.

Response: We do not agree with these commenters. The individuals impacted by our proposal are those already enrolled in an integrated D–SNP and who, absent our application of CMS' passive enrollment authority, would lose access to their current integrated care. Dually eligible individuals will have various SEPs available, including the Part D SEP for dual and other LIS-eligible beneficiaries discussed in section II.A.10 of this final rule and the new SEP at § 423.38(c)(10) discussed in section II.A.10 of this final rule that allows individuals who have been auto-enrolled, facilitated enrolled, passively enrolled, or reassigned into a plan by CMS an opportunity to change plans. These SEPs will allow any individual who does not wish to retain coverage

under his or her new integrated D–SNP to make a different election, including opting for coverage in FFS Medicare. We also note that the addition of the SEP at § 423.38(c)(10) to this final rule renders the SEP described in current § 422.60(g)(5) duplicative because it applies to all individuals who have been enrolled in a plan as a result of a CMS- or state-initiated enrollment action, including passive enrollment under § 422.60(g). To avoid operational complexity, we are therefore finalizing this provision by replacing the language describing the SEP for passively enrolled individuals at § 422.60(g)(5) with a cross-reference to the new SEP described at § 423.38(c)(10).

Comment: A commenter suggested that CMS provide additional opportunities for states to fully integrate Medicaid and Medicare noticing and beneficiary communications materials for integrated products.

Response: We appreciate the support for further integration of Medicare and Medicaid benefits information for integrated D–SNPs and note that CMS has made progress toward this goal in collaboration with some state partners. However, this comment is outside the scope of this regulation.

Comment: Several commenters requested clarification on how the SEP related to our proposed passive enrollment provision would be impacted by, or would interact with, the proposal to limit the Part D SEP for dual and other LIS-eligible beneficiaries.

Response: As previously discussed, dually eligible beneficiaries will have access to other SEPs, including the Part D SEP for dual and other LIS-eligible beneficiaries and the new SEP finalized in this rule at § 423.38(c)(10) that allows individuals who have been auto-enrolled, facilitated enrolled, passively enrolled, or reassigned into a plan by CMS or a state an opportunity to change plans.

Comment: A couple of commenters noted a lack of alignment between the length of the SEP for passive enrollees under § 422.62(b)(4)—that is, 60 days—and the 90-day disenrollment period afforded to enrollees passively enrolled into a Medicaid managed care organization under § 438.56.

Response: The commenters are correct that the length of the SEP for passive enrollees, as described in the proposal, and that of the Medicaid managed care disenrollment period are not the same. In certain integrated care programs, the combination of changes to the SEP for dual eligible beneficiaries (discussed in section II.A.10.of this final rule) and the 2-month period for the SEP in proposed § 422.60(g)(5) could lead to beneficiary confusion and unintended misalignments between Medicare and Medicaid. As noted previously in this preamble, we are finalizing § 422.60(g)(5) with modifications to replace the language describing the SEP for passively enrolled individuals with a cross-reference to the new SEP described at § 423.38(c)(10). This SEP will allow individuals to opt out of the passive enrollment within 3 months of notification of a CMS or state-initiated enrollment action or that enrollment action's effective date (whichever is later). We believe this change will better align the length of the SEP for individuals who are passively enrolled under § 422.60(g) with the Medicaid managed care disenrollment period under § 438.56.

Comment: A commenter encouraged CMS to monitor any negative and unintended consequences of our use of passive enrollment after implementation of our proposed expanded authority.

Response: We appreciate the commenters' concerns and clarify that we intend to use all currently available mechanisms to monitor any passive enrollments into integrated D–SNPs, including grievances and complaints reported to impacted plans and to 1–800–Medicare. We are committed to making all necessary adjustments as we gain experience with the application of passive enrollment in the circumstances provided for in this final rule, including future rulemaking as necessary.

After consideration of the comments we received, we are finalizing our proposal regarding the expansion of CMS' regulatory authority to initiate passive enrollment for certain dually eligible beneficiaries who are currently enrolled in an integrated D–SNP into another integrated D–SNP at § 422.60(g) with some modifications. Specifically, we are making the following modifications:

- We are making a technical revision to paragraph (g)(1)(iii) to clarify that a plan must meet all the requirements established in paragraph (g)(2) to be eligible to receive passive enrollment.
- We are revising paragraph (g)(2)(iii) to require a minimum Star Rating that applies for a plan to be eligible to receive passive enrollment. For a plan to be eligible to receive passive enrollment, it must have an overall quality rating, from the most recently issued ratings, under the rating system described in §§ 422.160 through 422.166, of at least 3 stars or is a low enrollment contract or new MA plan as defined in § 422.252.
- We are adding new paragraph (g)(4)(ii) to require that plans receiving passive enrollments under paragraph (g)(1)(iii) send two notices to enrollees that describe the costs and benefits of the plan and the process for accessing care under the plan and clearly explain the beneficiary's ability to decline the enrollment or choose another plan. In addition, we are adding new paragraph (ii)(A) to specify that the first notice provided under paragraph (ii) must be provided, in a form and manner determined by CMS, no fewer than 60 days prior to the enrollment effective date. We are also adding a new paragraph (ii)(B) to specify that the second notice must be provided, in a form and manner determined by CMS, no fewer than 30 days prior to the enrollment effective date. New paragraph (g)(4)(i) will retain the original requirement that one notice be provided to passively enrolled individuals under paragraphs (g)(1)(i) and (ii).
- We are modifying § 422.60(g)(5) by replacing the current language describing the SEP for passively enrolled individuals at § 422.60(g)(5) with a cross-reference to the new SEP described at § 423.38(c)(10), which provides a 3-month SEP when an enrollee has been auto-enrolled, facilitated enrolled, passively enrolled, or reassigned into a Part D plan as a result of a CMS or state-initiated enrollment action. We note that all D–SNPs are also Part D plans as they are required to provide the Part D prescription drug benefit pursuant to § 422.2 (definition of specialized MA plans for special needs individuals).

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. The requirements for tiering exceptions, set forth at § 423.578(a), require plan sponsors to establish and maintain reasonable and complete exceptions procedures that 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.

As we stated in the proposed rule, we believe that changes in the prescription drug marketplace necessitate revisions to existing regulations to ensure that tiering exceptions are adjudicated by plan sponsors in the manner the statute contemplates, and are understood by beneficiaries. Therefore, we proposed various changes to §§ 423.560, 423.578(a) and 423.578(c) to revise and clarify requirements for how tiering exceptions are to be adjudicated and effectuated (82 FR 56371).

We received the following general comments on this proposal and our responses follow:

Comment: We received many comments on the proposal. While most comments received were generally supportive of our efforts to update and improve tiering exceptions policy, there was mixed support for and opposition to specific aspects of what we proposed. Many commenters who supported our overall proposal noted that beneficiaries have difficulty understanding the existing policy, and stated that there is a need for a more simplified process. A commenter who opposed revising our existing policy for tiering exceptions stated that plans and enrollees already understand the current policy and there will be little positive outcome. Another commenter agreed that tiering exceptions are an important beneficiary protection, but stated a belief that they undermine plan sponsors' ability to manage their formularies, which are already reviewed by CMS for clinical accuracy. This commenter also stated that tiering exceptions provide no incentive for an enrollee to try a less expensive drug found on a lower tier if they are able to get a more expensive drug at a lower cost.

Response: We thank the commenters who supported our proposal for their support. We agree that this policy area has been confusing for beneficiaries and one of our goals in making changes is to make it more understandable. We believe that the proposed revisions will streamline and clarify the requirements for tiering exceptions, as well as help ensure that enrollees have appropriate access to medically necessary drugs.

We disagree with the comment that tiering exceptions provide no incentive for enrollees to try lower-cost drugs. On the contrary, § 1860D–4(g)(2) stipulates that, in order for a tiering exception to be approved, the enrollee's prescriber must determine that the preferred drug for treatment of the same condition has been or would be less effective or have adverse effects for that individual. If the enrollee cannot demonstrate that the requested drug is medically necessary, a tiering exception cannot be obtained.

We address comments about specific aspects of the tiering exceptions proposal in relevant sections below.

Comment: Several commenters requested that CMS ensure beneficiaries are educated about the availability of tiering exceptions. Some commenters expressed a belief that there is little information available to beneficiaries about tiering exceptions, and that it is difficult to apply to individual situations. Comments offered several suggestions, including improving existing educational publications and information provided through 1–800–MEDICARE, providing information in plain language, and developing notices that provide information at the pharmacy counter. Some commenters stated that CMS should require plan sponsors to improve information provided in their member materials, and noted that plans and pharmacies have a responsibility for educating beneficiaries about the availability of tiering exceptions.

Response: We agree that information about the availability of tiering exceptions must be provided to beneficiaries by CMS and their Part D plan sponsor. We note that such information is already contained in several CMS publications, including Medicare & You (CMS pub. 10050), Medicare Appeals (CMS pub. 11525), Your Guide to Medicare Prescription Drug Coverage (CMS pub. 11109) and Medicare Rights and Protections (CMS pub. 11534), as well as documents that plans are required to provide to enrollees, including the Evidence of Coverage, Part D formulary, and Annual Notice of Change. Information about the availability of tiering exceptions is also included in the standardized pharmacy notice (CMS–10147) provided to affected enrollees at the point of sale when a claim is rejected by their Part D plan sponsor, and in the standardized Part D denial notice (CMS–10146), which is provided to enrollees when their plan makes an adverse coverage determination. Such information is also found on *Medicare.gov.* CMS will continue to review plan documents and beneficiary publications to identify potential areas for improvement, and update the documents mentioned above as needed based on this final rule, including consideration of how to clarify when a tiering exception may be available.

Comment: Several commenters recommended that CMS ensure consistent understanding of tiering exceptions policy by providing specific guidance to plan sponsors related to the review of tiering exception requests, including examples using various formulary structures that illustrate the steps of the process, and guidance to determine the lowest applicable tier and appropriate alternative drugs. A commenter expressed concern that the proposed rule conflicts with current guidance in Chapter 18 of the Medicare Prescription Drug Benefit Manual.

Response: We appreciate the commenters' suggestions for additional guidance to ensure that plan sponsors understand the revised policy and properly process tiering exception requests. CMS manual guidance will be updated to reflect the changes made through this final rule. With respect to the comment about the existing version of Chapter 18, we note that existing guidance reflects existing regulations and policy.

Comment: A commenter asserted that utilization management tools, such as the use of tiered cost-sharing to encourage use of lower-cost drugs, put unnecessary burden on prescribers and cause access delays for beneficiaries. The commenter stated that exception requests usually require prescribers to submit a written statement supporting the exception request, and noted that prescribers are not compensated for time spent preparing these statements or obtaining utilization management information for the specific plans used by their patients. This commenter also suggested that if there was greater transparency on which medications are subject to utilization management tools, it would reduce the administrative burden placed on physicians.

Response: We thank the commenter for sharing their concerns. Because section 1860D–4(g)(2) of the Act specifies that a tiering exception could be granted ''if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both,'' we do not believe CMS has authority to require plans to provide tiering exceptions in the absence of such a statement from the prescriber. Under existing § 423.568(a), plans are required to accept oral requests for benefits at the coverage determination level, including exception requests, and CMS encourages plans to accept oral prescriber supporting statements for exception requests when appropriate.

Comment: A commenter recommended that SNPs, MMPs, and defined standard benefit plans be exempt from the tiering exceptions process. This commenter also asked that

CMS explain how tiering exceptions are applied to Low Income Subsidy (LIS) beneficiaries.

Response: We appreciate the commenter's recommendation. In accordance with § 423.578(a), the exceptions process applies to Part D plans that provide prescription drug benefits through the use of a tiered formulary. Given the fixed copays for LIS beneficiaries, that are based on whether the drug is a brand or generic product pursuant to § 423.782(a)(2)(iii)(A), tiering exceptions do not apply. Regardless of whether the beneficiary meets the medical necessity criteria for the drug in the higher tier, it would not change the brand vs. generic nature of the requested drug, so the cost-sharing would remain fixed.

b. Limitations on Tiering Exceptions

We proposed 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.'' This adds a cross-reference to revised paragraph (a)(6), which revises allowable limitations plan sponsors are permitted to establish in their tiering exceptions procedures.

At § 423.578(a)(6), we proposed to revise the regulations to specify how a Part D plan sponsor may limit tiering exceptions. The proposed revision strikes the existing regulation text which permits plans to disallow tiering exceptions for any non-preferred drug to cost-sharing associated with a dedicated generic tier. We proposed to replace it with new regulation text at § 423.578(a)(6) specifying that a Part D plan sponsor will not be required to offer a tiering exception for a brand name drug or biological product to a preferred cost-sharing level that applies only to generic alternatives. Under our proposal, 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 dedicated generic tier(s) and when the lower tier(s) contain a mix of brand and generic alternatives. In other words, plans would no longer 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 includes only generic drugs.

We proposed to revise existing tiering exceptions policy for brand name and generic drugs, and proposed a new policy for requests involving biological products. First, we proposed to revise § 423.578(a)(6) by adding 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 biosimilar and interchangeable biological products, licensed under section 351 the Public Health Service Act.

With the proposed revisions, 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. As discussed above, cost sharing for approved tiering exceptions for non-preferred generic drugs would be assigned to the lowest applicable cost-sharing associated with alternative drug(s) that could be either brand name or generic drugs.

We proposed 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 a 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)).

We proposed to codify existing CMS policy treating authorized generics as generics for purposes of tiering exceptions because the process used by CMS to collect Part D plan formulary data does not allow us to clearly identify whether a plan sponsor includes coverage of authorized generic National Drug Codes (NDCs). 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; rather, the plan sponsor would be permitted to limit tiering exceptions for a particular brand drug or biological product to the lowest cost sharing tier containing alternatives of the same drug type. Plans will 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 are met.

Finally, we proposed to revise and redesignate existing § 423.578(a)(7) as new § 423.578(a)(6)(iii), to 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 proposed 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.

The proposed changes retain the existing regulatory policy that permits Part D plan sponsors to disallow tiering exceptions for any drug that is on the plan's specialty tier. While we did not propose to specify it in regulation text, we stated in the preamble to the proposed rule (82 FR 56372) 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 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 received the following comments and our responses follow:

Comment: We received many comments on this aspect of our proposal. Most commenters were supportive of the proposal to remove the generic tier exclusion and replace it with limitations that apply to brand name drugs and biological products. Some commenters opposed our proposal to remove the generic tier exclusion, stating that this would discourage plans from offering $0 copayment tiers and increase costs for enrollees. Others opposed the proposal to allow plans to limit tiering exceptions for brand name drugs only when brand alternatives are on a lower tier, noting that allowing plans to limit tiering exceptions for brand drugs to the lowest

cost-sharing associated with brand alternatives does not provide sufficient relief for enrollees with a medical need for a brand drug because they cannot take a lower cost generic. Commenters expressed concern that this would eliminate beneficiaries' ability to seek tiering exceptions in many cases, and also stated that nothing in the statute permits these limitations.

Response: We thank commenters who supported the proposed changes for their support. As we stated in the proposed rule, we believe a policy that allows beneficiaries with a medical need for a non-preferred product to seek and obtain more favorable cost-sharing through the tiering exceptions process must be balanced by reasonable limitations to ensure that all enrollees have access to medically necessary drugs at the most favorable cost-sharing terms possible.

We disagree with the commenters opposed to our proposal to require plans to include dedicated generic tiers in their tiering exceptions procedures. As we discussed in the preamble to the proposed rule (82 FR 56371), most Part D formularies now include multiple generic tiers, as well as multiple higher-cost tiers that contain a mix of brand and generic drugs. To encourage the use of generic drugs, we proposed to revise the existing regulatory policy to permit tiering exceptions into dedicated generic tiers, but allow plans to limit those exceptions to requests involving non-preferred generic drugs. Because approval of a tiering exception continues to require that the enrollee demonstrate a medical need for the non-preferred drug, and because plans will not be required to permit exceptions for brand name drugs or biological products to the cost-sharing associated with dedicated generic tiers, we do not believe this change will result in changes to plan benefit design.

We disagree with the comments asserting that the statute does not permit tiering exceptions for non-preferred brand name drugs to be limited to the cost sharing associated with preferred brand name drugs. Section 1860D–4(g)(2) of the Act specifies that Part D plan sponsors offering a tiered drug benefit must have a process for tiering exceptions, consistent with guidelines established by the Secretary for making such determinations, where ''a nonpreferred drug *could* be covered under the terms applicable for preferred drugs'' (emphasis added). While we agree that the statutory language does not specifically refer to brand name and generic drugs, it clearly gives CMS authority to establish guidelines for plan procedures, and does not require that such exceptions be available in all circumstances.

Comment: Several commenters supported our proposal to treat authorized generic drugs in the same manner as generic drugs for tiering exceptions.

Response: We thank the commenters for their support.

Comment: We received some comments requesting that CMS specify that multi-source drugs and other drugs that do not meet the definition of a generic or authorized generic drug, but that a plan may place on a generic-labeled tier, also be treated as generic drugs for purposes of tiering exceptions.

Response: We disagree with these comments. As discussed above, we are revising the tiering exceptions regulations to specify that authorized generic drugs be treated as generic drugs. We recognize that other drugs may be treated in a similar manner to generic drugs, including being placed on generic-labeled drug tiers; however, we believe further expansion of what drugs are treated as generics would introduce additional complexity to a process that beneficiaries and plans already have difficulty understanding. For example, whether a brand drug is a ''multi-source'' drug is dependent on multiple factors and may change over time. An authorized generic is determined at the time of FDA approval and does not change as long as the drug is marketed under that approval, regardless of how many other interchangeable drugs may be introduced to or leave the market. Because tier placement of the same drug can vary widely across Part D plans, we believe that applying rules based on FDA approval type is the best way to limit confusion and create a consistent policy. Additionally, we believe that an enrollee who cannot take a brand drug on a lower-cost tier, regardless of the tier label, should be able to obtain the brand drug on a higher-cost tier at the more favorable cost-sharing of the brand drug on the lower-cost tier.

Comment: We received many comments related to our proposal to retain the current regulatory policy allowing plans to exclude specialty tier drugs from their tiering exceptions process. Commenters were divided on whether they supported or opposed this proposal. Some commenters asked CMS to confirm that drugs on the specialty tier will continue to be exempt from tiering exceptions.

Commenters who supported our proposal stated that tiering exceptions should not be allowed for specialty tier drugs because alternative drugs on lower tiers are not typically appropriate or therapeutically equivalent, even though they may treat the same condition.

Commenters who opposed this limitation on tiering exceptions noted that vulnerable beneficiaries who need to access specialty tier drugs often do not have alternative options on more preferred tiers and can accrue very high out of pocket costs. A few noted that cost-prohibitive out of pocket expenses can lead to decreased adherence to drug therapies and put patients at risk. Some commenters questioned CMS' authority to allow plans to exclude specialty tier drugs from the tiering exceptions process because the statute gives beneficiaries the right to request a tiering exception for any non-preferred drug when the formulary contains a preferred drug for the same condition that has lower cost sharing. A commenter stated that prohibiting tiering exceptions for specialty tier drugs discriminates against beneficiaries who need them.

Response: We appreciate the comments expressing concern about beneficiary access to very high cost drugs. While CMS is aware that access to needed drug therapies can be impacted by the out of pocket expenses associated with these drugs, we do not believe that requiring plans to offer tiering exceptions for specialty tier drugs will result in the desired effect. In order for a drug to be placed on the specialty tier, the plan's negotiated price for the drug must exceed a monthly threshold established by the Secretary ($670 for 2018). Along with the protection against tiering exceptions for specialty tier drugs that is afforded to plans, CMS also requires plans to limit enrollee cost sharing for the specialty tier to 25 percent coinsurance (up to 33 percent if the plan waives all or part of the Part D deductible), which aligns with the statutorily defined maximum cost sharing for the defined standard benefit at section 1860D–2(b)(2)(A). When high cost drugs are placed on the specialty tier instead of a Non-Preferred Brand or Non-Preferred Drug tier, which can have up to 50 percent coinsurance, the cost to enrollees who would not qualify for a tiering exception is often considerably lower than if the same drug were placed on one of these other non-preferred tiers. Additionally, many specialty tier drugs, particularly biological products, often do not have viable alternatives on lower-cost tiers. The statutory basis for approval of a tiering exception request is the presence of an alternative drug(s) on a lower cost-sharing tier of the plan's formulary; therefore, even if a plan sponsor permitted tiering exceptions for

specialty tier drugs, such requests would not be approvable if the plan's formulary did not include any alternative drugs on a lower tier.

We disagree with the comments positing that allowing plans to exclude the specialty tier from their tiering exceptions procedures is inconsistent with the statute. As discussed above in this section, section 1860D–4(g)(2) of the Act gives CMS authority to establish guidelines for Part D plan sponsors' tiering exceptions procedures, and does not require such exceptions to be available in all circumstances. For the reasons stated earlier, we believe that our current policy of allowing plans to exclude specialty tier drugs from their tiering exceptions procedures, coupled with the maximum allowable coinsurance of 25 percent to 33 percent for the specialty tier, affords the most beneficiaries the most protection from high out-of-pocket expenses associated with very high cost drugs.

Comment: A few commenters suggested that CMS permit plan sponsors to designate two specialty tiers on their formularies—a non-preferred specialty tier, as well as a preferred specialty tier that would have lower cost sharing. These commenters expressed a belief that permitting plans to have two specialty tiers would encourage increased competition among specialty drugs, giving plans greater leverage in price negotiations, resulting in more affordable access for Part D enrollees and lower costs for the program. The commenters also noted that permitting two specialty tiers could encourage enrollees to try preferred specialty products and could reduce the need for enrollees to seek coverage through the non-formulary exceptions process.

Response: While we appreciate these comments, we disagree with the suggestion to permit Part D plans to have a preferred and a non-preferred specialty tier. As discussed above, CMS limits specialty tier cost sharing to the statutorily mandated amount for the defined standard Part D benefit. While we did not propose to allow plans to establish multiple specialty tiers, we are making significant changes to existing tiering exceptions policy through this final rule, including removal of the generic tier exclusion and addition of the brand-to-brand limitation discussed above in subsection b. Additionally, while the plan's cost for a drug must exceed a CMS-specified monthly cost threshold in order to be placed on the specialty tier, CMS does not require all drugs exceeding that threshold be placed on the specialty tier. In other words, if plans wish to encourage the use of certain specialty drugs over others, they can do so within existing formulary benefit designs. As such, we are not making additional changes in this policy area before having an opportunity to consider the effects of the changes in this rule. CMS will continue to disallow plan benefit packages with more than one specialty tier.

Comment: We received some comments requesting that CMS clarify whether select care/select diabetic or other $0 copayment tiers can be excluded from a plan's tiering exceptions procedures. These commenters supported a policy that would permit such an exclusion, stating that requiring tiering exceptions to $0 or very low cost tiers would discourage plans from offering them and increase overall beneficiary out of pocket costs.

Response: We appreciate the commenter's requests for clarification. As discussed above, we proposed to revise the existing regulatory text that permits plans to exclude generic tiers from their tiering exceptions procedures. We did not propose to permit plans to exclude any formulary tiers other than the specialty tier, and do not agree that such an exclusion is advisable. As we stated in the proposed rule, we believe that tiering exceptions are an important enrollee protection and must not be restricted to such a degree. Under the proposed rule, which we are finalizing without modification, plans can establish tiering exceptions procedures where they do not have to offer such exceptions for brand name drugs or biological products to more preferred cost-sharing tiers that do not contain an alternative brand name or biological product, respectively. We believe that permitting additional restrictions that make certain low-cost tiers wholly inaccessible to beneficiaries with a medical need for a non-preferred drug would be inappropriate.

Comment: A commenter urged CMS to monitor Part D plan formularies to ensure that plans do not change their formularies in an effort to decrease opportunities for tiering exceptions. Another commenter suggested that CMS consider requiring plan sponsors to establish evidence-based formularies that tie enrollee cost-sharing to the appropriateness of medications based on safety and efficacy.

Response: All Part D plan formularies must be approved by CMS as part of the bid review process described at § 423.272. Under § 423.120(b)(1), formularies must be developed and reviewed by a pharmacy and therapeutic committee that makes clinical decisions based on scientific evidence and standards of practice and considers safety and efficacy when determining inclusion of a drug on a formulary, including tier placement.

Comment: We received a comment requesting that CMS clarify non-formulary drugs approved for a formulary exception continue to be ineligible for tiering exceptions. Another commenter suggested that CMS consider ways to make it easier for individuals applying for a formulary exception to also apply for a tiering exception, if applicable.

Response: We appreciate the commenter's request for clarification. We did not propose to revise the existing requirement set forth at § 423.578(c)(4)(iii) which establishes that an enrollee may not request a tiering exception for a non-formulary drug approved under the formulary exceptions rules at § 423.578(b). Under the proposed changes to tiering exceptions rules, which we are finalizing as proposed, an enrollee may not obtain a tiering exception for an approved non-formulary drug. We note that, if an enrollee obtains an exception to a utilization management requirement such as step therapy or a quantity limit, such enrollee may also request a tiering exception, pursuant to § 423.578(a) and (c). The model Part D coverage determination request form, developed by CMS with stakeholder feedback, permits an enrollee or their prescriber, on the enrollee's behalf, to request a tiering exception along with, for example, prior authorization. The form includes check boxes for various types of requests, including an exception to cost-sharing.

Comment: We received some comments opposed to requiring plans to consider tiering exceptions for non-preferred drugs to specialty tier cost-sharing when the specialty tier cost-sharing is more favorable for the enrollee. Some of these commenters stated that such a policy would be confusing for enrollees because the specialty tier is often a higher-numbered tier (for example, tier 5 on a 5-tier formulary). Commenters also stated that it would be overly burdensome for plans to administer such a policy, particularly if the exception request is for a drug on a copayment tier to a coinsurance tier (for example, tier 4—Non Preferred Drug has a $100 copayment and tier 5—Specialty has a 25 percent coinsurance). These commenters opined that allowing a drug with a copayment to be approved to a coinsurance tier would bypass formulary design and require extensive price review and calculation to determine which tier is more favorable. A commenter asked CMS to clarify whether plans would be permitted to

retain specialty tier supply limits such as a 30 day supply, even if the enrollee wishes to obtain a 90 day supply and a tiering exception is approved.

Response: We appreciate the comments received on this aspect of the proposal. We are persuaded by the comments received that requiring plans to consider tiering exceptions into the specialty tier would be confusing and difficult for plans to implement, and are not finalizing this aspect of the proposal. While we believe many of the concerns expressed by commenters would be addressed by clarifying that such a policy would only apply if the requested drug meets the specialty tier cost threshold, we recognize it would still be difficult to explain to enrollees, who probably would have no knowledge as to whether any given drug would meet the specialty tier cost threshold and would be very unlikely to request such an exception. As noted above, we did not propose regulation text for such a requirement, and therefore, while we are not finalizing it, we are also not making any changes to the proposed regulation text.

Comment: A few commenters stated that CMS should conduct an analysis of Part D plan formularies to ensure plans are not discriminating against beneficiaries by always placing certain classes of drugs on specialty tiers. A commenter asserted that, without standardized tiering in Part D, nothing prevents plans from putting high cost brand name drugs on specialty tiers to avoid having to offer tiering exceptions. The commenter stated that CMS should establish additional requirements for tiered formularies, such as requiring that all generic drugs be placed on tier 1 or tier 2. Another commenter recommended that CMS continue to explore improvements to benefit design and meaningful exceptions to high cost-sharing.

Response: Pursuant to existing Part D policy and the proposed definition of specialty tier, it is a tier dedicated to very high cost drugs, which are often brand name drugs or biological products. As noted in a previous response, pursuant to § 423.120(b)(1), formularies must be developed and reviewed by a pharmacy and therapeutic committee that makes clinical decisions based on scientific evidence and standards of practice, and considers safety and efficacy when determining inclusion of a drug on a formulary, including that drug's tier placement. While CMS does not prohibit plan sponsors from having a mix of both brand and generic drugs on each tier, it is our expectation that a tier label be representative of the drugs that make up that tier. Additionally, consistent with § 30.2.7 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, CMS reviews formularies for the placement of drugs in non-preferred tiers in the absence of therapeutically similar drugs in preferred tiers.

Comment: A few commenters stated that CMS should increase the $670 specialty tier cost threshold to reduce the number of drugs that qualify and, therefore, reduce out of pocket spending for beneficiaries.

Response: As we did not propose to change the specialty tier threshold in this rule, we decline to adopt this recommendation.

After consideration of the comments received, we believe our proposed revisions to § 423.578(a)(6) regarding the limitations plans are permitted to establish for tiering exceptions strike an appropriate balance between allowing plans to manage their formularies and ensuring enrollee access to this statutory protection. These revisions prohibit plans from excluding generic drug tiers from their tiering exceptions procedures, and permit plans to limit tiering exceptions for brand name drugs to the lowest applicable cost sharing associated with preferred brand name alternatives, and tiering exceptions for biological products to the lowest applicable cost sharing associated with preferred biological product alternatives. We are finalizing the proposed revisions to § 423.578(a)(6) and the proposed definition of specialty tier at § 423.560 without modification, noting the clarification discussed above that plans are not required to treat the specialty tier as a preferred cost-sharing tier for purposes of tiering exceptions. CMS continues to explore ways to ensure Part D enrollees are able to access very high cost, medically necessary prescription drugs.

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

We noted in the proposed rule that we have 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.'' While our proposal did not include regulation text specific to the meaning of an alternative drug, we clarified in the preamble that we interpret this language to refer 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.

We received the following comments on this section and our responses follow:

Comment: We received several comments related to how to determine which drugs should be considered alternatives for treating the enrollee's health condition. Some of these commenters were supportive of the additional information we provided in the preamble to the proposed rule about how to determine alternative drugs. Most of the commenters stated that a more specific regulatory definition of alternative drug is needed. Some commenters recommended that the definition specify that alternative drugs must be one or more of the following: supported in drug compendia or treatment guidelines for use in the same place in therapy, FDA-approved for the same indication as the requested drug, in the same therapeutic class and/or category as the requested drug, use the same route of administration as the requested drug, and/or have the same mechanism of action as the requested drug.

Several commenters provided various hypothetical scenarios using specific diagnoses and drugs and asked that CMS clarify whether a tiering exception would be allowed under our interpretation. A commenter asked CMS to provide examples that include how to determine what an appropriate alternative drug is. Another commenter stated that plan sponsors will continue to inaccurately apply rules for tiering exceptions because CMS does not define what a preferred alternative drug is. A few commenters stated that CMS' proposed interpretation of ''same condition'' will limit exception requests and negatively impact beneficiaries. A few commenters stated that this interpretation has no statutory basis, and one of the commenters asserted that our clarification basing what constitutes an alternative drug on the individual characteristics and condition of the enrollee would make it easy for plans to claim there are no alternatives for treating that enrollee and therefore no tiering exception would be allowed.

Response: The statutory language noted above related to approval of a tiering exception request broadly refers to preferred drugs ''for treatment of the

same condition.'' We believe that most of the criteria suggested by commenters would be more restrictive than the statute allows if plans were required to apply such criteria to all tiering exception situations, and we therefore disagree that such criteria should be specified in regulation. For example, if the mechanism of action or route of administration of a plan's preferred alternative drug would cause adverse effects for a particular enrollee versus the non-preferred drug for treating the same condition, this could be the basis for that enrollee to seek a tiering exception for the non-preferred drug. Also, CMS does not specify the classification system that must be used on Part D plan formularies; therefore, establishing a requirement that alternative drugs must be in the same therapeutic class would introduce inconsistency because what one plan considers the same drug class may be different than another plan for the same drugs. The changes to the tiering exception regulations that we are finalizing in this rule do not require plans to consider a drug for which the enrollee's condition is not a medically accepted indication to be an alternative drug for purposes of a tiering exception request. Because payment under Part D cannot be made for any drug that does not meet the definition of a Part D drug for the prescribed indication, such drug could not reasonably be considered an alternative drug for treatment of the enrollee's condition.

In response to comments suggesting that our interpretation of ''for treatment of the same condition'' is inconsistent with the statute, we disagree. As we noted in the proposed rule, we interpret this language to refer to the condition as it affects the enrollee. Given the language in section 1860D–4(g)(2) of the Act states that an exception could be covered if the prescribing physician determines that the preferred drug would not be as effective ''for the individual'' or would have adverse effects ''for the individual,'' we believe it is appropriate to interpret the standard for the ''same condition'' to be referring to the individual.

While we are not making any changes to the regulations with respect to defining alternative drugs, we wish to note that plan medical directors are required to be involved in the development and oversight of policies and procedures for processing exception requests, including criteria for determining alternative drugs, as part of their responsibility under § 423.562(a)(5) to ensure the clinical accuracy of all coverage determinations and redeterminations involving medical necessity. Additionally, § 423.566(d) requires that, before issuing an adverse coverage determination based on lack of medical necessity, including exception requests, it must be reviewed by a physician or appropriate health care professional. These policies requiring clinician involvement in the establishment and application of plan coverage rules contemplate that those individuals apply reasonable clinical judgment, based on sound medical and scientific evidence and acceptable standards of practice, in adjudicating exception requests, including consideration of alternative drugs on the plan's formulary.

While we agree that in certain situations and with certain medical conditions, what is reasonably considered an alternative drug may be limited in ways suggested by commenters, we disagree that such designations should be codified in regulation to apply to all tiering exceptions for the reasons previously stated, and because we do not see a good reason to codify these types of clinical considerations only for tiering exceptions, when we have not proposed to do so for other types of coverage determinations. We also believe these clarifications provide sufficient guidance for plans to determine what drugs should be considered alternatives for treating the enrollee's condition, and will ensure that plans do not apply unreasonable clinical or policy standards to their interpretation of the meaning of alternative drug so as to inappropriately refuse to allow tiering exceptions. Therefore, we are not adding a definition of alternative drug in this final rule.

As discussed earlier in this preamble, CMS will update any existing agency guidance related to tiering exceptions as needed to ensure that it comports with the requirements of this final rule.

Comment: A commenter asked CMS to clarify whether a tiering exception should be approved when the requested drug is not being prescribed for a medically accepted indication, or does not otherwise meet the definition of a Part D drug.

Response: Pursuant to the existing regulation at § 423.578(e), which we did not propose to revise, enrollees are not permitted to use the exceptions process to obtain coverage for a drug that is not being prescribed to treat a medically accepted indication as defined in section 1860D–2(e)(4) of the Act, or does not otherwise meet the definition of a Part D drug at § 423.100. Thus, a plan cannot approve a tiering exception request if the requested drug is not being used to treat a medically accepted indication or does not meet the definition of a Part D drug.

After consideration of the comments received on this section, we are finalizing our proposal without modification, and have chosen not to further specify how to determine what an alternative drug for treating the enrollee's condition is.

e. Approval of Tiering Exception Requests

We proposed 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 our 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 received the following comments and our responses follow:

Comment: We received several comments related to this aspect of our proposal. Commenters were divided, with some supporting our proposal and others opposed. Commenters in support of the proposal to require approval at the lowest applicable tier stated that this policy allows beneficiaries who cannot take less expensive drugs to obtain needed drugs at an affordable price. Some commenters noted that they supported this aspect of the proposal because we also proposed to allow plans to limit tiering exceptions for brand name drugs to the lowest tier containing alternative brand name drugs. A few commenters expressed a belief that this policy would be easy for beneficiaries to understand.

Commenters who opposed our proposal stated that requiring approval to the lowest applicable tier interferes with plans' ability to manage their formularies. A few commenters expressed a belief that our proposal is not consistent with the statute, which states that the requested drug could be covered at terms applicable to preferred drugs but does not specify that it be the terms applicable to the most preferred alternatives. A commenter stated that § 1860D–4(g)(2) does not specifically refer to a right to obtain a drug at the lowest cost-sharing tier. Another commenter stated that requiring plans to provide high cost drugs at the lowest tier instead of the next lower tier increases premiums for all beneficiaries and provides only slightly lower cost-sharing for a few individuals.

Response: We thank commenters who were supportive of our proposal for their support. We agree that our policy of approval to the lowest applicable tier containing alternatives provides the most relief for beneficiaries with a medical need for a non-preferred drug.

We disagree that our proposal is inconsistent with the statute. Section 1860D–4(g)(2) provides that if a plan sponsor uses formulary tiers and offers lower cost sharing for ''preferred drugs'' (plural) included in the formulary, an enrollee may request an exception to the tiered cost-sharing structure, and under such an exception, a non-preferred drug could be covered ''under the terms applicable for preferred drugs'' (plural) if the prescriber determines that ''the preferred drug'' (singular) for the same condition would not be as effective or would have adverse effects, or both. The statute clearly contemplates that while there can be multiple drugs that are preferred drugs relative to the requested drug, and the prescribing physician can determine that ''the'' preferred drug would not be as effective or would have adverse effects. We believe it is reasonable to interpret this provision to permit an enrollee to seek a tiering exception under which he or she would pay the cost sharing applicable to the most preferred drug among one or more preferred drugs.

After consideration of the comments received, we are finalizing without modification our proposal at § 423.578(c)(3), which specifies that cost-sharing for approved tiering exceptions is assigned at the lowest applicable tier when preferred alternatives sit on multiple lower tiers.

f. Additional Technical Changes and Corrections

Finally, we proposed various technical changes and corrections to improve the clarity of the tiering exceptions regulations and consistency with the regulations for formulary exceptions. Specifically, we proposed 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 will improve consistency between the regulation text for tiering and formulary exceptions.

We received no comments on the proposed technical changes and corrections and are finalizing them without modification.

After consideration of all comments received on the tiering exceptions proposal, we are finalizing the proposed regulation text without modification. As discussed above, CMS will review agency guidance and beneficiary communications and revise as needed to be consistent with this final rule.

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

As discussed in section II.A.1 of this final 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) once a month throughout the year, unlike other Part D enrollees who generally may switch plans only during the annual enrollment period (AEP) each fall.

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.
- 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.
- 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.

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 (MedPAC [30]), opportunities for marketing abuses.

Among the key obstacles the continuous 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;
- Inefficient use of 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 coordinated treatment of chronic conditions; and
- Diminishing incentives for plans to innovate and invest in serving potentially high-cost members.

To support plan sponsors' efforts to administer benefits to beneficiaries, including coordination of Medicare and Medicaid benefits, and maximize care management and positive health outcomes, we proposed to amend § 423.38(c)(4) to make the SEP for FBDE and other subsidy-eligible individuals available only in certain circumstances. Specifically, we proposed 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 do not 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

[30] Medicare Payment Advisory Commission, ''Report to Congress: Medicare Payment Policy,'' March 2008.

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 also proposed to remove the phrase ''at any time'' in the introductory language of § 423.38(c) for the sake of clarity.

We considered multiple alternatives related to the SEP proposal. In the proposed rule, we described and asked for comments on two alternatives:

Limit of two or three uses of the SEP per year. 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.

Limits on midyear MA–PD plan switching. We also considered an option that would prohibit SEP use into non-integrated MA–PD plans, but allow continuous use of the dual SEP to allow eligible beneficiaries to enroll into FIDE SNPs or comparably integrated products for dually eligible beneficiaries or standalone PDPs.

We received the following comments and our responses follow:

Comment: Some commenters supported the proposal and agreed that continuity of enrollment could maximize coordination of care and positive health outcomes. However, the majority of commenters opposed the proposal based on a variety of factors. Most of these commenters expressed concerns about the impact on the dual-eligible population which, they noted, not only has limited financial resources, but also higher rates of disability, higher rates of cognitive impairment, and lower health literacy. These circumstances, commenters noted, often contribute to more complex and changing health needs and difficulties with medication adherence. Citing these circumstances, many commenters believed these beneficiaries needed the flexibility to change their healthcare coverage at any time during the year.

Commenters also believed that the proposal was too complex and would be difficult for beneficiaries to understand and for plans to administer. They noted that limited and, in some cases, multi-layered SEPs were unnecessary when the existing ongoing SEP has worked well and has proved to be simpler to communicate and understand.

Many commenters also said that the proposal would have an even greater impact given the proposed changes related to midyear formulary changes. Commenters noted that since plans have the ability to change formularies or provider networks during the year, the ongoing dual SEP is a vital beneficiary protection.

Lastly, commenters said that the proposed dual SEP limitation could, in actuality, hamper CMS' stated goal of bringing Medicare and Medicaid into better alignment because it could inadvertently discourage dual eligible beneficiaries from enrolling in integrated products. Commenters noted that because beneficiaries are often hesitant to change plans, they may opt to stay in their current plan instead of trying an integrated option. In other cases, commenters expressed concern that beneficiaries who are assigned into a plan by CMS or a State may panic and disenroll immediately if they believe pressured to make an immediate decision. Commenters said that the ongoing SEP gives beneficiaries the comfort and time to make a deliberate and educated choice.

Response: We thank the commenters for their thoughtful feedback. We are mindful of the unique health care challenges that dual and other LIS-eligible beneficiaries may face. The goals of the proposal were to improve administration of benefits and coordination of care and we believed that this could best be accomplished through continuity of enrollment. While we acknowledge that many commenters prefer the ongoing nature of the existing dual SEP, we still believe that adopting some limitations is an appropriate step toward encouraging care coordination, achieving positive health outcomes, and discouraging extraneous beneficiary movement during the plan year.

In response to comments, we are modifying our approach. In lieu of the proposed dual SEP limitation that would only allow a onetime use per year with certain exceptions, we are instead revising the dual SEP so that it is similar to the ''two or three uses per year'' alternative discussed in the proposed rule. Specifically, the dual SEP is being amended so that it can be used once per calendar quarter during the first nine months of the year (that is, one election during each of the following time periods: January–March, April–June, July–September). During the last quarter of the year, a beneficiary can use the AEP to make an election that would be effective on January 1. In addition to this change, the exception outlined at § 423.38(c)(4)(ii) related to CMS and State-initiated elections will not be finalized as proposed. (Instead, as discussed below, CMS will be using its authority under § 423.38(c)(8)(ii) to establish a coordinating SEP for those who are enrolled into a plan by CMS or a State at new § 423.38(c)(10).

We believe that limiting use of the dual SEP, but in a less restrictive manner, strikes the appropriate balance of our stated goals and the concerns raised by commenters, for the reasons that follow. We consider this approach to be less confusing for both plan sponsors and beneficiaries than our proposal because it provides a date-based parameter that is easier to comprehend without the additional layers of exceptions. By still allowing multiple changes throughout the year, dual and other LIS-eligible beneficiaries will maintain additional flexibilities not afforded to other Part D-eligible beneficiaries, but there may be times when these individuals cannot change plans and have that choice effective the next month either because they already made an election during that calendar quarter (during the first nine months of the year) or because they are making an election during the AEP. We believe that having certain periods when individuals must maintain enrollment in a particular plan will increase opportunities for coordination of care and case management. Even though these periods of required continuity of enrollment will be shorter than what was proposed, we believe it still matches our stated goals and addresses the concerns expressed by commenters.

While we believe this limitation is an appropriate control to put in place, we also believe that it will not impact the vast majority of individuals eligible for the dual SEP. As discussed in the proposed rule, 2016 data demonstrated that most beneficiaries do not use the dual SEP and, of those who do use it, the majority (74.5 percent) only used it once. Analysis of 2017 data continues to show that beneficiaries who use the SEP use it only one time (85.5 percent). Of those who use it two times, the average time between elections is 3.4 months, which is roughly the duration of a calendar quarter.

Given this flexibility, we believe that dual and other LIS-eligible beneficiaries will have the freedom to choose a plan that works for their evolving health care needs during the year. For those that have an opportunity to enroll in an integrated product, they will be able to do so and know that if it does not suit their needs, they can choose another

plan in the near future. The same logic can be applied to those who want to explore other plan options during the year due to formulary, provider network, or health status changes. We note, though, that as discussed earlier, individuals who have been identified as an at-risk beneficiary or potential at-risk beneficiary under § 423.100 will not be able to use the dual SEP. As discussed in section II.A.1, we are specifying at § 423.38(c)(4) that this particular limitation applies once the beneficiary has been notified that he or she has been identified as a potential at-risk beneficiary or at-risk beneficiary, and the limitation will continue until such identification has been terminated consistent with § 423.153(f).

Comment: Many commenters recommended a wide range of modifications or alternatives to the dual SEP limitation outlined in the proposed rule. Suggestions included the following:

- Allow beneficiaries to disenroll to FFS at any time.
- Instead of limiting the use of the dual SEP, require a minimum enrollment duration in a plan.
- Limit to onetime use per year, without exceptions, to mitigate administrative burden.
- Delay any sort of SEP limitation and, instead, contemplate for future rulemaking.

Some commenters—both those who supported and opposed the concept of a limitation to the dual SEP—expressed a preference for one of the two alternatives discussed in the proposed rule. There were some who supported the concept of expanding the onetime annual election to 2–3 uses per year because it provided more flexibility. Some commenters expressed support for the more complex approach that would have allowed limited use of the dual SEP for enrollment in integrated products, standalone PDPs, and FFS, but not any non-integrated MA plans.

Along these lines, there was varied feedback for dual SEP use for enrollment into integrated products. Some said that it should be allowed as a onetime exception, some said that it should be an ongoing opportunity, while others said that it should be the only allowable use of the dual SEP. A commenter encouraged CMS to work with States to define which plans would be considered ''integrated'' and another commenter suggested that CMS maintain and publicize a list of integrated plans.

Response: We believe that the wide array of feedback that commenters provided on the proposal represents the complexity and varying interests of those who would be impacted by a change to the dual SEP. Given that the majority of commenters preferred more flexibility than what we proposed, we are opting to finalize a limitation that is along the lines of the ''two or three uses per year'' alternative described in the proposed rule.

We contemplated allowing multiple uses per year at any time, but thought that an approach that allowed for quarterly elections (that is, the dual SEP in coordination with the AEP) was preferable because it would be easier to keep track of and for beneficiaries to understand. With a multiple-use-per-year-at-any-time policy, if a beneficiary makes several elections in the beginning of the year, as they approach the end of the year it may be hard to remember how many elections they have made or whether any more are available. With an approach that allows for quarterly elections, however, they only need to remember if they made an election in the last few months. If they have not, it is likely that they are eligible for a quarterly dual SEP use or the AEP. A quarterly approach also mitigates scenarios where a beneficiary makes multiple elections in the first half of the year and is then locked into a plan for the latter half of the year.

Comment: In addition to the modifications/alternatives discussed above, a number of commenters believed that if limitations were established for the dual SEP, CMS should consider additional exceptions for certain beneficiary groups or conditions. Specifically, commenters believed exceptions would serve as important beneficiary protections for the following individuals/circumstances:

- Those who have a new or existing disability.
- Those with a new or altered disease state or diagnosis.
- American Indians and Alaska Natives who also receive services through the Indian Health Service.
- Enrollees whose prescription drugs are not covered under their plan's formulary or whose providers change during the year.
- Individuals whose caregiver arrangements change during the year.
- Individuals who must comply with Medicaid open enrollment periods or those who meet the ''for cause'' standards established for enrollees in Medicaid managed care plans.
- Those whose providers request an SEP on their behalf.

Response: We believe that by allowing the dual SEP to be used quarterly during the first nine months of the year in conjunction with the AEP at the end of the year, we are mitigating the need for the exceptions suggested by the commenters. Dual or other LIS-eligible beneficiaries who fall into any of these categories would still be able to use the dual SEP. The only way that they may be limited is if they had already made a recent election into a plan. If that were the case, they may have to wait several months to make another change. (A more detailed discussion of different election periods and when they are considered ''used'' and effective can be found below.) Again, we do not see the frequency of movement that would lead us to believe that this will be an issue for the vast majority of LIS-eligible beneficiaries.

We would note that in addition to the dual SEP, there are already a number of protections in place for all beneficiaries who have Part D coverage and are unable to change plans. For example, beneficiaries can request transition fills—prescription drugs that are not on a plan's formulary or that are on a plan's formulary but require prior authorization or step therapy under a plan's utilization management rules—during the first 90 days of enrollment in a new plan as provided under § 423.120(b)(3). In addition, beneficiaries can request a formulary or tiering exception to obtain a drug that is not on their plan's formulary or to obtain a drug at a lower cost-sharing tier.

While we understand that commenters believe that the ability to change plans at any time is an important beneficiary protection, we believe it is worth re-stating that the changes finalized at § 423.38(c)(4) will still provide for multiple uses of the dual SEP throughout the year and this is a flexibility that is not afforded to all Part D enrollees. During other parts of the year, dual and other LIS-eligible individuals will still have access to the AEP in the fall or, if applicable, the initial enrollment period (IEP) or the new MA open enrollment period (OEP) discussed in section II.B.1. Beneficiaries may also continue to be eligible for other SEPs outlined in § 422.62(b) and § 423.38(c), which includes circumstances like a change or residence or other exceptional circumstances as determined by CMS.

In addition, we will be finalizing the SEP opportunity that was contemplated in the proposed rule for beneficiaries assigned to a plan by CMS or a State. While this was proposed at new § 423.38(c)(4)(iii) as an additional use of the dual SEP, and would have been available before that election became effective or within 2 months of enrollment in the plan, we will be finalizing this as a new and separate

SEP at § 423.38(c)(10). We believe that establishing this as a separate SEP is more straightforward because it makes clear that this opportunity is separate and in addition to the elections allowable under the revised dual SEP.

This new SEP will allow individuals who have been auto-enrolled, facilitated enrolled, or reassigned into a plan by CMS, as well as those who have been subject to passive enrollment processes discussed in section II.A.8, an opportunity to change plans. Unlike the proposed SEP, this new SEP will be available even if a beneficiary meets the definition of an at-risk beneficiary or potential at-risk beneficiary. Beneficiaries would be able to use this new CMS/State assignment SEP before that enrollment becomes effective (that is, opt out and enroll in a different plan) or within 3 months of the assignment effective date, whichever is later. (Note that this SEP will not apply to individuals who have been subject to default enrollment processes discussed in section II.A.7, as they will be able to use the new Open Enrollment Period (OEP) to make an election.)

Comment: A commenter requested a mechanism for plan sponsors to determine if the enrollment prior to the enrollee's SEP request was assigned by the CMS or the State. Another commenter requested clarification that States may make passive enrollment decisions where otherwise permitted, such as in Medicare-Medicaid Plans (MMPs), regardless of whether an individual has exhausted his or her SEP options for the year.

Response: CMS is exploring possible mechanisms that would allow plan sponsors to determine if the enrollee's most recent enrollment transaction was one that was initiated by CMS or the State. In the interim, plan sponsors should ask the enrollee if they received a notice that indicates that they have been assigned to a plan and have certain SEP opportunities.

If a beneficiary is assigned to a plan by CMS or a State, the enrollment change does not count against any of their SEP opportunities. That is, if a State passively enrolls a dual-eligible beneficiary in April, the beneficiary would still have their second quarter dual SEP, as well as the SEP associated specifically with the passive enrollment.

Comment: Several commenters sought clarification on how the dual SEP limitation would affect and interact with other election periods. Commenters stated that it was unclear how the SEP changes in § 423.38 would relate to the AEP and OEP. A few commenters sought verification that the SEPs for Program of All-inclusive Care for the Elderly (PACE) eligible beneficiaries, institutionalized individuals, and enrollments into 5-star plans would be unaffected. A commenter requested clarification whether the once-per-year SEP falls outside of the AEP, or whether the SEP also applies during this same AEP timeframe.

Response: As noted in the proposed rule and above, other election periods, including the AEP and the new OEP, are still available to eligible individuals. The established SEPs that allow beneficiaries to enroll in 5-star plans and PACE, as well as the SEP that allows elections for those who move into, reside in, or move out of an institution, are unaffected. If used, they would not count as use of the dual SEP. If the beneficiary is eligible for multiple election periods, plan sponsors (or other enrollment facilitators) may need to determine which election period the beneficiary would like to use, especially if the election periods would result in different enrollment effective dates. This is consistent with subregulatory guidance in Chapter 2 of the Medicare Managed Care Manual (section 30.6), Chapter 3 of the Medicare Prescription Drug Manual (section 30.4), and current enrollment processing procedures for any enrollment request received when the individual is eligible for more than one election period.

The dual SEP will be considered ''used'' based on the application date. If, for example, an election is made in March and effective in April, we would consider the beneficiary as having used their first quarter (Q1) dual SEP, even though coverage would not be effective until the second quarter of the calendar year. If a dual or other LIS-eligible beneficiary makes an election during the AEP (October 15th through December 7th), coverage would be effective January 1.

If, for example, a beneficiary is reassigned into a new plan in the fall for coverage effective January 1, they would be able to make an election under the AEP or the new CMS/State assignment SEP. If they opt out of the reassignment before it becomes effective and choose to stay in their current plan, this would be considered a cancellation and no election period is required.

We recognize that when looking at all of the election periods and associated timeframes in whole, there are multiple opportunities both within this SEP and other election periods for an individual to make a choice that best meets their needs. We believe that enrollment is an individual-based exercise, and 1–800–MEDICARE, SHIPs, advocacy helplines, plans, and enrollment brokers, already have processes in place to work with individual beneficiaries and determine the election periods for which they may be eligible. Ultimately, as already outlined in Chapter 3 of the Prescription Drug Benefit Manual (section 30), it is the plan sponsor's responsibility to determine the enrollment period for each enrollment/disenrollment request. In some cases, plan sponsors may need to contact the beneficiary directly to confirm the election period.

Table 2 summarizes the election periods discussed above and the suggested hierarchy of election periods (highest to lowest). Readers should note that it is not a comprehensive list of all election periods and does not negate a plan sponsor's responsibility to contact a beneficiary if they believe that multiple election periods may be available. More detailed information will be provided in subregulatory guidance.

TABLE 2—ELECTION PERIODS

Election period	Available	Considered ''Used''
Part D IEP	Based on when first eligible for Part D	Upon effective date.
MA OEP (must meet OEP requirements)	Annually	Upon application date.
SEP—5-Star plans	Ongoing	Available as long as election is in 5-Star plan.
SEP—PACE	Ongoing for enrollment into PACE; two month window after disenrollment from PACE.	Available as long as election is in PACE plan; upon application date for election subsequent to PACE disenrollment.
SEP—Institutionalized	Ongoing if moving into/residing in facility; two month window after moving out of facility.	Available while in facility; upon application date for election subsequent to moving out of facility.

TABLE 2—ELECTION PERIODS—Continued

Election period	Available	Considered "Used"
SEP—CMS/State Assignment	Within 3 months * of assignment or notification of assignment, whichever is later.	Upon application date.
SEP—Change in Dual/LIS Status	Within 3 months * of status change or notification of change, whichever is later.	Upon application date.
Dual SEP	Ongoing—One use per calendar quarter during the first nine months of the year.	Upon application date.
AEP	Annually	Multiple elections can be submitted during AEP, last rec'd will be considered the choice.

* As discussed below, the finalized SEPs will allow for a 3-month opportunity to change plans, not the 2-month window noted in the proposed rule.

Comment: A few commenters requested clarification on how plan sponsors would be able to determine if a beneficiary has used their allowable dual SEP election. Commenters asked whether this information would be available in MARx or as a batch enrollment query (BEQ). Commenters also asked who is responsible for validating the SEP and noted that beneficiaries may be frustrated if they are unaware that they have exhausted their allowable use of the dual SEP and their enrollment is denied. A commenter asked that plans not be penalized for rejections related to the dual SEP.

Response: Plan sponsors continue to be responsible for determining the eligibility and enrollment period for enrollment/disenrollment requests. As noted earlier, plan sponsors and other enrollment facilitators may need to ask questions of the beneficiary to determine if they are eligible for the dual SEP or another election period. As a part of this process, we assume that beneficiaries are informed about the enrollment process and told that a submitted enrollment form does not always guarantee enrollment in a plan. Further, the enrollment module in MARx will be updated to no longer allow use of the dual SEP more than once per calendar quarter during the first nine months of the year. Enrollment transactions submitted for an individual who has already used their quarterly opportunity will be rejected, and sponsors would notify the individual of the denial, as they do today. While the commenter did not specify which penalties they wanted waived, as stated earlier, the vast majority of beneficiaries do not use the dual SEP multiple times, let alone within a 3-month period, so any rejected transactions should be minimal.

Comment: A commenter asked that we confirm that the dual SEP applies to individuals considered full-benefit dual eligible beneficiaries under § 423.773(c)(1).

Response: The dual SEP, with the parameters established in this rule, is available for full benefit dual eligible individuals and other subsidy-eligible beneficiaries as defined at § 423.772.

Comment: A few commenters recommended that we modify the proposed SEP at § 423.38(c)(9) to allow for a three-month or unlimited window post LIS-change, not a 2-month window. These commenters said that the outreach and education time can be lengthy and two months does not provide the beneficiary with enough time to make a fully-informed choice. In addition, a commenter requested that we clarify whether a change in co-pay level only is considered a change in LIS-eligible status and would prompt eligibility for the dual SEP. Another commenter asked how the change in status SEP would affect those going through the deeming process.

Response: We appreciate this insight from commenters and believe that a three-month window should give the beneficiary adequate time to understand their coverage changes and determine if it is in their best interest to change plans. Accordingly, we are revising § 423.38(c)(9) to allow individuals to make an election within 3 months of a gain, loss, or change to Medicaid or LIS eligibility, or notification of such a change, whichever is later. A change in co-pay level, or any change, resulting from the deeming process, would be considered a change in LIS eligibility.

As discussed previously, the SEP for dual/LIS status change is separate from the dual SEP. If, for example, a Medicare beneficiary becomes eligible for Medicaid during the year, they would be able to use the dual/LIS status change SEP to change plans. In addition, because they are now a dually-eligible beneficiary, they would also be able to make their allowable quarterly dual SEP election during the first nine months of the year.

Comment: A commenter noted that the Medicaid managed care rule at 42 CFR 438.56(c)(2)(i) includes a 90-day period for plan changes following enrollment, and that dual/LIS SEPs should align so as to avoid conflicts between Medicare and Medicaid rules.

Response: We appreciate the identification of the potential conflict. We believe that because of the various election periods that are available, including the new SEPs that are being finalized in this rule, there should not be a coordination issue with Medicaid managed care rules. Specifically, a beneficiary can still use the dual SEP quarterly during the first nine months of the year, the new three-month SEP for change in Medicaid status, the new three-month CMS/State assignment SEP, and the AEP.

Comments: A commenter recommended that if the proposal was finalized, CMS should allow beneficiaries the right to file an appeal to switch plans in instances where their Part D plan has made a material change (such as to its formulary or to its pharmacy network) during the plan year.

Response: Enrollment decisions are not appealable and we do not believe it would be prudent to set up an enrollment appeals process at this time. Given that dual and other LIS-eligible beneficiaries will still be able to use the dual SEP on a quarterly basis during the first nine months of the year, we believe that there is a readily accessible remedy for this enrollment issue. The beneficiary will still be able to change plans, but in the event that they have already used up their dual SEP election, they may have to wait to make another change, unless they are eligible for one of the many other SEPs. Again, we expect this circumstance to be extremely rare.

Comment: A few commenters recommended that in addition to MA and Part D plans, CMS apply the SEP limitations to Medicare-Medicaid Plans

(MMPs) as part of the Financial Alignment Initiative demonstration.

Response: We clarify that under the Financial Alignment Initiative capitated model demonstrations, MA regulations—including those governing SEPs—apply to MMPs unless waived. As has been the case to date under the demonstrations, we will continue to use our demonstration authority to waive applicable MA regulatory requirements in three-way contracts as necessary, and in partnership with each state, to achieve each individual demonstration's objectives.

Comment: A commenter requested clarification regarding the federal vs. state authority over the dual SEP.

Response: Other than state laws relating to state licensure and plan solvency the standards established under Part D supersede any state law or regulation with respect to Part D plans.

Comment: Many commenters provided valuable feedback related to our request for suggestions on how to educate the affected population and other stakeholders of changes to the dual SEP. Suggestions included the following:

- Development of more outreach materials, including non-English materials.
- Direct notification to affected individuals.
- Increased resources for SHIPs.
- Coordination with the Administration for Community Living and State ombudsmen.
- Television advertisements.
- Educational opportunities sales agents, providers and community partners.
- Broader education about the dual SEP in general.

Response: We appreciate the feedback provided by commenters and will keep these suggestions in mind as we proceed with implementation of the dual SEP limitation beginning in plan year 2019.

Comment: A commenter recommended changes to Medicaid managed care disenrollment rules outlined at 42 CFR 438.56.

Response: Medicaid disenrollment rules are outside the scope of proposals set forth in the proposed rule and, as such, will not be considered for this rulemaking.

After review of the comments, and as discussed above, we are finalizing the proposed changes to § 423.38 with the following modifications:

- Paragraph (c)(4) is revised to allow eligible beneficiaries (that is, those who are dual or other LIS-eligible) use of the dual SEP once per calendar quarter during the first nine months of the year. We are further specifying that the limitation applicable to at-risk beneficiaries and potential at-risk beneficiaries (as defined under § 423.100 and discussed in section II.A.1) is effective upon notification of that status and ends upon termination of that status consistent with § 423.153(f).
- New paragraph (c)(9), which provides dual and other LIS-eligible beneficiaries who have a change in their Medicaid or LIS-eligible status an SEP, is modified to allow a 3-month window to make a change.
- Proposed paragraph (c)(4)(iii) allowing eligible beneficiaries who have been assigned to a plan by CMS or a State use of the dual SEP before that election becomes effective or within 2 months of their enrollment in that plan will not be finalized. Instead, a new CMS/State assignment SEP is established at § 423.38(c)(10) to allow individuals in a similar circumstance (that is, auto- or facilitated enrolled, reassigned, default or passively enrolled by CMS or a state) an opportunity to change plans upon notification or within 3 months of the assignment effective date, whichever is later.

Further detail on the SEP changes will be provided in subregulatory guidance. As suggested by a commenter, we will monitor the impact of this change and consider future modifications if there is evidence that beneficiaries are being harmed.

11. Medicare Advantage and Part D Prescription Drug Plan 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 ratings for domains, ratings for individual measures, and underlying performance data. We also post additional measures on the display page [31] at *www.cms.gov* for informational purposes. The goals of the Star Ratings are to display quality information on Medicare Plan Finder to help beneficiaries, families, and caregivers make informed choices by being able to consider a plan's quality, cost, and coverage; to provide information for public accountability; 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 made strides in recognizing the challenges of serving high risk, high needs populations while continuing the focus on improving health care for these important groups.

In this final rule, as part of the Administration's efforts to improve transparency, we are codifying 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 changes we proposed and are finalizing include more clearly delineating the rules for adding, updating, and removing measures and modifying how we calculate Star Ratings for contracts that consolidate. As we explained in the proposed rule, codifying the Star Ratings methodology will provide plans with more stability to plan multi-year initiatives, because the rulemaking process will create a longer lead time for changes and MA organizations and Part D sponsors 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 II.A.11.c. of this final rule (regarding plans for the transition period before the codified rules are used) how section 1853(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 believe 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

[31] *http://go.cms.gov/partcanddstarratings* (under the downloads).

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 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 (b)(3) and 423.153(c)(5)). 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 proposed 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 proposed specific text, to be codified at § 417.472(k), requiring that 1876 cost contracts to agree to be rated under the quality rating system specified at subpart D of part 422. Cost contracts are also required by regulation (§ 417.472(j)) to make CAHPS survey data available to CMS. As is the case today, no Quality Bonus Payments (QBP) will 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 the ratings can meet the needs of beneficiaries using them 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 primary goals of the ratings, they also provide feedback on specific aspects of care and performance that directly impact outcomes, such as process measures and the beneficiary's perspective. The ratings focus on aspects of care and performance 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 were added and amended to 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).[32] 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 regulations 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

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

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, plans, and advocates. The following guiding principles have been used historically in making enhancements and updates 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 used these goals to guide our proposal and intend to use them to guide how we interpret and apply the final regulations. For each provision we proposed, we solicited comment on whether our specific proposed regulation text best serves these guiding principles. We also solicited 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 also solicited feedback from stakeholders on how well the existing stars measures create meaningful quality improvement incentives and differentiate plans based on quality. We solicited comments on those topics, and have considered them in adopting this final rule, as noted in the responses below, and will consider them for future rulemaking. We specifically asked for 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 methodology to establish cut points accurately reflects plan quality.
- How CMS should measure overall improvement across the Star Ratings measures. In the proposed rule, we specifically requested input on additional improvement adjustments that could be implemented, and the effect that these adjustment could have on new entrants (here meaning 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 increasing implementation of 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 noted in the proposed rule that we are considering developing a survey tool for collecting standardized information on physicians' experiences with health and drug plans and their services.

CMS appreciates the feedback we received on our proposals and on the solicitations for comment on the various topics. In the sections that follow, which are arranged by topic area, we summarize the comments we received on the background section and policies, proposals and solicitations summarized there and provide our responses to the comments. (In each section in II.B.11.c through w, we summarize the proposals from the corresponding section of the proposed rule, the applicable comments, and our responses.)

Comment: Most commenters supported both the principles and the decision to codify the methodology for the Part C and D Star Ratings. Of the commenters who supported those aspects of our overall proposal, a few suggested adding principles, such as the measure data should be timely and that distinctions between measure-level Star Ratings (cut points) should be meaningful.

Response: CMS appreciates the support to codify the methodology for the Part C and D Star Ratings. We will codify the methodology in this final rule as outlined in this preamble, and will consider the additional principles raised by the commenters for adoption in the future as we continue to refine the principles in consultation with experts and stakeholders through the regulatory process.

Comment: Several commenters requested CMS to continue updating the methodology though the Call Letter instead though regulation. Commenters were concerned that the regulatory process would lead to CMS not being able to act quickly when there are public health or patient safety concerns or when treatment guidelines are changed. Commenters also cited other concerns, including introducing a burdensome regulatory process that delays the implementation of essential measures which can improve the quality of care for patients with chronic illness, as reasons to not to finalize this proposal but to continue using the Call Letter process to modify the Star Ratings methodology. They also noted that there are already multiple opportunities for comment on new measures; thus, the regulatory process does not create additional transparency. A few commenters supported the general effort to put the Star Ratings principles and process into regulation, but encouraged CMS to adopt a few exceptions (such as allowing new measures (but not measures with substantive changes) to enter Star Ratings through the Call Letter process).

Response: CMS understands the commenters' concerns about how the regulatory process may, in some cases, prevent CMS from quickly changing or adopting measures. However, given the

level of support for the proposal and the need to provide the industry with longer lead times for new measures, we will finalize the proposal to implement substantive changes through regulation and use the Call Letter to make non-substantive changes, suggest and solicit feedback on new measures that will be proposed in regulation, and address emergent public health or patient safety concerns by retiring existing measures as needed or introducing new measures for the display page that will be proposed for Star Ratings as appropriate. We also address comments on our proposals related to the type of updates and changes that we proposed to adopt without rulemaking, pursuant to specific rules proposed for §§ 422.164 and 423.184, in section II.A.11.h.

Comment: A commenter requested that measure changes take 3 years to implement in the Star Ratings and that five years should elapse before those changes could impact payment.

Response: We thank the commenter for the suggestion, but are finalizing the timeframes proposed in the proposed rule because the majority of commenters supported the proposed timeframes. Some of the commenters did raise concerns about extending the timeframes for implementing and updating measures. Changing the timeframes for measures updates to at least 3 years will significantly slow the implementation of substantive and non-substantive changes, in particular, when the changes are non-substantive.

Comment: A commenter encouraged CMS to adopt financial incentives for stand-alone prescription drug plans based on Part D Star Ratings.

Response: CMS thanks the commenter for the suggestion, but CMS cannot adopt such financial incentives without statutory authority. The Quality Bonus Payment (QBP) program for MA plans is statutory and the statute does not allow CMS to pay QBPs to stand-alone prescription drug plans.

Comment: We solicited comments on potentially adding measures in the future that evaluate quality from the perspective of adopting new technology. Many commenters supported adding a measure related to the use of technology, but multiple commenters cautioned that CMS rely on and use evidence that technology impacts health outcomes or improves the experiences of beneficiaries in order to adopt specific measures of that type. A number of commenters cautioned CMS to move carefully and slowly on promoting technology due to the potential for unintended consequences. A few commenters did not support measuring the adoption of technology, because such adoption may not always be in the best interest of the patient or enrollee. A few commenters did not support such measurement because adoption of technology is hard to measure well and may not lead to greater member satisfaction or correlate with other measures of plan performance. Those commenters discouraged such a focus, believing that beneficiaries will vary in their interest in whether plans and providers adopt new technologies, so measures of such adoption many not inform plan choice. A few commenters also feared that measures of adoption of technology may end up reflecting geographic differences and the socioeconomic status of members enrolled in the plan rather than the quality or performance of the plan itself. With respect to CMS' proposal to possibly add new measures that address the issue of new technology in the future, such as telemedicine, a commenter pointed out that ''Use of new technologies'' is not clearly defined and can span a number of technologies implemented across plans but not in a uniform manner or across all service areas. A commenter recommended that CMS continue to look at the incorporation of new technologies into Star Ratings measures but withhold any proposals for CY 2019 and CY 2020 until more formal proposals can be put forth for notice and comment prior to adoption. A commenter specifically urged measures of e-prescribing and e-prior authorization in Star Ratings. Another commenter urged CMS to explicitly capture in CAHPS composites (that is, the combination of two or more survey items into a measure) the use of telemedicine, as current survey wording may not do so.

Response: CMS appreciates comments received on adding measures that evaluate quality from the perspective of adopting new technology and will continue to monitor developments in this area for future consideration. Although we are not finalizing the adoption of such a measure in this rule, we will continue to investigate how best to address incorporating new technologies into the Star Ratings measures. We note that for HEDIS 2019, NCQA is examining the addition of telehealth services in existing HEDIS measures where appropriate. NCQA's proposed method would use specific codes and code modifiers to clearly define which telehealth services would be allowed for each specific measure. Proposed changes to incorporate telehealth services will be posted for the HEDIS 2019 public comment period in February. We appreciate receiving the comment about telemedicine and CAHPS; we recognize telemedicine is an evolving area and may propose changes to CAHPS survey questions in the future after discussions with the Agency for Healthcare Research and Quality.

Comment: A commenter specifically requested CMS provide certified software for measures not developed by external stewards, such as the Medication Therapy Management (MTM) and SNP Care Management measures.

Response: These measures are based on data reported to CMS through the Part C and D Reporting Requirements. CMS is not clear how providing certified software for these measures will facilitate the submission of these measures. CMS also notes that the MTM measure is developed by an external steward (PQA).

Comments: Many commenters indicated the need for greater alignment with providers (physicians, hospitals, medical groups, accountable care organizations, and plans) to make the quality measures more consistent, both to reduce burden and duplication and to more effectively incentivize behavior. For example, a few commenters urged use of measures aligned with the Merit-based Incentive Payment System (MIPS) program.

Response: CMS thanks the multiple commenters for these suggestions and appreciate the concern about burden and duplication, as well as the potential value of consistently reinforcing the same message. CMS is continuing to work with measure developers to increase consistency in measurement across settings.

Comment: Several commenters encouraged CMS to develop measures related to how well the care that is received by beneficiaries reflects the beneficiaries' concerns, values, and goals.

Response: CMS is tracking work by measure developers in this area and thanks the commenters for the suggestion.

Comment: Many commenters supported CMS continuing to develop and implement new measure concepts beyond those in current or currently anticipated measure sets. Among the most common suggestions were outcome measures, especially new patient-reported outcome measures, quality of life, and functional status measures (including Healthy Days at Home). Several commenters also encouraged measuring care for cancer, prevention of diabetes and other chronic conditions, long-term management of chronic obstructive pulmonary disease (COPD), as well as advanced care

planning, advanced directives and palliative care. A few other commenters highlighted concerns about measure gaps, such as for pain management, autoimmune disorders, mental illness, dementia/cognitive impairment, anticoagulation drug safety, and measures specific to patients with multiple co-morbidities, especially co-morbid diabetes and cardiovascular disease. A few commenters referred to NQF-endorsed measures used in other programs, such as change in functional status after spine or hip replacement surgery. A commenter encouraged CMS to utilize a comprehensive measure of adult vaccination, while another encouraged adoption of a vaccine cost-sharing measure. A commenter urged CMS to develop more medication adherence and appropriate use measures and to assign a high weight in the Star Ratings program. Another commenter suggested that any future transition of care measures include detailed information on all drug therapies prescribed and broader sharing of discharge information.

In addition, a few commenters urged CMS to provide quality and performance information about physicians within plans or to measure plans on the engagement of their network of physicians in value-based purchasing designs (that is, payment designs that reward or increase payments based on quality or capitated payments to physicians/practitioners, medical groups and ACOs).

Several comments highlighted promoting and measuring network adequacy and potential delays in care or medication related to this, and a few encouraged CMS to reward plans that maintain adequate networks with increased Star Ratings. A number of commenters urged CMS to measure access to medical specialists and subspecialists, such as Mohs surgeons, cataract surgeons, and ophthalmologists, while a couple of commenters supported the assessment of pharmacy networks broken down by specialty drug access. The two comments about networks of physician and surgeon specialists urged CMS to leverage extant measurement with the MIPS and Quality Payment Program (QPP) to also help measure plan network adequacy. A commenter urged CMS to look beyond simple numbers of physicians and specialists, since contracting and affiliation in medical groups and ACOs may effectively limit the access patients have to the full network.

Response: CMS appreciates the breadth of suggestions for new measures and will take these under consideration, including internal discussion and sharing them with the measure developers. We will also study the value and feasibility of deriving additional metrics (such as additional patient-reported outcome measures) from existing data collection efforts, like HOS.

Comment: Several commenters urged the development of geographic and/or provider market characteristic adjusters in order to normalize variations outside plans' control. Some stated such adjustments would specifically prevent measure bias against state-contracted SNPs.

Response: CMS appreciates this comment and will take it into consideration. As we consider adjustments to the Star Ratings measures, we need to ensure that the adjustments do not mask true differences in the quality of care across the country.

Comment: A few commenters requested information about a Star Ratings policy for natural disasters.

Response: CMS provided a detailed proposal concerning treatment of Star Ratings measures for contracts affected by disasters in the 2019 draft Call Letter that would apply to the 2019 and 2020 Star Ratings. We plan to propose codifying this policy through future rulemaking for performance periods after 2019 and ratings after the 2021 Star Ratings.

Comment: Several commenters questioned whether the Star Ratings regulations apply to PACE organizations.

Response: The MA Star Ratings regulations do not apply to PACE organizations but to the extent that a PACE organization offers a plan including qualified prescription drug coverage, it is a Part D sponsor and therefore subject to the Part D regulations. This would include the Part D Star Ratings regulations adopted in this final rule as 42 CFR 423.182–423.186. We have not produced Star Ratings for PACE organizations to date and are exploring the PACE waiver authority to continue to exclude PACE organizations from this requirement.

Comment: Several commenters made suggestions for possible Medicare Plan Finder enhancements, including adding the capability to compare plans by population type as well as mobile enhancements. A commenter suggested including the overall Star Ratings in the Medicare & You handbook.

Response: We appreciate these comments, but believe they are outside the scope of the proposed rule. However, we note that CMS is currently exploring options for improving the Plan Finder experience for Medicare beneficiaries, and that, although the timelines for publishing the Medicare & You handbook do not allow for including the overall Star Rating in the initial release that occurs in the fall, the overall Star Ratings are included in updated versions of the handbook that are released after the initial release and publication.

Comment: We received one comment that PBMs and Part D plan sponsors have delegated their responsibilities for the Star Ratings program to network pharmacies without providing the pharmacies with additional compensation.

Response: CMS appreciates these comments, but due to the non-interference clause, CMS is prevented from interfering in contract arrangements between sponsors, pharmacies and other providers. CMS has indicated to measure stewards and other stakeholders that if such pharmacy performance metrics are used as a condition of pharmacy network status, measure specifications should be appropriately scaled, for example, ensure adequate sample size, and that incentives to achieve performance should be appropriately allocated.

Comment: We received several comments recommending beneficiaries designated for lock-in be excluded from certain Star Ratings measures.

Response: Thank you for the comment. Our Star Ratings proposal did not address this topic, and we plan to take these comments under advisement. For more information about CARA, please see section B.

Comment: CMS had solicited feedback on the potential development of a physician survey to gather information for Star Ratings measures. The majority of commenters opposed the development of a physician survey due to the increased financial and administrative burden it would entail for both plans and health care providers/physicians who would be surveyed. Other commenters raised concerns about the ability of physicians to differentiate across plans when physicians interact with multiple plans. Multiple commenters were concerned that a physician could not accurately complete a survey on this topic since physicians often do not personally know the plan in which a beneficiary is enrolled. Some commenters noted that it may be difficult to determine who within a provider's practice should complete the survey. Other concerns raised include small sample sizes, subjectivity of responses, and potential for incomplete data.

Response: CMS appreciates the input provided by commenters regarding the

burden and multiple challenges in developing a survey to evaluate physician experience interacting with both Medicare health and drug plans. We are not finalizing any aspect of the physician survey in this rule, but will take these comments into consideration as we continue to explore the feasibility and the value to the Star Ratings program in collecting feedback through a physician survey.

Comment: A handful of commenters were concerned about the administration of a physician survey in integrated plans where the physician is employed by the plan which may bias the survey results.

Response: We acknowledge that responses may not be unbiased in situations when the physician is employed by the plan. CMS will take this into account as we consider whether to develop a physician/clinician survey in the future.

Comment: Among the commenters supporting the development of a physician survey, commenters noted that the physician is in close contact with plans on behalf of their patients so this would complement the existing CAHPS survey for enrollees. A couple of commenters noted that a physician survey would be a way to measure network adequacy, appeals, benefit limit exceptions, and grievances. A few commenters recommended that CMS consider a broader survey of clinician experiences, including nurses, therapists, care coordinators, and pharmacists from a variety of settings. A commenter requested that a physician survey be voluntary.

Response: CMS appreciates the support for the development of a physician survey and will solicit feedback from the industry on additional topics to be included on the survey if we move forward with the development in the future. We believe obtaining feedback from physicians is important; however, we will consider all of the comments provided before we make a determination about proceeding with developmental work.

Comment: A commenter suggested the development of a general physician survey regarding experiences with managed care compared to fee-for-service to understand the larger healthcare landscape, while another commenter suggested obtaining feedback through other avenues outside of the Star Ratings program.

Response: CMS appreciates these suggestions but they are out of scope for the potential development of surveys for the purpose of Star Ratings.

We specifically address adoption of the Star Ratings System regulations for the MA and Part D programs in sections II.B.11.c through w.

c. Basis, Purpose and Applicability of the Medicare Advantage and Prescription Drug Plan Quality Rating System

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

We proposed, 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 proposed some changes, such as how we handle consolidations from the current Star Ratings program, but overall the proposal was to continue the Star Ratings system as it has been developed and has stabilized. Under the proposal, data would be collected and performance 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 election period held in late 2020 for the 2021 contract year. Because of the timing of the release and use in conjunction with the annual coordinated election period, these would be the ''2021 Star Ratings.''

We proposed that the current quality Star Ratings system and procedures for revising it remain in place for the 2019 and 2020 Star Ratings. Section 1853(b) of the Act authorizes an advance notice and rate announcement to announce and solicit comment for proposed changes to the MA payment methodology, which CMS has interpreted to include the Part C and D Star Ratings program because of the payment consequences of Star Ratings under section 1853(o) of the Act. 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,[33] 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 21487 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 of the Act, and the process for announcing changes to the Star Ratings system falls within the scope of section 1853(b) of the Act. Although not expressly required by section 1853(b) of the Act, 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 Comment [34] 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 proposed as the first measurement period under these new regulations, but we may discontinue that process at a later date as the Advance Notice/Call Letter process and rulemaking process may provide sufficient opportunity for public input. In addition, CMS issues annually the Technical Notes [35] 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. Our proposed rule included continued use of the draft and final Call Letters as a means to provide subregulatory application),

[33] Advance Notices and Rate Announcements are posted each year on the CMS website at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

[34] Requests for Comment are posted at *http://go.cms.gov/partcanddstarratings* under the downloads.

[35] *http://go.cms.gov/partcanddstarratings* (under the downloads) for the Technical Notes.

interpretation, and guidance of the final version of these proposed regulations where necessary. Our proposed regulation text does not detail these plans for the RFC and Technical Notes because we believe such regulation text will be unnecessary. We proposed to codify the first performance period (2019) and first payment year (2022) to which our proposed regulations will apply at § 422.160(c) and § 423.180(c).

We received no comments on our proposed basis, purpose, and applicability regulations. For the reasons outlined in the proposed rule and summarized here, we are finalizing the regulation text proposed at §§ 422.160 and 423.180 with one significant modification regarding the applicability of the regulations governing the Star Ratings of a surviving contract in a contract consolidation. In light of the passage of section 53112 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), the consolidation policy described at §§ 422.162(b)(3) and 423.182(b)(3) will be implemented for the 2020 QBP ratings and 2020 Star Ratings. We will finalize additional text at §§ 422.160(c), 422.162(b)(3)(v), 423.180(c) and 423.182(b)(3)(iii) to apply the regulations that govern the calculation of Star Ratings for surviving contracts when the contract consolidation is approved on or after January 1, 2019, consistent with the ACCESS Act provision.

d. Definitions

We proposed the following definitions for the respective subparts in part 422 and part 423 in paragraph (a) of §§ 422.162 and 423.182 respectively.

- *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 website 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 measures 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 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.

We received no comments on the proposed definitions in paragraph (a) of §§ 422.162 and 423.182 and are therefore finalizing without modification.

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 plan benefit packages (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. Although we discussed and solicited comment on the feasibility and burden of collecting data at the PBP (plan) level and the reliability of ratings at the plan level, we proposed to continue the practice of calculating the Star Ratings at the contract level and that all PBPs under the contract would have the same overall and/or summary ratings at paragraph (b)(1) of §§ 422.162 and 423.182.

However, beneficiaries select a plan, rather than a contract, so we discussed in the proposed rule how we 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. In the proposed rule, we summarized our findings. 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 PBPs. If reporting were done at the plan level, a significant number of D–SNP plans will not be rated and in lieu of a Star Rating, Medicare Plan Finder will display that the plan is ''too small to be rated.'' However, when enough data are available, plan level quality reporting will reflect the quality of care provided to enrollees in that plan. Plan-level quality reporting will 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 will significantly increase plan burden for data reporting and will have to be balanced against the availability of additional clinical information available at the plan level. Plan-level ratings will 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 will 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 will also decrease our ability to measure true performance at the plan level and add complexities to the rating system. We solicited 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 asked 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 solicited 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 also indicated that we were exploring whether some measure data could be reported at a higher level (parent organization versus contract) to ease and simplify reporting while continuing to remain useful (for example, call center measures as we anticipate that parent organizations use a consolidated call center to serve all contracts and plans) for the Star Ratings. Further, we said 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.[36] 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 solicited comments and suggestions about requiring reporting at different levels (for example, parent organization, contract, plan, or geographic area) by measure. In addition, section 50311(d) of the Bipartisan Budget Act of 2018 after publication of the proposed rule, amended section 1853 to require the Secretary to determine the feasibility of quality measurement at the plan level for all MA plans. CMS will use the feedback received from the proposed rule as we consider reporting options in the future and continue to evaluate this issue consistent with the Bipartisan Budget Act provision.

We proposed to continue calculating the same overall and/or summary Star Ratings for all PBPs offered under an MA-only, MA–PD, or PDP contract and

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

to codify this policy in regulation text at §§ 422.162(b) and 423.182(b). We also proposed 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. Specifically, we proposed, at paragraph (b)(1) that CMS will calculate overall and summary ratings at the contract level and proposed regulation text that cross-references other proposed regulations regarding the calculation of measure scoring and rating, and domain, summary and overall ratings. Further, we proposed 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 proposed that the contract level score will 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.

We received the following comments related to our proposals, and our responses follow:

Comment: Most commenters opposed moving to plan-level reporting and expressed overwhelming support for retaining the current contact-level measurement. Commenters raised concerns about the additional complexity, administrative burden and reporting requirements of plan-level reporting. Additionally, commenters reiterated our concerns regarding the reliability of the scores at the plan level, as well as the inability to report some measure due to inadequate sample sizes. A commenter urged CMS to continue reporting Star Ratings at the contract level for PDPs.

Response: CMS appreciates commenters' support for contract-level reporting and acknowledge the complexities of moving to plan-level reporting given the challenges of accurately measuring quality with smaller groups and sample sizes and the additional administrative burden that would be placed on contracts.

Comment: A handful of commenters supported plan-level reporting also recognized it may not be practical for all quality measures. Some of the commenters noted the utility for beneficiaries who choose among plans. A commenter suggested CMS require Part D plans to report certain medication-related measures at the Formulary ID level.

Response: We agree that ideally for consumer choice, plan-level reporting or Formulary ID level reporting for Part D plans would be preferable, because it provides more detailed and targeted data. However, we need to consider the operational and methodological challenges of reporting at the plan level, including the ability to accurately measure performance at that level.

Comment: A commenter stated that plan-level reporting would be open to potential gaming by contracts constructing the plan-level geographic areas to maximize Star Ratings for the greatest number of enrollees. The commenter suggested that contracts would consider how well each plan was performing in the Star Ratings program to determine the geographic area of each plan.

Response: We appreciate this comment and will take it into account as we consider this issue in the future.

Comment: A commenter noted that plan-level reporting would stifle innovation and discourage plans from serving difficult areas. This would limit the ability of contracts to implement innovative models in one plan prior to expanding.

Response: We appreciate this comment since we clearly do not want our Star Ratings policies to stifle innovation. We will take this comment into consideration as we continue to consider options for different levels of reporting.

Comment: A handful of commenters expressed interest in measurement at the local health services area, including by state. Many of these commenters noted that it will be challenging to move to reporting at the local geographic area. Issues to be considered include how to handle contracts that serve major metropolitan areas that cross state lines. A couple of commenters suggested that CMS consider creating additional contract numbers or market-level designations for a contract. A commenter recommended that CMS discontinue the moratorium that does not allow for existing H numbers to be split to allow more meaningful measurement.

Response: CMS is committed to examining the feasibility of alternative levels of reporting, including by geographic area. The suggestions provided by commenters through the proposed rule will be taken into consideration as alternatives are explored. Additionally, section 50311(d) of the Bipartisan Budget Act of 2018 (P.L. 115–123) enacted after publication of the proposed rule, amended section 1853 to require the Secretary to determine the feasibility of quality measurement at the plan level for all MA plans. CMS plans to obtain additional feedback from stakeholders on this issue given the challenges of developing options that would be feasible for both the industry and CMS. CMS' contractor for the Star Ratings program is planning to convene a Technical Expert Panel following the publication of the final rule and this is one of the issues the panel will address. This panel will periodically meet to provide feedback on different critical Star Ratings issues. Information from the Technical Expert Panel will be publicly shared.

Comment: A commenter expressed concern about pursuing market area reporting as such reporting could result in limiting the health care options for higher-need populations.

Response: CMS appreciates this comment and does not want to limit options for higher-need populations. We will take the comment into consideration as we continue to consider options for different levels of reporting.

Comment: A handful of commenters recommended adjusting the Star Ratings to account for variables that contribute to underperformance in certain geographic areas, network characteristics and patient characteristics by applying, for example, the case-mix adjustment process currently used for the CAHPS measures.

Response: CMS appreciates this comment and will take it into account as we continue to consider options for different levels of reporting. As we contemplate case-mix adjustment, we need to ensure that we are not adjusting away true differences in the quality of care across contracts in different geographic areas or with different network structures.

Comment: A commenter raised concerns of the possibility for gaming in connection with separate ratings for new contracts. If CMS is to proceed, the commenter would like to see simulations of the ratings.

Response: CMS appreciates this comment and clearly does not want to implement changes that would encourage gaming of the Star Ratings system. We will take this comment into consideration as we continue to analyze different ways to rate contracts.

Comment: A commenter raised a question about a potential error on page 82 FR 56380 in the sentence that reads ''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 commenter noted that the current practice weights the PBP scores by eligible population.

Response: The text from the proposed rule is correct. The eligible population and the enrollment reported as part of the measure specification are the same.

Comment: A handful of commenters from sponsoring organizations suggested separate reporting by Dual SNPs and non-Dual SNPs, and rolling up all Dual SNP PBPs and non-Dual SNP PBPs separately within a contract. A couple of commenters noted that moving to plan level reporting for all SNPs is complex with many pros and cons so they recommended that CMS continue contract-level reporting until all of the consequences can be fully evaluated.

Response: CMS appreciates these comments, including the issues raised by commenters regarding the complexities of moving to plan/PBP-level reporting by SNPs and non-SNPs. Given that some contracts just have SNP PBPs and other contracts offer both SNP and non-SNP plans, CMS needs to evaluate how this would impact reporting of measures and calculations. We agree that all of the benefits and disadvantages need to be weighed before a final decision is made about how to proceed and CMS is committed to continuing to obtain feedback from the industry on changes to the level of reporting. CMS continues to evaluate this issue. Additionally, in light of the passage of the Bipartisan Budget Act of 2018, CMS is required to examine the feasibility of plan-level reporting for both SNP and non-SNP plans. Any related changes would be proposed through future rulemaking.

Comment: A couple of commenters supported the idea of reporting the call center and appeals measures at the parent organization level since in most cases these functions are organized at the parent organization level, while a couple of commenters did not like having different levels of reporting for different measures, arguing that it would create more complexity in the Star Rating program.

Response: CMS appreciates the suggestions received from commenters and will continue to look at the advantages of moving to a different level of reporting for these and other measures. Any related changes would be proposed through future rulemaking.

Comment: A commenter supports CMS' current process for rolling up SNP plan-benefit package level information to the contract level.

Response: CMS thanks this commenter for their support for our current policy of calculating SNP measures.

Comment: A handful of commenters recommended that CMS not make any changes in the unit for reporting until additional analyses are completed that ensures that any changes are fair and equitable to all sponsors. A commenter suggests an industry-wide workgroup to discuss potential changes to reporting levels and operational challenges.

Response: We acknowledge these comments and agree that we need to do more analysis and obtain additional feedback from sponsors before we make any changes in the level of reporting. We support the desire to make sure that any changes are fair and equitable to all sponsoring organizations. As noted in a previous response, CMS' contractor for the Star Ratings program is planning to convene a Technical Expert Panel following the publication of the final rule and this is one of the issues the panel will address.

For the reasons indicated in the proposed rule and our responses to the related comments, we are finalizing the provisions as proposed in paragraphs (b)(1) and (2) of §§ 422.162 and 423.182 and § 417.472(k) without substantive modification. However, we realized that paragraphs (b)(1) as proposed did not specify that summary ratings also include the reward factor and the Categorical Adjustment Index as described in §§ 422.166(f) and 423.186(f); we are finalizing additional text to clarify that in paragraphs (b)(1). In addition, we are slightly revising the last two sentences of paragraphs (b)(2) of the same regulation sections to clarify that the rule for including plan-level only measures is applicable to the SNP-specific measures that are reported only at the plan level.

f. Contract Consolidations

We proposed a change in how contract-level Star Ratings are assigned in the case of contract consolidations. We noted in the proposed rule how we have historically permitted MAOs and Part D sponsors to consolidate contracts when a contract novation occurs to better align business practices. As noted in MedPAC's March 2016 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2016-report-to-the-congress-medicare-payment-policy.pdf*), 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 proposed to modify the calculation of Star Ratings for surviving contracts that have consolidated to address these concerns. Instead of assigning the surviving contract the Star Rating that the contract would have earned without regard to whether a consolidation took place, we proposed to assign and display on MPF 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 our proposal, the calculation of the measure, domain, summary, and overall ratings will be based on these enrollment-weighted mean scores. We estimated that the number of contracts impacted by the proposal would be 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 proposed, however, that the process of weighting the enrollment of each contract and applying this general rule will 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 was to 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 proposed to codify our new policy at §§ 422.162(b)(3) and 423.182(b)(3). First, we proposed 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 proposed in § 422.162(b)(3) both a specific rule to address the QBP rating for the first year after the consolidation and a rule for subsequent years. As Part D plan sponsors are not eligible for QBPs, § 423.182(b)(3) was proposed without the QBP aspect. We proposed 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, we proposed to use the enrollment-weighted means as calculated below to set Star Ratings for MPF publication:

- The Star Ratings measure scores for the consolidated entity's first plan year will 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 surveys) will 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 will be pulled in January 2020 so enrollment in January 2020 will be used. The call center measures will use mean enrollment during the study period. We stated that we believed that these proposals for survey-based measures are more nuanced and account for how the data underlying those measures are gathered and that the enrollment-weighted means better reflect 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, we proposed to calculate the Star Ratings will be calculated as follows:

- The enrollment-weighted measure scores using the July enrollment of the measurement period of the consumed and surviving contracts will be used for all measures except HEDIS, CAHPS, and HOS.
- We proposed that HEDIS and HOS measure data will be used as reported in the second year after consolidation. The current reporting requirements for HEDIS and HOS already combine data from the surviving and consumed contract(s) following the consolidation, so we did not propose 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.
- We proposed to require that the CAHPS survey sample (that would be selected following the consolidation) would 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 will be selected will be 6,000.

CMS proposed that these rules would be used to calculate the measure scores in the first and second year after consolidation; following those two years, CMS proposed to 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 will be after the consolidation, so our proposal limited the special rules for calculating post-consolidation the Star Ratings to the 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 proposed 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, if the first year the consolidated entity is in operation is plan year 2020, the 2020 QBP rating displayed in HPMS in November 2018 will 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 will have been their QBP ratings accurately reflects their performance for payment purposes. In subsequent years after the first year following the consolidation, QBPs status will be determined based on the consolidated entity's Star Rating posted on MPF. 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, we stated that we believed the ratings used for QBP status determinations would reflect the care provided by both the surviving and consumed contracts.

In conclusion, we proposed a new set of rules regarding the calculation of Star Ratings for consolidated contracts to be codified at paragraphs (b)(3) of §§ 422.162 and 423.182. We solicited 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 also solicited feedback on 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 requested 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.

Following publication of our proposed rule, Congress enacted the Bipartisan Budget Act of 2018. Section 53112 of the Act amended section 1853(o) to require an adjustment to the Star Ratings, quality bonus under

section 1853(o) and rebate allocation under section 1854 based on the quality rating to ''prevent the artificial inflation'' of Star Ratings after consolidation. That required adjustment applies for consolidations approved on or after January 1, 2019. The statutory change requires the adjustment be applied when a single MA organization consolidates contracts and reflect an enrollment-weighted average of scores or ratings for the underlying contracts. We believe that our proposal is generally consistent with the new statutory requirement, with minor exceptions. The proposal would not have applied until a later period, but, as noted in section II.A.11.c of this final rule, we will finalize these provisions to be applicable beginning with the 2020 QBPs and 2020 Star Ratings produced in fall 2019 to be consistent with the statute. Our proposal was for consolidations involving a single parent organization while the statute focused on consolidations involving a single MA organization; applying the proposed policy to consolidations at the level of the parent organization instead of the specific MA organization captures more consolidations. We read the Bipartisan Budget Act as setting a floor rather than a ceiling on our authority to establish and set the rules governing the Stars Rating system. In addition, our proposal also was more specific as to how enrollment-weighted ratings at the measure and contract level would be used following the consolidation. We believe the additional detail in our proposal is explicitly authorized as the statutory change leaves it to the Secretary to identify the specific appropriate adjustments.

We received the following comments on our proposals and solicitations for feedback, and our responses follow:

Comment: Commenters expressed overwhelming support for our rules outlined at §§ 422.162(b)(3) and 423.182(b)(3) to calculate contract-level Star Ratings in the case of contract consolidations. Commenters stated that this would be a more accurate picture of the performance of the underlying contracts. Commenters noted that this would help eliminate the gaming that can occur when consolidations of multiple contracts in distinct geographic areas result in artificial increases the Star Ratings and Quality Bonus Payment (QBP) ratings. A number of commenters suggested that this approach was fair and equitable to all stakeholders. Some commenters supported this change as a short-term solution, but they wanted CMS to consider how in the future the ratings could more accurately reflect the care provided at the local market area. Commenters recognized that quality reporting at the local market area is a sizeable change and would not be feasible for a number of years.

Response: CMS appreciates the commenters' support for revising how Star Ratings and QBP ratings are calculated when two or more contracts consolidate. We believe that the Bipartisan Budget Act indicates that Congress is similarly concerned about these issues and our proposal to address them. We also agree with commenters that local market area reporting would be preferable in cases when the contracts are geographically dispersed. Although moving to local market area reporting has many challenges, CMS is committed to work with stakeholders to examine the feasibility of local market area reporting. Any potential changes that would change the consolidation policy in the direction of local market area reporting would be proposed in future rulemaking.

Comment: A commenter recommended that CMS issue contract numbers at the state level and then base Star Ratings at the state level to avoid consolidations across disperse geographic areas.

Response: State-based contract numbers would be administratively burdensome for both contracts and CMS, would significantly increase reporting burden of contracts, and would create measurement challenges since many contracts at the state level will not have a sufficient number of enrollees by state to calculate reliably the quality measures that are part of the Part C and D Star Ratings program. Contracts that serve disperse geographic areas often have the majority of their enrollees in one or two states with smaller enrollment in other states.

Comment: A commenter suggested using the unrounded final summary mean rather than the rounded final Star Rating.

Response: CMS is assuming this commenter is referring to the QBP rating for the first year of the consolidation. For all other years, the QBP rating of the contract would be based on the Star Ratings posted on Medicare Plan Finder; therefore for the second year following a consolidation, the same rules for calculating the Star Ratings for QBP and for MPF posting would apply (that is, §§ 422.162(b)(3)(iii)). The preliminary QBP rating is produced and posted in HPMS in November of each year for the bids that will be submitted the following year. The QBP appeals process is based on these ratings posted in November. In April prior to the bids being due, CMS would update the QBP rating using an enrollment-weighted QBP ratings of all contracts involved in the consolidation which are already rounded.

Comment: A commenter asked CMS to consider a grace period that would neither reward nor disadvantage the surviving contract as a result of acquiring a poor performing contract.

Response: Under our current policy, a sponsor can gain financially by consolidating enrollees from a poor-performing contract into a contract that receives a QBP and thereby receive bonus payments that it would not have been entitled to receive had the consolidation not occurred. The revised methodology for calculating Star Ratings and QBPs for the surviving contract takes into consideration the performance of all contracts involved; thus, it is a more accurate measure of performance. We do not believe that a more accurate reflection of performance can be fairly termed a ''reward'' or a ''disadvantage'' of contract consolidation.

Comment: A handful of commenters expressed concern regarding the consolidation policy stating that they thought the calculations were too complex. A commenter stated it would limit the beneficiary options to enroll in plans with richer benefits since there would not be the same incentives to consolidate lower performing contracts into higher performing ones receiving QBPs.

Response: Most of the calculations for the revised consolidation policy will be handled by CMS, though contracts will have an opportunity to review the calculations as part of the normal Star Rating review process. The consolidation policy should not make it more difficult for contracts to produce the data that are needed for the Star Ratings program. The premise behind all of the calculations is to combine the already gathered (or currently gathered) data from all contracts involved in the consolidation using an enrollment-weighted average. This policy should not create a situation which limits options for beneficiaries to enroll in plans with richer benefits. As always, beneficiaries may is able to choose in their service area any plan that best meets their needs. If a beneficiary decides to remain in a contract that consolidates, the ratings for that contract will now more accurately reflect performance of that contract.

Comment: A commenter suggested that CMS post by year end in HPMS a worksheet with the exact enrollment and overall Star Rating values which CMS intends to use for determining QBP ratings for consolidated contracts.

Response: In November of each year, CMS posts in HPMS the preliminary QBP ratings for the bids that will be submitted the following year. This starts the QBP appeals process. In April of each year prior to bids being submitted, CMS posts in HPMS the final QBP rating following the appeals process. In November of each year or at year end, CMS would not be aware of future consolidations that would be announced near the time of the bid so would be unable to post a combined rating for the consolidated contracts at this time. As long as CMS is aware of the consolidation by April at the time of the HPMS posting, the combined rating for the consolidated contracts would be posted at that time. A parent organization would have sufficient information to calculate the enrollment weighted QBP rating of a consolidated contract using the preliminary QBP ratings posted in HPMS in November of each year.

Comment: A handful of commenters requested that CMS clarify the timing of this provision. These commenters expressed a preference for it not to begin until the 2021 Star Ratings and 2022 QBPs.

Response: The proposed rule stated that all of the changes related to Star Ratings would go into effect for performance periods in 2019 (thus, for the 2021 Star Ratings and 2022 QBPs). However, in light of the passage of the Bipartisan Budget Act provision which requires enrollment-weighted adjustments to the Star Ratings for contract consolidations approved on or after 1/1/19, we are finalizing the regulation text on this policy to be applicable to consolidations that occur on or after the same date. The final regulations at §§ 422.162(b)(3) and 423.182(b)(3) will apply to the star ratings of surviving contracts from contract consolidations that are approved on or after January 1, 2019. Thus, the policy will be implemented for the 2020 Star Ratings and the 2020 QBPs. We note that while the statute is specific to MA ratings, we are finalizing the same policy for Part D Ratings on the same timeframe to have consistent methodology across Part C and D for beneficiaries choosing a contract.

Comment: A few commenters were interested in a similar policy for consolidations between different parent organizations.

Response: We treat the purchase of a contract, multiple contracts or all of the contracts offered by a parent organization by different parent organization is known as a novation, not a consolidation, even though the consolidation will generally also require similar contract documents and approvals from CMS. Where one entity is buying all or part of the business of another entity, we did not propose and do not intend to apply the consolidation policy finalized in this rule. In novations, the structure of each of the individual contracts being purchased does not change and the contracts still provide the same services within the same service area before and after the novation is completed, only the company that owns the business and is the MA organization under the contract has changed. The Star Rating for each individual contract transfers with the contract and remains intact until the next rating cycle. Novations can occur at any point during the calendar year.

A consolidation by contrast is when two or more contracts owned by the same parent organization are combined into a single contract. The overall service area of the two contracts are combined, the contract number of the consumed contract(s) is retired and the contract number of the surviving contract now provides all of the services in the combined service area. To consolidate contracts, all of the contracts must be owned by the same parent organization. Consolidations can only occur at the change from one year to another year and must be submitted and approved by CMS by a specific deadline in the annual contracting process. If one parent organization buys another contract owned by a different parent organization, the sponsor could consolidate multiple contracts using the rules outlined in this rule the year after the novation takes place. With a consolidation, the rule finalized here for the calculation of the Star Rating of the surviving contract would apply.

Comment: A commenter wanted CMS to propose other alternatives and offer additional opportunities to comment, but no additional detail was provided on suggested alternatives.

Response: CMS appreciates the request for other alternatives. Commenters to the proposed rule did not suggest other ways to handle contracts that consolidate and expressed overwhelming support for this policy. CMS will continue to consider if there is a better way to account for differences in performance across geographic areas and will provide opportunities to engage stakeholders and obtain additional input.

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the provisions as proposed at §§ 422.162(b)(3) and 423.182(b)(3), except for modifying the timeframe applying these new rules. The revised consolidation policy would be applicable for the Rating for any surviving contract after a consolidation that is approved on or after January 1, 2019. Although the statute related to consolidations is specific to MA ratings, we are finalizing the same policy for Part D ratings on the same timeframe to have consistent methodology across Part C and D for beneficiaries choosing a contract.

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. 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 so they are not information collections governed by

section 1852(e). 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 use the same Part D measures focusing on administration of the drug benefit as is used for stand-alone PDPs. 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 proposed 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 proposed 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 proposed, 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 proposed 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 regulation text will clearly establish the sponsoring organization's responsibility to submit data that can be reliably used to calculate ratings and measure plan performance.

We received the following comments on this proposal, and our responses follow:

Comment: A few commenters supported codifying language to clearly establish the sponsoring organization's responsibility to submit data that can be reliably used to calculate ratings and measure plan performance.

Response: CMS appreciates stakeholders' support of our effort to codify language to ensure that that the data submitted are accurate and reliable. We are finalizing the language as proposed.

Comment: Responses were mixed on whether audit data should be used in the Star Ratings. A couple of commenters opposed including measures in the Star Ratings program that rely on audit findings as a data source. Other commenters stated given the Beneficiary Access and Performance Problems measure that previously included enforcement actions was moved out of the 2019 Star Ratings and to the display page, they strongly urged CMS to re-incorporate audit information, including information about enforcement actions, in Star Ratings. Those in favor of using audit information noted that the key purposes of Quality Rating System are to provide comparative information to Medicare beneficiaries, to base payment on quality, and to oversee the overall performance of plans. These commenters opposed CMS removal of audit findings and enforcement actions from the Star Ratings since deficiencies, in particular repeat deficiencies, may impact beneficiary access to drugs and services and the Star Ratings will not reflect these issues.

Response: We appreciate the commenters' feedback and concerns received on the use of audits, compliance actions, and enforcement actions in the Star Ratings. In the proposed rule, the Beneficiary Access and Performance Problems measure was not proposed for the 2021 Star Ratings even though some stakeholders strongly support including some recognition in the Star Ratings program when serious or repeat deficiencies are uncovered in audits or other means. These stakeholders argue that such deficiencies directly impact beneficiary access to needed services and drugs and therefore should be part of the Star Ratings program. We will continue to consider the comments as we continue our dialogue with stakeholders on this issue and any future changes will be proposed in future rulemaking.

For the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing the provisions regarding the data sources for measures and ratings as proposed in §§ 422.162(c) and 423.182(c) with two modifications. In § 422.162(c)(1), we are finalizing additional text to clarify that CMS administrative data will be used in the scoring for measures; the new text aligns the Part C regulation with the parallel Part D regulation. As noted in the proposed rule (82 FR 56382), some measures are based on data that CMS (or a contractor) has related to performance by sponsoring organizations and we are including a reference to CMS administrative data consistent with that longstanding policy. In addition, in § 423.182(c)(2), we are finalizing additional text to clarify that the reported data permit measurement of health outcomes and other indices of quality, consistent with the scope of the measures in the Star Ratings program.

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 proposed in §§ 422.164 and 423.184 specific rules to govern the addition, update, and removal of measures. We also proposed to apply these rules to the measure set proposed

in this rulemaking, to the extent that there are changes to the measure set between the effective date of this final rule and the Star Ratings based on this final rule (that is the ratings based on the performance periods beginning on or after January 1, 2019).

As discussed in more detail in the following paragraphs, we proposed 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 proposed 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 (without rulemaking) 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 proposed specific rules for updating and removal that would be implemented through subregulatory action, so that rulemaking would not be necessary for certain updates or removals. CMS proposed to announce application of the regulation standards in the Call Letter attachment to the Advance Notice and Rate Announcement process issued under section 1853(b) of the Act.

First, we proposed 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 proposed to make certain of these changes without future rulemaking by applying the standards and authority in the regulation text. CMS proposed to solicit feedback of its application of such rules using the draft and final Call Letter each year. In addition, CMS proposed in paragraph (a) of each section to issue a complete list of the measure set for each year in the Technical Notes or similar guidance document.

Second, we proposed, 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 proposed 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. We explained that this rule was designed 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, paragraph (b) would authorize CMS to remove the measure from that year's rating.

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

In the proposed rule, we explained that our proposal regarding the addition of measures was guided by the principles we reiterated in this final rule in section II.A.11.b. 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, that are 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 proposed to codify that CMS would continue to review measures of this type for adoption 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 proposed that CMS would develop its own measures as well when appropriate to measure and reflect performance in the Medicare program. For the 2021 Star Ratings, we proposed 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 would be added and measures would be removed from the Star Ratings program to meet our policy goals. As new measures are added, we noted in the proposed rule that our general guidelines for deciding whether to propose new measures through future rulemaking would 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.

As explained in the proposed rule, CMS 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 would be done through future rulemaking and include explanations for how and why we propose to add new measures. We also proposed to follow the process in our proposed paragraphs (c)(2) through (4) of §§ 422.164 and 423.184 when a new measure has been identified for inclusion in the Star Ratings. We proposed to initially solicit feedback on any potential new measures through the Call Letter and to codify that as a requirement at paragraph (c)(2) of each section.

As new performance measures are developed and adopted, we proposed, 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 creates 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 in the draft 2020 Call Letter on whether to add the new measure.
- *April 2019:* Summarize feedback in the 2020 Call Letter on adding the new measure.
- *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 proposed 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 proposed 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 or specifications) to existing measures would be proposed and finalized through rulemaking. In paragraphs (d)(2) of §§ 422.164 and 423.184, we proposed 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 noted in our proposal that this process for substantive updates would be similar to the process proposed 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 remains relevant and measures a critical topic for the Star Ratings. Adding the substantively updated measure to the Star Ratings would be proposed through rulemaking.

We proposed 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 would be incorporated into the measure and announced using the Call Letter. We proposed to use such updated measures to calculate and assign Star Ratings without the updated measure being placed on the display page. Our proposal was explained as consistent with current practice.

In paragraphs (d)(1)(i)–(v) of §§ 422.164 and (d)(1)(i)–(v) of 423.184, we proposed to codify a non-exhaustive list of non-substantive updates announced during or prior to the measurement period and how we will 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 will be considered non-substantive and will 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 is not considered substantive because the sponsoring organization generally benefits from that change. This type of administrative change has no impact on the current clinical practices of the plan or its providers, and thus will 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 it does not change the intent of the measure but provides more information about how to meet the measure specifications:

++ Adding additional tests that will 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 solicited 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 noted our interest 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 solicited 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 proposed 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 proposed the two circumstances under which a measure will be removed entirely from the calculation of the Star Ratings. The first circumstance we identified was a change or changes in clinical guidelines that mean that the measure specifications are no longer believed to align with or promote positive health outcomes. We explained that as clinical guidelines change, we would need the flexibility to remove measures from the Star Ratings that are not consistent with current guidelines. We proposed 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 noted 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 the proposed rule, we also explained how 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 proposed, at paragraph (e)(1)(ii), 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 explained that we would 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 decision that the measure has low reliability. Although some measures may show uniform high performance across contracts and little variation between them, we noted we seek evidence of the stability of such high performance, and we noted 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 with 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. Below, we summarize the comments we received on adding, updating, and removing measures, and provide our responses and final decisions.

Comment: Commenters agreed with the criteria CMS proposed to select new measures for the Star Ratings program. Commenters also agreed with the proposed measure categories (the measure categories used to assign weights to measures as noted in §§ 422.166(e) and 423.186(e)), though a few commenters asked CMS to include more outcome measures. A few commenters also requested that measures be claims-based and not based on medical chart review.

Response: CMS appreciates the support for our criteria for selecting new measures. CMS agrees with the desire to add more outcome measures to the Star Ratings program and welcomes all suggestions (submitted through the annual Call Letter process) for outcome measures to include in the Star Ratings program. We realize that medical chart review is burdensome and we are continuing to look at ways to minimize chart review measures. For example, CMS is exploring whether using encounter data for quality measurement would minimize burden for plans while resulting in equally accurate and appropriate reflections of performance and quality.

Comment: The majority of commenters agreed with CMS' proposal for selecting new measures, announcing and soliciting feedback on new measures, finalizing new measures through rulemaking, reporting new measures on the display page for a minimum of 2 years prior to becoming a Star Rating measure, and keeping new measures on the display page if CMS finds reliability or validity issues with the measure specifications. Supporters of these proposals noted that the introduction of new measures through rulemaking allows greater lead time for plans to incorporate new measures, supports stability in the Star Rating program, maximizes stakeholder input, and provides additional transparency in the Star Ratings selection process. Commenters mentioned that increased lead time for the introduction of new measures is important especially in any payment program. Commenters noted the need for plans to have sufficient time to allocate resources, make changes to operations, adjust supporting information systems, and plan any specialized educational materials and events. A commenter suggested that new measures remain on the display page for 3 years which would allow plans to develop internal processes for quality measurement and improvement, which the commenter suggests would lead to improved health outcomes for beneficiaries; another commenter expressed the opinion that reporting a new measure on the display page for 2 years is too long. Commenters who expressed concern that the time on

display was too long or suggested exceptions to allow for shorter times on display both referred to the need to reflect changes in clinical standards and to respond to public health urgencies.

Response: CMS appreciates receiving feedback on the proposed policy to introduce new measures into the Star Ratings program through rulemaking. We acknowledge that there is some desire and policy rationale to keep measures on the display page for longer than 2 years, but CMS is trying to balance the need to introduce new measures in a timely manner with giving sponsors sufficient lead time for the introduction of new measures. We believe that a 2 year period provides the appropriate balance.

Comment: Some commenters opposed the requirement to propose new measures through rulemaking rather than continuing to announce new measures through the Call Letter process. The commenters cited the long lag between the time measures are developed/approved and the time they are included in the Star Ratings, and requested a more expedited approach for the inclusion of new measures. Commenters noted that adding more lead time would stifle the adoption of new quality measures aligned with the latest innovative advances in medicine and technology and, thus, prevent Star Rating measures from reflecting the latest treatment guidelines and current standards of care. Further, commenters mentioned introducing new measures through rulemaking could unnecessarily delay implementation of measures needed to address clinical area gaps, preventable safety issues, emerging public health concerns, and the adoption of evidence-based measures. As a result, commenters believed CMS' ability to incentivize improvements in the quality of care for Medicare beneficiaries would decrease. A few commenters suggested that, if CMS does implement the rulemaking process for the introduction of new measures, CMS should consider granting exceptions in circumstances in which there are urgent public health and patient safety issues to be addressed through quality measures.

Response: CMS recognizes that introducing new measures through rulemaking will make the process longer than CMS' former process of introducing new measures through the Call Letter, but we believe doing so balances the need for expediency with the need for greater transparency and stability for the ratings program. CMS also believes the rulemaking process adds an additional opportunity to fine tune measures and thus ensure greater measurement accuracy and enhanced stability in the Star Ratings program. We note that using rulemaking to adopt measures will bring the MA and Part D quality ratings system in line with other quality ratings systems and quality data collection programs that are used for Medicare payment. We understand the desire to have measures that address public health concerns adopted quickly in the Star Ratings program. CMS is committed to implementing these types of measures as quickly as possible so they can at least be publicly reported on the display page prior to being a Star Ratings measure.

Comment: A few commenters requested that new measures be fully defined, tested, and validated by measure stewards prior to being considered for Star Ratings, even for CMS developed measures. A commenter requested that CMS adopt only measures which have been NQF endorsed, publicly reported by NCQA (or the measure steward) for at least one measurement period, and reported on the CMS display page for at least one measurement period. The commenter also recommended that CMS not report new (first year) measures on the display page.

Response: CMS agrees that measures need to be fully defined, tested and validated by measure stewards before used as the basis for Medicare payment. Placing new measures on the display page provides transparency about CMS' intention to use the measure in the future as part of Star Ratings and an opportunity for sponsors to see their scores and performance before the measure is used in the Star Ratings. The display measures are not assigned Star Ratings or used in the development of measure, domain, summary, or overall Star Ratings, so there are no payment consequences. Retaining new measures on the display for two years gives CMS additional opportunities to identify any data issues prior to the measures being included in the Star Ratings program. CMS will use endorsed measures as they are available. For some areas which CMS judges to be important for the Star Ratings program, endorsed measures may not be available. CMS emphasizes that if reliability issues with a display measure are identified, the regulations proposed and finalized in this rule at §§ 422.164(c)(4) and 423.184(c)(4) prevent the measure from moving to a Star Ratings measure. Although a number of commenters to the proposed rule were concerned about the rulemaking process preventing CMS from quickly responding to public health and patient safety issues, CMS believes that reporting new measures as soon as possible on the display page will addresses these concerns.

Comment: The majority of commenters agreed with the process for updating existing measures.

Response: We appreciate the support for the process for updating existing measures.

Comment: Some commenters objected to the proposal for updating measures through rulemaking because of the delay between the time measures are updated/approved and the time they are re-introduced into the Star Ratings program. These commenters requested a more expedited approach for updating measures. Most commenters supported CMS in its proposal to codify a non-exhaustive list for identifying non-substantive measure updates. Some commenters requested additional information on how the determination is made as to whether a change is substantive versus non-substantive. A few commenters wanted a more exhaustive list of what are considered non-substantive changes.

Some commenters expressed the opinion that all measure updates, even non-substantive changes, should be announced in advance of the measurement period. In addition, a few commenters expressed the opinion that all measure updates, whether substantive or non-substantive, should be subject to rulemaking. These commenters noted some of the same concerns expressed for supporting the addition of new measures through rulemaking rather than through the Call Letter process. These concerns included allowing plans greater lead time to incorporate updates, have sufficient time to allocate resources to incorporate updates, make changes to operations, adjust supporting information systems, and plan any specialized educational materials and events. A commenter, however, expressed the opinion that no measure updates, substantive or non-substantive, should be required to go through rulemaking, because this would lead to unnecessary gaps in measurement for critically important issues.

Response: CMS appreciates the comments we received on our proposal for updating measures. Although there is some disagreement among commenters on whether and which updates should go through rulemaking, we believe our proposal balances the commenters' concerns by only requiring substantive measure updates to go through the rulemaking process. Non-substantive updates, such as coding updates, which are not significant changes to the measure specifications would continue to be announced

through the Call Letter process. CMS does not have authority to determine or direct when measure stewards update measure specifications. If non-substantive measure specifications are made during the measurement period, CMS believes it is of value to incorporate those measure specification updates in that year's Star Ratings measures. Non-substantive updates are most often minor code updates and are not significant changes to the measure specifications. CMS proposed and is finalizing in this rule a comprehensive list of measure changes it considers non-substantive in §§ 422.164(d)(1) and 423.184(d)(1); we explained (above and in the proposed rule) the basis for our determination that these changes and others like them should be implemented without delay or additional rulemaking. The list is not exhaustive because additional situations or types of changes may also result in little or no change to the results of measurement (or generally benefit sponsoring organizations) in a similar way. We believe that the standard adopted here—that of non-substantive changes—is adequately clear to provide notice to stakeholders and balance the competing policies identified by commenters. CMS encourages plans and other stakeholders to provide suggestions for additional non-substantive measure updates to add to the current list through future rulemaking.

Comment: A few commenters expressed disagreement with the proposal to continue collecting a legacy measure until an updated measure has been on display for 2 years.

Response: CMS appreciates comments on its proposal to keep legacy measures in the Star Ratings during the period when the related updated measure goes through rulemaking and is placed on the display page for 2 years. We intend that a legacy measure may remain in the Star Ratings until the updated measure is ready to move into Star Ratings only when the area covered by the measure is critical to reflecting whether plans are providing appropriate care or for a similar reason that the information provided by the legacy measure is important to the Star Ratings.

Comment: There was general agreement among commenters with CMS' proposed process for removing measures from the Star Ratings program and for announcing the removal in advance of the measurement period. However, some commenters did question the criteria for how CMS judges measures to be 'topped out' or have low statistical reliability.

Response: CMS appreciates the overall support for its proposal for removing measures from the Star Ratings program. Measure scores are determined to be 'topped out' when they show high performance and little variability across contracts, making the measure statistically unreliable. However, although some measures may show uniform high performance across contracts and little variation between them, CMS needs to balance these concerns with 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 which address the specific clinical concerns.

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the provisions related to the adoption, update, and removal of measures as proposed at paragraphs (c), (d), and (e) of §§ 422.164 and 423.184 with a minor modification to add the phrase ''nationally endorsed'' to § 422.164(c)(1) so that the regulation text is identical to the parallel Part D provision at § 423.184(c)(1).

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

We proposed 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 *ma-pdpcahps.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.

As indicated in the proposed rule, CMS will not codify a list of measures and specifications in regulation text in light of the regular updates and revisions contemplated by the rules we have finalized at paragraphs (c), (d) and (e) of §§ 422.164 and 423.184. We would, as finalized in §§ 422.164(a) and 423.184(a), issue annually the full list of measures in the Technical Notes for each year's Star Ratings.

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TABLE 3: PROPOSED INDIVIDUAL STAR RATING MEASURES FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2019

The measure descriptions listed in the 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.

Measure Category and Weight: For discussion of CMS' final decision to change the weight of measures in the Patients' Experience and Complaints category and in the Measures Capturing Access category from a weight of 1.5 to a weight of 2, see section 'II.B.11.q. Measure Weights' of this preamble. For the final measure weight assignments, see paragraphs §§ 422.166(e) and 423.186(e) of this regulation.

TABLE 3A: 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

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
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
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

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 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
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

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
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
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

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
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
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

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
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
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-pdpcahps.org/en/quality-assurance/)

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

TABLE 3B: 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
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	09). Effects e	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 from1 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

Measure	Metric	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements by Contract Type
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
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 *statin drug*) 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

Measure	Metric	Domain	Measure Category and Weight	Data Source	Measurement Period	NQF Endorsement	Statistical Method for Assigning Star Rating	Reporting Requirements by Contract Type
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)

We summarize the comments received on the proposed measures and respond to them by measure in Table 3C for the Part C measures, for performance

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periods beginning on or after January 1, 2019.

TABLE 3C—PART C MEASURES

Measure	
Breast Cancer Screening (BCS)	*Comment:* A commenter expressed concerns that due to physical and mental limitations, all permanently institutionalized beneficiaries, including those under age 65, should be excluded from the Breast Cancer Screening measure. This commenter suggested that rather than undergo a mammogram, an alternative screening option would be an Automated Breast Ultrasound (ABUS). *Response:* CMS appreciates this feedback. CMS has shared comments received on this measure with NCQA, the measure steward, for consideration when their advisory panels re-evaluate this measures, as part of the standard HEDIS process.
Colorectal Cancer Screening (COL)	*Comment:* CMS received no comments on this measure.
Annual Flu Vaccine	*Comment:* CMS received a number of general comments on CAHPS measures. *Response:* CMS appreciates the feedback on the CAHPS measures. Since the comments on CAHPS measures were mostly not measure specific, please see the CAHPS summary of comments received as well as CMS responses following the Parts C and D Measure Tables. *Comment:* CMS received one comment that the annual flu vaccine measure should use claims data as they are more reliable. Another commenter stated that beneficiaries in Puerto Rico are reluctant to vaccinate against the flu which unfairly impacts plans in Puerto Rico, and that asking beneficiaries to remember when they received a flu shot is a burden on them. *Response:* The flu item is a HEDIS measure collected through the CAHPS survey. Flu shot information is collected through a survey since there are a variety of places where people can get flu shots and the plan may not have a record of a flu shot in their administrative data depending on where the flu shot was received. We note that CMS applies standards of reliability to CAHPS results, directly and through significance testing. The item asks whether respondents received a flu shot since July in order to reflect the timeframe when beneficiaries typically receive flu shots. This is a process measure, and CMS does not adjust process measures for beneficiary refusals to avoid biasing the data.
HOS Measures:	
Improving or Maintaining Physical Health.	*Comment:* CMS received a number of general comments on HOS measures. *Response:* CMS appreciates the feedback on the HOS measures. Since the comments on HOS measures were mostly not measure specific, please see the HOS summary of comments received as well as CMS responses following the Parts C and D Measure Tables.
Improving or Maintaining Mental Health.	*Comment:* Several commenters suggested the HOS measures Improving or Maintaining Physical Health and Improving or Maintaining Mental Health fail to consider the natural aging process or accommodate vulnerable beneficiaries and those with degenerative or progressive diseases. They pointed out that as time passes, patients are more prone to experience certain health deterioration and argued that changes in status—positive or negative—should not be attributed to the actions of the health plan. They again suggested that CMS drop the two year look-back design of the survey. *Response:* HOS yields two patient-reported outcome measures of change in global functioning, by using 2-year change in scores on the Physical Component Score (PCS) and the Mental Component Score (MCS), both of which come from the Veterans RAND 12-Item Health Survey (VR–12) portion of the larger survey. HOS assesses health outcomes for randomly selected beneficiaries from each health plan over a two-year period by using baseline measurement and a two-year follow up. In general, functional health status is expected to decline over time in older age groups, mental health status is not, and the presence of chronic conditions is associated with declines in both*.[37] Longitudinal HOS outcomes (including death) are adjusted for baseline age and other well studied risk factors, including chronic conditions, baseline health status, and socio-demographic characteristics that include gender, race, ethnicity, income, education, marital status, Medicaid status, SSI eligibility, and homeowner status. Because each beneficiary's follow up score is compared to their baseline score and adjusted for these risk factors, each beneficiary serves as his/her own control. CMS recognizes that Physical Component Summary (PCS) and Mental Component Summary (MCS) may decline over time and that health maintenance, rather than improvement, is a more realistic clinical goal for many older adults. Therefore, MA Organizations are asked to improve or maintain the physical and mental health of their members. Change scores are constructed and the results compare actual to *expected* changes in physical and mental health.
Monitoring Physical Activity (PAO)	*Comment:* CMS received no comments on this measure.
Adult BMI Assessment (ABA)	*Comment:* CMS received one comment suggesting the BMI measure be removed from the Star Ratings program due to the commenter believing the measure to be 'topped out.' A measure is considered 'topped out' when it shows high performance across all contracts decreasing the variability across contracts and making the measure unreliable. *Response:* CMS appreciates the feedback; however, from a review of the Star Ratings data for this measure, there are many contracts rated below 4 stars. There have been significant increases in ratings for this measure in recent years so CMS is carefully monitoring this measure to see if it should be proposed for retirement from the Star Ratings in the future.
Special Needs Plan (SNP) Care Management.	*Comment:* A commenter recommended that the SNP Care Management measure be retired until clear technical guidance on the measure specifications can be issued by the agency and if the measure is reintroduced, the cut points should be stratified based on SNP type (for example, C–SNP, D–SNP), since the commenter believes various SNP types have different outcomes on this measure.

TABLE 3C—PART C MEASURES—Continued

Measure	
	Response: There are no upcoming clarifications or changes to this measure specifications for the 2021 Star Ratings. Note that the SNP care management measure is collected at the PBP level and the requirement to complete a timely HRA for every plan member (which is the performance metric measured) applies to all SNP types. Sponsors are reminded that as part of the data validation process of plan-reported data, a reviewer must submit and review draft findings to the sponsor prior to submission via HPMS. Once data validation findings are submitted to HPMS, sponsors may formally submit their disagreement to CMS if necessary.
	Comment: A commenter suggested that some Star Rating measures are driven primarily by member outreach. As such, some plans with large dual-eligible populations are disproportionately negatively impacted by members who are more transient and with frequent address and phone number changes that directly result in fewer successful contacts and lower engagement. For outreach-driven measures, the commenter urges CMS to exclude members who were unreachable after a justifiable number of documented good faith attempts.
	Response: The requirement to complete a timely HRA for every plan member (which is the performance metric measured) applies to all SNP types and is regulatory. There are no upcoming specification changes that will affect this measure for the 2021 Star Ratings. Note that plans may report when members are unreachable after documented attempts and when members refuse to complete the HRA, but those data are not used in calculating this measure.
SNP measures:	
Care for Older Adults (COA)—Medication Review, Care for Older Adults (COA)—Functional Status Assessment, Care for Older Adults (COA)—Pain Assessment.	*Comment:* A commenter expressed concerns about the varying performance on SNP measures based on the SNP type stating that the performance on these measures is heavily biased related to type of SNP plan, rather than indicative of plan quality.
	Response: These measures are indicators of high quality care for all plans that focus on special needs populations. However, for HEDIS 2019, NCQA is considering modifications to these measures, to broaden the denominators to all patients with multiple chronic conditions. CMS will keep considerations in mind that measures not be primarily driven by plan type, rather than differences in quality of care.
Osteoporosis Management in Women who had a Fracture (OMW).	*Comment:* CMS received comments that there should be different exclusions for some health conditions including osteoporosis because, for some patients, the treatments identified in the measure specification (that is for compliance) are not medically appropriate. Commenters noted that many challenges exist in treating and screening certain health conditions for patients with advanced illness. A commenter suggested that the Star Ratings clinical metrics may not be sound for frail patients with advanced illness.
	Response: CMS appreciates receiving feedback on this measure. For HEDIS 2019, NCQA is examining potential cross-cutting exclusions for those with advanced illness from selected HEDIS® measures, including the *Osteoporosis Management in Women Who Had a Fracture* measure. Proposed changes to implement advanced illness exclusions will be posted for the HEDIS 2019 public comment period in February 2018. Please see additional comments related to Patients with Advanced Illness below.
Diabetes Care (CDC)—Eye Exam	*Comment:* CMS received no comments on this measure.
Diabetes Care (CDC)— Kidney Disease Monitoring.	*Comment:* CMS received a few comments suggesting the Diabetes Care—Kidney Disease Monitoring measure be removed from the Star Ratings program due to the commenters belief the measure is 'topped out.' A measure is considered 'topped out' when it shows high performance across all contracts decreasing the variability across contracts and making the measure unreliable.
	Response: CMS appreciates the feedback, however, from a review of the Star Ratings for this measure, there are many plans rated below 4 stars. A. As noted above in this preamble, among other considerations, CMS wants to balance how critical measures are to improving care and the availability of alternative related measures. If, for example, no other measures captures a key focus in Star Ratings, a 'topped out' measure with lower reliability may be retained in Star Ratings. Currently, there are no alternative kidney disease monitoring measures appropriate for MA Star Ratings.
Diabetes Care (CDC)—Blood Sugar Controlled.	Comment: CMS received no comments on this measure.
Controlling Blood Pressure (CBP) ..	*Comment:* CMS received a recommendation that in alignment with current clinical practice guidelines, ambulatory and home blood pressure readings that are documented in the treating provider's medical record be considered acceptable for the purposes of assessing the efficacy and appropriateness of a clinician's treatment plan.
	Response: CMS appreciates feedback on this measure. NCQA is currently reevaluating the Controlling High Blood Pressure measure and proposing to allow for readings taken from remote monitoring devices that transmit results directly to the provider. Details on this potential change will be posted for the HEDIS 2019 public comment period in February 2018.
Rheumatoid Arthritis Management (ART).	*Comment:* CMS received comments that evidence of treatment for rheumatoid arthritis not limited to disease-modifying anti-rheumatic drugs (DMARD) should be considered for compliance (that is, added to the numerator for the measure). Commenters noted that some patients have limited tolerance for DMARDs along with a much higher rate of serious adverse medication effects, particularly serious infections.

TABLE 3C—PART C MEASURES—Continued

Measure	
	Response: CMS appreciates receiving feedback on this measure. For HEDIS 2019, NCQA is examining potential cross-cutting exclusions for those with advanced illness from selected HEDIS® measures, including the *Disease-Modifying Anti-Rheumatic Drug Therapy for Rheumatoid Arthritis* measures. Proposed changes to implement advanced illness exclusions will be posted for the HEDIS 2019 public comment period in February 2018. Please see additional comments related to Patients with Advanced Illness below. We understand from public statements that NCQA plans to reevaluate the Rheumatoid Arthritis Management measure and review the evidence for rheumatoid arthritis treatment with their advisory panels.
Reducing the Risk of Falling (FRM)	*Comment:* CMS received no comments on this measure.
Improving Bladder Control (MUI)	*Comment:* CMS received no comments on this measure.
Medication Reconciliation Post-Discharge (MRP).	*Comment:* CMS received no comments on this measure.
Plan All-Cause Readmissions (PCR).	*Comment:* A commenter suggested that in order to provide MA organizations with greater visibility into plan performance, CMS should work with the NCQA to eliminate the calculation whereby a national average observed rate is multiplied by the observed to expected ratio of readmissions for Plan All-Cause Readmissions. A commenter noted that NCQA has announced in early 2018 substantive changes in the Plan All-Cause Readmissions measure. *Response:* CMS appreciated feedback on this measure. The calculation mentioned that uses the observed readmission rate divided by the expected readmission rate for a contract multiplied by the national average is the process to calculate the case-mix adjusted contract rate. A case-mix adjusted rate is used to ensure that the comparisons between contracts is fair and meaningful. It takes into account how sick patients were when they went into the hospital the first time. CMS will discuss with NCQA the need to better explain the calculations involved in the reporting of the measure. *CMS decision:* In that NCQA is planning to make significant changes to the Plan All-Cause Readmissions measure (changes to be published in 2018 and applied in measurement year 2019) CMS is not finalizing this as part of the measure set for the 2019 performance period and the 2021 Ratings. CMS is finalizing this as a display measure and consistent with § 422.164(d)(2) will include this measure on the display page for 2 years.
Getting Needed Care	*Comment:* CMS received a number of general comments on CAHPS measures. *Response:* CMS appreciates the feedback on the CAHPS measures. Since the comments on CAHPS measures were mostly not measure specific, please see the CAHPS summary of comments received as well as CMS responses following the Parts C and D Measure Tables.
Getting Appointments and Care Quickly.	*Comment:* CMS received many general and specific comments on CAHPS measures. *Response:* CMS appreciates the feedback on the CAHPS measures. Since the comments on CAHPS measures were not always measure specific, please see the CAHPS summary of comments received as well as CMS responses following the Parts C and D Measure Tables. *Comment:* CMS received one comment that this composite is unfair to plans in Puerto Rico because beneficiaries in Puerto Rico are not necessarily used to having a specific appointment time. *Response:* We thank the commenter for this comment. We have conducted some exploratory work related to this topic and may propose changes in the future after consulting with AHRQ.
Customer Service	*Comment:* CMS received a number of general comments on CAHPS measures. *Response:* CMS appreciates the feedback on the CAHPS measures. Since the comments on CAHPS measures were mostly not measure specific, please see the CAHPS summary of comments received as well as CMS responses following the Parts C and D Measure Tables.
Rating of Health Care Quality	*Comment:* CMS received a number of general comments on CAHPS measures. *Response:* CMS appreciates the feedback on the CAHPS measures. Since the comments on CAHPS measures were mostly not measure specific, please see the CAHPS summary of comments received as well as CMS responses following the Parts C and D Measure Tables.
Rating of Health Plan	*Comment:* CMS received a number of general comments on CAHPS measures. *Response:* CMS appreciates the feedback on the CAHPS measures. Since the comments on CAHPS measures were mostly not measure specific, please see the CAHPS summary of comments received as well as CMS responses following the Parts C and D Measure Tables.
Care Coordination	*Comment:* CMS received many general and specific comments on CAHPS measures. *Response:* CMS appreciates the feedback on the CAHPS measures. Since the comments on CAHPS measures were not always measure specific, please see the CAHPS summary of comments received as well as CMS responses following the Parts C and D Measure Tables.
Complaints about the Health Plan ..	*Comment:* A commenter recommended creating an excluded category/sub-category for complaints related to CMS/SSA system/enrollment issues or limitations which would effectively remove complaints of that type from this measure. *Response:* Data exchanges between CMS and SSA occur regularly and mostly without incident. When issues occur, CMS often looks to plan sponsors to communicate accordingly to their members and utilize CMS resources, such as the MA–PD help desk, to help address their matter without referral to CMS and generation of complaints. CMS is not instituting such a category/sub-category at this time. Plan Sponsors should continue to work alongside their CMS caseworker as appropriate to provide assistance. *Comment:* A few commenters requested updates to the CMS CTM standard operating procedures (SOP). There was a request to provide instructions for plans to return issues (either as a CMS issue or as a closed complaint) determined by 1–800–Medicare to be errors. Another request was that complaints found to not be the fault of the plan be considered CMS issues, or reassigned to another entity.

TABLE 3C—PART C MEASURES—Continued

Measure	
	Response: CMS regularly utilizes feedback from plans and other stakeholders to identify opportunities for continuous improvement of CMS resources such as 1–800–Medicare. Due to the volume of CTM complaints received annually, CMS cannot investigate for individual errors. CMS expects such matters to be rare, and any impact on plans to be evenly distributed. Plan Sponsors should not seek recategorization of marketing complaints because, as a result of plan investigation, they have determined the allegation is unfounded. However, if a marketing complaint has been misclassified, and the narrative reflects that the alleged misrepresentation occurred by a Call Center representative, SHIP, etc., then a Plan Request to make the complaint a ''CMS Issue'' is appropriate. CMS appreciates the feedback and will include additional language in the next version of the CTM Plan SOP. *Comment:* A commenter suggested that CMS create an excluded category intended for cases that are educational and/or are referrals to the contract. *Response:* It is not CMS' intention for the CTM to communicate plan information or simply provide education. *Comment:* A commenter stated concerns that duplicate complaints count against plan sponsors. *Response:* CMS' CTM SOP includes procedures for the removal of duplicate complaints with the same complaint identification numbers, so there is no impact on plan sponsors. CMS has taken numerous steps over the years to reduce the instances of this occurring and expect that plan sponsors have noticed significant improvement in this area. If a beneficiary's issue persists or is not be resolved by a plan, multiple complaints may be entered into the CTM. These complaints are not duplicative, but reflect unresolved or similar issues. CMS does not support removing such complaints. Inclusion of these complaints effectively rewards plan sponsors who are prompt with acknowledging and resolving complaints, and provide excellent customer service to beneficiaries. *Comment:* A commenter requested clear processes for when the assignment/reassignment date should be reset by CMS caseworkers, so that plan sponsors can better strategize their actions. *Response:* Assignment/reassignment date by CMS caseworkers is a topic outside the scope of this rule.
Members Choosing to Leave the Plan.	*Comment:* A couple of commenters suggested that the disenrollment rate does not reflect the plan's quality and the beneficiary experience. They note that the disenrollment rate is impacted by the pricing and coverage strategies of the contract. Among those commenters dissatisfied with what the disenrollment rate reflects and does not reflect, a commenter suggested that this measure be moved to the display page. *Response:* CMS is statutorily required to report voluntary disenrollment rates as part of the Balanced Budget Act of 1997. Disenrollment rates are a strong measure of a beneficiary's satisfaction with a contract. Beneficiaries who are interested in seeing why enrollees voluntarily leave a contract can obtain this information as a drill down to the disenrollment rates on Medicare Plan Finder. CMS respectfully disagrees that pricing strategies and the coverage provided by the contract should not be considered in assessing the quality and performance of contracts since they have a direct impact on access to services. *Comment:* A commenter suggests that CMS conduct additional analyses to see if the disenrollment rates should be adjusted by the proportion of SNP members. *Response:* CMS appreciates this comment and will analyze the data to see if any future changes are needed. Any potential changes would be subject to future rulemaking. The current Star Ratings adjustments for dual status are incorporated as part of the CAI.
Health Plan Quality Improvement ...	For the summary of comments received and CMS' responses for this measure, please see section 'j. Improvement Measures' of the Preamble.
Plan Makes Timely Decisions about Appeals.	*Comment:* CMS received a comment opposing the inclusion of dismissals in the Plan Makes Timely Decisions about Appeals measure. The commenter expressed concern that if the inclusion of dismissals is a positive factor in the measure, it would create incentives for the MA organization to increase the opportunities to enter dismissals. *Response:* CMS appreciates the comment about dismissals. To clarify, the measure for the 2021 Star Ratings includes cases dismissed by the IRE because the plan has subsequently approved coverage/payment. In prior years, we excluded all cases dismissed/withdrawn by the IRE from this measure. The inclusion of dismissals would only apply to cases dismissed by the IRE because the plan issued an untimely but favorable decision. In other words, plans may send late Part C appeals to the IRE while simultaneously (or shortly thereafter) approving the late cases which results in the case being dismissed by the IRE, thus masking that the plans' decisions were untimely. Inclusion of cases where the plan has subsequently approved for coverage/payment that are dismissed or withdrawn at the IRE level could provide a more accurate assessment of plans' timeliness in their Part C appeals processing. Without excluding this group of dismissals, a plans' performance may be artificially improved as a result, especially if dismissals were directly related to the plans' (untimely) approvals. If an MA plan fails to provide the appellant with a reconsidered determination within the required timeframes, this failure constitutes an affirmation of its adverse organization determination, and the plan must submit the case file to the IRE for review. This new measure would more accurately reflect that MA plans are not making timely decisions. CMS does not believe this would create the incentive described by the commenter. CMS acknowledges these comments and is actively evaluating these measures and the use of the IRE data as their data source for future enhancements. *Comment:* CMS received a comment recommending that this measure be weighted by membership by calculating the measure similarly to the Part D Auto-Forward measure to ensure plans of all sizes are measured equally. *Response:* The Part C and Part D appeals systems are different, they have different rules for how appeals are handled. There are no auto-forwards in Part C and the number of late appeals examines how well the contract is processing the appeals in a timely manner. Additionally each measure has different specifications.

TABLE 3C—PART C MEASURES—Continued

Measure	
Reviewing Appeals Decisions	Please see response for Part D Appeals Upheld measure.
Call Center—Foreign Language Interpreter and TTY Availability.	*Comment:* A few commenters recommended that CMS revise the measure's sampling methodology for volume and for volume by language (including consideration of plans with larger enrollment sizes), or revise the foreign languages and testing frequency. An additional commenter recommended that CMS adjust the foreign languages tested to the languages actually spoken in that plan's area, and mentioned that 99 percent of local residents speak Spanish in Puerto Rico. The commenter also suggested using a single, combined measure (or rate) for both Part C and D. *Response:* The Accuracy and Accessibility Study is performed to (1) ascertain the accuracy of responses to plan benefit questions provided by customer service representatives when calling the call center in addition to (2) testing the availability of interpreters for Limited English Proficient callers and (3) testing TTY functionality. A simple random sample method is used. To reduce the burden on a call center with multiple phone lines, we select samples across the call centers instead of the phone lines. The precision requirement of the sample size is calculated at the call center level and is based on the question response accuracy rates obtained from the accuracy survey, and the rate of completed calls made through Limited English Proficiency (LEP) accommodations and TTY services. This methodology was chosen by CMS, in part, because the accuracy of the information provided to a caller in response to specific benefits questions should not be impacted by enrollment size or physical call center location. If contract enrollment size is positively correlated with higher variability and wider margins of error in these key metrics of this study, CMS would expect to see contracts with higher enrollments having the key metrics closer to 50 percent than the contracts with lower enrollments. We have not observed that in the data and will therefore continue to use the methodology as designed. Call centers using more or fewer representatives are held to the same expectation that the information provided to callers is accurate. Foreign language testing was never intended to be proportionate to the demographics of any contract. Plan sponsors are required to provide an interpreter for any caller speaking a foreign language, and CMS seeks to ensure that more vulnerable populations have equal access to interpreters. Rather than test all foreign languages which would be overly burdensome and costly, CMS selects 6 foreign languages from among the top 10 most frequently spoken languages in the U.S., according to the Office for Civil Rights (which makes its selections from U.S. Census Data). The number of calls by foreign language is equally divided and randomly assigned to each call center across the biweekly calling schedule. The number received by the call center is dependent upon each call successfully reaching the call center (for example, disconnects in an IVR or other factors will impact the ability of the call to reach a representative). Internal analysis across all plans shows that the methodology is sound and CMS has confidence in the data. When testing in Puerto Rico, Spanish is the native language and English is treated as a foreign language. Because some of the accuracy calls are placed in the native language *in addition to foreign language testing,* Spanish calls are placed at a higher volume for plans in Puerto Rico. By design, the Accuracy and Accessibility Study schedules and places calls to phone numbers that may or may not be the same for Part C and Part D. Also, the study is conducted at the call center level (not the phone number level), and not all plans use the same call center for Part C as for Part D. Finally, the accuracy questions used in this study either relate to Part C benefit questions or to Part D benefit questions. Because the questions are different for each, CMS believes performance should be measured separately for the Part C and Part D programs.
Statin Therapy for Patients with Cardiovascular Disease (SPC).	*Comment:* CMS received two comments seeking clarification regarding the categorization and weighting discrepancies between the Part C and Part D statin measures. Two organizations recommended classifying both SPC and SUPD as process measures with a weight of one. *Response:* CMS appreciates the feedback. The Part C Statin Therapy for Patients with Cardiovascular Disease (SPC) measure is the 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. This Part C measure focuses on patients who were dispensed one prescription and whether the patient filled the medication at least once. Therefore, it is a process measure. The Part D measure is the 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. Receiving multiple fills indicates the patient continues to take the medication and therefore suggests adherence. Continuing to take the prescribed medication is necessary to reach clinical/therapeutic goals. Thus, the Part D measure is an intermediate outcome measure. We believe that for these measures as proposed (and finalized in this rule) are properly categorized.

We summarize the comments received on the proposed measures and respond to them by measure in Table 3D for the Part C measures, for performance periods beginning on or after January 1, 2019.

TABLE 3D—PART D MEASURES

Measure	
Call Center—Foreign Language Interpreter and TTY Availability.	Please see comments received and CMS' responses for this measure in the above Part C Measures table for the measure *Call Center—Foreign Language Interpreter and TTY Availability.*

[37] Ware JE, Kosinski M. *SF–36 Physical and Mental Health Summary Scales: A Manual for Users of Version 1, Second Edition.* Lincoln, RI: QualityMetric, Incorporated, 2001.

TABLE 3D—PART D MEASURES—Continued

Measure	
Appeals Auto-Forward	*Comment:* CMS received one comment suggesting that CMS align the Part D Appeals Auto-Forward measure with the Part C Plan Makes Timely Decisions about Appeals measure. The commenter also complained that cases that can be approved, but because the approvals are untimely, the cases are forwarded to the IRE; the commenter said this can cause delays in patient care as the member, provider, and plan await the IRE's decision. *Response:* CMS appreciates receiving comments on this measure. However, the Part C and Part D appeals systems are not interchangeable. Each appeal system has its own set of rules and procedures which mean that combining or aligning these measures is not appropriate. We direct the commenter to the appeal regulations at §§ 422.590 and 422.592 as compared to §§ 423.568(h). Further, we note that the MA and Part D plans have full control of the appeal prior to it having been sent to the IRE. In the example cited, if the plan had approved the original request from the member, the appeal would not have needed to be raised to the IRE level or incurred the additional waiting time.
Appeals Upheld	*Comment:* CMS received a comment requesting that CMS adjust the Reviewing Appeals Decisions measure to remove from the measure denials due to lack of response from providers from the denominator and the numerator. The commenter also requested to align timeframes for the plan with the IRE stating that the IRE is generally held to the same adjudication timeframes as the plan but if additional information is needed from a prescriber, the IRE is allowed to extend the adjudication timeframe to obtain this information. The commenter further said that a plan is not afforded this time and must deny based on the information provided in order to prevent cases from being auto-forwarded to the IRE. Therefore, the commenter requested to measure fairness based on the information the plan had at the time of the plan's decision. Plans should also not be penalized for appeals that were overturned when providers provided ''new'' information to the IRE, which was not originally submitted by the provider at the time of the plan's original coverage determination or redetermination. A commenter from a plan noted that this measure did not reflect the commenter's true plan performance. Additionally, this commenter noted several instances where cases were overturned by the IRE due to allowing non-Part D supported indications to be considered and disregarding the commenter's CMS approved clinical policies. Due to these issues, the commenter proposed an alternative formula to capture Appeals Upheld data and measure plan performance in this area. *Response:* CMS appreciates the comment. Plans and sponsors must have procedures in place for requesting and obtaining information necessary for making timely and appropriate decisions. The IRE's decision is based on the information gathered during its review process. Adjusting appeal timeframes is not within the scope of this proposal, however, we note that the IRE must issue a decision within the same appeals timeframe as the plan. Please refer to 42 CFR 423.600(d). The timeframes for the plan and the IRE are aligned. At this time, CMS will continue to include this measure in the Star Ratings CMS acknowledges these comments, and is actively evaluating these measures, and the use of the IRE data as their data source. For future enhancements.
Complaints about the Drug Plan	Please see comments received and CMS' responses for this measure in the above Part C Measures table for the measure *Complaints about the Health Plan.*
Members Choosing to Leave the Plan.	Please see comments received and CMS' responses for this measure in the above Part C Measures table for the measure *Members Choosing to Leave the Plan.*
Drug Plan Quality Improvement	For the summary of comments received and CMS' responses for this measure, please see section 'j. Improvement Measures' of the Preamble.
Rating of Drug Plan	*Comment:* CMS received a number of general comments on CAHPS measures. *Response:* CMS appreciates the feedback on the CAHPS measures. Since the comments on CAHPS measures were mostly not measure specific, please see the CAHPS summary of comments received as well as CMS responses following the Parts C and D Measure Tables. *Comment:* A commenter suggested we consider this measure 'topped out.' *Response:* We do not agree this measure is 'topped out'' since many contracts receive less than 4 stars. Previous analyses of CAHPS scores have suggested that seemingly small differences of 1 point on a 0–100 scale are meaningful; differences of 3 points can be considered medium, and differences of 5 points can be considered large.[38] For instance, a 3-point increase in some CAHPS measures has been associated with a 30 percent reduction in disenrollment from health plans, which suggests that even ''medium'' differences in CAHPS scores may indicate substantially different care experiences.[39]
Getting Needed Prescription Drugs	*Comment:* CMS received a number of general comments on CAHPS measures. *Response:* CMS appreciates the feedback on the CAHPS measures. Since the comments on CAHPS measures were mostly not measure specific, please see the CAHPS summary of comments received as well as CMS responses following the Parts C and D Measure Tables. *Comment:* CMS received one comment that this composite penalizes Part D plans where patients do not prefer to fill prescriptions by mail. *Response:* CMS disagrees that this composite penalizes plans based on how beneficiaries choose to fill prescriptions; rather, the item focuses on ease of getting prescriptions filled when using the plan. The composite covers two topics: How often it was easy to use your plan to get the medicines your doctor prescribed (assessed by one item) and ease of filling prescriptions (assessed by combining two items about how often it was easy to use your plan to fill a prescription at your local pharmacy, and how often it was easy to use your plan to fill a prescription by mail). The combined pharmacy/mail score is averaged with the first item's score to produce the composite score. This averaging weights mail and pharmacy according to how many respondents say they use each method, so mail would not count at all if no one in the plan uses mail. *Comment:* A commenter suggested we consider this measure 'topped out.'

TABLE 3D—PART D MEASURES—Continued

Measure	
	Response: We do not agree this measure is 'topped out' since many contracts receive less than 4 stars. Previous analyses of CAHPS scores have suggested that seemingly small differences of 1 point on a 0–100 scale are meaningful; differences of 3 points can be considered medium, and differences of 5 points can be considered large.[40] For instance, a 3-point increase in some CAHPS measures has been associated with a 30 percent reduction in disenrollment from health plans, which suggests that even ''medium'' differences in CAHPS scores may indicate substantially different care experiences.[41]
MPF Price Accuracy	*Comment:* A commenter asked CMS to identify which of the two possible calculations will be included in the MPF Accuracy measure. The commenter noted that CMS had previously proposed to update the measure to include frequency and magnitude of prescription drug event (PDE) prices that exceed MPF information beginning with the 2016 data but reverted to the old measurement (only magnitude) with the 2018 Star Rating release. *Response:* The MPF Accuracy measure will only measure the magnitude of difference, as has been done in the past. CMS will continue to calculate each contract's accuracy index which measures the amount that the PDE price is higher than the MPF price. CMS will consider for future rule-making, with stakeholder input, to include both frequency and magnitude of PDE prices that exceed MPF information in the Accuracy measure. *Comment:* A commenter suggested that this measure is 'topped out'. A measure is considered 'topped out' when it shows high performance across all contracts decreasing the variability across contracts and making the measure unreliable. *Response:* As announced through the 2019 Call Letter, CMS is proposing enhancements to this measure for the CY2022 Ratings. The enhanced measure will first be put on display before being added into the Star Ratings program pursuant to the rules in § 423.184.
Adherence Measures:	
Medication Adherence for Diabetes Medications, Medication Adherence for Hypertension, Medication Adherence for Cholesterol (Statins).	*Comment:* A few commenters requested that CMS consider excluding beneficiary prescriptions from these measures or create a reporting mechanism that allows plans to identify prescriptions for removal that are documented as ''discontinued'' or prescriptions with therapy changes; the commenter stated that these changes would avoid the appearance that beneficiaries with discontinued medications are non-adherent. A commenter expressed concerns about the thresholds for the medication adherence for diabetes and cholesterol measures citing that they are reaching unsafe levels and do not reflect individual needs such as in the aging elderly population. They described several circumstances that can adversely affect adherence measures and suggest noncompliance, such as prescription data entry errors and changes in therapy due to clinical indicators. A commenter commended CMS on including adherence measures in the Star Ratings. Another commenter recommended that CMS weight MA–PD and PDP measures differently based on the plan's ability to influence outcomes on a measure. It was recommended that CMS require beneficiaries to provide a contact phone number at the time of enrollment in order to assist plans in reaching members to impact adherence. Another commenter was concerned about the significant negative impact by LIS members on adherence measures. *Response:* We appreciate the feedback. CMS' mission is to promote quality care for our beneficiaries. In our May 11, 2012 HPMS memo entitled 'Prohibition on Submitting PDEs for non-Part D prescriptions', we outlined our concerns related to beneficiary privacy protections and data validation for the submissions of non-Part D data. If Part D sponsors were to attempt to collect the data it is unclear how sponsors could implement sufficient internal controls to meet audit standards necessary to ensure the quality of the data. In addition, requiring physicians to attest to therapy changes or discontinuation of a prior prescription would be an added burden and counterproductive to CMS' Patients over Paperwork initiative. In the case of changes in therapy (such as holding or discontinuing medication), we believe that the 80 percent compliance threshold incorporates these circumstances as the ideal compliance expectation is 100 percent. We will pass along these comments to the measure steward (PQA) but we are unable to use supplemental data to calculate the measures. Data entry error is also a concern of CMS. We believe that Part D sponsors have the ability to identify and correct many data errors at the point-of-sale and afterward. Similar to the CMS Part D Potential Exclusion Warning Report that identifies PDEs for adjustment or deletion, plan sponsors could use their POS edits systems to screen for data entry errors. For example, screening criteria based on a maximum or minimum daily dose or units per day could identify outliers. In the example above, if the term ''3 days'' was accidently entered instead of ''30 days,'' this could result in a daily dose that is significantly higher than the expected maximum daily dose and would be an outlier. The claim could be denied at the POS with a message of 'potential data entry error' notifying the pharmacist or technician the need to review and make a correction. In addition, CMS provides monthly lists to each plan sponsor of their members who are identified as non-compliant starting in April of each year, this procedure provides Part D plans ample time to review their data and submit corrections. Also, we disagree that stand-alone PDPs have very little influence on beneficiaries' medication adherence. There are many strategies that can be used to improve a beneficiary's medication adherence in addition to prescriber interventions, such as refill reminders, formulary and benefits design, and medication therapy management programs. Plan sponsors can also leverage network pharmacy relationships to address medication adherence issues, facilitate medication synchronization, or provide education and counseling. In the absence of a contact phone number for the beneficiary, it may be beneficial to use these interventions to reach the beneficiary at the place of dispensing. Furthermore, MA–PDs and PDPs are rated separately to account for delivery system differences. Lastly, as finalized in the 2019 Call Letter, adherence measures will now be included in the CAI to account for LIS beneficiaries.

TABLE 3D—PART D MEASURES—Continued

Measure	
MTM Program Completion Rate for CMR.	*Comment:* A commented requested CMS move away from MTM process measures and include outcomes-based MTM measures in the Star Ratings program in the future. In the interim, it was recommended that CMS evaluate changes to the MTM Comprehensive Medication Review Completion Rate (CMR) measure methodology and that CMS partner with PQA to develop and understand the feasibility of implementing outcome and/or patient-experience based MTM measures. *Response:* The CMR completion rate measure is an initial measure of the delivery of MTM services, and we continue to look forward to the development and endorsement of outcomes-based MTM measures as potential companion measures to the current MTM Completion Rate CMR measure. We will consider new MTM measures when available. Past analyses did not find a correlation between a sponsor's rate of MTM program eligibility and the CMR completion rate, but we will continue to monitor and work with the PQA to consider if any adjustments are needed to this measure's specifications. *Comment:* A commenter opposed inclusion of the MTM CMR completion rate measure in the Star Ratings due to compliance issues. The commenter suggested allowing completion of CMRs with the beneficiary's prescriber when unable to contact the beneficiary. *Response:* As outlined in 42 CFR 423.153(d)(vii)(B)(2), if a beneficiary is offered the annual comprehensive medication review and is unable to accept the offer to participate, the pharmacist or other qualified provider may perform the comprehensive medication review with the beneficiary's prescriber, caregiver, or other authorized individual. Current guidance clarifies that while providers are required to offer a CMR to all beneficiaries enrolled in the MTM program, regardless of setting, in the event the beneficiary is cognitively impaired or otherwise unable to participate, we recommend that the pharmacist or qualified provider reach out to the beneficiary's prescriber, caregiver, or other authorized individual, such as the resident's health care proxy or legal guardian, to take part in the beneficiary's CMR. This applies to beneficiaries in any setting and is not limited to beneficiaries in long term care (LTC). This does not apply to situations where the sponsor is simply unable to reach the beneficiary or there is no evidence of cognitive impairment. Therefore, we are unable to consider changes to the measure absent a change in regulation or guidance.
Statin Use in Persons With Diabetes (SUPD).	*Comment:* A few commenters supported CMS in including this SUPD measure in the Star Ratings. A commenter noted support of the addition of a quality metric monitoring the use of statins in patients with diabetes, however, feels that CMS did not provide a thoughtful explanation for not selecting the Part C HEDIS measure of Statin Therapy in Patients with Diabetes (NCQA measure), which had also been under consideration. This measure includes more robust clinical considerations for patient eligibility and thus appropriateness of statin use. *Response:* CMS thanks commenters for feedback on this measure. Both the NCQA and PQA measures of statin therapy were proposed for inclusion in the Star Ratings, one for Part C and the other for Part D. As the Pharmacy Quality Alliance (PQA) is the developer of the Statin Use in Persons with Diabetes (SUPD) measure, CMS will share these comments with the PQA for their consideration. *Comment:* CMS received two comments seeking clarification regarding the categorization and weighting discrepancies between the Part C and Part D statin measures. Two organizations recommended classifying both SPC and SUPD as process measures with a weight of one. *Response:* Please refer to the Part C measure response for Statin Use for Patients with Cardiovascular Disease (SPC).

CAHPS: Summary of Additional Comments Received and CMS's Responses

Comment: CMS received a few comments that CAHPS measures are subjective and not reliable. A few commenters stated the CAHPS survey responses are not actionable.

Response: CMS strongly disagrees that patient experience of care survey measures are not reliable. CAHPS and other patient experience measures have been endorsed as critical aspects of healthcare by the Institute of Medicine and the World Health Organization.[42] [43] CAHPS surveys focus on aspects of healthcare quality that patients themselves say are important to them and for which patients are the best and/or only source of information. Patient experience surveys such as CAHPS focus on how patients experienced key aspects of their care, not merely how satisfied they were with their care. Patient experience encompasses the range of interactions that patients have with the healthcare system, including their care from health plans, and from doctors, nurses, and staff in hospitals, physician practices, and other healthcare facilities.[44] While patient experience is an inherently important dimension of healthcare quality, it is also the case that the preponderance of evidence shows that better patient experience is associated with better patient adherence to recommended treatment, better clinical processes, better hospital patient safety culture, better clinical outcomes, reduced unnecessary healthcare use, and fewer

[38] Paddison CAM, Elliott MN, Haviland AM, Farley DO, Lyratzopoulos G, Hambarsoomian K, Dembosky JW, Roland MO. (2013). ''Experiences of Care among Medicare Beneficiaries with ESRD: Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey Results.'' *American Journal of Kidney Diseases* 61(3): 440–449.

[39] Lied, T.R., S.H. Sheingold, B.E. Landon, J.A. Shaul, and P.D. Cleary. (2003). ''Beneficiary Reported Experience and Voluntary Disenrollment in Medicare Managed Care.'' *Health Care Financing Review* 25(1): 55–66.

[40] Paddison CAM, Elliott MN, Haviland AM, Farley DO, Lyratzopoulos G, Hambarsoomian K, Dembosky JW, Roland MO. (2013). ''Experiences of Care among Medicare Beneficiaries with ESRD: Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey Results.'' *American Journal of Kidney Diseases* 61(3): 440–449.

[41] Lied, T.R., S.H. Sheingold, B.E. Landon, J.A. Shaul, and P.D. Cleary. (2003). ''Beneficiary Reported Experience and Voluntary Disenrollment in Medicare Managed Care.'' *Health Care Financing Review* 25(1): 55–66.

[42] Institute of Medicine. Crossing The Quality Chasm: A New Health System for the 21st Century. Washington DC: National Academy Press; 2001.

[43] Smith, P.C. (Ed.). (2009). Performance measurement for health system improvement: experiences, challenges and prospects. Cambridge University Press.

[44] Agency for Healthcare Research and Quality. What Is Patient Experience?. Content last reviewed March 2017. Agency for Healthcare Research and Quality, Rockville, MD. *http://www.ahrq.gov/cahps/about-cahps/patient-experience/index.html.*

inpatient complications.[45] [46] Therefore, while we acknowledge that the CAHPS survey captures individuals' perspectives on their experiences of care, it is anchored in measureable aspects of care and so can be measured reliably.

Additionally, CAHPS surveys follow scientific principles in survey design and development and have been rigorously developed and tested to assess the experiences of Medicare beneficiaries. The surveys are designed to reliably assess the experiences of a large sample of patients and use standardized questions and data collection protocols to ensure that information can be compared across health care settings. The contract-level reliability of 2017 MA and PDP CAHPS measures meet high standards, with the median reliability of publicly-reported MA CAHPS measures exceeding 0.72 for all measures and exceeding 0.90 for a majority of measures, with 0.70 being a conventional standard for reliability. Finally, there are criteria for sample size eligibility that must be met for contracts to be included in data collection, and CMS also offers contracts the option of augmenting their CAHPS sample sizes if they wish to obtain more precise overall results and/or perform subgroup analyses with larger samples.

Comment: Several commenters stated that CAHPS scores may be influenced by factors outside the plan's control, such as cost and coverage, provider behavior, cultural differences including language, and timing of the survey. A few suggested that beneficiaries who are frail, have cognitive impairments, or who have low socio-economic status may not be able to respond to survey items accurately. A commenter requested allowing proxy methods.

Response: For MA and PDP CAHPS, CMS uses mixed-mode data collection to increase the likelihood of survey participation and representativeness.[47] [48] Survey responses are also case-mix adjusted to account for certain respondent characteristics not under the control of the health or drug plan such as age, education, dual eligible status and other variables. We note that plans do have some control over plan-design features such as cost and coverage as well as provider behavior, so it would not be appropriate to adjust for these.

CMS currently provides translations of the MA and PDP CAHPS Survey in Spanish, Chinese, and Vietnamese, and we are developing a Korean translation. All translations are the product of translation and review by native speakers of the target languages and have had multiple rounds of qualitative testing with Medicare beneficiaries with characteristics similar to the MA and PDP CAHPS population. By providing survey translations, CMS promotes standardization by assuring that questions are presented similarly to beneficiaries across and within languages, which also promotes comparability of the results across vendors and contracts. The survey administration protocol for MA and PDP CAHPS does not permit ''live,'' ''individual,'' or ''real-time'' translation of the survey by an interpreter, as such an approach does not promote comparability of data and there is no mechanism for assuring the accuracy and consistency of the translation. If plans need additional translations they should contact us at *MP-CAHPS@cms.hhs.gov.* The MA and PDP CAHPS protocol does allow for the use of proxy respondents in cases where a respondent is unable to complete the survey.

Comment: A commenter stated that the CAHPS survey is long, and a couple commenters expressed concern about low response rates.

Response: CMS shortened the MA CAHPS survey in 2017 by removing questions and measures not used in Star Ratings, and we also improved phone contact information. As a result of CMS's continuing efforts to improve response rates, overall MA and PDP CAHPS response rates increased from 2016 to 2017, despite national trends of declining response rates for most other surveys. Further, meta-analyses of surveys that follow the rigorous probability sampling and survey approaches used by MA and PDP CAHPS find little relationship between response rates and nonresponse bias.[49] Moreover, research specific to patient experience, CAHPS, and MA and PDP CAHPS surveys finds no evidence nonresponse bias affects comparison of case-mix adjusted scores between contracts or other similar reporting units.[50] [51] [52] [53] [54]

Comment: A commenter requested more insight into statistical components such as case-mix adjustment, statistical significance, and reliability, and another requested that CMS provide all case-mix adjustment flags to the survey vendors to facilitate an additional validation.

Response: CMS provides a detailed explanation of the CAHPS methodology including case-mix adjustment in the annual Star Ratings Technical Notes, in CAHPS plan reports provided to each contract each year, and on the MA and PDP CAHPS web page (*https://www.ma-pdpcahps.org*). CMS also provides survey vendors all of the necessary data to perform case-mix adjustment validation. Plans are welcome to contact *MP-CAHPS@cms.hhs.gov* with specific questions about MA and PDP CAHPS.

Comment: A commenter requested that plans be able to add their own questions to the surveys to validate and clarify responses.

Response: CMS allows plans to add a limited number of items to the MA and PDP CAHPS survey that do not affect responses to the survey or pose undue burden to the beneficiary. These rules are to ensure the highest possible response rate as well as comparability of the data across contracts.

HOS: Summary of Additional Comments Received and CMS's Responses

Comment: CMS received several comments on the HOS measures. Some commenters supported patient reported

[45] Price, R.A., Elliott, M.N., Zaslavsky, A.M., Hays, R.D., Lehrman, W.G., Rybowski, L., & Cleary, P.D. (2014). Examining the role of patient experience surveys in measuring health care quality. Medical Care Research and Review, 71(5), 522–554.

[46] Price, R.A., Elliott, M.N., Cleary, P.D., Zaslavsky, A.M., & Hays, R.D. (2015). Should health care providers be accountable for patients' care experiences?. Journal of general internal medicine, 30(2), 253–256.

[47] Fowler Jr, F.J., Gallagher, P.M., Stringfellow, V.L., Zaslavsky, A.M., Thompson, J.W., & Cleary, P.D. (2002). Using telephone interviews to reduce nonresponse bias to mail surveys of health plan members. Medical care, 190–200.

[48] Elliott, M.N., Zaslavsky, A.M., Goldstein, E., Lehrman, W., Hambarsoomians, K., Beckett, M.K., & Giordano, L. (2009). Effects of survey mode, patient mix, and nonresponse on CAHPS® hospital survey scores. Health services research, 44(2p1), 501–518.

[49] Groves, R.M., & Peytcheva, E. (2008). The impact of nonresponse rates on nonresponse bias: a meta-analysis. Public opinion quarterly, 72(2), 167–189.

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outcome measures. Several commenters, however, suggested that the HOS has drawbacks in design, methodology, administration, and reporting that disproportionately affect SNP populations and fail to accommodate diverse populations and the most vulnerable beneficiaries. Some commenters stated that the longitudinal two year look-back design of the HOS is especially challenging in populations with high rates of degenerative or progressive conditions coupled with pervasive low socioeconomic status and high social risk factors. Commenters suggested that CMS should change sampling methodology to require larger sample sizes or allow plans to request oversampling of typically under-represented groups. In addition, some commenters would like to discontinue the use of proxies for self-report as, the commenters argue, there is strong evidence indicating proxies' responses are not equivalent to beneficiaries' responses.

Response: CMS is supportive of increasing sample sizes and is not opposed to oversampling to ensure a representative sample but to date has received no HOS oversampling requests from any plans. We are currently reexamining the HOS with a focus on diverse, dual-eligible populations and will explore the feasibility of increasing the required sample size. CMS already adjusts the HOS data to control for many beneficiary characteristics not under the control of the plan, including age, gender, race, ethnicity, income, education, marital status, Medicaid status, SSI eligibility, homeowner status, chronic conditions, and baseline health status. CMS does not plan to discontinue the HOS proxy response option. Because the HOS has both mail and telephone components, it is likely that some mail questionnaires would be completed by proxies whether permitted or not. CMS considers it preferable to collect information about whether the beneficiary or a proxy answered the survey than to assume the beneficiary answered the questions. Every attempt is made to obtain a response from the beneficiary before a proxy response is allowed. Also, when a proxy was used at baseline and the beneficiary remains unable to complete the follow up survey, attempts are made to re-contact the same proxy in order to reduce variability in responses. Finally, frailer members, including the most vulnerable beneficiaries, who are unable to complete the survey independently are excluded from the HOS if a proxy response option is not available.

Comment: Several commenters mentioned the two year look-back period is challenging to beneficiaries. A commenter suggested that keeping the identity of sample respondents confidential limits opportunities for improvement activities, and another suggested the resulting data may be too old to be actionable. A few commenters recommended the elimination of HOS measures because the measures are too generic for Star Ratings and the information from the surveys is not actionable.

Response: The Health Outcome Survey (HOS) yields two patient-reported outcome measures of change in global functioning, by using 2-year change in scores on the Physical Component Score (PCS) and the Mental Component Score (MCS), both of which come from the Veterans RAND 12-Item Health Survey (VR–12) portion of the larger survey. These measures are of unique and high value, as demonstrated by their higher weight in calculating the Overall Star Ratings. Critics of the HOS often point out the 3 years between HOS baseline data collection and health plans receiving member-level results, which include the identities of respondents. Contributing to the perceived ''lag'' is the longitudinal component of the HOS; beneficiaries who complete the baseline HOS must be resurveyed two years later to generate data for the HOS ''outcome'' measures. HOS data are hardly ''old.'' In fact, HOS baseline results are distributed nine months after data collection ends, and performance measurement reports and beneficiary-level data are distributed about one year after follow-up data collection ends. Further, CMS contends that a majority of plans improve or maintain the physical and/or mental health of their membership over time. That is, the measure requires time to capture change and in fact does capture positive change or maintenance of global functioning for the majority of plans' members. The Physical Component Score (PCS) and the Mental Component Score (MCS), as derived from the VR–12, have been validated in multiple studies of VA and elderly populations. The appendix of each contract's annual performance measurement report explains how the measures are calculated and adjusted to minimize bias in results. CMS encourages all plans to familiarize themselves with the methods described in the reports and to utilize the background materials available on the HOS website that validate the *Improving or Maintaining Physical Health and Improving or Maintaining Mental Health* measures.

Comment: Commenters also suggested that CMS provide HOS translation and instrument adaptation for languages in addition to English, Spanish, or Chinese.

Response: CMS responds to requests for translations of the survey into other languages from vendors, who in turn reflect the requests of plans. CMS currently provides translations of the HOS in Spanish and Chinese, and a Russian translation will be available in 2019. All translated versions are the product of translation and review by native speakers of these languages and are subject to multiple rounds of qualitative testing with Medicare beneficiaries with characteristics similar to the HOS population. As a result, the adoption of a translated survey tool takes a significant amount of time. By providing survey translations, CMS promotes standardization and assures that questions are presented similarly to beneficiaries across and within languages, which also promotes comparability of the results across vendors and contracts. The survey administration protocol for HOS does not permit ''live,'' ''individual,'' or ''real-time'' translation of the survey by interpreters because such an approach does not promote comparability of data and there is no mechanism for assuring the accuracy and consistency of the translation. However, the HOS protocol does allow for the use of proxy respondents in cases where a beneficiary is unable to complete the survey.

Comment: A commenter reported that they have observed that plans with lower membership generally have higher scores on HOS measures than plans with higher enrollment.

Response: We appreciate the comment. CMS is not aware of any formal studies that have been done to address the hypothesized link between contract size and performance on longitudinal measures.

Patients With Advanced Illness: Comments Received and CMS's Responses

Comment: CMS received several comments concerning the exclusion from measures of patients with advanced illness and in palliative care; those who have refused treatment, assessment, or recommended screenings; and those who are unable to achieve the desired clinical threshold despite having reached the maximum medical therapy and self-care practices available for the condition. Commenters recommended that exclusions or adjustments to measures be made for these patients, or that alternate metrics be developed for these patients, since for many of them comfort or improving

quality of life is a greater part of care than curative treatments. In particular, some commenters identified specific HEDIS and HOS measures which should be excluded or modified for patients with advanced illness: Rheumatoid Arthritis, Statin Use, Improving or Maintaining Physical Health, and Improving or Maintaining Mental Health. Commenters note that there are many challenges treating and screening certain health conditions for patients with advanced illness. A commenter suggested that the seriously ill population be excluded from preventive and HOS measures, as feasible. While commenters agreed that MA plans should advance preventive care and maintain or improve physical health for the majority of their enrollees, they argued that there will always be a subset of enrollees facing serious illness and continued decline. Commenters encouraged CMS to work with measure stewards such as NCQA and explore other options that can exclude the seriously ill population from such measures. Commenters suggested that the exclusion of the seriously ill population from these measures will protect against discriminatory enrollment, and will not unfairly evaluate plans that support this population in making diagnostic and treatment decisions based on the patient's preferences. Finally, some commenters suggested that patients with advanced illness who have refused services and treatments should also be excluded from measure calculations. They stated a patient's goal for comfort rather than further treatment should be primary. A commenter suggested that the under 65 population residing in nursing homes should be excluded from measures for many of the same reasons they wanted those with advanced illness excluded—advanced sickness, nearing the end of life, refusing treatment, and sometimes a patient's choice on comfort not care.

Response: CMS appreciates feedback on the noted measure adjustments and exclusions. For HEDIS 2019, NCQA is examining potential cross-cutting exclusions for those with advanced illness from selected HEDIS measures that may not be clinically appropriate for these individuals. NCQA is considering various advanced illness conditions and service use (for example, indications of frailty, receipt of palliative care or nursing care services) for potential exclusion. We anticipate that NCQA will consider these comments as their advisory panels re-evaluate measures as part of the standard HEDIS process. Proposed changes to implement advanced illness exclusions will be posted for the HEDIS 2019 public comment period in February 2018. CMS currently has no plans to exclude members with serious illness from the HOS.

Additional Comments and Responses

Comment: CMS received one suggestion that CMS create a new, fixed identification code for each measure that would be consistent year-over-year.

Response: The measure codes are not published publicly for beneficiaries. CMS publishes a Star Ratings measure history in the Technical Notes each year that cross references the measure codes. Plans are welcome to use their own internal coding systems.

Comment: A commenter suggested that CMS make PDEs available for members in drug assistance programs.

Response: CMS thanks the commenter for this suggestion. However, this suggestion is outside the scope of the proposed rule. This comment will be shared with others in CMS who will be interested in the suggestion.

Comment: A commenter suggested that CMS exclude beneficiaries' Part D trial medication use from the measures.

Response: CMS believes this request is specific to the adherence measures. The adherence measures require at least two fills on different dates for any drug within the drug class for inclusion in the measure. The two claim requirement essentially excludes many trial prescription periods where the beneficiary failed the initial drug and is switched to a different drug class. Since the adherence measures are for chronic conditions, CMS expects that the beneficiary would continue on one drug within the drug class in the measure. Identifying trial periods using PDEs outside this definition would be difficult to determine and accepting other source data would be prohibited as previously stated.

Summary of Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, CMS is finalizing the Part C and Part D performance measures for the performance periods beginning on or after January 1, 2019 with one modification. In that NCQA is planning to make substantive changes to the Plan All-Cause Readmissions measure that would affect measurement year 2019, CMS is not finalizing this as a measure in the 2021 and 2022 Star Ratings but will move this measure to the display page for two years. CMS's finalization of the proposed measures does include the specifications (metric and performance period), domain assignment, measure category, data source for the measures, and statistical method for assigning Star Ratings (based on §§ 422.166(a) and 423.186(a)) as listed in the proposed table. However, we note that our finalization of the proposed measures does not include the weight of each category as presented in the proposed table. For discussion of CMS's final decision to change the weight of measures in the Patients' Experience and Complaints category and in the Measures Capturing Access category from a weight of 1.5 to a weight of 2, see section 'q. Measure Weights' of this preamble. See also §§ 422.166(e) and 423.186(e) of this regulation for final measure weight assignments. Finally, we note that the summary of comments received and CMS's responses for the Health Plan Quality Improvement and the Drug Plan Quality Improvement measures are presented in the next section ('j. Improvement Measures') of this preamble.

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 proposed 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 would 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. We proposed to codify these criteria at paragraph (f)(1)(i) through (iii) of §§ 422.164 and 423.184. We proposed to annually identify the subset of measures to be included in the improvement measures 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). We again proposed to follow 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 proposed this standard for determining contracts eligible for an improvement measure at paragraph (f)(2).

We proposed at §§ 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 performance over the time period.

As proposed, 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) will 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 will 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) will 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 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.
- The improvement measure scores will be converted to measure-level Star Ratings by determining the cut points using hierarchical clustering algorithms.

We proposed at §§ 422.166(a)(2)(iii) and 422.186(a)(2)(iii) that the improvement measure score cut points would be determined using two separate clustering algorithms. We explained in the preamble that improvement measure scores of zero and above will use the clustering algorithm to determine the cut points for the Star Rating levels of 3 and above. Improvement measure scores below zero will be clustered to determine the cut points for 1 and 2 stars. Although the preamble of the proposed rule indicated this level of detail, our proposed regulation text, at proposed paragraphs (f)(4)(v) and (vi) of §§ 422.164 and 423.184, did not. In paragraph (4)(v), we referred only to ''hierarchical clustering algorithms'' without specifying the detailed treatment for scores of greater than, equal to, or less than zero; in paragraph (4)(vi), we cross-referenced the text proposed at §§ 422.166(a)(2) and 423.186(a)(2), which did include the specific text specifying the detailed treatment for scores of greater than, equal to, or less than zero in connection with the ratings for the improvement measures. While our proposed regulation text was ultimately consistent, it included cross-references not explained in the preamble.

We also proposed that the Part D improvement measure cut points for MA–PDs and PDPs would be determined using separate clustering algorithms. The Part D improvement measure cut points for MA–PDs and PDPs would be reported separately. Finally, we proposed 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 would be categorized as having no significant change. The measure would be included in the count of measures used to determine eligibility for the improvement measure and in the denominator of the improvement measure score. We explained in the proposed rule that 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 proposed in section II.A.12.r another hold harmless provision to be codified at §§ 422.166(g)(1) and 423.186(g)(1).

We requested 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.

We received the following comments on our proposals, and our responses follow:

Comment: The overwhelming majority of commenters supported the concept of the improvement measures.

Response: CMS appreciates the overwhelming support for the underlying rationale of the improvement measures.

Comment: A commenter opposed the codification of the improvement measures and urged CMS to discontinue its use in the Star Ratings program. The commenter believes that the improvement measures are unnecessary, distort the signal provided by the Star Ratings, blur the distinction between high performing contracts and other contracts, and can lead to misclassification.

Response: CMS believes that continuous improvement is an important component of the Star Ratings program and necessary to achieve the ultimate goal of providing the best care to beneficiaries and realizing the most positive outcomes. The improvement measures provide a distinct aspect of performance and as implemented, provide a true reflection of this aspect of performance. CMS is cognizant of the challenges of improvement for contracts that have high performance; thus, CMS implemented the hold harmless provisions. One hold harmless provision addresses high performance at the measure level, and the other addresses high performance at the highest rating level. The hold harmless provisions coupled with the two-step clustering for converting the improvement measure scores to measure-level Star Ratings safeguard against possible misclassification. CMS appreciates the comments and will continue to look at ways to further enhance the Star Ratings.

Comment: Some commenters suggested excluding CAHPS and HOS measures from the improvement measure because they believe the measures are subjective in nature. A commenter further justified the removal of the survey measures citing the challenges in sample selection that have occurred in recent years that have led some plans to appeal their results as not statistically significant.

Response: CMS reviews and selects the improvement measures annually and publishes the list in the draft Call Letter, we proposed to follow the same

process going forward. 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). CAHPS and HOS measures are patient experience not patient satisfaction surveys. The voice of the beneficiary is a critical component of the information needed for the Star Ratings program to realize its goals. If an issue arises with any aspect of the standard protocol regarding sampling in the Star Ratings program, CMS carefully reviews any impact of the deviation and assesses the risk of unintended consequences on the integrity of the ratings. Further, CMS develops and tests analytical adjustments to mitigate and address all such concerns. Although there did exist minor deviations in the protocol for sampling in the Star Ratings in the past, CMS is confident that the ratings were not affected and the measures possessed all attributes necessary to preserve and maintain the high standards of the Star Ratings program.

Comment: Many commenters supported an expansion of the measure-level hold harmless provision for a contract that receives 4 or more stars in each of the two-years for a measure. Some commenters noted the lack of alignment between the highly-rated contracts' hold harmless provision for the application of the improvement measure(s) for the identification of a contract's highest rating at § 422.166(g)(1) and § 423.186(g)(1) and the measure-level hold harmless provision at (§ 422.164(f)(3) and § 423.184(f)(3).

Response: CMS appreciates the thoughtful consideration of the hold harmless provisions for the improvement measure methodology. As noted, the hold harmless provision at the measure level applies a different threshold than the hold harmless provision for a highly-rated contract's highest rating. A measure, in general, assesses a single, distinct aspect of care while an overall or summary rating provides a global indicator of quality of care and performance.

At the basic building block of the rating system, the measure, a measure-level rating of 4 stars allows opportunity for improvement with a focus on a singular concept. A measure-level Star Rating of 5 does not allow the same degree of possible improvement. The measure-level hold harmless provision was designed to protect a contract from being adversely impacted by the improvement measure(s) without discouraging continuous improvement. CMS believes that changing the hold harmless to measures that receive at least 4 stars each year would serve to hamper advances and innovation in the care of all populations; in addition, it could serve to discourage continuous improvement by suggesting that 4 stars—rather than 5—is the highest achievement on the measure.

CMS is cognizant of the additional challenges of improvement for highly-rated contracts; improvement is more difficult for a contract with high performance as compared to a lower-rated contract that has more opportunity for improvement. The hold harmless provision for a contract's highest rating provides the safeguard for contracts that receive an overall or summary rating of 4 stars or more without the use of the improvement measures and with all applicable adjustments (CAI and the reward factor). A highly-rated contract will have their final highest rating as the higher of either the rating calculated including or excluding the improvement measures.

CMS believes there should be a differentiation in the hold harmless provisions to appropriately address the amount of information each provides, to incentivize contracts to continuously improve, and to provide adequate safeguards for high achieving contracts.

Comment: A few commenters expressed explicit support for the current methodology for determining the improvement rating including the use of separate clustering algorithms to convert the improvement measure scores to a measure-level Star Rating and the separate clustering algorithms for the Part D summary rating for PDPs and MA–PDs.

Response: CMS appreciates these comments.

Comment: A commenter suggested that CMS develop a measure to assess a decline in performance.

Response: The current improvement measures capture both improvement and decline. The calculation for the improvement measure score and the associated methodology to convert the improvement measures scores to measure-level Star Ratings are designed such that a contract that has below average improvement, indicated by an improvement measure score less than zero, will receive an improvement measure-level Star Rating less than 3 stars.

Comment: A commenter expressed concern with the improvement methodology and believes it creates a double-jeopardy situation because it includes both significance testing and national performance.

Response: The Star Ratings are designed to incentivize contracts to provide the best quality and care to beneficiaries. The methodology employed to determine the improvement measure-level Star Ratings is designed to align with the underlying principles of the Star Ratings methodology. The use of statistical significance allows the changes of each individual measure used for the determination of the improvement measure score to be assessed for meaningful differences. The use of the clustering algorithm to determine the cut points and ultimately, the assignment of the measure-level Star Ratings, allows a contract's performance to be assessed relative to all contracts that are required to report. The determination of the measure-level Star Ratings is done in a manner to minimize misclassification. The clustering for the improvement measures is done twice to ensure that a contract with average or above average performance, demonstrated by an improvement measure score of zero or above, will receive a measure-level Star Ratings of at least 3 stars. A contract whose performance declined, demonstrated by an improvement measure score of less than zero, will receive a measure-level Star Rating less than 3 stars. Further, CMS designed the hold harmless provisions as a safeguard for contracts maintaining high performance at the measure-level or at the contract's highest Star Rating to ensure that the improvement measure-level Star Ratings provide a true signal.

Comment: A commenter suggested reducing the number of improvement measures with a focus on newer measures.

Response: CMS appreciates this comment. 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). CMS has focused on all measures that meet these criteria to create incentives to improve care across a broad spectrum of measures. Limiting the set of measures used to determine the improvement measure to strictly new measures has the potential of limiting

the focus of improvement activities by a contract. CMS is committed to incentivizing contracts to provide the best quality and care to beneficiaries. Striving for continuous improvement across all aspects of care would be compromised if the focus of improvement was restricted to newer measures only.

Comment: A commenter suggested that CMS ensure that MA contracts that are subject to the use of the improvement measures realize a benefit from their inclusion.

Response: CMS has developed a hold harmless provision for a highly-rated contract's highest rating. All other contracts have the improvement measure(s) included in their rating. CMS believes the information provided by the ratings must be a true reflection of the quality and experience of beneficiaries enrolled in the contract. Ensuring that MA contracts that are subject to the use of the improvement measures realize a benefit from their inclusion has the potential of distorting the signal and does not align with the Star Ratings program's guiding principles.

Comment: A commenter suggested removing the improvement measure in the future to streamline and simplify the Star Ratings program.

Response: CMS disagrees with the commenter. CMS recognizes the importance of acknowledging quality improvement in health and drug plans. The improvement measures provide an additional dimension to the Star Ratings program. At this time, there are no plans to remove the measures from the Star Ratings program as we are committed to improving the quality of care and experiences for Medicare beneficiaries.

Comment: A commenter questioned whether the measures *Getting Needed Care* and *Customer Service* are included in the improvement measure set.

Response: Annually, CMS reviews the Star Ratings measure set to identify the improvement measures. Both *Getting Needed Care* and *Customer Service* meet the inclusion criteria for an improvement measure and will be designated as improvements measures in the 2021 Star Ratings program. A specification change prompted a temporary exclusion of these measures from the improvement measure in the 2018 Star Ratings.

Comment: A commenter believes that there exists a potential disadvantage for SNPs and Medicare/Medicaid plans due to their propensity of having lower enrollments which ultimately results in fewer of these types of plans from meeting the requirements for the calculation of an improvement measure rating. The issue, the commenter believes, is attenuated by the sampling requirements for a subset of the population, like the HOS measures.

Response: CMS appreciates these comments. The contract must have a minimum number of numeric scores and measures of a certain type to reliably determine an improvement measure score. To date, we have not seen an issue with smaller contracts obtaining an improvement measure score.

Comment: Some commenters suggested increased transparency in the determination of the improvement measure because of the complexity of its determination. Other commenters expressed the concern regarding their ability to predict the improvement measure-level Star Ratings. Further, commenters requested clearer explanations of the methodology.

Response: The Star Ratings program is designed to incentivize contracts to provide the best care to their beneficiaries. The improvement measure employs two consecutive years of data. To realize the goal of the best care, contracts must continually seek ways to improve the care they provide. The improvement measures provides a quantification of the improvement made in the two-year period.

CMS will apply the methodology explained in the preamble and adopted in the regulations at §§ 422.164(f) and 423.184(f). The improvement methodology is detailed in the annual Technical Notes available at *http://go.cms.gov/partcanddstarratings.* CMS is always willing to answer questions related to the calculation of the Star Ratings including the improvement measure methodology. Further, upon request, CMS will provide a detailed calculation worksheet for a contract's improvement measures. Contracts should contact the Part C & D Star Ratings Team at *PartCandDStarRatings@cms.hhs.gov* for answers to any questions related to the MA Star Ratings.

Comment: A commenter urged CMS to review the rules guiding the selection of the improvement measures to ensure that each measure is under the control of the contract and that the measure is not topped out.

Response: CMS supports the request for reviewing the measures designated for use in the improvement measures. CMS annually reviews the measures used in the Star Ratings and releases the measures that will be used to determine the improvement measures in the draft Call Letter. Although some measures may show uniform high performance across contracts suggesting that they are topped out, CMS needs to balance these concerns with 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 which address the specific clinical concerns. MAOs and Part D sponsors have control over all measures included in the Star Ratings' program; thus, the measures selected for the improvement measure(s) are all under the control of the contract.

Comment: A commenter suggested several adjustments to address their belief that the improvements measure is based on the following perceived flawed assumptions: all plans have the same opportunity to improve on both mature and new measures year after year; high- and low-performing plans have equal opportunity for improvement; and the hold harmless provision protects plans. The suggested adjustments included: The use of a log scale for evaluating performance instead of a linear scale; weighting improvement achieved relative to current performance; and adjusting the threshold for significant improvement. (The commenter suggested changing the level of significance to 0.025 as opposed to 0.05, or in other words employing the threshold of 1.645 instead of 1.96 in the testing for significance.)

Response: CMS appreciates the comments and the suggested enhancements for the improvement measure methodology. CMS remains cognizant of the additional challenges for improvement for contracts with high performance on their highest rating and at the individual measure level. CMS does not believe the underlying assumptions for the methodology for the determination of the improvement measure-level Star Ratings is flawed. There is less room for improvement for contracts that are highly-rated, thus there is a hold harmless provision for a contract's highest rating. In addition, there is less room for improvement for a measure score if a contract is performing at the highest rating, 5 stars, for each of the two consecutive years examined for the improvement score. CMS implemented a hold harmless provision at the measure level to ensure a contract receiving 5 stars for each year of the two years examined would not be subject to the possible categorization of a significant decline for the measure.

At this time, CMS employs a level of significance of 0.05 for all significance testing across the aspects of the methodology. The use of a 0.05 level of significance is typical for statistical analyses. CMS will consider the

suggestions as we enhance the Star Ratings methodology to best address the concerns of our stakeholders while maintaining the integrity of the Star Ratings system.

Comment: Some commenters suggested that the improvement measures should consider measure-level Star Ratings and the measure score in the hold harmless provision. Some commenters provided examples of an increase in a measure-level Star Rating for a specific measure used in the improvement measure that was accompanied by a significant decrease in the measure score. Commenters believe that such scenarios should be part of the hold harmless provision or considered counted as an not applicable (NA) measure, those not factoring in the determination of the improvement measure score.

Response: CMS will consider a potential enhancement to the hold harmless provision that considers both the measure-level Star Rating and the measure score. Any changes would be proposed through future rulemaking.

Comment: Some commenters suggested that a measure that receives 5 stars for each of the two years should be a positive influence on the improvement measure score and counted as a significant improvement.

Response: CMS appreciates this feedback. A measure used for the determination of the improvement measure score that receives a measure-level Star Rating of 5 stars in each of the two years examined would be subject to the 5-star measure hold harmless rule and would benefit from the 5-star measure-level Star Rating in the calculation of the summary or overall rating. In addition, contracts do have the opportunity to earn a reward factor for high and stable relative performance across measures pursuant to §§ 422.166(f)(1) and 423.186(f)(1) discussed in section II.A.11.s of this final rule.

Comment: Some commenters recommended a predictable gold standard be established for determining meaningful improvement as a set percentage reduction of a sub-optimal measure rate. The commenters believe this approach would result in a more tailored approach of meaningful improvement per contract and recognize the natural concept of diminishing returns. For example, if a 5 percent reduction in the sub-optimal rate was classified as meaningful, an increase of 1 percent for a contract whose rate was 80 percent in year 1 would be a meaningful improvement (1/(100 − 80) or 5 percent) while a contract with a rate of 60 percent in year 1 would need an increase in their rate of 2 percent (an increase to 62 percent) for a 5 percent reduction which would be classified as a meaningful reduction in their suboptimal rate (2/(100 − 60) or 5 percent).

Response: We will consider these comments for the future as we make enhancements to this measure.

Comment: A few commenters recommended that CMS either adjust its methodology and assign ''not applicable'' when determining ''Improvement, Decline, or No Change'' for measures that increased in measure-level Star Ratings in the year two of the comparison or add these measures to the ''held harmless'' provision for measures. The commenters noted that the current methodology for a measure is based on measure scores as opposed to measure-level Star Ratings.

Response: CMS appreciates this feedback. CMS will further consider the measure-level hold harmless provisions to examine the influence of the measure scores and measure-level Star Ratings on the improvement measures.

Comment: Some commenters supported a revision to the hold harmless measure provision for an improvement measure when a contract received 5-star ratings for each of the 2 years examined. Although the commenters believe that the current measure-level hold harmless does align with its intent to prevent an adverse impact on a contract's rating, a few commenters suggested modifying the provision to allow a measure-level Star Rating of 5 stars for each of the 2 years examined to be counted as a significant improvement in the measure's associated net improvement category. Other commenters suggested a hold harmless provision if mathematically it is not possible to have a 5-star measure score difference that would be classified as significant improvement. A commenter suggested another version of a measure-level hold harmless in which an adjustment factor would be employed for contracts that had incremental improvement at the measure-level score but who could not attain ''Significant Improvement'' due to performance requirements above 100 percent (mathematically) and when the current measure-level hold harmless provision would not be applied. Further, the commenter believes the adjustment factor would acknowledge the increased difficulty in moving from 2 to 3 versus 4 to 5.

Response: CMS appreciates this feedback. CMS will further consider these suggestions for a future enhancement to the hold harmless provision at the measure-level.

Comment: A commenter suggested using a logarithmic scale instead of a linear scale in the significance testing for classifying significant changes to the measure score to address the law of diminishing returns.

Response: CMS appreciates the careful consideration of the improvement measure methodology. CMS is cognizant of the additional challenges for both highly-rated contracts and contracts that receive a 5 star measure-level rating for each of the two years examined used determining the improvement measure. Improvement is easier at the summary levels for a contract that is not highly-rated. Likewise, improvement for an individual measure is easier when there is more room for improvement.

The current hold harmless provisions were designed to address the concern related to the concept of diminishing returns. The improvement measure safeguards for contracts at the highest-rating level by contract-type and at the measure-level determination of the improvement scores allow a transparent method of addressing the challenges of improvement for high performing contracts.

The suggested use of a logarithmic scale instead of a linear scale will be considered during our ongoing review of the methodology. Any enhancements to the methodology must be balanced by the approachability of the methodology to our stakeholders including the beneficiaries.

Comment: A commenter suggested creating an improvement score for measures that could potentially be part of the improvement measures, but only have one year's worth of data. The commenter noted that improvement activities begin during the first year of a measure being included in the Star Ratings program. The focus on a first year measure coupled with the significant impact of the improvement measure on a contract's rating according to the commenter justified first year measures being included in the improvement measure.

Response: CMS has designed the improvement measures to assess the level of improvement from one year to the next.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized above, we are finalizing the improvement measure provisions as proposed in §§ 422.164(f) and 423.184(f) with minor modifications. First, in the regulation text at §§ 422.164(f)(4)(vi) and 423.184(f)(4)(vi), we have corrected the

cross reference to §§ 422.166(a)(2)(i) through (iii) and 422.186(a)(2)(i) through (iii) for the clustering of the improvement measure to clarify the methodology for converting the improvement measure scores to measure-level Star Ratings. Second, we are also finalizing § 422.164(f)(4)(vi) without the sentence that provided for separate measure thresholds for the Part D improvement score for MA–PDs and PDPs in favor of revising the first sentence as follows: ''The Part D improvement measure cut points for MA–PDs will be determined using separate clustering algorithms in accordance with §§ 422.166(a)(2)(i) through (iii) and 423.186(a)(2)(i) through (iii) of this chapter.''

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 proposed 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/PartCDDataValidation.html* and *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html.*

We proposed, in paragraphs (g)(1)(i) through (iii), rules for specific circumstances where we believe a specific response is appropriate. First, we proposed 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 will also apply when a plan chooses not to submit and has an audit designation of ''non-report'' or NR. Second, we proposed 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. We explained in the preamble that as the sponsoring organization is responsible for these data and submits them to CMS, a negative inference is appropriate, to conclude that performance is likely poor. Third, we proposed a new specific rule to implement 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 will 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. As stated in the proposed rule, we believe that removal of the measure from the ratings calculation will 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 proposed to use statistical criteria to determine if and how a contract's appeals measure-level Star Ratings would be reduced for missing IRE data. We explained that the proposed 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 past stakeholder concerns about CMS's 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.[55] The first submission for the TMP was for the measurement year 2016 related to Part C organization determinations and reconsiderations and Part D coverage determinations and redeterminations. The timeframe for the submitted data was dependent on the enrollment of the contract, with smaller

[55] 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.*

contracts submitting data from a 3-month period, medium-sized contracts submitting data from a two-month period, and larger contracts submitting data from a one-month period.[56]

We proposed to use TMP data and other data sources whenever possible, such as information from audits, to determine whether the data at the Independent Review Entity (IRE) are complete and to evaluate the level of missing data. 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.

We proposed 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 proposed 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 proposed methodology employs 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 will 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 solicited comment on this proposal and its scope; we were looking in particular for comments related to how to use the process in this proposal to account for data integrity issues discovered through means other than the TMP and audits of sponsoring organizations.

CMS's 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 is 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 receives a measure-level Star Rating of 1 star for the appeals measure.

Under the proposed methodology, 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 is used to identify contracts that may be subject to an appeals-related IRE data completeness reduction. We proposed a minimum error rate to establish a threshold for the identification of contracts that may be subject to a reduction. The establishment of the threshold focuses 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 3-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 over a 3-month period 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 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.

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

The calculated error rate formula (Equation 2) for the Part D measures is determined by the quotient of the number of untimely cases not auto-forwarded to the IRE and the total number of untimely cases.

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

Under the proposed methodology, 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 TMP time period. Contracts with mean annual enrollments greater than 250,000 that submitted data from a 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.

[56] 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.

We proposed that contract ratings 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 is calculated using a Score Interval (Wilson Score Interval) at a confidence level of 95 percent.

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

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

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 is 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 is 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 $\hat{p}$ and the total number of cases represented as n, Equation 3 can be streamlined as Equation 4:

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

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

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

For each contract subject to a possible reduction, the lower bound of the interval estimate of the error rate will be compared to each of the thresholds in Table 4. If the contract's calculated lower bound is higher than the threshold, the contract will 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 4, and were proposed in narrative form at paragraph (g)(1)(iii)(D) of both regulations.

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

We noted in the proposed rule that a contract's lower bound could be statistically significantly greater than more than one threshold. We proposed that the reduction 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. Therefore, in this example, the contract will be subject to the reduction that corresponds to the 60 percent threshold, which is three stars.

TABLE 4—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 proposed 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 noted in the proposed rule 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 proposed 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 proposed an example in paragraph (g)(2) of another circumstance where CMS will be authorized to reduce ratings based on a determination that performance data are incomplete, inaccurate, or biased: the failure of a contract to adhere to the HEDIS, CAHPS, or HOS reporting requirements. We also proposed this other situation would result in a reduction of the measure rating to 1 star.

We noted in the proposed rule that we had taken several steps in past years to protect the integrity of the data we use to calculate Star Ratings. We welcomed 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 and 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.

We received the following comments on our proposals and our responses follow:

Comment: There was overwhelming support for the use of scaled reductions for the completeness of the IRE data for the appeals measures. Some commenters explicitly stated that the use of scaled reductions avoids the one-size-fits-all approach.

Response: CMS appreciates the overwhelming support for the proposed scaled reduction methodology.

Comment: Some commenters suggested other potential criteria for consideration for the scaled reductions methodology. A commenter suggested CMS consider the volume of appeals instead of plan size for determining the reductions. Other commenters suggested including enrollment as part of the rules for the allowable excluded number of cases, using the timely percentages as basis for scaled reduction, or using the errors relative to enrollment level as the thresholds.

Response: CMS appreciates the careful consideration of alternative options for the scaled reduction methodology. A thorough examination and identification of potential unintended consequences must be done for any possible modification to the Star Ratings methodology. Additional analysis will be done to further explore relations among enrollment, appeals volume, untimely, and timely percentages. CMS believes the proposed methodology provides the best foundation for scaled reductions and will consider these comments as we contemplate future enhancements.

Comment: Some commenters expressed support for the data integrity policies for non-appeals measures. A commenter supported the proposal to reduce a contract's measure-level Star Rating to 1-star for measures related to Part C and D reporting requirements measures when the contract does not meet CMS expectations for data validation. Another commenter supported the reduction for HEDIS measures that received an audit designation of ''Biased Rate.'' Another commenter supported the high standard of 95 percent on validation audits, but believed it is important to distinguish between generally well-functioning plans that may have an occasional error versus plans that have significant, systematic errors.

Response: CMS appreciates the support of the data integrity policies. The data integrity policies align with our commitment to data quality and preserves the integrity of the Star Ratings. CMS believes the data integrity policies are designed to distinguish between occasional errors and systematic issues. For example, both the validation audits and scaled reduction methodology allow for the occasional error and target only those contracts that exceed a specified error rate.

Comment: A commenter requested clarification on how CMS plans to use the Data Validation Audit.

Response: The Data Validation Audit is one method to ensure the data used for Star Ratings are accurate. The two Star Rating measures (SNP Care Management (Part C) and Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) (Part D)) are based on Part C and D Reporting Requirements data and calculated using data reported by plan sponsors and validated via an independent data validation using CMS standards. Per the Star Ratings Technical Notes, contracts that did not score at least 95 percent on data validation for these reporting sections and/or were not compliant with data validation standards/sub-standards for at least one of the data elements used to calculate the measures are not rated in this measure, and the contract's measure score is reduced to 1 star. CMS has relied on the Data Validation Audit to confirm the integrity of these plan-reported data since these measures were first added to the Star Ratings program. In the 2019 draft Call Letter CMS proposed to define a contract as being non-compliant if it either receives a ''No'' or a 1, 2, or 3 on the 5-point Likert scale in the specific data element's data validation in order to align with changes in the Data Validation Audit.

If further clarification is needed, please feel free to contact the Part C&D Data Quality Team at: *PARTCDQA@cms.hhs.gov*

Comment: Some commenter expressed concern or opposed using audit findings as a data source to validate the appeals measures.

Response: The Timeliness Monitoring Project (TMP) data will be the primary data used to validate the completeness for the Part C and D appeals measures. However, CMS may also use audit data to validate the appeals measures if additional information is uncovered during the audit process that demonstrates that the data for the appeals measures are not complete.

Comment: A commenter requested clarification regarding the use of TMP data that are submitted at the parent-organization level. Specifically, the commenter was unsure if the reporting level would be at contract level or all contracts under the parent organization would receive the same scaled reduction.

Response: Although the data for the TMP are submitted by the parent organization, the observations are recorded at the contract level. The TMP data for each parent organization are disaggregated to contract-level data. The scaled reduction would be separately and independently determined for each contract under a parent organization. If a contract has no untimely cases or no cases that should have been forwarded to the IRE in the TMP timeframe, the contract would not be subject to a possible IRE data completeness reduction for the associated appeals measure. This analysis would be done on a contract-by-contract basis using only data for the applicable contract.

Comment: A commenter expressed concern about the lack of a data-driven methodology used to determine data integrity issues. Further the commenter asked for a data-driven, streamlined approach that does not use audit data.

Response: The Star Ratings program and its associated methodology generally employ a comprehensive, scientific, data-driven approach. CMS has moved away from relying on audit data for determining the completeness of the appeals measures with the introduction of the TMP data. However, we are not adopting a rule to prohibit use of audit data where such data are reliable and relevant to understanding and determining whether the data used for a particular measure (even appeals measures) are erroneous, incomplete or biased.

Comment: Some commenters requested additional information on the timeline for contracts to submit

information on scaled reductions along with simulations to allow contracts to better understand the impact of the scaled reduction methodology. Another commenter requested that CMS share all simulated data related to scaled reductions.

Response: CMS will issue a memo each year outlining the timeframe associated with the TMP data collection. The TMP data used for the Star Ratings program will align with the measurement period of the Star Ratings year.

The first submission for the TMP focused on the 2016 measurement year for Part C organization determinations and reconsiderations and Part D coverage determinations and redeterminations. CMS gained valuable insight about the audit universes, and the completeness of the IRE data.

In December 2017, CMS provided each contract with the results of its TMP analysis. The Part C and D IRE data completeness percentage provided is equivalent to the calculated error rate discussed in the scaled reduction methodology section outlined in the NPRM. A contract can simulate the scaled reduction for the 2018 Star Ratings appeals measures by following the methodology for scaled reductions. First, a contract can use the data provided to determine whether it would be subject to a possible reduction due to lack of IRE data completeness based on the calculated error rate and projected number of cases not forwarded to the IRE. (To determine the projected number of cases the factor based on the enrollment needs to be multiplied by the number of cases detailed on the December report.) Next, if the contract is subject to a possible reduction, the lower bound of the Wilson Score interval is calculated using the formulas in the NPRM along with the calculated error rate. The lower bound can then be compared to the thresholds in Table 3 to identify the reduction to the associated appeals measure-level Star Ratings.

Comment: A commenter did not believe the exclusion of a measure affected by data integrity issues is sufficient to prevent gamesmanship. Instead, the commenter suggested a hybrid approach that the commenter believes is less punitive. This method would exclude measures that received 4 or 5 stars and would levy an automatic reduction to 1 star for data integrity issues for measures that received 3 or less stars.

Response: The accuracy of the measure data is key to the Star Ratings methodology. Excluding a measure from the Star Ratings due to data integrity issues instead of using a measure-level Star Rating of 1 distorts the signal of the true quality and performance of a contract and does not align with the intent of the data integrity policies. We therefore disagree with the commenter.

Comment: Some commenters supported expanding polices to reduce Star Ratings when the data are not reported or do not meet validation requirements. A few commenters suggested the use of scaled reductions for all measures in the Star Ratings program including HEDIS measures. Another commenter supported expanding the scaled reductions to other measures with special consideration of organizations demonstrating commitment to compliance.

Response: CMS appreciates the support of the data integrity policy and will consider expanding the policies to be as comprehensive as feasible. Currently, for most measures, including HEDIS measures, we do not have enough information to calculate scaled reductions.

Comment: Some commenters expressed concern regarding the possible use of audit data. The commenters stated that using audit data results in artificially inflated ratings for contracts that are not audited compared to contracts that are audited. A commenter stated the goals and analytic approaches associated with an audit do not align with those of the Star Ratings program. In addition, a commenter wanted any findings from enforcement activities excluded from the Star Ratings since not all contracts are audited each year. A commenter requested information about how CMS would ensure equity between audited and non-audited contracts. In addition, another commenter asked for clarification of the 'other data' that may be used for assessing data completeness. A commenter encouraged CMS immediately remove the impact of audit findings on the Star Ratings for the determination of 2019 QBPs.

Response: CMS appreciates the comments. All contracts are required to submit TMP data on an annual basis. The TMP data are typically the same data used for CMS program audits but are collected from all MA and Part D sponsoring organizations which shall ensure equity among all contracts. As part of the 2019 draft Call Letter, CMS proposed to remove the Beneficiary Access and Performance Problems (BAPP) measure from the Star Ratings. This proposal was finalized in the 2019 Final Call Letter to remove the BAPP measure from the Star Ratings program effective for the 2019 Star Ratings.

Comment: A commenter suggested a hold harmless provision when there are data issues. The commenter provided the example of the measure of providing translation services that was removed from the Star Ratings in the past for contracts that have worked hard to perform well on a measure.

Response: CMS removes measures from the Star Ratings if a systematic issues exists with data quality across all (or a majority of) contracts as described in §§ 422.164(b) and 423.184(b). It is the policy of CMS not to assign measure-level Star Ratings if data issues are present across the board that suggest that the measure results are not reliable. When systemic data issues are present for a measure, it is difficult to accurately determine performance across contracts. The policy proposed for adding, updating and removing measures is presented in §§ 422.164 and §§ 423.184. The removal of measures from the Star Ratings is detailed in in §§ 422.164(b) and §§ 423.184(b).

Comment: A few commenters expressed concern that the CMS approach for data integrity issues for HEDIS measures is duplicative of the HEDIS audit process.

Response: The data integrity policy for HEDIS measures uses the information provided by the NCQA compliance auditor, and thus aligns with their findings.

Comment: A commenter stated that the reductions in the Star Ratings for integrity blurs the distinction between quality measurement and compliance and audit activities. Further, the commenter stated that the focus of the ratings should be clinical quality and beneficiary satisfaction. Another commenter expressed concern of the continuation of the downgrade to 1-star for the HEDIS and measures related to the Part C&D reporting requirements.

Response: CMS considers data quality as paramount to accurate and reliable measurement. As such, CMS uses multiple sources of information to assess the multiple facets of data quality. The Star Ratings were designed to provide a true signal of the quality and performance of a contract. Star Ratings that are generated from data that lack quality or, in other words, flawed data—whether because of bias, incompleteness, or inaccuracy—impact the integrity of the ratings. Star Ratings that do not provide a true signal of the quality and performance of the Medicare health and drugs plans offered under a contract threaten the core of the Star Ratings program. CMS is committed to maintaining the integrity of the ratings. By taking steps to downgrade measure ratings when underlying data

quality issues exists, CMS is preserving the integrity of the Star Ratings and incentivizing sponsoring organizations to take steps to improve data integrity and eliminate problems.

Comment: Some commenters suggested modifications to other facets of the data integrity policy. A commenter suggested that if an identified data issue did not harm beneficiaries, plans should be able to resubmit the data with limited penalty. Other commenters stated that CMS should provide contracts the opportunity to correct data errors without penalties. A commenter suggested that contracts should be offered a preliminary review of their data midway through the reporting year to allow identification of any issues and the chance to correct them before the end of the year. Another commenter suggested that CMS take into account the necessary distinction between a deliberate submission of inaccurate data and the unintentional occurrence of minor errors and mistakes when addressing data integrity. In addition, the commenter outlined an approach to penalize plans based on beneficiary impact, nature of issue, health plan activity, history of data integrity issues, and timing that would be reviewed by a third party.

Response: CMS appreciates the careful consideration and suggestions for potential revisions to the data integrity policy. The data underlying a measure score and rating must be complete, accurate, and unbiased to allow the Star Ratings to be a true reflection of a contract's quality and performance. CMS's longstanding policy has been to reduce a contract's measure rating if a contract's measure data are incomplete, inaccurate, or biased but, as the proposal of scaled reductions indicates, CMS will consider and implement alternatives and improvements. We must, however, remain mindful of the timing and resource considerations at play with the annual release of Star Ratings.

Data validation is a shared responsibility among CMS, CMS data providers, contractors, and Part C and D sponsors. CMS encourages organizations to routinely monitor their data and immediately alert CMS if errors or anomalies are identified so CMS can address these errors. Contracts are afforded opportunities to review their data before the Star Ratings are calculated, during data collection and during the Plan Preview periods for the Star Ratings. CMS will continue to review the policies and solicit feedback from stakeholders.

Comment: A few commenters expressed concern about the perceived punitive nature of the data integrity policies. A commenter suggested that contracts should be rewarded if they have near-perfect performance. For example, the commenter suggested that contracts that receive a 5-Star Rating on the Part D Appeals Timeliness measure and do not qualify for the Part D Appeals Upheld measure because they received less than 10 appeals, should automatically receive a 5-Star Rating on the Part D Appeals Upheld measure.

Response: CMS believes the integrity of the data is fundamental to the Star Ratings program. CMS maintains high standards for data quality to ensure that the Star Ratings are a true reflection of the quality, performance and experience of the beneficiaries enrolled in MA and Part D contracts. CMS employs a data-driven approach for determining the measure-level Star Ratings. The data integrity policies serve to preserve the integrity of the Star Ratings and encourage contracts and sponsors to strive for the highest data quality; they are not designed or intended to be punitive. The measure level reductions for data integrity concerns are not made to punish a sponsor but rather to reflect that the data available are incomplete and inaccurate.

In the commenter's example, the contract did not meet the minimum number of cases reviewed by the IRE to be measured in the Appeals Upheld measure. This specification is necessary to ensure an adequate sample of cases for which to evaluate the contract's original decisions. The contract's TMP results regarding the completeness of the IRE data has no relevance on whether CMS can evaluate the contract in this measure. It remains that CMS cannot reliably calculate a percent of cases upheld by the IRE if there are too few IRE cases reviewed for the contract.

Comment: A commenter suggested the removal of the Part C and D appeals measures until CMS can adequately address the underlying data integrity issues that are associated with the IRE and contracts.

Response: CMS is firmly committed to the integrity of the Star Ratings systems. CMS believes that the data integrity policy and the rating reductions are necessary to avoid falsely assigning a high star to a contract, especially when deficiencies have been identified that show CMS cannot objectively evaluate a sponsor's performance in an area. To address challenges in validating the appeals measures, CMS implemented the collection of the TMP data. Concerns and reviews to assure data integrity will remain for as long as necessary to collect data in order to provide reliable Star Ratings and comparable information about plan quality and performance. CMS believes that our rule, as proposed and finalized, strikes the right balance in support of the underlying policies.

For the reasons set forth in the proposed rule and our responses to the related comments summarized above, we are finalizing data integrity provisions as proposed at §§ 422.164(g) and 423.184(g) without substantive modification. We are finalizing the following minor editorial changes to the regulation text: (1) In § 422.164(g)(1)(ii) to add a reference to ''substandards'' as well as standards that govern data validation; (2) in § 422.164(g)(1)(iii) to improve the flow of the last sentence in the introductory paragraph and to correct the verb tenses in paragraphs (A), (C) and (K); (3) in § 423.184(g)(1)(i) to identify the data that are subject to data validation; (4) in § 423.184(g)(1)(ii) to add the sentence proposed as paragraph (ii)(A) to the introductory paragraph and redesignate the remaining paragraphs; and (5) in redesignated § 423.184(g)(1)(ii)(A), (C), and (F) to correct the verb tenses and capitalization of ''Star Ratings''. Finally, in § 423.184(g)(1)(ii) A–L we aligned the regulatory text with § 422.164(g)(1)(ii) A–N where appropriate. § 422.164(g)(1)(ii) A–N has more provisions to account for the differences in calculations between Part C and D appeals measures.

l. Measure-Level Star Ratings

We proposed 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 proposed to continue to determine cut points by applying either clustering or a relative distribution and significance testing methodology; we proposed to codify this policy in paragraphs (a)(1) of each section. We proposed in paragraphs (a)(2) and (a)(3) of each section that for non-CAHPS measures (including the improvement measures, which were specifically addressed in paragraphs (a)(2)(iii), we would use a clustering methodology and that for CAHPS measures, we would use relative distribution and significance testing. Measure scores will be converted to a 5-

star scale ranging from 1 to 5, with whole star increments. A rating of 5 stars will indicate the highest Star Rating possible, while a rating of 1 star will be the lowest rating on the scale. We proposed to use the two methodologies described as follows to convert measure scores to measure-level Star Ratings.

We proposed to use the clustering method for 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 proposed 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 stated that we would continue use of this software, but that improvements in statistical analysis would not result in rulemaking or changes in these eventual rules providing for the use of a clustering methodology. We stated our belief 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. We proposed that this final range of values and labels would be used to determine the set of cut points for the Star Ratings as follows: The measure score that corresponds to the lower bound for the measure-level ratings of 2 through 5 will 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 will be the same except that the upper bound within each cluster label will determine the set of cut points; the measure score that corresponds to the cut point for the ratings of 2 through 5 will be included in the star-specific rating category; and in cases where multiple clusters have the same measure score value range, those clusters will be combined, leading to fewer than 5 clusters. Under our proposal to use clustering to set cut points, we stated that we would require the same number of observations (contracts) within each rating and instead will use a data-driven approach.

As proposed in paragraphs (a)(2)(iii) of each section the improvement measures for Part C and Part D would be determined using the hierarchical clustering algorithm twice, once for raw scores of zero or greater and again for raw scores below for the identification of the cut points that will allow the conversion of the improvement measure scores to the star scale. The Part D improvement measure score clustering for MA–PDs and PDPs will be reported separately. Improvement scores of zero or greater would be assigned at least 3 stars for the improvement Star Rating, while improvement scores of less than zero would be assigned either 1 or 2 stars. For contracts with improvement scores greater than or equal to zero, the clustering process will 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 will result in two clusters with measure-level Star Ratings of 1 or 2..

We proposed in paragraphs (a)(3) of each section to use another method using 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 will 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 are rounded to the nearest integer on the 0–100 reporting scale, and each base group includes those contracts whose rounded mean score is at or above the lower limit and below the upper limit. Then, the number of stars assigned is 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 C4, which we proposed to codify in narrative form at §§ 422.166(a)(3) and 423.186(a)(3), details the CAHPS star assignment rules for each rating. We proposed that all statistical tests, including comparisons involving standard error, would be computed using unrounded scores.

We proposed 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 4, at item (c), 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 standard error is 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 will 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 5—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.
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 requested comments on our proposed methods to determine cut points.

In the proposed rule, we also acknowledged our past practice of publishing pre-determined 4-star thresholds for certain measures. We asked commenters who supported the return of the pre-determined 4-star thresholds to provide suggestions on how to minimize the risk of ''misclassifying'' a contract's performance. For example, misclassification occurs when scoring a ''true'' 4-star contract as a 3-star contract, or vice versa. The potential for misclassification is increased if the cut points result in the creation of ''cliffs'' between adjacent categories within the Star Ratings that could lead to the potential of different ratings between contracts with nearly identical Star Ratings that lie on the opposite sides of a fixed threshold. In addition, we ask commenters that supported pre-determined thresholds ways in which CMS can continue to create incentives for quality improvement. We also solicited comments on alternative recommendations for revising the cut point methodology. We summarized examples of alternatives we were considering: Methodologies that will 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 2 or 3 most recent years; and setting caps on the degree to which a measure cut point could change from one year to the next. We solicited comments on these particular methodologies and recommendations for other ways to provide stability for cut points from year to year.

We received the following comments on our proposals and our responses follow:

Comment: There was widespread support for the use of the clustering algorithm to determine the cut points, although the overwhelming majority recommended some changes to how CMS determines the cut points.

Response: CMS appreciates the support of the use of the clustering algorithm for the determination of the cut points. CMS carefully reviewed the feedback which reflects very diverse and conflicting opinions on the appropriate way to set cut points. CMS is actively considering a wide range of options for modifying the approach for determining cut points and needs to fully simulate alternative options in order to avoid implementing an option that could have unintended consequences. Thus, we are finalizing the clustering algorithm for the determination of cut points (for non-CAHPS measures) as proposed while we continue to simulate alternative options. CMS will use the feedback from this NPRM to guide and examine options for an enhanced methodology for converting the measure scores to measure-level Star Ratings, which would be proposed in a future regulation.

Comment: The majority of commenters listed or identified several desirable attributes for the cut points, including having them be predetermined and released before the beginning of the measurement period, and increasing the stability and predictability of them. A handful of commenters noted that the cut points must represent meaningful differences among the star categories.

Many commenters expressed concern about the influence of outliers on the cut points. Some of the suggestions for decreasing the influence of outliers included removing them from the clustering algorithm, using a trimmed data set, or raising the minimum measure-level denominator threshold from 30 to 100 to reduce the number of outliers based on small numbers. In addition, many commenters that expressed a preference for stability supported a cap, a restriction on the maximum movement for a measure's cut points from one year to the next, to achieve the desired characteristic. A commenter suggested employing a cap similar to NCQA's method which relies on assigning a cap based on the maximum change in the relative distribution of the measure scores. The commenter believed this would allow

CMS's clustering methodology to move cut points (for example, moving the 4 and 5 star cut points up) without extreme changes based on the movement of relatively few MA contracts. Another commenter who supported stability stated that the thresholds from one year to the next should not be allowed to decrease. The majority of commenters who supported caps did not provide a specific value or methodology, but rather the advantages that caps would allow.

Some commenters suggested averaging cut points over multiple years for stability. Many commenters referenced CMS's previous policy that identified 4-star predetermined thresholds for specific measures and supported their return. A few commenters supported a weighted average based on several years of data to determine the cut points. A few commenters supported using a multiple-year trend to project measure cut points in advance of the measurement period.

Response: We appreciate the careful consideration of possible modifications to the methodology used for determining the cut points for the conversion of measure scores to the measure-level Star Ratings scale. CMS is examining a number of potential options for determining cut points that would capture the greatest number of desirable attributes that our stakeholder have identified (pre-determined, stable, predictable cut points with minimal (if any) influence by outliers, restricted movement across years) while maintaining the integrity of the Star Ratings in order to propose a new or enhanced policy for establishing measure-level ratings in the near future. We believe that the number and scope of alternatives require additional consideration and testing before we can finalize a different methodology for setting cut points for non-CAHPS measures. In the meantime, we believe that the clustering methodology presents a valid approach to accurately reflect the quality of care for MA and Part D sponsors, while creating incentives for continued quality improvement. The goal of clustering is to assign stars that maximize the differences across star categories and minimize the differences within star categories to minimize the risk of misclassification. The clustering methodology also accounts for changes in the distribution of scores over time. We understand the desire to create more stability in the assignment of cut points and in performance expectations, but we want to ensure that any potential alternative methodologies do not create unintended consequences.

Comment: Some commenters stated their support for transparency. Some commenters believe that increased transparency can be achieved by releasing all data for the Star Ratings program. A commenter suggested that CMS improve transparency in national performance reflected in display measures by calculating and publishing individual measure cut points for display measures instead of national averages. Other commenters believe transparency would be achieved by the implementation of pre-determined thresholds before the start of the measurement period.

Response: CMS appreciates these comments. CMS agrees with the commenters that transparency in the ratings system is important. Each year CMS releases public use files of the performance data underlying the Star Ratings, available at *http://go.cms.gov/partcanddstarratings.* In addition, the cut points for the specific Star Ratings' year are available in the annual Technical Notes using the same link used for the data sets. A Cut Point Trend document is updated and released annually to provide a single source for multiple years of Star Ratings cut points. The Cut Point Trend document is organized in a user-friendly format by measure and is available using the aforementioned link.

Display measures are collected through data sources such as Medicare Part C and Part D reporting requirements, Part D Prescription Drug Event (PDE) data, Healthcare Effectiveness Data and Information Set (HEDIS) information, and Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys. The display measures are not included in determination of the Star Ratings on Medicare Plan Finder and thus, are not assigned Star Ratings. Display measures provide useful information about plan quality that sponsors can take action upon in order to improve the quality of care provided to their members. To allow comparisons, national averages of the display measure scores are available in the annual MA Part C & D Measure Technical Notes. (The display measure data set and Technical Notes are posted on the same site as the MA Star Ratings information.)

CMS is examining a number of potential options for determining cut points that would capture the greatest number of desirable attributes that the commenters have identified (pre-determined, stable, predictable cut points with minimal (if any) influence by outliers, restricted movement across years) while maintaining the integrity of the Star Ratings. CMS is simulating the alternatives to the current cut point methodology. Further, CMS is identifying potential unintended consequences and examining ways to mitigate any identified risk to the integrity of the Star Ratings program. CMS is finalizing the clustering algorithm for the determination of cut points as proposed based on the positive and useful aspects of that methodology and to allow us the time to fully consider the options suggested by our stakeholders for enhancements to make it an even stronger methodology for converting the measure scores to measure-level Star Ratings. Any changes would be proposed in a future regulation.

Comment: Some commenters suggested alternative methodologies to determine cut points. A commenter suggested the use of a forced distribution rather than clustering to capture the true distribution of plan performance; assigning cut points by applying an adjustment factor to the prior year's results based on historical performance; or calculating the average change in the median from the prior 3 years and apply that to determine the current cut points. A few commenters suggested using the industry average. A commenter suggested using the industry average as the basis of a 3-star rating.

Response: CMS appreciates these comments. CMS believes that using a data driven approach to determine cut points aligns with our policies and guiding principles. As part of our guiding principles, we want to develop an enhanced methodology that ensures that the ratings are a true reflection of plan quality and minimizes the risk of misclassification. A forced distribution carries a high risk of misclassification because the cut points would not maximize the differences of contracts across star categories and minimize the differences of contracts within the same star category. An average as the basis of a 3-star rating would not accurately take into account the skewed distribution of many measures. CMS is examining a number of potential options for determining cut points while maintaining the integrity of the Star Ratings, including examining whether we can adjust prior performance results to determine current cut points. CMS will propose and solicit comment on an enhanced cut point methodology in a future regulation.

Comment: Some commenters stated that the current clustering algorithm to identify the cut points for the Star Ratings' measures does not always accurately reflect the quality improvement that contacts have achieved especially for measures scores

with a limited range in their distribution. Some commenters explicitly stated their opposition to some of the proposed methodologies. A commenter was against a moving average approach amid concerns of the longevity of such a method. Another commenter did not support caps due to the belief that caps would mask true performance. Another commenter did not support weighted clustering. A commenter suggested benchmarking independent of clustering to determine the cut points; the commenter justified the recommendation based on the belief that increases in the average measure scores over time leads to decreased variability of plan performance and tight clustering of plan performance which results in insignificant percentile scores having large impacts on the Star Ratings.

Response: CMS appreciates our stakeholder's feedback and will use it to guide the development of an enhanced methodology. So as not to implement a methodology that may inordinately increase the risk of misclassification, CMS will analyze and simulate the options to assess the impact of the methodology on the Star Ratings. The goal of clustering and the elimination of pre-determined 4-star thresholds for the 2016 Star Ratings was to more accurately measure performance.

The current methodology for converting measure scores to measure-level Star Ratings for non-CAHPS measures identifies the gaps that exist within the distribution of scores based on the criterion for assigning the groups. If the distribution is extremely restricted such that 5 unique groups cannot be formed, the output will result in 5 groups that are not unique. In this rare situation, there would be less than 5 star categories and the ordered groups will be assigned the higher ratings on the scale.

Comment: A commenter expressed concern about determining cut points using all MA data because such an approach fails to take into account the significant underlying differences in enrollment of plans. The commenter supported both stratified reporting and the determination of cut points after grouping plans into relevant cohorts (stratification at the contract level on key population characteristics, such as proportion Dual/LIS/Disabled).

Response: CMS appreciates this feedback. The Star Ratings system does not determine cut points for subsets of the population because it does not align with its underlying principles. However, CMS has developed the Categorical Adjustment Index (CAI), which is a factor that is added to or subtracted from a contract's Overall and/or Summary Star Ratings to adjust for the average within-contract disparity in performance associated with a contract's percentages of beneficiaries with Low Income Subsidy/Dual Eligible (LIS/DE) and disability status. These adjustments are performed both with and without the improvement measures included. The value of the CAI varies by a contract's percentages of beneficiaries with Low Income Subsidy/Dual Eligible (LIS/DE) and disability status. In addition, CMS displays Part C and D performance data stratified by race and ethnicity at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.html.*

Comment: A commenter expressed support of the identification of cut points, as they can provide insight into performance throughout the year, leading to greater quality improvements.

Response: CMS appreciates this support of the identification and utility of cut points.

Comment: A commenter requested simulations on the proposed cut point methodologies.

Response: CMS remains committed to transparency. CMS regularly solicits and values the feedback from our stakeholders. The feedback received guides the development of the policy options. CMS will continue to remain transparent in the development process for an enhanced cut point methodology as we move forward to propose a modified, new, or different policy for the assignment of measure-level Star Ratings.

Comment: A commenter urged CMS to re-evaluate the cut points to ensure the Star Ratings accurately reflect plan quality and are based on evidence. The commenter expressed concern about the number of measures within the MA Star Ratings program that are based on physician action and compliance. In order for plans to comply with and earn incentives from CMS, the commenter believes that plans must often set unrealistic targets within their physician contracts in order for the plan to score well due to the Star Ratings cut points. The commenter believes that there may be instances when compliance with a measure is contrary to appropriate care, and contracts may be penalized.

Response: CMS appreciates this comment. Plans should always set clinically appropriate targets for their physicians. There is no reason why the current methodology for setting the cut points to assign ratings to raw performance scores would require a physician to provide inappropriate care.

Comment: CMS received a handful of comments related to converting CAHPS scores to stars. There was support for the current methodology (which was proposed) although several commenters suggested the cut points are too narrow and a few would like to re-implement pre-determined cut points for CAHPS. A commenter stated that the relative distribution and significance testing methodology in CAHPS is biased in a negative direction and that these adjustments do not appropriately address the variability in CAHPS survey results.

Response: We appreciate comments received on the CAHPS methodology. Three factors enter into CAHPS star assignment: The ranking of the contract in relation to other contracts, a statistical significance test that takes into consideration the degree of certainty that the score is above or below the national average, and examination of measure reliability. The significance test is applied in the same way in the positive and negative directions and is not biased. CAHPS measures meet high standards of reliability and thus variability in the scores reflects variability in performance. This methodology improves the performance of the star system and ensures that 4 and 5 stars are reserved for contracts with strong evidence of high performance and that 1 and 2 stars are reserved for contracts with strong evidence of low performance. We note that the base group is not an entitlement to a certain Star Rating.

Previous analyses of CAHPS scores have suggested that seemingly small differences of 1 point on a 0–100 scale are meaningful; differences of 3 points can be considered medium, and differences of 5 points can be considered large.[57] For instance, a 3-point increase in some CAHPS measures has been associated with a 30 percent reduction in disenrollment from health plans, which suggests that even ''medium'' differences in CAHPS scores may indicate substantially different care experiences.[58]

[57] Paddison CAM, Elliott MN, Haviland AM, Farley DO, Lyratzopoulos G, Hambarsoomian K, Dembosky JW, Roland MO. (2013). ''Experiences of Care among Medicare Beneficiaries with ESRD: Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey Results.'' *American Journal of Kidney Diseases* 61(3): 440–449.

[58] Lied, T.R., S.H. Sheingold, B.E. Landon, J.A. Shaul, and P.D. Cleary. (2003). ''Beneficiary Reported Experience and Voluntary Disenrollment in Medicare Managed Care.'' *Health Care Financing Review* 25(1): 55–66.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized above, we are finalizing the methodology to determine cut points as proposed in §§ 422.166(a) and 423.186(a). CMS is committed to incorporating the feedback received from commenters on the methodology for determining cut points for non-CAHPS measures and will thoroughly analyze other potential methodologies to ensure that unintended consequences are avoided and the cut points resulting from any enhancements are consistent with principles and policy goals for the Star Ratings system. Changes to the methodology for the determination of cut points for non-CAHPS measures will be proposed in a future rule.

We are finalizing the methodology to determine cut points for CAHPS measures in §§ 422.166(a)(3) and 423.186(a)(3) substantively as proposed. We are finalizing the regulation text with minor technical revisions to improve readability.

m. Hierarchical Structure of the Ratings

We proposed to continue our existing policy to use a hierarchical structure for the Star Ratings. Currently, and as proposed, the basic building block of the MA Star Ratings system is the measure. Because the MA Star Ratings system consists of a large collection of measures across numerous quality dimensions, the measures will be organized in a hierarchical structure that provides ratings at the measure, domain, Part C summary, Part D summary, and overall levels. The proposed regulations text at §§ 422.166 and 423.186 are 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 will indicate the highest Star Rating possible, while a rating of 1 star will 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 will 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 proposed to codify these policies at paragraphs (b)(2), (c)(1) and (d)(1) of §§ 422.166 and 423.186.

We received the following overall comments on our proposal and our response follows:

Comment: All commenters supported the existing hierarchical structure of the Star Ratings program and its associated policies.

Response: CMS appreciates the continued support of the existing organization of the Star Ratings measures and the policies associated with it. CMS firmly believes the structure increases the utility and efficiency of the rating system and appreciates the positive response to it.

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 proposed 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–PD plans and four for Part D measures for stand-alone PDP and MA–PD plans. We proposed 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 6—PART C DOMAINS

Domain
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.
Health Plan Customer Service.

TABLE 7—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 proposed to continue this policy at paragraph (b)(2)(ii). We also proposed 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; we explained this was necessary 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 will 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 proposed 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.

We received the following comments on our proposal and our responses follow:

Comment: Commenters supported the use of the current domains and the associated policies related to the calculation of the Star Ratings for domains.

Response: CMS appreciates our stakeholders' support of the use of the domains and associated policies related to the domains.

Comment: A commenter noted the usefulness of the domains for displaying the data on Medicare Plan Finder (MPF). In addition, the commenter believed the domains helped consumers interpret the data on MPF.

Response: The domains were designed to summarize a plan's performance on a specific dimension of care. CMS appreciates the positive feedback related to domains and the agreement that they serve not only to organize data on MPF, but also serve as an aid to consumers' interpretation of the data displayed.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized above,

we are finalizing the provisions identifying the domains and for rating at the domain level as proposed at §§ 422.166(b) and 423.186(b) without modification.

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 proposed, 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 stand-alone plan will receive a summary rating only for, respectively, Part C measures and Part D measures.

First, in paragraphs (c)(1) of each section, we proposed 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 proposed 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 proposed the specifics for these adjustments) for Parts C and D, respectively.

Second, and also consistent with current policy, we proposed 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. We proposed to codify the necessary text as paragraph (c)(2)(i) of §§ 422.166 and 423.186 the same rules will be applied to both the Part C and Part D summary ratings for the minimum number of rated measures. We proposed that these regulations would also apply to calculating the summary Part C and Part D ratings of MA–PD plan; the MA–PD plan would have to meet the minimum number of rated measures for each summary rating type. We also proposed (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 proposed 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. We explained in connection with this proposal how the policies proposed in §§ 422.166(h) and 423.186(h) regarding posting summary ratings on MPF would apply. The summary rating would be displayed in HPMS and Medicare Plan Finder to the nearest half star if a contract had 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 solicited comments on the calculations for the Part C and D summary ratings. We received the following comments on our proposal and our responses follow:

Comment: The majority of the commenters supported the policies, methodology, and display of the summary ratings as proposed.

Response: CMS appreciates the ongoing support of the summary ratings.

Commenter: A commenter recommended a revision to the rule that requires a contract to have numeric scores for at least 50 percent of the required measures for the summary-specific rating to have a summary rating calculated. The commenter suggested a change to the rule such that a summary rating would be calculated if a contract had at least half of the weighted value of the full measure set for the summary-specific rating.

Response: CMS appreciates the feedback for a possible revision to the rule that determines whether a summary rating would be calculated. 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. The summary ratings include information from multiple dimensions of quality and performance. CMS plans to evaluate the suggestion of using 50 percent of the total weighted value of the measure set as the threshold for calculating summary ratings to examine whether such a change would still allow an accurate reflection of the quality of the health plan or prescription drug plan.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized above, we are finalizing the provisions governing summary ratings as proposed at §§ 422.162(c) and 423.182(c) without modification.

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 proposed 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 proposed 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 has scores for at least 50 percent of the required measures for the contract type. As with the Part C and D summary ratings, the Part C and D improvement measures will 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, the measures ''Members Choosing to Leave the Plan'' and ''Complaints about the Plan'' use the same data for both the Part C and Part D measure for an MA–PD plan and under the proposal, would be counted only once for the overall rating. As with summary ratings, we proposed 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).

We also explained in the proposed rule how the overall rating would be posted in accordance with our general proposed policy at §§ 422.166(h) and 423.186(h), including the 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 an 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 proposed, 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 will be treated as qualifying plans for the purposes of QBPs as described in § 422.258(d)(7) of this chapter. The QBP levels for each rating area are announced through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act. We noted that this aspect of the proposal would merely codify existing policy and practice.

We received the following comments on our proposal and our responses follow:

Comment: Commenters supported the use of the overall rating as a global rating that summarizes a contract's quality and performance, as well as the proposal to use the current policies for calculating and publishing the overall rating.

Response: CMS values the support of the overall rating and its associated methodology.

Comment: A commenter suggested a revision to the rule for calculating the overall rating for an MA–PD contract. As done currently and proposed, an MA–PD contract must have both (Part C and Part D) summary ratings and measure scores for at least 50 percent of the required measures based on contract-type (exclusive of the improvement measures) to have an overall rating. The commenter suggested that an overall rating for an MA–PD contract require measure scores that total at least half of the weighted value of the full measure set.

Response: CMS appreciates the suggestion of alternative requirements for the calculation of an overall rating. Changing the requirement for the calculation of an overall rating to be based on the majority of the total weight of the Star Ratings measures has the potential of confusing the global nature of the overall rating. There are substantially more Part C measures in the Star Ratings and the total weight of the Part C measures exceeds that of the Part D measures. By requiring a contract to have both a Part C and D summary rating coupled with the requirement of at least 50 percent of the measures, CMS has minimized the potential for the overall rating being determined primarily by dimensions of health plan quality instead of both health plan and prescription drug plan quality.

Comment: A commenter suggested the use of a percentile rank threshold for the determination of a 5-star overall rating, thus allowing the recognition of top performers along with the ability to enroll members year-round.

Response: While CMS thanks the commenter for its suggestion, CMS disagrees with using percentile ranking as a threshold for calculating overall ratings. One of the underlying design principles of the MA and Part D Star Ratings is to incentivize plans to provide the best health care possible to our beneficiaries. This underlying principle is reflected in the manner that measure scores are converted to Star Ratings, as well as the aggregation of the measure-level Star Ratings to an overall rating. (Measure-level Star Ratings are the basic building block, of the overall rating.) A percentile rank threshold approach for the overall rating does not align with the principles of the Star Ratings methodology and would arbitrarily apply a threshold that could be perceived as a subjective value that would ultimately separate 5-star contracts from all other contracts.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized above, we are finalizing the provisions for overall ratings as proposed at §§ 422.162(d) and 423.182(d) without modification.

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, which is weighted as 1. This weight aligns the Part C and D Star Ratings program with value-based purchasing programs in Medicare fee-for-service which take into account improvement.

We proposed 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 also solicited feedback about increasing the weight of the patient experience/complaints and access measures and stated our interest 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 asked for feedback about increasing it from a weight of 1.5 to between 1.5 and 3, similar to outcome measures. This increased weight would reflect CMS's commitment to serve Medicare beneficiaries by putting patients first, including their assessments of the care received by plans. We solicited comment on this point, particularly the potential change in the weight of the patient experience/complaints and access measures.

Table C7 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 II.A.11. of the proposed rule, we proposed (as Table C2) the measure set and included the category and weight for each measure, consistent with this proposal for weighting measure by category. We proposed 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. For the first exception, we proposed to codify current policy in paragraphs (e)(2) of each section and 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 8—PROPOSED 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 will 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
Process	Process measures capture the health care services provided to beneficiaries which can assist in maintaining, monitoring, or improving their health status.	1

For the second exception, we proposed (at §§ 422.166(e)(3) and 423.186(e)(3)) again to codify current policy and to apply a special rule for MA–PD 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 a population of beneficiaries in Puerto Rico. We proposed, 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 with service areas that are wholly located in Puerto Rico. We requested comment on our proposed weighting strategy for Measure Weights generally and for Puerto Rico, including the weighting values themselves.

We received the following comments on our proposal and our responses follow:

Comment: Multiple commenters requested CMS not to increase the weight of patient experience/complaints and access measures from a weight of 1.5 up to 3. Many of the commenters requested to maintain the current weight; however, others requested that CMS decrease the weight of patient experience measures citing survey reliability and sampling concerns with patient experience surveys. They stated that patient-reported data are not as reliable as claims, prescription drug event data, medical charts, and other data sources. They believe that these measures are unfairly subjective and that more weight should be placed on more reliable and objective measures like clinical and outcome measures. Many cited concerns with response rates, sample size of patient experience surveys, and other factors in which the plan has less control, as well as industry concerns around accuracy of survey responses and research suggesting a weak relationship between care received and survey responses. A commenter supported increasing the weight of access and patient experience measures that are not based on survey data. A commenter opposed the weight increase until we have better measures in these areas.

Response: We refer commenters to section II.A.11.i and Table C2A and the narrative comment and responses that follow, which give background and additional justification for CAHPS measures. While we acknowledge that the CAHPS survey captures individuals' perspectives on their experiences of care, it is anchored in measureable aspects of care and so can be measured reliably. In addition, CAHPS surveys were developed with broad stakeholder input, including a public solicitation of measures and a Technical Expert Panel, and the opportunity for anyone to comment on the surveys through multiple public comment periods through the **Federal Register**. CMS encourages all plans to familiarize themselves with the survey methodology and to review the background materials available on the MA and PDP CAHPS website that validate the CAHPS measures.

CMS has pledged to put patients first and to empower patients to work with their doctors to make health care decisions that are best for them. An increased weight for patient experience/complaints and access measures reflects

CMS's commitment to serve Medicare beneficiaries by including their assessments of the care received by plans. In addition, CAHPS measures and positive clinical outcomes have been shown to be related. While patient experience is an inherently important dimension of healthcare quality, it is also the case that the preponderance of evidence shows that better patient experience is associated with better patient adherence to recommended treatment, better clinical processes, better hospital patient safety culture, better clinical outcomes, reduced unnecessary healthcare use, and fewer inpatient complications.[59] [60] A recent study found that higher quality for patient experience had a statistically significant association with lower rates of many in-hospital complications and unplanned readmissions to the hospital within 30 days. In other words, better patient experience according to the CMS hospital Star Ratings is associated with favorable clinical outcomes.[61] An increased weight also reflects the importance of these beneficiary-centered issues in plan performance.

Further, access to health services is a critical issue in the healthcare sector and to Medicare beneficiaries. Lack of access can result in unmet health needs, delays in receiving the appropriate care, inability to access preventative services, unreasonable financial burdens, and preventable hospitalizations.[62] For these reasons, access measures, such as appeals measures and call center measures, are crucial in the Star Ratings system. Increasing the weight for these measures highlights the importance of capturing access to care within MA and Part D plans.

To best meet the needs of our beneficiaries, CMS believes that we must listen to their perceptions of care, as well as ensure they have access to needed care. Commenters representing beneficiaries strongly supported an increase in the weight of the patient experience of care and access measures. Therefore, we will finalize an increase in the weight for these two categories of measures from 1.5 to 2. Given the importance of hearing the voice of patients when evaluating the quality of care provided, CMS intends to further increase the weight of these measures in the future, so we welcome stakeholder feedback on how to improve the CAHPS survey, including the topics it covers, and suggestions for additional access measures or modifications to existing ones. We expect this change to increase the highest rating for approximately 8 percent of contracts and to have no impact on the majority of other contracts, while also demonstrating CMS's commitment to evaluate the quality of care provided as experienced by beneficiaries. Please send feedback about CAHPS to *MP-CAHPS@cms.hhs.gov* and feedback about access measures to *PartCandDStarRatings@cms.hhs.gov*.

Comment: A handful of commenters strongly supported the proposed weight increase of patient experience/complaints and access measures. They emphasized the importance of the beneficiary and caregiver perspectives and noted that the beneficiary's voice is an important indicator for plan performance in key areas such as the ease of access to needed drugs and treatments as well as plan responsiveness to appeal requests. Commenters said that by increasing the weights of these measures, CMS ensures that beneficiaries are seeing Star Ratings that reflect what they are likely to find important about their plan selections. These commenters also believed that assessments of quality and value by the patient are currently under-valued in Part C and D. Therefore, they believed patient experience/complaints and access measures should receive a higher weight than the current 1.5.

Response: CMS appreciates this feedback and agrees the voice of the beneficiary must be heard as part of evaluating the quality of health and drug plans.

Comment: CMS received several comments requesting to decrease and reclassify HOS measures on Improving or Maintaining Physical and Mental Health to receive a patient experience weight of 1.5 or process measure weight of 1, as opposed to their current outcome weight of 3. Some commenters believed there are methodological limitations to the HOS, and they stated that it does not provide a reliable evaluation of the patient experience because it relies on variables such as memory and the patient's physical and mental status at the time of survey completion. We also received comments that because the HOS measures are patient-reported measures (in response to survey questions) they are not true measures of health outcomes and should be weighted no higher than 1 or 1.5.

Response: We refer the commenter to Table C2 in section II.A.11., which gives background and additional justification for HOS measures. The HOS assesses health outcomes for randomly selected beneficiaries from each health plan over a two-year period by using baseline measurement and a two-year follow up. CMS recognizes that the Physical Component Score (PCS) and the Mental Component (MCS) may decline over time and that health maintenance, rather than improvement, is a more realistic clinical goal for many older adults. MAOs are asked to improve or maintain the physical and mental health of their members. Change scores are constructed and the results compare actual to expected changes in physical and mental health. Therefore, the Improving or Maintaining Physical and Mental Health measures are not patient experience measures because they measure whether plan member's physical and mental health is the same or better than expected after 2 years. While the data come from the HOS, they measure beneficiary outcomes and therefore are appropriately classified as outcome measures with a weight of 3.

Additionally, the HOS was developed and continues to be refined under the guidance of a Technical Expert Panel comprised of individuals with specific expertise in the health care industry and outcomes measurement. HOS analysts apply the most recent advances in summarizing physical and mental health outcomes results and appropriate risk adjustment techniques. CMS also solicits stakeholder input, including public solicitation of measures and the opportunity for anyone to comment on the survey through multiple public comment periods through the **Federal Register**.

Comment: A few commenters sought clarification on differences in the weights between the Part C and Part D Statin measures. Two organizations recommended classifying both the Part C Statin Therapy for Patients with Cardiovascular Disease (SPC) and the Part D Statin Use in Persons with Diabetes (SUPD) measures as process measures with a weight of 1. A commenter supported the weight for the Statin measure developed by PQA.

Response: CMS appreciates the feedback and clarifies the weighting decision for each measure below. The Part C Statin Therapy for Patients with Cardiovascular Disease (SPC) measure is

[59] Price, R.A., Elliott, M.N., Zaslavsky, A.M., Hays, R.D., Lehrman, W.G., Rybowski, L., & Cleary, P.D. (2014). Examining the role of patient experience surveys in measuring health care quality. Medical Care Research and Review, 71(5), 522–554.

[60] Price, R.A., Elliott, M.N., Cleary, P.D., Zaslavsky, A.M., & Hays, R.D. (2015). Should health care providers be accountable for patients' care experiences?. Journal of general internal medicine, 30(2), 253–256.

[61] Trzeciak, Stephen et al. ''Association Between Medicare Star Ratings for Patient Experience and Medicare Spending per Beneficiary for US Hospitals.'' Journal of patient experience 4.1 (2017): 17–21. PMC. Web. 2 Feb. 2018.

[62] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Access-Measures.pdf.*

the 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. The Part C measure focuses on patients who were dispensed one prescription and whether the patient filled the medication at least once. Therefore, it is a process measure and will receive a weight of 1. The Part D measure is the 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. Receiving multiple fills indicates the patient continues to take the medication and therefore suggests adherence. The Part D measure is not a process measure. Continuing to take the prescribed medication is necessary to reach clinical/therapeutic goals. Thus, the Part D measure is an intermediate outcome measure and will receive a weight of 3.

Comment: A couple of commenters requested a decrease in the improvement measures from the current weight of 5 to a weight of 3 (like outcome measures). They stated the measures diminish the importance of clinical measures and mislead Medicare beneficiaries about which are the highest quality health plans.

Response: CMS recognizes the importance of acknowledging quality improvement in health and drug plans. The decision to assign a weight of 5 for the improvement measures was originally made to align the Part C and D Star Ratings program with value-based purchasing programs in Medicare fee-for-service which heavily weight improvement. As part of the Part C and D Star Ratings program, we are committed to improving the quality of care and experiences for Medicare beneficiaries. Through assigning a weight of 5 to improvement, CMS encourages MA and Part D contracts to focus on improving the quality of care provided.

With regard to overall ratings, improvement measures contribute significantly less than outcome measures overall. For example for the 2018 Star Ratings for an MA–PD that does not include a SNP, the overall contribution of the improvement measures to the overall rating is close to 14 percent, but the overall contribution of outcome and intermediate outcome measures is 33 percent.

CMS believes that continuous improvement is necessary to reach the goal of providing the best care to our beneficiaries. While the improvement measures are weighted the most of any category in the Star Ratings, the improvement measure is a single measure that encompasses care across multiple dimensions.

Comment: A commenter recommended that CMS weight MA–PD and PDP measures differently based on the plan's ability to influence outcomes on a measure, for example statin use in persons with diabetes. PDPs should have less weight placed on measures that largely depend on provider behavior, which they have very little ability to impact.

Response: Currently the only Part D outcome measures are adherence measures. CMS disagrees that stand-alone PDPs have very little influence on beneficiaries' medication adherence. There are many strategies that can be used to improve a beneficiary's medication adherence in addition to prescriber interventions, such as refill reminders, formulary and benefits design, and medication therapy management programs. Plan sponsors can also leverage network pharmacy relationships to address medication adherence issues, facilitate medication synchronization, or provide education and counseling. In the absence of a contact phone number for the beneficiary, it may be beneficial to use these interventions to reach the beneficiary at the place of dispensing. Furthermore, MA–PDs and PDPs are rated separately to account for delivery system differences. Lastly, adherence measures will now be included in the CAI to account for LIS beneficiaries which we discuss in more detail in section II.A.11.t.

Comment: A commenter recommended decreasing the weighting of a topped out measure rather than discontinuing the measure.

Response: Measure scores are determined to be 'topped out' when they show high performance and little variability across contracts, making the measure unreliable. CMS removes 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. However, CMS will retain measures at the same weight 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. CMS will take this comment into consideration as we make future enhancements in the Star Ratings program.

Comment: Multiple commenters supported assigning new measures a weight of 1 for the first year.

Response: CMS appreciates the support of the proposed weighting for new measures.

Comment: A commenter supported the weighting for the adherence measures in Puerto Rico.

Response: CMS appreciates the support of the proposed Puerto Rico weights.

For the reasons set forth in the proposed rule and our responses to the related comments summarized above, we are finalizing the provisions governing the weight of measures as proposed in §§ 422.166(e) and 423.186(e) with modification. CMS is finalizing the weight of patient experience/complaints and access measures at 2 in paragraphs (e)(iii) and (iv) given the importance of hearing the perspectives and voice of patients in times of need.

r. Application of the Improvement Measure Scores

Consistent with current policy, we proposed 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 proposed, 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.

Under our proposal, 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 would be 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 MA–PD contract's 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), we proposed the overall rating would exclude the improvement measures; 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 contract that receives a summary rating (with applicable adjustments) of 4 stars or more without the use of the improvement measure, a comparison of the rounded summary rating with and without the improvement measure would be 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 (with applicable adjustments) of 2 stars or less without the use of the improvement measure 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 proposed text to clarify that summary ratings use only the improvement measure associated with the applicable Part C or D performance.

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

We received the following comments on our proposal and our responses follow:

Comment: A commenter recommended the exclusion of the hold harmless provision for a highly-rated contract if the contract would realize a decrease in their overall rating. In addition, the commenter supported a hold harmless provision for plans that would be at risk of receiving a low performing icon due to application of the quality improvement measures.

Response: CMS currently and as proposed, has a safeguard for highly-rated contracts. CMS applies the hold harmless provision for a highly-rated contract's highest rating. As proposed, a contract that receives 4 stars or more without the use of the improvement measures and with all applicable adjustments (CAI and the reward factor) will have their final overall rating as the higher of either the rating calculated including or excluding the improvement measure(s). CMS believes the hold harmless provision is appropriate to apply for highly-rated contracts since they have less room for improvement and, consequently, may have lower scores for the improvement measure(s).

CMS believes that the Star Ratings should signal the true quality of the contract. A hold harmless provision for contracts that are in jeopardy of a low performing icon does not align with the intent of the Star Ratings program and threatens its integrity. Low performing contracts, including those at risk of receiving a low performing icon, have plenty of room for improvement and should not need a hold harmless provision.

Comment: A commenter expressed support for all rules that guide the application of the improvement measure(s) in calculating overall and summary ratings.

Response: CMS appreciates the support of the policies that guide the application of the improvement measure(s) in the Star Ratings.

Comment: Overall, commenters supported the use of the hold harmless provision for a highly-rated contract's highest rating. However, several commenters advocated a modification to the hold harmless provision for highly-rated MA–PDs such that the overall rating would be determined by the highest rating among the overall rating calculated with including both improvement measures, excluding both improvement measures, using only the Part C improvement measure, or using only the Part D improvement measure.

Response: CMS appreciates the support of a hold harmless provision for a highly-rated contract's highest rating. CMS is committed to providing a true signal of the overall quality to beneficiaries who use Medicare Plan Finder to aid in the selection of a plan that is right for them. Eliminating the use of one of the improvement measure ratings in calculating the overall rating has the potential to distort the signal for beneficiaries. The overall rating is designed as a global rating of the quality of both the health plan and prescription drug plan benefits for an MA–PD. While we do agree there is justification for a hold harmless provision for a highly-rated MA–PD, CMS is committed to preserving the integrity of the rating system. Removing one facet of the rating system (Part C or Part D improvement measure) while not the other, has the potential to undermine the primary function of the rating system. Therefore, we are not finalizing the revisions requested by the commenter(s).

Comment: Some commenters did not support excluding the improvement measure(s) from use in a contract's highest rating (with applicable adjustments) if the contract received 2 stars or less without the use of the improvement measure. The commenters believed that limiting the measure to only plans with at least 2.5 stars goes against the objective of the improvement measure in encouraging and rewarding improvements in performance, particularly among lower-rated plans.

Response: CMS appreciates the careful review of the proposed policy related to the application of the improvement measure(s) for a contract's highest rating. After thoughtful deliberation of the recommendation of our commenters, CMS has decided to modify the proposed methodology for the application of the improvement measures. The methodology will be changed such that if the highest rating for a contract is less than 4 stars without the use of the improvement measure(s) and with all applicable adjustments (CAI and the reward factor), the rating will be calculated with the improvement measure(s). The modification of the application of the improvement measure(s) preserves the safeguard for a highly-rated contract's highest rating, but removes what could be perceived as a safeguard for contracts with a highest rating of 2 stars or less. In other words, if an MA–PD has an overall rating of less than 4 stars without the use of the improvement measures and with all applicable adjustments, the improvement measures will be used in the calculation of the overall rating. If an MA-only contract has a Part C summary rating of less than 4 stars without the use of the Part C improvement measure and with all applicable adjustments, the Part C improvement measure will be used in the determination of the contract's Part C summary rating. If a PDP has a Part D summary rating of less than 4 stars without the use of the Part D improvement measure and with all applicable adjustments, the Part D improvement measure will be used in the determination of the contract's Part D summary rating. (An MA–PD will have the Part C or Part D improvement measure included in the calculation of the respective Part C and Part D summary ratings, because the summary ratings are not the highest rating for this type of contract.) The only modification will be for contracts with a highest rating of 2 stars or less. After consideration of the comments received, we believe it is reasonable to also include any applicable improvement measure(s) for contracts with a highest rating of 2 stars or less so that the highest rating reflects whether the overall quality is improving, staying the same, or declining.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized above, we are finalizing the provisions addressing use of the improvement measure in summary and overall ratings as proposed at §§ 422.162(g) and

423.182(g) with one substantive modification. We are not finalizing what was proposed for contracts with a 2-star summary or overall rating (with applicable adjustments). We are also finalizing a revision to the rule for summary or overall ratings (with applicable adjustments) of less than 4 stars to include as well contracts with overall or summary ratings of 2 stars.

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 is assessed using its weighted mean relative to all rated contracts without adjustments.

We proposed to codify the calculation and use of the reward factor in §§ 422.166(f)(1) and 423.186(f)(1); our proposal was to generally codify the current practice for the reward factor. Under our proposal, the contract's stability of performance would 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 would be, like current practice determined independently of the thresholds for PDPs.

We proposed to update annually 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. Under the proposal 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 deviation [63] 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 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 would be calculated both with and without the improvement measures.

Under the methodology CMS proposed for this factor, a contract's weighted variance would be categorized into one of three mutually exclusive categories, identified in Table C8A, based upon the weighted variance of its measure-level Star Ratings. Its ranking would be 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 would be categorized into one of three mutually exclusive categories, identified in Table C8B, 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 would be 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 would be 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 would be based on the distribution of all rated contracts and determined with and without the improvement measure(s) and exclusive of any adjustments. Table C8A details the criteria for the categorization of a contract's weighted variance for the summary and overall ratings. Table C8B details the criteria for the categorization of a contract's weighted mean (performance) for the overall and summary ratings. Like current practice, the values that correspond to the cutoffs would be 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.

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

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 were proposed to 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 C9 shows the values of the reward factor based on the weighted variance and weighted mean categorization; we proposed to codify these values (in a narrative description) in paragraph (f)(1)(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 proposed to continue the use of a reward factor to reward contracts with consistently high and stable performance over time. Further, we proposed to continue to employ the same methodology 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.

We received the following comments on our proposal and our responses follow:

Comment: The majority of commenters were supportive of the continued use of the reward factor. A commenter expressed support specifically related to the reward methodology and the codification of the calculation of the reward factor.

Response: CMS appreciates our stakeholders' support of the reward factor.

Comment: A commenter expressed support of the use of a reward factor for the overall rating, but was concerned that the proposed (and current) methodology for calculating the reward factor did not consistently award contracts that maintained high performance and demonstrated incremental improvement at the measure level. Further, the commenter linked the potential for a high performing contract not receiving a reward factor to flaws in the assignment of measure cut points.

Response: CMS appreciates the careful consideration of the reward factor. Since the reward factor is a rating-specific factor, a contract can qualify for the reward based on its summary or overall (or both) rating if a contract has both high and stable relative performance. CMS believes the reward factor methodology identifies the contracts that have both high and stable relative performance and recognizes that such performance may exist overall (Part C and D performance) or in one particular area (health plan quality and performance domain on Part C measures or the prescription drug plan quality and performance domain on Part D measures). Since the reward factor is based on a relative performance, it serves to incentivize plans and recognize plans that provide the highest and consistent level of care as reflected in their ratings. Ratings calculated using a consistent methodology allow to the identification of top performers based on rankings.

Comment: A commenter suggested that CMS annually publish the list of reward factor recipients. The commenter referenced the publication of the Categorical Adjustment Index (CAI) final adjustment categories for contracts to support the request. Further, the commenter believed that the publication of the reward factor recipients would maintain the attributes of fairness and transparency of the Star Ratings system.

Response: CMS appreciates this feedback. As noted in the comment, the CAI final adjustment categories per contract are available in the annual public use files available using the following link: *http://go.cms.gov/partcanddstarratings.* While the thresholds for the reward factor are published each year in the Technical Notes, the recipients of the reward factor are not part of the public use files. However, we are persuaded that this is important information for beneficiaries and could assist in providing greater transparency into the development and assignment of the Star Ratings. Therefore, CMS will begin incorporating information related to the distribution and characteristics of contracts receiving the reward factor in the annual Fact Sheet for the 2021 Star Ratings.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized above, we are finalizing the provisions as proposed at §§ 422.162(f1) and 423.182(f)(1) without modification.

t. Categorical Adjustment Index

As we discussed in the proposed rule, 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.[64] We also reviewed reports about the impact of socio-economic 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.* More recently, we have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE[65]) and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS's 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.[66]

We have also engaged NCQA and the PQA to examine their measure specifications used in the Part C and Part D 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 the specifications for the measure are adjusted 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 enrollees 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 enrollees 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 proposed to codify the calculation and use of the CAI in §§ 422.166(f)(2) and 423.186(f)(2), while we consider other alternatives for the future.

As has been done with the 2017 and 2018 Star Ratings, we proposed that 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 (A) the measures are already case-mix adjusted for SES (for example, CAHPS and HOS outcome measures); (B) 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); (C) the measure is scheduled to be retired or revised during the Star Rating year in which the CAI is being applied; or (D) the measure is applicable to only Special Needs Plans (SNPs) (for example, SNP Care Management, Care for Older Adults measures). We proposed to codify these paragraphs for determining the measures for CAI values at paragraph (f)(2)(ii). In addition, the 2017 and 2018 Ratings were based on a group of measures from within the cohort identified using these rules.

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 an LIS at any time during the applicable measurement period, the 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

[64] The February release can be found at *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/performancedata.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.*

[65] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[66] 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.*

counts of beneficiaries for enrollment and categorization of LIS/DE and disability would be restricted to beneficiaries who 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 proposed to codify these standards for determining the enrollment counts at paragraph (f)(2)(i)(B).

Using the subset of the measures that meet the basic inclusion requirements, we proposed 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 will be independently analyzed. For each contract, the proportion of enrollees 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 will be calculated. CMS proposed to 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: (A) A median absolute difference between LIS/DE and non-LIS/DE beneficiaries for all contracts analyzed is 5 percentage points or more or [67] (B) the LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup in all contracts. We proposed to codify these paragraphs for the selection criteria for the adjusted measures for the CAI at paragraph (f)(2)(iii).

In addition, we proposed that the Part D measures for PDPs would be analyzed independently at paragraph (f)(2)(iii)(C). 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. We explained that under our proposal 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 proposed 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 solicited comment on the proposed methodology and criteria for the selection of the measures for adjustment.

We also addressed how we would release our findings publicly. While the CAI would be employed, we proposed to 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 posted would include the minimum, median, and maximum values for the within-contract variation for the LIS/DE differences. We also proposed that the set of measures for adjustment for the determination of the CAI would be announced in the draft Call Letter in paragraph (f)(2)(iii).

We proposed, 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. We proposed an approach to determine the adjusted measure scores that 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.

We explained that under our proposal, the sole purpose of the adjusted measure scores would be for the determination of the CAI values. They 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.

As described in §§ 422.166 (f)(2)(v) and 423.186(f)(2)(v) 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 will 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.

We explained in the proposed rule that 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 have 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. That 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 proposed to continue this adjustment at paragraph (f)(2)(vi) 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 the Medicare enrollment data from the same measurement period used for the Star Ratings year. We proposed that 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

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

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.

We explained that 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 would be 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) would be 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 proposed methodology, which is currently used, 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. We proposed that the maximum value for the modified LIS/DE indicator value per contract will be capped at 100 percent and that all estimated modified LIS/DE values for Puerto Rico would be rounded to 6 decimal places when expressed as a percentage.

We proposed 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 proposed 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 proposed 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.)

In the proposed rule, CMS noted that while recommendations from the ASPE report, findings from measure developers, and work by NQF on risk adjustment for quality measures is considered, we are continuing to collaborate with stakeholders. As noted, we seek 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 solicit 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.

As noted in the proposed rule, 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. We are continuing to consider options on to how to measure and account for social risk factors in our Star Ratings program. Although a sponsoring organization's administrative costs may increase as a result of enrolling significant numbers of beneficiaries with LIS/DE status or disabilities, our research thus far has demonstrated that 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. Because CMS will like to better understand whether, how, and to what extent a sponsoring organization's administrative costs differ for caring for low-income beneficiaries, we explicitly solicited 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 stated our belief that the proposal demonstrated our continued 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.

We received the following comments on our proposal and our responses follow:

Comment: There was immense support and acclaim for the work that CMS continues to do related to the impact of sociodemographic factors on the Star Ratings.

Response: CMS appreciates the continued support of our stakeholders, government agencies, and the research community.

Comment: Overall, commenters supported the continued use of the CAI, but the majority of commenters suggested some enhancements to the current methodology (which we would continue to use under our proposal). Many commenters believe that the selection rules for adjusted measures are somewhat arbitrary or restrictive and result in a small subset of adjusted measures. These commenters suggested expanding the number of measures for adjustment. The suggested enhancements for increasing the number of adjusted measures focused on modifying the selection rules. Commenters suggested revising the second set of selection criteria that are based on the within-contract disparity analysis across contracts, which would result in a larger set of adjusted measures. The suggested modifications included a revision of the percentage used for the median absolute difference between LIS/DE and non-LIS/DE beneficiaries for all contracts analyzed. Some commenters suggested changing the currently employed value of 5 percentage points to a lower values, such as 1 or 2 percentage points. A commenter suggested that the percentage for the rule vary based on the measure, such that the number is meaningful for the particular measure. A commenter suggested modifying the selection rule from the proposed one that uses the entire range of the within-contract disparities to instead identify the measures where the LIS/DE subgroup performed better or worse than the non-LIS/DE subgroup (basing the second selection rule to the middle 90 percent of the differences in the distribution of the within-contract disparity analysis).

Response: CMS is grateful for the continued support of our stakeholders related to the design and development

of the CAI. CMS developed two sets of rules to determine the adjusted measure set: First, the rules to determine the measures that comprise the candidate measure set for adjustment and second, the rules applied to the candidate set to identify the measures to be adjusted to determine the values of the CAI. The candidate measure set includes the measures in the Star Ratings that have varying levels of a LIS/DE/disabled effect. The second set of rules relies on the analysis of the variability of the within-contract differences of LIS/DE and non-LIS/DE beneficiaries. The application of the second set of selection rules identified the measures in the candidate set that demonstrated an LIS/DE effect at a level that qualified them for adjustment.

After thoughtful and careful deliberation of the recommendations of our stakeholders, CMS will finalize modified selection rules for identifying the adjusted measures: We will not finalize the second set of rules for determining the adjusted measure set that we proposed at paragraphs (f)(2)(iii)(A) through (C) that provided for identifying measures for adjustment based on an analysis of the dispersion of the LIS/DE within contract differences. Under the rule we are finalizing, the 2021 CAI values will be determined using all measures in the candidate measure set for adjustment identified by application of paragraphs (f)(2)(ii)(A) through (D). A measure will be adjusted if it remains after applying the following four bases for exclusions as follows: The measure is already case-mix adjusted for SES (for example, CAHPS and HOS outcome measures); 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); the measure is scheduled to be retired or revised during the Star Rating year in which the CAI is being applied; or the measure is applicable to only Special Needs Plans (SNPs) (for example, SNP Care Management, Care for Older Adults measures). With this modification to the CAI calculations, the ratings will continue to be data driven in order to be a true reflection of plan quality and enrollee experience, and continue to treat all contracts fairly and equally. The modification will only eliminate the selection rule in regards to the size of the within contact differences. This selection rule was originally developed based on a goal of adjusting measures only when there are substantive LIS/DE within contract measure disparities. Commenters suggested that this selection rule should be relaxed or eliminated. In cases where there is little or no difference in the LIS/DE within contract performance, there will be very minimal or no impact on the calculation of the CAI values. Previously, we have excluded measures from this calculation when the effects were very small. With this modification based on the comments received and further analysis, these measures will be included but will have a very minimal impact on the CAI values.

Comment: Some commenters suggested including a hold harmless provision for the application of the CAI for plans with limited LIS/DE populations. Some commenters believed contracts should not be subject to negative adjustments because they have a low percentage of LIS/DE or disabled enrollees. A commenter suggested a hold harmless provision for contracts that upon the application of the CAI, would have their ratings fall below a particular threshold.

Response: As summarized in the NPRM, research indicates disparities exist in performance measures that are influenced by an individual's sociodemographic factors. The CAI was designed to account for the disparities that were revealed in our research and to adjust for those disparities in order to allow fair comparisons among contracts. The CAI is determined using the data from the Star Ratings program. Instead of a one-size fits-all approach to address the impact of the socioeconomic factors on the Star Ratings, the CAI allows a tailored approach by the categorization of a contract into final adjustment category that is based on the percentage of LIS/DE and disabled beneficiaries enrolled in a contract. In addition, the CAI values are a series of values based on the rating-type (overall, Part C summary, Part D summary). Further, the CAI values for the Part D summary ratings are contract-type specific and a different set of values are developed for MA–PDs and PDPs.

CMS remains committed to our fundamental principles, which includes incentivizing contracts to provide the best quality of care to all of their enrollees and providing accurate information to beneficiaries to allow comparisons among contracts for plan choice. A hold harmless provision for the CAI that specifically targets contracts with limited LIS/DE populations or contracts that would realize a negative impact does not align with the underlying principles of the Star Ratings program or the fundamental design principles of the CAI. Such a provision could have the unintended consequence of limiting quality improvement and innovation for the care of the LIS/DE/disabled population, as well as distort the signal of the Star Ratings.

Comment: Several commenters were critical of codifying an interim response and expressed concern that it would impede a long-term response.

Response: CMS's goal is to develop a long-term solution that addresses the LIS/DE/disabled effect revealed in our research. Any response, long- or short-term, must align with our policy and program goals. CMS is confident that we can maintain our agility and responsiveness even when codifying the interim solution. The use of the CAI as an interim response affords CMS the time to carefully consider each potential solution, to continue our collaboration with stakeholders, to incorporate the findings of the research community, and to include the anticipated recommendations in ASPE's second Report to Congress that will be released in 2019.

Comment: Some commenters encouraged the continued collaboration with ASPE and measure developers.

Response: CMS remains firmly committed to our continued research and collaboration with our stakeholders including researchers, industry, measure stewards, and other governmental agencies. The development of a long-term solution that best addresses any sensitivity of the Star Ratings to the beneficiaries enrolled in MA and PDP contracts is only possible through continued collaboration and feedback from our stakeholders.

Comment: Some commenters believe that the CAI is an insufficient adjustment and advocated for a larger adjustment. Further, some of the commenters justified a larger adjustment due to the higher costs associated with caring for traditionally underserved vulnerable populations. A few of the commenters suggested the use of an equity bonus, as suggested in ASPE's first Report to Congress, to address the additional costs for serving traditionally underserved populations.

Response: CMS believes that any policy response must delineate the two distinct aspects of the LIS/DE or disability issue—quality and payment. The Star Ratings program focuses on accurately measuring the quality of care provided, so any response must focus on enhancing the ability to measure actual quality differences among contracts. To address the LIS/DE and disability issue CMS must accurately address any sensitivity of the ratings to the composition of the beneficiaries enrolled in a contract at the basic

building block of the rating system, the measure. CMS believes the CAI addresses the quality measurement aspect of the issue at hand. In addition, CMS has encouraged the measure stewards to examine our findings and undertake an independent evaluation of the measures' specifications to determine if measure re-specification is warranted. Additionally, the payment response which is not the focus of this regulation focuses on payment accuracy for beneficiaries with different dual statuses, differentiated by aged or disabled status, by improving the predictive performance of the CMS–HCC risk-adjustment model to take into account the unique cost patterns of each of these subgroups of beneficiaries.

Comment: Some commenters suggested adjusting for both within- and between-contract differences. The commenters referenced one of the two findings in ASPE's Report to Congress that found differences in plan performance between contracts serving primarily LIS/DE and disabled populations and those who do not even after adjusting for patient-mix.

Response: As summarized in the NPRM, CMS's focus on within-contract disparities for the development of the CAI aligns with the recommendations of the research community including the National Quality Forum (NQF), MedPAC, and ASPE. CMS conducted an in-depth examination of the possible sensitivity of the Star Ratings to the composition of a contract's enrollees using a multi-faceted, comprehensive approach. One analysis permitted the estimation of within-contract differences associated with LIS/DE or disability to quantify the LIS/DE/disabled effect. Within-contract differences are differences that may exist between subgroups of enrollees in the same contract (for example, if LIS/DE enrollees within a contract have a different mean or average performance on a measure than non-LIS/DE enrollees in the same contract). These differences may be favorable or unfavorable for LIS/DE and/or disabled beneficiaries. Between-contract differences in performance associated with LIS/DE or disability status (''between-contract LIS/DE and/or disability disparities'') are the possible additional differences in performance between contracts associated with the contract's proportion of LIS/DE and disabled enrollees that remain after accounting for within-contract disparities by LIS/DE and disability status. If LIS/DE or disabled beneficiaries are more or less likely than other beneficiaries to be enrolled in lower-quality contracts, then between-contract disparities may represent true differences between contracts in quality. Because of this possibility, we are concerned that adjustment of between-contract disparities could mask true differences in quality.

Adjusting for within-contract disparities is an approach aligned with the consensus reflected in the NQF report on sociodemographic adjustment, which states that, ''. . . *only the within-unit effects are adjusted for in a risk adjustment procedure because these are the ones that are related specifically to patient characteristics rather than differences across units*'' (National Quality Forum, 2014). Our research focused on measuring within-contract differences in performance for LIS/DE and/or disabled compared to non-LIS/DE and non-disabled beneficiaries.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act, Pub. L. 113–185) instructs the Office of the Assistant Secretary for Planning and Evaluation (ASPE) to conduct a study that examines the effect of individuals' SES on quality measures, resource use, and other measures for individuals under the Medicare program. Because ASPE's research agenda aligns closely with our goals, we have worked and continue to work collaboratively with ASPE and other governmental agencies to broaden and expand the focus of the issue. In December, 2016 ASPE released its findings to Congress using readily available data which includes data from the Star Ratings program. In it, ASPE supported the use of the CAI in the Star Ratings program including our focus on the within-contract disparities.

ASPE will release a second Report to Congress in the fall of 2019 that will focus on the impact of SES on quality and resource use in Medicare using measures (for example, education and health literacy) from other data sources. Once the report is released, CMS will carefully review the report and all recommendations contained within it.

Comment: A commenter specifically offered to collaborate with CMS.

Response: CMS appreciates the willingness, support, and dedication of our stakeholders to improve the health of our beneficiaries. We value the feedback and suggestions provided by our stakeholders. Comments and suggestions are welcome throughout the year. Outside of formal comments periods, stakeholders can contact us via email at the following address: *PartCandDStarRatings@cms.hhs.gov.*

Comment: A commenter suggested comparison of like plans for adjustment specifically comparing Dual-Special Needs Plans (D–SNPs) to D–SNPs. The commenter believed this would allow an apples-to-apples comparison in regards to performance reimbursement.

Response: The CAI adjusts for the average within-contract disparities across all contracts required to report using the adjusted measures set as the basis of the adjustment. Contracts, including D–SNPs, are categorized based on their percentages of LIS/DE and disabled beneficiaries. The adjustment is designed to be monotonic, or in other words, contracts with higher percentages of LIS/DE or disabled beneficiaries will realize a larger adjustment. While the CAI does not compare D–SNPs to D–SNPs, the adjustment does account for the higher percentages of LIS/DE and disabled beneficiaries in a contract by categorizing the contracts in the higher final adjustment categories and thus, the categories with the higher adjustments.

The CAI is designed to address the sensitivity of the Star Ratings to the composition of the enrollees in a contract. The Star Ratings are designed for quality measurement and not for payment purposes. The design and development of the CAI was done to address measurement and not payment.

Comment: A commenter suggested increasing the adjustment for the two highest adjustment categories) in order to have a more significant impact on the overall Star Rating The commenter believed the underlying efforts are significantly different for contracts with high percentages of LIS/DE/disabled enrollees. Further, the commenter believed there are administrative challenges and higher costs associated with promoting beneficiary compliance in servicing vulnerable populations.

Response: The use of a consistent methodology and a data-driven approach precludes the possibility of an increase in the adjustment in a subset of the final adjustment categories. The CAI is designed from a quality measurement perspective and not payment. (The CAI methodology is detailed in the CAI Supplement available at *http://go.cms.gov/partcanddstarratings.*)

Comment: A commenter recommended enhancing the categorization of contracts specifically noting that the number of initial categories for MA–PDs increased from 50 to 60 categories when comparing the 2017 to 2018 CAI, but the number of initial categories for PDPs categories remained at 16 categories.

Response: The number of groups in each dimension (LIS/DE and disabled) are determined after reviewing each of the distributions using the percentages of LIS/DE and disabled across all contracts (MAs and PDPs are examined

separately) using the applicable data. The MA LIS/DE distribution for the 2018 CAI had shifted slightly as compared to the data for the 2017 CAI development, so the decision was made to increase the number of initial groups for the LIS/DE dimension and maintain the same number of groups for the disabled dimension. The number of initial categories for the 2018 CAI values was increased from 50 (10 LIS/DE groups and 5 groups for disability) to 60 (12 LIS/DE groups and 5 groups for disability). The use of additional initial categories in 2018 did not significantly impact the number of final adjustment categories (FAC) since the collapsing of the initial categories is done to maintain monotonicity and maintain a minimum number of contracts per FAC, while striving for a minimum differential between the FACs. After examining the distributions for PDPs, the use of the same number of initial groups for each dimensions was determined to be appropriate. Additional initial categories do not enhance or refine the final adjustment categories, but rather can cause instability in the CAI values.

Comment: A few commenters suggested stratifying all measures by LIS/DE and disabled status.

Response: At this time, the National Committee for Quality Assurance (NCQA) [68] and the Pharmacy Quality Alliance (PQA) [69] have recommended stratification for a subset of their measures that are used in the Star Ratings program. CMS is waiting for ASPE to complete their research under the IMPACT Act before developing an Agency-coordinated approach to the display of measures.

Comment: A commenter suggested the creation of a structural measure that reflects the support for LIS/DE and disabled beneficiaries provided by a contract.

Response: CMS appreciates the suggestion. CMS is currently examining the feasibility of a health equity measure that could be potentially proposed in the future.

Comment: A few commenters recommended that CMS proceed with caution, citing concerns with creating a double-standard or tiered system, or masking disparities. A commenter expressed strong support of CMS in seeking to utilize the Star Rating system to encourage continuous quality improvement in the MA and Prescription Drug programs, providing oversight to ensure accuracy and transparency, and not accepting any changes to performance measurement that would lead to masking disparities and harming disadvantaged patients. Another commenter recommended that CMS monitor how adjustments to the Star Ratings affect the quality of care received by LIS/DE and disabled enrollees.

Response: CMS is committed to making informed decisions based on thoughtful and careful consideration of any unintended consequences of a particular approach. CMS has focused on the within-contract disparities, because we do not want to mask true differences in quality across contracts. CMS is transparent in the development process and seeks the input of our stakeholders, HHS partners, and other government agencies. CMS thoroughly examines any proposed modification using a comprehensive approach which commonly includes multiple rounds of simulations. Further, CMS strives to identify any potential unintended consequences of any possible change and to develop strategies to mitigate any potential risks to the integrity of the Star Ratings system. Upon implementation, CMS maintains vigilance in its review and monitoring of the change to ensure that the policy goals that prompted the modification have been met.

Comment: Several commenters suggested working with measure developers.

Response: CMS has been working closely with the measure developers for the measures used in the Star Ratings program and will continue to do so.

Comment: A commenter suggested that CMS set minimum standards for measure developers that include testing and considerations for adjustments. Further, the commenter believes that the research should be made public to align with the goal of transparency.

Response: While CMS does collaborate with the measure developers of the measures used in the Star Ratings program, they remain independent entities that are the stewards and shepherds of their own measures. Both National Committee for Quality Assurance (NCQA) and Pharmacy Quality Alliance (PQA) have well-defined processes in place for revising or updating their measures. Public comment is solicited during their review process, as well as feedback from their many stakeholders including the medical community.

Comment: A commenter inquired about the future use of the stratified measures proposed by PQA and NCQA.

Response: Both NCQA and PQA will be modifying the measure specifications for a subset of their measures that are used in the Star Ratings program and will require stratified reporting. A summary of the NCQA analysis and recommendations can be accessed at: *http://www.ncqa.org/hedis-quality-measurement/research/hedis-and-the-impact-act.* A summary of the modification of the PQA measures can be accessed at: SDS Risk Adjustment PQA PDC CMS Part D Stars. CMS will be reviewing the data submitted as a result of these changes in the measure specifications which impacts the measures' reporting requirements. CMS will be developing a proposal for the use of the revised data through future rulemaking.

Comment: A commenter supported an additional adjustment for all plans serving vulnerable populations outside of the CAI.

Response: At this time, CMS' response to the LIS/DE/disabled effect is the CAI. As our research and that of our stakeholders, government agencies, and measure developers evolves, CMS will be developing a long-term response and will take the commenters' recommendations into account as part of that.

Comment: Some commenters suggested incorporating other factors that are well-known as predictors of medication adherence and other Star Rating quality outcomes.

Response: CMS continues to conduct research on the underlying factors driving the LIS/DE/disability effect. In addition, CMS has been working closely with the measure developers for the measures used in the Star Ratings program. Further, we continue to collaborate with stakeholders and other governmental agencies including ASPE. ASPE will release a second Report to Congress in the fall of 2019 that will focus on the impact of SES on quality and resource use in Medicare using measures (for example, education and health literacy) from other data sources.

Comment: Some commenters stated that geographic and unique characteristics that could affect Star Ratings performance should also be assessed and addressed.

Response: CMS continues to conduct research on the underlying factors driving the LIS/DE/disability effect. CMS has examined the sociodemographic correlates with a subset of the HEDIS measures used in the Star Ratings program. CMS is committed to identifying the cause of any sensitivity of the Star Ratings to the composition of enrollees in a contract. CMS continues to examine geographic variation, as well as unique attributes of both beneficiaries and contracts that

[68] A summary of the NCQA analysis and recommendations can be accessed at: *http://www.ncqa.org/hedis-quality-measurement/research/hedis-and-the-impact-act.*

[69] The PQA summary can be accessed at: SDS Risk Adjustment PQA PDC CMS Part D Stars.

may play a role in the disparity in performance among subpopulations.

Comment: A commenter took the opportunity to note that, as the Agency moves forward with developing a Quality Rating System (QRS) for Medicaid managed care organizations, many of the considerations that apply to the Medicare Star Ratings program will likely have implications for, and interactions with, this new Medicaid QRS.

Response: Although this comment is outside the scope of this rule, we note that the MA Star Ratings Team is engaged with the team leading the development of the QRS for Medicaid.

Comment: Some commenters encouraged CMS to explore adjusting for social risk factors at the measure-level or for the overall Star Rating System. A commenter specifically recommended that at minimum, age and gender should be used for adjusting all measures in the Star Ratings program.

Response: A measure specification details the adjustments for a measure. Only a measure steward may make revisions to the measure specification. CMS continues to engage in conversation with the measure stewards of the Star Ratings measures.

CMS is continuing research and collaboration with our stakeholders to develop a long-term response to the sensitivity of the Star Ratings to the composition of enrollees in a contract.

Comment: A commenter requested additional detail regarding the selection of the Medication Adherence for Hypertension for adjustment in the MA–PD and PDP contracts while not providing an adjustment on the other two medication adherence measures.

Response: As discussed in the proposed rule, CMS initially developed and used two sets of rules to determine the adjusted measure set: First, the rules to determine the measures that comprise the candidate measure set for adjustment and second, the rules applied to the candidate set to identify the measures to be adjusted to determine the values of the CAI. The second set of rules relied on the analysis of the variability of the within-contract differences of LIS/DE and non-LIS/DE beneficiaries.

After thoughtful and careful deliberation of the recommendations of our stakeholders, CMS will modify the selection rules for identifying the adjusted measures by eliminating the second set of rules for determining the adjusted measure set. The 2021 CAI values will be determined using all measures in the candidate measure set for adjustment, thus eliminating the second set of selection rules. A measure will be adjusted if it remains after applying the exclusions as follows: The measure is 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).

For the 2021 Star Ratings program, all three medication adherence measures will be designated as an adjusted measure for the determination of the CAI.

Comment: A commenter expressed support of the additional adjustment for contracts operating in Puerto Rico.

Response: CMS appreciates the positive feedback regarding the additional adjustment for contracts that operate solely in Puerto Rico. CMS believes the adjustment allows for an equitable application of the CAI for the subset of contracts for which it applies.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized above, we are finalizing the provisions as proposed at §§ 422.166(f)(2) and 423.186(f)(2) with modifications to §§ 422.166(f)(2)(iii) and 423.186(f)(2)(iii). The 2021 CAI values will be determined using all measures in the candidate measure set for adjustment. A measure will be adjusted if it remains after applying the exclusions as follows: The measure is 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).

u. High and Low Performing Icons

We proposed regulation text to govern assignment of high and low performing icons at §§ 422.166(h)(1) and 423.186(h)(1). We proposed to continue current policy that a contract receives a high performing icon as a result of its performance on the Part C and D measures. The high performing icon is 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 proposed that 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 will 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 will 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 were proposed for codification at §§ 422.166(h)(1)(i) and (ii)(A) and 423.186(h)(1)(i) and (ii)(A).

We also proposed, at paragraph (h)(1)(ii)(B), 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) would be warned, via explanatory messaging of the plan's poorly-rated performance, and directed to contact the plan directly to enroll.

We received the following comments to our proposal and our responses follow:

Comment: Commenters overwhelmingly expressed support for the icons, as well as our policy of disabling the online enrollment option for contracts with the low-performing icon. A commenter suggested requiring 3 years of high performance to qualify for a high-performing icon, and another commenter suggested CMS include a full explanation for beneficiaries when the low-performing icon is assigned.

Response: We appreciate this support and the suggestions made. We will take them under consideration.

Comment: We received one comment requesting that CMS create a separate icon to provide beneficiaries with information about a contract's audit performance.

Response: CMS does note on Medicare Plan Finder when contracts are under sanction. We appreciate this suggestion to share additional information regarding contract audit scores and Civil Money Penalties on Plan Finder.

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the provisions for high and low performing icons and enrollment process limitations as proposed at §§ 422.166(h)(1) and 423.186(h)(1) without modification.

v. Plan Preview of Star Ratings

We proposed in §§ 422.166(h)(2) and 423.186(h)(2) 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. We currently use two preview periods. 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 includes 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 are 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. We proposed that CMS continue to offer plan preview periods before each Star Ratings release (meaning the display in the MPF), but to not codify the details of each period because over time the process has evolved to provide more data to sponsors to help validate their data. We explained in the proposed rule that we envision the plan preview periods to continue to evolve in the future and do not believe that codifying specific display content is necessary.

We also emphasized in the proposed rule how 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 has traditionally been and will in the future 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 received the following comments on our proposal and our responses follow:

Comment: Several commenters expressed support for the continuation of plan preview periods. One specifically mentioned agreeing with CMS' decision not to codify the details at this time.

Response: CMS appreciates this support.

Comment: Several commenters acknowledged the importance of reviewing their data throughout the year. A commenter suggested that CMS release Star Ratings for marketing purposes by August 15 each year; another suggested that preview periods be at least four weeks long. Several commenters also suggested additional data they believed would be helpful for CMS to provide during plan previews. For example, a few specifically requested that CMS release improvement measure calculation worksheets for all contracts during the preview. Another commenter requested more timely and frequent drug list and PDE edit updates to ensure reporting accuracy, as well as additional reporting on adherence measures.

Response: CMS strives to allow plans as much time as possible to preview their data but there are operational constraints that limit how soon Star Ratings can be made available for plan preview. The data time frame for several measures currently runs through June of each year, and CMS does not receive all of the data until the end of July. The first plan preview currently starts in early August, the second plan preview starts in September, and the public release on MPF is in October. In between plan preview periods CMS must make any necessary corrections to the data, so four-week preview periods are not feasible operationally. Many datasets and reports are available for ongoing monitoring purposes prior to Star Rating plan previews. We urge Part C and D sponsors to regularly review their underlying measure data that are the basis for the Part C and D Star Ratings and immediately alert CMS if errors or anomalies are identified so any issues can be resolved prior to the first plan preview period. For measures that are based on data reported directly from sponsors, any issues or problems can and should be raised well in advance of CMS's plan preview periods.

CMS appreciates comments received about additional data that could be provided during previews. The improvement calculation emulation worksheets are available to sponsoring organizations to preview their own improvement scores per contract during the second plan preview; these can be requested by contacting *PartCandDStarRatings@cms.hhs.gov*.

We note the NDC files are updated three times for a given measurement year's PDEs. For 2018 PDEs, the PQA, as custodian of a measure, publishes the NDC lists in both February and July 2018, and again in February 2019 allowing sponsors multiple opportunities to identify missing NDCs/drugs prior to the release of the April 2019 report that includes all 2018 to-date processed PDEs and the first Star Ratings plan preview in August/early September 2019. Furthermore, the PQA's NDC update schedule does not preclude a Part D sponsor from internally updating its NDC list more frequently, monitoring its performance and implementing timely interventions including those that could occur at the point-of-sale. We believe this implementation timeframe is reasonable and appropriate, and defer to the measure custodian for revisions.

For several Patient Safety measures CMS provides each Part D contract a file containing their beneficiary-level adjusted and unadjusted rates that can be used by the contract to independently test their internal reporting processes and assess the impact of adjustment factors. In particular, the adherence measure report provides up to 70,000 beneficiary enrollment episodes (including begin and end dates) where the beneficiary was not adherent, along with the adjusted and unadjusted numerator and denominator days used in the beneficiary's PDC calculations. The size of the adherence beneficiary sample should be sufficient to perform the PDC calculation to address systematic issues as requested.

Comment: Several commenters suggested that CMS post national Star Ratings data during the plan preview period.

Response: The purpose of the plan previews is for sponsors to review and raise any questions about their own plan's data prior to the public release of data for all plans on *Medicare.gov*. This allows for any necessary corrections to be made prior to the Star Ratings data being public. Releasing national Star Ratings data (meaning data about other plans' ratings) would not serve this purpose. Further, to the extent that errors are identified and changes need to be made to data, it would mean that updates to the national data render earlier release inaccurate and less useful.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized above, we are finalizing the provisions for plan previews as proposed at §§ 422.166(h)(2) and 423.186(h)(2) without modification.

w. Technical Changes

We also proposed a number of technical changes to other existing regulations that refer to the quality ratings of MA and Part D plans; we proposed to make technical changes to refer to the proposed new regulation text that provides for the calculation and assignment of Star Ratings. Specifically, we proposed:

- In § 422.258(d)(7), to revise paragraph (d)(7) to specify that beginning with 2012, the blended benchmark under paragraphs (a) and (b) 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) must be increased according to criteria in paragraphs (d)(7)(i) through (v) 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 specify that 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 and that 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 mean 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 state 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 state maintain a Part D summary plan rating score of at least 3 stars pursuant to the 5-star rating system specified in part 423 subpart D. A Part D summary plan rating is calculated as provided in § 423.186.

We welcomed 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.

We did not receive any comments on the proposed technical changes and therefore are finalizing them. However, we noted in our review that in several of these technical corrections, the text mistakenly referred to ''subpart 166'' or ''subpart 186'' which is incorrect. The quality rating system regulations are finalized in subpart D of part 422 and part 423, so we are finalizing these technical changes with the correct reference to ''subpart D''.

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 proposed rule, we intended to clarify that the any willing pharmacy requirement applies to all pharmacies, regardless of how they have organized one or more functional lines of pharmacy business. Second, we proposed to revise the definition of retail pharmacy and define mail-order pharmacy. Third, we proposed to clarify our regulatory requirements for what constitutes ''reasonable and relevant'' standard contract terms and conditions. Finally, we proposed 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.

We received the following comments and our response follows:

Comment: A large number of Part D enrollees expressed appreciation for our series of any willing pharmacy proposals, while other commenters expressed concerns with our preamble discussion because they believed that CMS was considering eliminating or otherwise changing the ability for Part D plan sponsors to develop and maintain preferred pharmacy networks. Some commenters contended that Part D enrollees are able to exercise freedom of choice without any willing pharmacy mandates, and that preferred pharmacy networks are popular among beneficiaries. A number of other independent pharmacies requested that we consider extending any willing pharmacy provisions to preferred pharmacy networks in future rulemaking, and several Part D plan sponsors thanked us for recognizing that we should not limit the ability of Part D plan sponsors to develop and maintain preferred pharmacy networks.

Response: We believe that the commenters who thought our proposal was intended to restrict Part D plan sponsors' ability to have preferred pharmacy networks misunderstood the proposal. The proposed rule's discussion of any willing pharmacy standard terms and conditions requirements, proposed definitions of retail and mail-order pharmacies, and accreditation requirements in standard terms and conditions were not intended to limit Part D plan sponsors' ability to develop and maintain preferred pharmacy networks. On the contrary, we explicitly stated in the proposed rule that we were attempting to ensure that Part D plan sponsors could continue to develop and maintain preferred networks while complying with the any willing pharmacy requirement, which applies to standard terms and conditions.

Comment: Some commenters asked us to abandon the any willing pharmacy construct within the Part D program. A commenter pointed out that the any willing pharmacy provision would require Part D plan sponsors to contract with any pharmacy who agrees to meet the terms and conditions of the organization, whether or not the pharmacy's participation in the network is necessary for the Part D plan sponsor to satisfy geographic access needs. This commenter contended that the any willing pharmacy provision is unnecessary because sponsors are already motivated to provide access to a broad number of pharmacies because Part D enrollees select a health or prescription drug plan based on its ability to provide broad access by having pharmacy networks in place across many geographic areas. Other commenters stated that CMS' proposal only addressed pharmacy complaints and was unnecessary because the proposed rule provided nothing to suggest that Part D enrollees were dissatisfied with how Part D plan sponsors develop and maintain their contracted pharmacy networks. Other commenters believed that our any

willing pharmacy proposals violate the spirit of the non-interference clause at § 1860D–11(i) of the Act. Additionally, a number of pharmacies submitted comments that Part D plan sponsors offer reimbursement rates below acquisition costs, that CMS should codify its sub-regulatory guidance regarding unreasonably low reimbursement rates as a means to subvert the convenient access standards, or that the extended definition of reasonable and relevant should prevent financial terms and conditions that result in a negotiated reimbursement rate, that, inclusive of payment and adjustment, results in a loss to the provider, as such a term that would not be ''reasonable.''

Response: The any willing pharmacy requirement is statutory and CMS does not have the discretion to abandon it. CMS has already established through rulemaking that Part D plan sponsors must contract with any pharmacy that meets the Part D plan sponsor's standard terms and conditions for network participation (§ 423.120(a)(8)(i)) and offer 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 (§ 423.505(b)(18)). It is within our authority and appropriate for CMS to provide additional clarification of these regulatory requirements when necessary to help ensure they are being effectuated in accordance with the statutory requirement. While we did not propose to further specify ''reasonable and relevant'' standard terms and conditions in this rulemaking, and generally would prefer not to do so for the reason we have provided in prior rulemaking (that is, to provide plans with maximum flexibility to structure standard terms and conditions) (see 70 FR 4254), we will consider it in the future if we find that our current requirements are no longer sufficient to implement the statutory any willing pharmacy requirement as a result of the changing pharmaceutical distribution marketplace.

Additionally, the non-interference clause at section 1860D–11(i) of the Act does not prohibit us from establishing or clarifying regulatory requirements to implement the any willing pharmacy requirement. Since the inception of the Part D program, consistent with the non-interference clause, CMS has declined to intervene in negotiations or disputes involving payment-related contractual terms. However, within the limits of our authority, we also have a duty to implement and enforce other statutory requirements to promote competition and have pursued goals such as increasing the transparency of prices and minimizing barriers to entry to the extent possible while still ensuring quality. Accordingly, CMS has always interpreted the any willing pharmacy requirement to require Part D sponsors to offer reasonable and relevant contract terms and conditions to minimize barriers to pharmacy network participation and we maintain that requirement in this rule. Our clarifications are intended to ensure that such contract terms and conditions offered by Part D sponsors remain reasonable and relevant in light of the changes and innovations in pharmacy practice and business models since the beginning of the Part D program.

Finally, the proposed rule explicitly addressed the any willing pharmacy requirement in relationship to complaints received from Part D enrollees (such as, confusion concerning Part D enrollee cost-sharing expectations). Further, although we believe they misunderstood our proposal, many of the Part D enrollees that commented on our proposed rule specifically communicated their dislike of preferred pharmacy networks.

We believe our clarifications on application of the statutory any willing pharmacy requirement, address Part D enrollee and marketplace confusion, maintain Part D plan sponsor flexibility, and address recent innovations pharmacy business and care delivery models.

Comment: Several commenters expressed concern that our proposals would lead to more fraud, waste, and abuse in the Part D program. A commenter provided two examples of fraud, waste, and abuse that resulted in both pharmacies being terminated and prohibited from reapplying to be a contracted network pharmacy. Another commenter expressed concerns that they encountered fraudulent claims in situations where Part D enrollees received prescriptions by mail that they never requested from a pharmacy in another state and from a provider in yet another state. A commenter suggested that CMS should allow Part D plan sponsors to suspend claims when fraud is suspected.

Response: While we thank the commenters for their views, we fail to see how our clarifications would have any impact on Part D plan sponsors' abilities to combat fraud, waste, and abuse. Part D plan sponsors are required at § 423.504(b)(4)(vi) to take appropriate steps to combat fraud, waste, and abuse, and such terms and conditions are in no way prohibited, so long as they are reasonable and relevant. That is, should a pharmacy violate the relevant terms and conditions, or have a history of doing so, a Part D plan sponsor would have no obligation to contract with the pharmacy under the any willing pharmacy requirement.

Comment: Some commenters suggested that CMS should explore policy options to encourage Part D plan sponsors to offer medically complex patients reduced/zero cost sharing when utilizing high-touch pharmacy models to support both patient-centered care and the goals of Medication Therapy Management.

Response: We thank the commenters, however these comments are beyond the scope of this rule.

a. Any Willing Pharmacy Required for All Pharmacy Business Models

With the pharmaceutical distribution and pharmacy practice landscape evolving rapidly, and because pharmacies' business and service delivery models now frequently perform multiple pharmacy practice functions, 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 specialty drugs. 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. In the original rule that implemented the Part D program (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 received a number of complaints 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. Therefore, we clarified in the preamble to the proposed rule that, although Part D plan sponsors may continue to tailor their standard terms and conditions for 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 Part D plan sponsor's pharmacy type classification.

We received the following comments and our response follows:

Comment: A commenter contended that CMS is reading ''that meets the terms and conditions under the plan'' out of the statute.

Response: We take this comment to mean that commenter believes that we are reading ''A prescription drug plan shall permit the participation of any pharmacy'' at section 1860D–4(b)(1)(A) of the Act to the exclusion of ''that meets the terms and conditions under the plan'' in the same paragraph. We disagree. We are concerned that such an interpretation conflates a Part D plan sponsor's ability to develop and maintain preferred pharmacy networks *with* the any willing pharmacy provision, thereby effectively nullifying the any willing pharmacy provision. The ''reasonable and relevant'' requirement strikes the right balance in the inherent tension between the statutory any willing pharmacy and preferred pharmacy network provisions. We believe it is necessary to require terms and conditions to be reasonable and relevant to avoid subverting the any willing pharmacy requirement entirely. Consequently, CMS requires the standard terms and conditions under the plan to be reasonable and relevant.

In order to be reasonable and relevant, such terms and conditions must pertain to the pharmacy's business and services as allowed under its license(s). While traditionally such terms and conditions could easily be established based upon classification as a retail or mail-order pharmacy, our intent is to illustrate that those traditional labels likely do not sufficiently encompass today's evolving pharmacy practice. Pharmacies complained to us that they had been excluded from network participation, not because they were unwilling or unable to meet the standard contracting terms and conditions, but because their business and service delivery models represented hybrids that did not squarely meet any of the definitions by which Part D plan sponsors typically classify pharmacies. Again, CMS is not prescribing what the terms and conditions have to be; we were only clarifying that they must actually be reasonable and relevant to those functions performed, and not theoretically reasonable and relevant based upon outdated pharmacy classifications that do not accurately reflect today's pharmacy business model(s) and practices.

Comment: Some commenters contended that our proposal effectively classifies all pharmacies as similarly situated and would require Part D plan sponsors to require a single standard contract for all pharmacies, regardless of their business models or type of classification. We received comments from several pharmacies with innovative pharmacy practice models, including one that possesses elements of mail-order, retail, and long term care but doesn't squarely meet any one of those definitions.

Response: We disagree. We explicitly stated in our proposed rule and reiterate here that Part D plan sponsors may continue to tailor their standard terms and conditions to various types of pharmacies. We also said that pharmacies whose pharmacy practice business and service delivery model crosses multiple functions would be considered to be similarly situated for each of the pharmacy types they represent. By referring to pharmacy types, we mean the types of services provided by the pharmacy. While some pharmacies may still offer exclusively one type of service, an increasing number of pharmacies are offering innovative and multiple types of services that do not fit within the traditional pharmacy classifications. Consequently, we are merely stating that Part D plan sponsors need to offer standard terms and conditions that are reasonable and relevant for the types of services being provided by the pharmacy, which could be accomplished via multiple contracts or addenda that are specific to types of services. For example, a pharmacy that predominantly provides retail services but also provides mail services would presumably be offered terms and conditions that are reasonable and relevant to both types of services. It is up to Part D plan sponsors to determine if this is best accomplished with multiple contracts based upon service type, addenda to a single contract, or another type of contract that accommodates unique and innovate pharmacy practice business and care delivery models.

Comment: Some commenters suggested that best practice requires pharmacies that perform multiple functions to maintain and use a unique National Provider Identifier (NPI)/National Council for Prescription Drug Programs (NCPDP) identification number for each designation/function. Other commenters added that the NCPDP telecommunication standards named under HIPAA for pharmacy claim submission allow the pharmacy to indicate the appropriate pharmacy service type at a claim level, thus enabling the Part D plan sponsor to determine under which network the claim is processed for reimbursement and allows pharmacies to be held accountable at a claim level to the threshold associated with that designation. A commenter suggested that our proposed changes would require modification of NCPDP standards, which is a time intensive process.

Response: CMS thanks the commenters for their perspective. Because telecommunications standards accommodate a retail pharmacy service type which pharmacies could continue to use, we do not believe our any willing pharmacy clarifications will require changes to NCPDP standards. The industry, through NCPDP, could redefine the retail pharmacy service type. Nevertheless, claims processing should not be impacted.

Comment: A number of pharmacies commented that Part D plan sponsors or PBMs only make standard terms and conditions for a retail network available to pharmacies that express interest in network participation and do not advertise the existence of any other ''type'' of network.

Response: Part D plan sponsors must provide the standard terms and conditions that are requested by the pharmacy. While pharmacies may request any standard terms and conditions offered by the Part D plan sponsor, it is incumbent upon the pharmacy to request terms and conditions that are applicable to the business model(s) and types of services the pharmacy provides so that the terms and conditions offered are reasonable and relevant. The pharmacy cannot expect to receive reasonable and relevant terms and conditions if the Part D plan sponsor is not made aware of different types of services the pharmacy seeking network participation provides.

Comment: Several commenters agreed that declining a pharmacy's request for network participation exclusively on the basis of its multiple pharmacy service offerings is inappropriate, and that Part D plan sponsors should be permitted to grant applying pharmacies entry into the network for services based on the

pharmacy's ability to comply with the terms and conditions specific to each service model individually. Commenters urged us to clarify that nothing precludes a Part D plan sponsor from structuring standard terms and conditions addressing a particular pharmacy practice model or models and applying those terms and conditions to pharmacies providing multiple pharmacy services. Other commenters urged us to clarify whether CMS is stating that a pharmacy can participate under multiple contracts with a Part D plan sponsor and/or whether a pharmacy can choose which terms and conditions under which it wants to participate with that Part D plan sponsor. Additionally, other commenters urged us to clarify whether Part D plan sponsors should develop standard terms and conditions applicable to unique and innovative pharmacy business models as they arise, or, if they should engage in individual negotiations to determine mutually acceptable reasonable and relevant terms with such pharmacies. Another commenter suggested CMS should acknowledge that contractual terms and conditions that do not directly address unique pharmacy and business and service models would likely not be reasonable and relevant. Finally, another commented asked, if pharmacies are counted in multiple categories, what is the impact on inclusion in access standards?

Response: We thank the commenters for their support and for requesting these clarifications. We have recognized since our January 2005 final rule that pharmacies may have multiple functional lines of business, including retail pharmacies that may offer home delivery services (see 70 FR 4235 and 4255). Additionally, existing operational guidance states ''[Part D] Plan sponsors may submit data for pharmacies that serve multiple roles as retail or mail order and LTC, HI, or LA pharmacies'' (see our Pricing Data Requirements and Submission Calendar guidance, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html*). To the extent a pharmacy serves multiple roles, that pharmacy may be counted toward multiple access standards.

We agree with the commenters' assessments of our intent. While Part D plan sponsors should develop standard terms and conditions applicable to unique and innovative pharmacy business models, we can envision circumstances where individual negotiations to determine mutually acceptable reasonable and relevant terms with such pharmacies could also apply. Later in this section of this final rule, we discuss in greater detail situations where individual negotiations may be appropriate. For example, if a pharmacy offers retail and home infusion services, the Part D plan sponsor must offer that pharmacy its standard terms and conditions for both the retail and home infusion pharmacy functions. If the pharmacy is able to agree to and demonstrate compliance with the Part D plan sponsor's standard retail terms and conditions, but not the Part D plan sponsor's standard home infusion terms and conditions, the pharmacy should be granted access to the Part D plan sponsor's contracted retail pharmacy network, and not the Part D plan sponsor's contracted home infusion network (until such time that the pharmacy is willing and able to comply with the Part D plan sponsor's standard home infusion terms and conditions). When the pharmacy is willing and able to comply with both the Part D plan sponsor's retail and home infusion terms and conditions, that pharmacy may be counted for purposes of both retail convenient access standards and home infusion network adequacy standards.

As discussed previously, Part D plan sponsors must provide standard terms and conditions that are applicable to the pharmacy requesting the terms and conditions. Conversely, we would not expect Part D plan sponsors to provide standard terms and conditions that are not applicable to the pharmacy requesting the terms and conditions. We agree with the commenter that standard contracting terms and conditions that do not directly address unique pharmacy and business and service models would likely not be reasonable and relevant.

Comment: A number of commenters urged CMS to routinely review Part D plan sponsors' terms and conditions and require complete transparency as to what constitutes ''reasonable and relevant'' by disclosing standard contracting terms and conditions to the public. Other commenters urged that CMS should create an independent audit and review process, perhaps by a third party, by which a pharmacy can challenge and/or appeal specific standard terms and conditions that it believes do not meet the any willing pharmacy reasonable and relevant standard. Another commenter recommended that CMS should allow Part D plan sponsors the flexibility to develop standard terms and conditions as they deem appropriate, but require them to submit a justification for reasonableness and relevance.

Response: We did not propose the changes that the commenters recommend, and for reasons noted elsewhere in this preamble, we decline to adopt them now. However, we reserve the right to review all contracting terms and conditions and investigate complaints regarding compliance with our rules.

b. Revise the Definition of Retail Pharmacy and Add a Definition of Mail-Order Pharmacy

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 provision, as codified at § 423.120(a)(1)–(7), requires 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 benefits (which may include a 90-day supply of drugs or biologicals), including extended days' supplies, through a pharmacy (*other than* a mail-order 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 in that rule that ''home infusion pharmacies will not count toward Part D plans' pharmacy access requirements (at § 423.120(a)(1)) because they are not retail pharmacies'' and assumed most specialty pharmacies to be a specialized subset of home infusion pharmacies, such that access to specialty pharmacies that did not provide home infusion services could be adequately addressed by out-of-network rules at § 423.124 (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 non-retail pharmacies like home infusion and LTC pharmacies do not count toward the retail pharmacy access requirements, we allow Part D plan sponsors to count certain non-retail pharmacies, specifically I/T/U, FQHC, and RHC pharmacies toward the retail pharmacy access requirements (see 70 FR 4248). Consequently, in light of the rapidly evolving pharmacy practice landscape, and given that it expressly excludes only one type of non-retail pharmacy, that is, mail-order pharmacies, without a corresponding definition of that term, we believe that our definition of retail pharmacy has been a source of confusion.

Therefore, to clarify what a retail pharmacy is, we proposed to revise the definition of retail pharmacy at § 423.100. First, we noted that the existing definition of ''retail pharmacy'' is not in alphabetical order, and we proposed a technical change to move it such that it will appear in alphabetical order. Second, we proposed 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 be ''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.''

As mentioned previously, 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.'' 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. 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 Part D enrollees regarding how Part D plan sponsors classify pharmacies for network participation, the Plan Finder, and Part D enrollee cost-sharing expectations. Additionally, we received complaints from pharmacies that may offer home delivery services by mail among other services offered by their overall operation, but that are not mail-order pharmacies as Part D plan sponsors have traditionally defined the term. These pharmacies have complained because Part D plan sponsors singularly classified them as mail-order pharmacies for network participation despite their other non-mail-order services 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 the Part D plan sponsor's mail-order benefit at mail-order cost sharing. Therefore, to clarify what a mail-order pharmacy is, we proposed 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.

We solicited comment on our proposed modification to the definition of retail pharmacy and our proposed definition of mail-order pharmacy. Specifically, we solicited 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.

We received the following comments and our response follows:

Comment: A number of commenters expressed strong support for our definitions of retail pharmacy, mail-order pharmacy, and for declining to further define specialty pharmacy and non-retail pharmacy.

Response: We thank the commenters for their support.

Comment: A commenter asked why the definition of retail pharmacy excluded physician- and hospital-owned pharmacies.

Response: We thank the commenter for the question and assume the commenter is referring to the phrase ''without being required to receive medical services from a provider or institution affiliation with that pharmacy.'' This language exists in our current definition at § 423.100. However, this language does not refer to pharmacy ownership and instead has to do with being closed to the walk-in general public. To the extent that a physician, physician group, hospital, or health system owns and operates a retail pharmacy that accepts and dispenses prescriptions that are not limited to its own prescriber network, such a pharmacy could be counted toward the convenient access standards.

Comment: Several commenters requested that we expand our definition of ''network pharmacy'' and interpretation of ''any willing pharmacy'' to include dispensing physicians. Alternatively, other commenters suggested that CMS should reiterate that accreditation provisions do not apply to dispensing physicians as physicians are not pharmacies, and urged us not to impede any provisions that impede physician dispensing.

Response: We thank the commenters but these comments are outside the scope of this rule.

Comment: A number of commenters suggested that we should add ''primarily,'' ''predominantly,'' ''routinely,'' or other similar terms to the definitions of retail and mail-order pharmacy, similar to Medicaid's definition. Some commenters suggested that we adopt Medicaid's definition. Some commenters suggested that we should specify a threshold for these terms or by which a pharmacy could be considered one type of pharmacy or another, such as 50 or 95 percent of the pharmacy's prescription volume. A commenter added that there is a fundamental difference between a retail pharmacy that provides some home delivery by mail and a mail-order pharmacy that provides some retail services. Another commenter urged us to specify that a retail pharmacy cannot simultaneously be a mail-order pharmacy, or vice-versa.

Response: We thank the commenters for their perspectives. As discussed in the preamble to the proposed rule, the pharmacy types we defined and proposed to modify and define in regulation describe pharmacy practice business and service delivery functions that an individual pharmacy may perform, solely, or in combination. We are clarifying the definition of retail pharmacy for purposes of establishing which pharmacies in a Part D plan sponsor's contracted pharmacy network can count toward Part D convenient access standards under § 423.120(a)(1). The purpose of these definitions is not related to contracting terms between the Part D plan sponsor and pharmacy, or any willing pharmacy. We understand that our proposed definitions of retail

and mail-order pharmacy could be narrower, but we do not believe that we need to establish a threshold for purposes of evaluating convenient access standards and are not otherwise defining it for purposes of establishing which terms and conditions are reasonable and relevant.

Similarly, we proposed a definition of mail-order pharmacy for the very specific reason of clarifying Part D enrollee cost-sharing expectations and differentiating national mail-order pharmacies that contract with Part D plan sponsors to provide the Part D plan sponsors' mail-order benefits from pharmacies that otherwise deliver some or all of their business through mail service without providing the Part D plan sponsors' mail order benefits. It was not intended to preclude terms and conditions that are reasonable and relevant to mail-service delivery by all pharmacies.

Comment: Some commenters requested that we should define a threshold for ''extended days' supply'' since retail pharmacies also dispense extended days' supplies.

Response: The level playing field provision of the statute (section 1860D–4(b)(1)(D) of the Act) provides parity for retail pharmacies to provided extended days' supplies like mail-order pharmacies. While the statute refers to 90-days' supplies, we are aware that, based on package sizes, extended days' supplies span a range, for example, between 63 and 100 days, and that Part D plan sponsors have operationalized parity with retail pharmacies for these quantities, in part, to reduce waste. We therefore believe it would be inappropriate for us to proscribe a threshold that could unintentionally restrict the arrangements for extended days' supplies that Part D plan sponsors have made with retail pharmacies or generate dispensing waste.

Comment: A number of commenters objected to our use of the phrase ''to the walk-in general public'' in our proposed definition of retail pharmacy, and some asked us to expressly state that mail-order pharmacies are closed to the walk-in general public. Other commenters felt that the definition of mail-order pharmacy was overly restrictive and only applied to closed-door mail-order pharmacies.

Some commenters expressed concern about traditional mail-order pharmacies that have constructed the appearance of an open-door pharmacy in an effort to participate in a retail network even though such pharmacy conducts virtually all of their business by mail and has no or very few patients that walk in for prescriptions. Additionally, some commenters expressed concern that while such pharmacies may technically be open to the walk-in general public, they are located in obscure locations, such as in industrial parks, or have minimal signage. Commenters added that when such pharmacies appear in the directory as ''retail'' pharmacies, it creates beneficiary confusion. In that vein, a commenter provided an extensive list of standards they believed should be required to determine if a pharmacy maintains a legitimate retail pharmacy presence. Some commenters believed they would not be able to classify such pharmacies as mail-order pharmacies because technically having a public-facing door, they met the definition of retail.

Other commenters expressed concern that the idea of retail as a ''walk-in'' enterprise is outdated because patients increasingly expect to receive their medications delivered even by their local community retail pharmacies. Similarly, a commenter ask that we replace the word ''to'' with ''for.''

Response: We thank the commenters for these perspectives. Our definition of retail pharmacy is necessary for purposes of applying the convenient access standards and does not address whether terms and conditions of a standard network contract are reasonable and relevant. Only the actual business being performed by the pharmacy can dictate what terms and conditions may be reasonable and relevant. Additionally, we note that our definition of retail pharmacy does not specify that the pharmacy operates *exclusively* to the walk-in general public, nor did our proposed definition of mail-order pharmacy specify that the pharmacy operate *exclusively* by mail. Because the statutory convenient access provision explicitly discusses the dispensing of drugs *directly to* patients, we will maintain the word ''to'' in lieu of ''for.''

In these examples, assuming there is legitimate pharmacy practice activity, such pharmacies maintain a substantial mail-order line of business, and a minimal retail line of business, but nonetheless, both. We reiterate that it is incumbent upon the pharmacy to inform Part D plan sponsors of all the types of services they provide so that the Part D plan sponsor may provide applicable reasonable and relevant standard terms and conditions. Moreover, while the standard terms and conditions for the retail function could reasonably incorporate the elements the commenter listed, we do not believe it is appropriate for CMS to specify such granular requirements in our definition of retail pharmacy.

CMS is also aware that some state pharmacy practice acts do not distinguish mail-order pharmacies from other types of pharmacies, and may have a requirement for all pharmacies to offer general public access. Therefore, specifying that a mail-order pharmacy be closed to the general walk-in public may unintentionally create a conflict with some state pharmacy practice acts.

Comment: Several commenters suggested that dispensing and delivering drugs to an individual's home gives rise to unique quality, safety, privacy, and timeliness considerations as compared to retail dispensing, which CMS explicitly recognized when it considered its own timely delivery standard on mail-order pharmacies. Another commenter added that if distinctions in terms and conditions relevant to mail-order, specialty, and compounding pharmacies are not allowed to be used for standard networks, Part D enrollee safety may be jeopardized. Another commenter suggested that the definition of mail-order pharmacy should ensure that pharmacies are licensed in all of the states *in which they are practicing.* Several commenters contended that they have trusted relationships with their patients and, because some of their patients are Part D enrollees who have dual residences during various parts of the year, that their patients prefer to continue to work with their pharmacy instead of a mail-order pharmacy that would mail prescriptions to them at their other residence.

Response: We thank the commenters for their perspectives. We believe that the commenter who thought our proposal was intended to restrict Part D plan sponsors' ability to make distinctions in standard terms and conditions relevant to mail-order, specialty, and compounding pharmacies misunderstood the proposal. We agree that mailing prescriptions involves unique considerations, for which reasonable and relevant standard terms and conditions may be required for retail pharmacies or other unique pharmacy practice business and service delivery models that include a mail component. Reasonable and relevant standard terms and conditions applicable to the functions a particular pharmacy practice business or service delivery model performs may be required, even if those functions cross multiple traditional pharmacy type classifications.

Existing quality assurance regulations at § 423.153(c)(1) require that Part D plan sponsors have representation that

network providers are required to comply with minimum standards for pharmacy practice as established by the states. Every state, and the District of Columbia (state) requires pharmacies to be licensed in the state in which they are located.[70] However, CMS recognizes that there are differential licensure requirements for prescriptions mailed across state lines. Some states require out-of-state pharmacies to be licensed in their state, by nature of mailing prescriptions to Part D enrollees located in their state, but others do not. Additionally, to the extent a state does not require a pharmacy mailing prescriptions into it to be licensed in such state, it would be unreasonable for a Part D plan sponsor to require that a pharmacy be licensed in such state, particularly if licensure in such state requires an address, physical or otherwise, in such state. Therefore, CMS does not believe that the commenters' additional licensure language is necessary for the definition of mail-order pharmacy and additionally has concerns about the imposition of such a standard term or condition for pharmacies, retail or otherwise, which perform a mail function.

Comment: A commenter contended that our proposal appeared to be based on the assumption that Part D plan sponsors prohibit pharmacies from participating in their networks *because* they provide drugs through home delivery, adding that this is not generally an accurate understanding of pharmacy contracting practices. The commenter added that it was more likely that a Part D plan sponsor would require a pharmacy that wants *to receive payment* for drugs delivered to a Part D enrollee's home to meet certain terms and conditions relating to the quality, safety, and timeliness of such drug delivery as a condition of coverage of such drugs. Some commenters referred us to some Part D plan sponsors' standard terms and conditions. Another commenter opined that pharmacies that complained to us may not have adequately understood their contracting terms and conditions secondary to participation in a pharmacy services administrative organization (PSAO), citing anecdotes that PSAOs do not adequately communicate terms and conditions to the pharmacies they represent.

Response: We thank the commenter for this perspective, but we disagree. Pharmacies referred us to standard contracting terms and conditions that explicitly prohibited pharmacies in retail networks from mailing any prescriptions, with network termination as the consequence, and not case-by-case nonpayment of covered Part D drugs mailed by that pharmacy. In addition to the areas addressed in the proposed rule, we were particularly concerned by requirements in standard terms and conditions that stipulated thresholds for obtaining patient assistance, prescription dispensing capacity, or personnel and equipment requirements that are not commensurate with or reasonable to the size and prescription volume of the pharmacy. The comment related to whether a pharmacy participated in a PSAO is outside the scope of this rule.

Comment: A number of commenters were opposed to our incorporation of the concept of cost sharing into our proposed definitions of retail and mail order pharmacy. Some commenters believed this would also require us to define retail cost sharing and mail-order cost sharing as terms in regulation. Others suggested that because we did not also propose to define these terms in regulation, our proposed definitions were effectively meaningless, and we would not have solved the problem we were trying to address.

Other commenters opposed the incorporation of cost sharing in the definitions or retail and mail-order pharmacy, contending that the proposal instituted a price structure in violation of section 1860D–11(i)(2) of the Act. Another commenter believed that inclusion of cost sharing in the definitions of retail and mail-order pharmacy would force Part D plan sponsors to offer higher payments to all network pharmacies when most pharmacies have agreed to receive lower payment rates. Another commenter offered that because Part D plan sponsors are not required to have a mail-order benefit, and thus would not have preferential mail-order cost-sharing, such a plan could not operationalize our proposed definition of mail-order pharmacy and would risk beneficiary confusion.

Response: As discussed in the proposed rule, because the statute itself discusses retail and mail-order pharmacy in terms of differential cost sharing between the two, it is not unreasonable that we would incorporate those concepts into a regulatory definition. CMS has always left the definition and fee structure of the mail-order benefit and mail-order cost sharing to Part D plan sponsors. Therefore, we disagree that our proposal sought to impose a price structure. Rather, we wanted to align the definitions of retail and mail-order pharmacy with Part D plan sponsors' own operational definitions of mail-order benefit and mail-order cost sharing.

Comment: A number of commenters, both in favor and opposed, similarly interpreted our proposed definition of mail-order pharmacy in such a way that would restrict Part D plan sponsors' ability to impose standard terms and conditions regarding the provision of mail services.

Response: It has become clear from these comments that commenters, both in favor and opposed, misinterpreted our proposed definition of mail-order pharmacy well beyond our intended purposes for defining it (that is, for purposes of Part D enrollee cost-sharing expectations, the Plan Finder, and how Part D plan sponsors classify pharmacies for network participation). We consider the key feature of the mail-order benefit to be extended days' supplies at preferential cost sharing (see the 2014 Final Call Letter available at (see the 2014 Final Call Letter available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Announcement2014.pdf*). CMS has always left the definition of the mail-order benefit to Part D plan sponsors. Insofar as a Part D plan sponsor defines their mail-order benefit to provide services to an expanded geographic service area (for example, all 50 United States, departments, territories, and the District of Columbia), standard terms and conditions that require pharmacies who contract to provide the mail-order benefit to provide services to those areas could be reasonable and relevant. We make a distinction, however, between service level requirements applicable to mailing prescriptions, and those that pertain to providing the Part D plan sponsor's mail-order benefit. While standard terms and conditions imposing service level requirements applicable to mailing prescriptions may be reasonable and relevant, we would not expect a Part D plan sponsor to require a pharmacy that provides home delivery service by mail to also require such pharmacy to contract to provide the Part D plan's mail-order benefit in order to do so.

Because our proposed definition of mail-order pharmacy was fundamentally unlike our other pharmacy type definitions which are

[70] This also applies to the U.S. territories of Puerto Rico, Guam, and the U.S. Virgin Islands, which have their own boards of pharmacy. Other U.S. territories may not have designated boards of pharmacy. For the few pharmacies located there, pharmacies are licensed through the territory's all-inclusive department of health or require and subsequently reciprocate licensure from another U.S. state or territory.

necessary to establish access standards, we no longer find it would be beneficial to have a defined term. Additionally, we will rely on Part D plan sponsors to make sure their Part D enrollees understand which pharmacies are contracted to provide their mail-order benefit (if they have one), and to ensure they have reasonable and relevant terms and conditions for all pharmacies that deliver by mail that take into consideration the difference between traditional mail order that services the entire country from those that operate in more targeted geographic areas. Consequently, we are not finalizing our proposed definition of mail-order pharmacy, and will not define mail-order pharmacy in regulation at this time.

Comment: A number of commenters expressed concern that it is not clear how non-PBM-owned specialty pharmacies or other innovative business models fit into the proposed definitions of retail and mail-order pharmacy. Various commenters urged us to adopt a definition of specialty pharmacy, including network adequacy standards for specialty pharmacies, specialty drugs, or both. However, commenters were divided on the critical elements that should comprise such a definition or set of standards. Commenters variably considered accreditation, other quality standards and service level expectations, drug cost, certain drugs, and certain disease states, or suggested the adoption of existing definitions from various trade associations. A commenter suggested that a regulatory definition is needed because specialty pharmacies may try to hold themselves out to be retail pharmacies in an attempt to avoid accreditation or skimp on the level of services required for specialty drugs. Conversely, a commenter believed our proposal to define mail-order pharmacy and clarify the definition of retail pharmacy without defining specialty pharmacy might create a perverse incentive for medications normally dispensed in less expensive dispensing channels (for example, retail pharmacies) to be diverted to more expensive dispensing channels (for example, specialty pharmacies). A commenter asked how Part D plan sponsors and PBMs could be expected to follow regulations if terms are not defined, as this leads to a subjective definition on a plan-by-plan basis and could lead to confusion. Finally, absent a definition or access standards, some commenters urged us to monitor whether Part D enrollees have appropriate access to products that are distributed through specialty pharmacies, and a commenter provided a study methodology.

Response: Because specialty pharmacies' pharmacy practice business and service delivery models are so varied, we hesitate to say they are a particular ''type'' of pharmacy. As discussed in the proposed rule, because the pharmacy practice landscape is changing so rapidly, and because the considerations are so varied, we continue to believe any attempt by us to define specialty pharmacy could prematurely and inappropriately interfere with the marketplace. Consequently, although we will continue to consider it for future policy-making, we continue to decline to propose a definition of specialty pharmacy at this time. Unless they perform a retail function, specialty pharmacies would be classified as non-retail pharmacies. Additionally, as we discuss later in this section of this final rule, CMS supports Part D plan sponsors that want to negotiate additional terms and conditions in exchange for, for example, designating a pharmacy with a special label such as a ''specialty'' pharmacy in the Part D plan sponsor's contracted pharmacy network. Although we appreciate the commenter's concerns, we are concerned about circulating definitions of specialty pharmacy that limit high-touch clinical services to high-cost, high-risk medications when such services for inexpensive, yet high-risk, medications may also be warranted, particularly in frail or fragile Part D enrollees who are still in the community. Nonetheless, we reiterate here that Part D plan sponsors must offer specialty pharmacies standard terms and conditions that are reasonable and relevant to the specialty pharmacy's pharmacy practice business or service delivery model.

We thank the commenters for their suggestions on methodologies, and may consider this for future analysis or policy making.

Comment: Some pharmacies commented that Part D plan sponsors are fulfilling pharmacy network requirements for home infusion pharmacies by reporting retail pharmacies that do not meet the guidelines discussed in Chapter 5 of the Medicare Prescription Drug Benefit Manual, Section 50.4. Other commenters added that retail and mail-order pharmacies should not be included in the home infusion network adequacy calculation. Some commenters offered that CMS should develop an expanded set of any willing pharmacy regulations specific to long term care pharmacy, and that CMS should revisit its definition of long term care pharmacy, including basing its definition of long term care pharmacy services more on patient care characteristics rather than particular settings of care. A commenter objected to CMS' prohibition on using active pharmaceutical ingredients (APIs) to compound prescription drugs instead of those produced by manufacturers. Another commenter alleged that our use of compounding pharmacy as an example, despite existing policies regarding compounded prescriptions, seemed to indicate that we were encouraging the participation of more compound pharmacies in the Part D program.

Response: We thank the commenters for this perspective. While we may consider these items for future policy making, they are outside the scope of this rule. However, we reiterate, to *the extent a pharmacy serves multiple roles, they* must be offered reasonable and relevant standard terms and conditions applicable to the pharmacy practice functions they perform, *and they may be counted toward multiple access standards.*

In summary, we have removed the concept of retail cost sharing from our definition of retail pharmacy, and we are not adopting a definition of mail-order pharmacy. The definition of retail pharmacy at § 423.100 will be ''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 without being required to receive medical services from a provider or institution affiliated with that pharmacy.''

c. Treatment of Accreditation and Other Similar Any Willing Pharmacy Requirements in Standard Terms and Conditions

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 obtain preferred status or to belong to a specially labeled subset (for example, because we have not defined the term, ''specialty pharmacies''). Therefore, we implemented the requirements of section 1860D–4(b)(1)(A) of the Act by requiring that standard terms and conditions must be ''reasonable and relevant,'' but declined to further define

''reasonable and relevant'' in order to provide Part D plan sponsors with maximum flexibility to structure their standard terms and conditions.

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 or other network 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. However, we raised the concern that inconsistent and/or duplicative application of such requirements held out to promote quality may be circumventing the any willing pharmacy requirements and does not, in fact, represent the ''floor.''

We solicited comment on the role of pharmacy accreditation in the Part D program. We received the following comments and our response follows:

Comment: A number of commenters suggested CMS should codify its existing guidance regarding specialty drugs.

Response: We thank the commenters and will consider this for future rulemaking.

Comment: A number of commenters representing Part D plan sponsors, PBMs, and independent specialty pharmacies believed that we were conflating preferred pharmacy networks with specialty pharmacies.

Response: We thank the commenters for this perspective. We clarify that we did not intend for these terms to be interpreted as interchangeable. Section 1860D–4(b)(1)(B), as codified at § 423.120(a)(9), allows Part D plan sponsors to establish preferred pharmacy networks. Additionally, the term ''preferred pharmacy'' is defined at § 423.100. However, because CMS does not define ''specialty pharmacy,'' we have left the definition and fee structure of ''specialty pharmacies'' and ''specialty networks'' to Part D plan sponsors. Part D plan sponsors may create a specially labeled subset of ''specialty pharmacies'' for their pharmacy network called a ''specialty network.'' Such specially labeled pharmacies could be further differentiated as standard/non-preferred or preferred.

Comment: Several commenters thanked us, while a number of commenters were concerned, that we were altogether eliminating the ability of Part D plan sponsors to impose accreditation requirements. A commenter suggested that CMS was backtracking from our previous guidance that accreditation can serve as part of the ''floor'' for standard contracting. A commenter urged us to allow accreditation that supports access needs. Several commenters urged us to affirmatively prohibit accreditation.

Response: As discussed previously, 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 with a special label such as a ''specialty'' pharmacy or as a preferred pharmacy in the Part D plan sponsor's contracted pharmacy network.

However, CMS remains concerned that, in some cases, Part D plan sponsors may be requiring accreditation or ''quality assurance'' standard terms and conditions that may unnecessarily preclude pharmacy network participation or limit the availability of certain drugs to certain pharmacies, especially if such terms and conditions are not being required consistently among similarly situated pharmacies. While we recognize that allowances must be made for waiving standard terms and conditions in certain situations to accommodate unique geographic issues or ensure access to specific drugs, we generally believe ''quality assurance'' requirements, more so than other terms and conditions, that are meant to establish a ''floor'' in any willing pharmacy standard terms and conditions, would be consistently required and less varied across the plan network. To the extent the exception becomes the rule, it is questionable that such quality assurance or accreditation terms and conditions reflect standard terms and conditions.

In situations where it is necessary for terms and conditions to be altered, CMS believes it may be more appropriate for Part D plan sponsors to explore reasonable alternatives with such pharmacies, in lieu of waiving such requirements outright if they are truly necessary for ensuring a minimum quality standard. This may involve negotiations to determine mutually acceptable reasonable and relevant terms and conditions that could also be offered to other pharmacies that have not yet achieved such quality standards as a means to establish a more achievable de facto ''floor.'' Insofar as standard terms and conditions contain any such requirement, it must be reasonable and relevant to the pharmacy practice functions performed by the pharmacy's business and service delivery model, and particularly with regard to a standard held out to promote quality, as the ''floor,'' we would expect it to be applied consistently.

Comment: Several commenters provided that accreditation is best performed by an independent, third-party actor, and that accreditation serves as an independent validation of excellence. A commenter contended that hundreds of pharmacies that have obtained their pharmacy accreditation certifications are small, community, and regional pharmacies, however, a number of pharmacies commented that they have achieved accreditation, but have done so through other accrediting bodies that Part D plan sponsors would not recognize or because they were forced to do so. A number of commenters contended that if accreditation is to be required, the accreditation standards must be public, transparent, and/or consensus based. Several commenters believed that CMS should establish accreditation standards, and that CMS approval should be the only requirement for acceptance of accreditation, similar to LTC pharmacies and DMEPOS providers. Some commenters contended that our allowance of pharmacy accreditation in the Part D program requires CMS to communicate standard criteria to Part D plan sponsors and PBMs. Many commenters contended neither Part D plan sponsors nor PBMs may arbitrarily exclude pharmacies utilizing other nationally recognized accreditation organizations, and that Part D plan sponsors/PBMs should not be able to mandate the use of particular accreditation organizations. A commenter offered an extensive edit to § 423.505 to this effect.

Response: Small, community and regional pharmacies have complained to us about excessive barriers to entry, and

alleged that they only underwent accreditation because they were forced to do so. Otherwise, they would have been cut out of approximately 75 to 80 percent of the market. While we support the use of third party accreditation, we are concerned that Part D plan sponsors may require or do not recognize one accreditation certification versus another when pharmacies have already obtained an accreditation certification from a different organization, voluntarily or as a requirement from another plan sponsor or PBM. We believe it is unrealistic to expect pharmacies to obtain multiple accreditation certifications, which would be required if multiple Part D sponsors require accreditation by a specific accrediting organization.

We expressed concern in the proposed rule that inconsistent and/or duplicative application of such requirements held out to promote quality may be circumventing the any willing pharmacy requirements and does not, in fact, represent the ''floor.'' However, we reiterate here that we support Part D plan sponsors that want to negotiate an accreditation requirement in exchange for, for example, designating a pharmacy with a special label such as a ''specialty'' pharmacy or as a preferred pharmacy in the Part D plan sponsor's contracted pharmacy network. While we did not propose specific accreditation standards, we will consider it in the future if we find that our current requirements are no longer sufficient to implement the statutory any willing pharmacy requirement as a result of accreditation requirements imposed by Part D plan sponsors. Similar to our work with the Pharmacy Quality Alliance, CMS generally supports the adoption of quality standards that are public, transparent, and consensus-based. While CMS appreciates the commenters' concerns that accreditation is best performed by an independent, third-party actor, we did not consider such a policy change in the proposed rule and would need to consider the issue further.

We also thank the commenter for their suggested edits to § 423.505 and may consider them for future policy making.

Comment: Some commenters objected to our use of the term ''credentialing,'' contending that credentialing and accreditation are different things and accreditation picks up where credentialing leaves off. Some commenters provided that, as a tool of quality assurance, PBMs look to accreditation as a validation of excellence to ensure that their network has the capacity to fully provide highly specialized services, and rejected any suggestions that the value or impact of accreditation in promoting quality assurance is mitigated by the manner of a network agreement deployed by a Part D plan sponsor.

Response: While some Part D plan sponsors or PBMs may use alternate terminology, we have seen documents that label such additional Part D plan sponsor- or PBM-specific criteria as ''credentialing.'' Nonetheless, we have attempted to clarify the terminology in this final rule by also incorporating ''other network criteria.'' *We reiterate that while the Part D program does not define* ''*specialty pharmacy*'' *or* ''*specialty network,*'' *any* such requirements in Part D plan sponsors' standard terms and conditions must be reasonable and relevant to the pharmacy practice functions performed by the specific pharmacy's business and service delivery model, *and particularly with regard to standard terms and conditions held out to promote quality, which, as the* ''*floor,*'' *must be applied consistently.*

Comment: A commenter provided that North Dakota and New Hampshire have enacted laws prohibiting PBMs from requiring additional accreditation other than the requirement of the applicable state board of pharmacy. Another commenter offered that they have seen situations where state standards are insufficient, unenforced, or unmonitored.

Response: CMS thanks the stakeholder for this information, and encourages commenters to keep us apprised of such examples. However, at present, we continue to believe state pharmacy practice acts represent a reasonably consistent minimum standard of practice.

Comment: Some commenters believed that our rule would limit the dispensing of specialty drugs only to drugs for which there are FDA-mandated REMS processes, which is such a small proportion of drugs that it is insufficient as a quality standard for the growing number of Part D enrollees treated by specialty drugs.

Response: This was not our intent. As we discussed in the proposed rule, because a pharmacy's ability to dispense certain drugs is not dependent on it having the ability to dispense other drugs, it is not relevant for Part D plan 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. Beyond drugs whose dispensing is limited by FDA-mandated REMS processes or applicable state law(s), Part D plan sponsors may limit, on a drug-by-drug basis, the dispensing of additional Part D drugs which require extraordinary special handling, provider coordination, or patient education, when appropriate dispensing cannot be performed by a network pharmacy (that is, a contracted network pharmacy that has not agreed, is not capable, or is not appropriately licensed to provide this level of service for such drugs, individually, or in combination). (For operational guidance on this policy, see Section 50.3 of Chapter 5 of the Medicare Prescription Drug Benefit available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf*) A Part D plan sponsor may, however, require pharmacies to dispense a roster of certain drugs or drugs for certain disease states in order to participate in the Part D plan sponsor's preferred pharmacy network or be designated as belonging to a specially-labeled subset of the Part D plan sponsor's contracted pharmacy network (for example, the Part D plan sponsor's ''specialty network'').

As an example, a pharmacy which identifies as a ''specialty pharmacy'' approaches a Part D plan sponsor to participate in the Part D plan sponsor's contracted pharmacy network. The Part D plan sponsor must provide the pharmacy with standard terms and conditions that are reasonable and relevant to the pharmacy practice functions performed by the specific pharmacy's business and service delivery model (including consistently applied terms and conditions held out to promote quality). The Part D plan sponsor may have additional terms and conditions for that pharmacy to secondarily participate in either the Part D plan sponsor's preferred pharmacy network or ''specialty network.'' Even if the pharmacy holds itself out as a ''specialty pharmacy,'' if the pharmacy is not capable or does not agree to meet such additional terms and conditions, the Part D plan sponsor may preclude that pharmacy from participating in the Part D plan sponsor's preferred pharmacy network or ''specialty network.'' However, the Part D plan sponsor may not preclude the pharmacy from participating in the broader contracted pharmacy network, so long as it is willing and able to meet reasonable and relevant standard terms and conditions. Additionally, consistent with our longstanding policy, we would not expect Part D plan sponsors to limit the dispensing of certain drugs

(including, but not limited to, drugs on the ''specialty/high cost tier'') or drugs for certain disease states, individually, or in combination, to a subset of network pharmacies if a contracted network pharmacy not belonging to such subset: (1) Is capable of and appropriately licensed under applicable state and Federal law(s), including FDA-mandated REMS processes, for doing so, and (2) agrees to meet the Part D plan sponsor's reasonable and relevant extraordinary special handling, provider coordination, or patient education requirements in standard terms and conditions.

Comment: A commenter contended that, since there is no entity that accredits LTC pharmacies specifically, Part D plan sponsor/PBM accreditation requirements are particularly onerous for LTC pharmacies.

Response: CMS thanks the commenter. In 2005, CMS published Long Term Care guidance, which included Long Term Care Pharmacy Performance and Service Criteria (available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/LTCGuidance.pdf*). As discussed previously, CMS would not expect Part D plan sponsors or PBMs to impose accreditation requirements beyond CMS Long Term Care Pharmacy Performance and Service Criteria.

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 Part D plan 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 Part D plan 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 proposed to establish deadlines by which Part D plan sponsors must furnish their standard terms and conditions to requesting pharmacies. The first deadline we proposed 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 website. 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 proposed 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 proposed concerns the promptness of Part D plan sponsors' responses to pharmacy requests for standard terms and conditions. As discussed previously, we proposed to require all Part D plan sponsors to have standard terms and conditions developed and ready for distribution by September 15. Therefore, we proposed 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 will be required to clearly identify for interested pharmacies the avenue (for example, phone number, email address, website) 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 will 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 will be required to provide the pharmacy with a copy of the contract terms for its review within the two-day timeframe. This requirement will 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 solicited 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.

We received the following comments and our response follows:

Comment: Many commenters expressed support for our proposal to establish timeframes for the delivery of standard contracting terms and conditions to requesting pharmacies.

Response: CMS appreciates the supportive comments.

Comment: Some commenters recommended changes to the date we proposed as the deadline by which all Part D plan sponsors would be required to have standard terms and conditions available for requesting pharmacies. We proposed a September 15 deadline for making available contracts with an effective date of the following January 1. Some commenters recommended earlier deadlines of July 15 or September 1, maintaining that such dates would afford more time for pharmacies to review and execute contracts and have their network participation reflected in the Medicare Plan Finder (MPF) display of the sponsor's plan information for the upcoming year. This information is posted on October 1 to support the annual election period (AEP), which begins on October 15. The commenters noted that sponsors must submit their Part D bids by early June each year, which they claim includes a certification of their networks, and therefore they should be in a position after that date to develop standard terms and conditions that support the benefit plans they proposed to CMS. Another commenter suggested that the deadline be set at 30 days prior to the start of the upcoming plan year (for example, approximately December 1 of each year).

Response: In setting the deadline by which Part D plan sponsors must have standard terms and conditions available for requesting pharmacies, we must strike a balance between a date by which Part D plan sponsors can be reasonably certain of their plan pricing for the coming year and a date by which pharmacies must start the contracting process so that they can participate meaningfully in a sponsor's Part D network, including the beneficiary election process, for a particular plan year. To do that, we selected September 15 because it was a date by which we could be certain that the annual bid

review process would be completed. It was also a date that would afford pharmacies seeking standard contracts the opportunity to have their participation in a Part D plan sponsor's network made public during the annual election period since sponsors can make five MPF data submissions after September 15 that will be reflected in the five MPF display updates CMS makes during the AEP.

We believe the proposed July 15 and September 1 deadlines are too early. The bid review and negotiation process following the bid submission deadline in early June usually does not conclude until the end of August. Before this date, the pricing and formularies associated with a Part D plan sponsor's Part D bids may vary, and it would be a burden on Part D plan sponsors to require them to develop standard terms and conditions in an uncertain pricing environment. Also, Part D plan sponsors are not required to certify their pharmacy network as part of their bid submission, and it is common for sponsors to continue to build their pharmacy networks after the bid deadline. The suggested December 1 deadline would tilt too far in the other direction, giving Part D plan sponsors more time to develop standard terms and conditions but effectively locking pharmacies seeking such contracts out of the AEP, to the detriment of the pharmacies as well as their potential Part D customers.

Based on our review of the many comments in support of the September 15 deadline we proposed and our consideration of the alternative dates suggested by some commenters, we believe September 15 effectively allows us to administer the any willing pharmacy requirement in a way that best balances the needs of Part D plan sponsors and pharmacies. Therefore, we will finalize the date as proposed.

Comment: Several commenters addressed our proposal to establish a requirement that Part D plan sponsors respond within 2 business days to a pharmacy's request for standard terms and conditions. Many agreed with our proposed deadline, while others recommended longer time frames, ranging from 5 to as many as 15 business days. Most commenters recommending a deadline of more than 2 days noted that we had proposed a particularly tight timeframe which left little time to accommodate unforeseen or extenuating circumstances that might arise related to responding to a pharmacy's request. These included difficulties in verifying contact information and in determining the type of contract (for example, retail, mail order) a requesting pharmacy should be provided.

Response: CMS originally proposed the 2-day response deadline in an effort to ensure that Part D plan sponsor's responses to requests from pharmacies for standard terms and conditions are not met with undue delays, so that the pharmacies can begin their review of the terms at the same time sponsors are conducting their due diligence on the requesting pharmacies. We appreciate that many commenters with significant experience in building contracted Part D pharmacy networks have explained how the 2-day timeframe leaves little room for any foreseeable communication or processing glitches and how a longer timeframe would be more practical to implement. While we see the need for a longer timeframe, we also do not want to establish a new deadline that reduces the sense of urgency that sponsors should bring to their compliance with their obligations under the any willing pharmacy requirement. After considering the range of recommended response deadlines, we believe that 7 business days are sufficient to allow Part D plan sponsors time to address any extenuating circumstances that may arise from a contract request and is a reasonable maximum period for pharmacies to have to wait to receive the contracting documents they requested. The 7-day timeframe provides a more forgiving margin within which a sponsor can resolve its own or a pharmacy's error related to a request for standard terms and conditions. Such errors could include a lack of clarity in a pharmacy's initial request or the submission of a request to a part of the sponsor's organization unrelated to its Part D administration, making it necessary to re-assign the request to the correct department for response. Any of these issues would likely take additional days to address, placing the sponsor out of compliance with the stricter 2-day timeframe. Given the range of potential missteps in the contracting process, it is important to establish a timeframe broad enough to accommodate the resolution of most types of issues. We believe that 7 business days, a period of a little more than a calendar week, is a long enough period for sponsors to respond to all forms of pharmacy requests for standard terms and conditions. Any longer timeframe would diminish requesting pharmacies' opportunity to have contracts in place during the AEP. Under the 7-day timeframe, a pharmacy requesting standard terms and conditions in mid-September should expect to receive the documents by late September or early October, assuming that the sponsor requires takes the maximum 7 business days to provide both a non-disclosure agreement and the actual contracting terms. This timeframe could permit a pharmacy to enter into a contract by the start of the AEP on October 15 and have information about its participation in the sponsor's Part D network made public through its own notices to its customers as well as through sponsor marketing materials and the MPF. A timeframe longer than 7 business days would likely push pharmacies' opportunity to contract into November, thus excluding them from the critical early weeks of the AEP.

Comment: Some commenters noted that they recommended a required response time of more than two days to allow time for sponsors to determine the type of contract for which the requesting pharmacy qualifies. For some commenters, this process involves requiring a pharmacy to complete a questionnaire before the requested terms and conditions are provided. Commenters also expressed concern that a required response time would compromise Part D plan sponsors' ability to conduct background checks on requesting pharmacies as part of necessary fraud prevention efforts.

Response: In our proposal, we made a distinction between sponsors providing requested copies of standard terms and conditions and sponsors executing such agreements. We noted that Part D plan sponsors could ask pharmacies to demonstrate that they are qualified to enter into a particular contract before executing the contract. Our goal in proposing required timeframes for responses to requests for standard terms and conditions was to ensure that pharmacies have the same opportunity that Part D plan sponsors have to conduct due diligence prior to entering into a contractual relationship. We took this step in an effort to remove the roadblock that some requesting pharmacies have faced when sponsors have required pharmacies to apply for a contract before they are even permitted to see the terms. We do not propose to mandate that Part D plan sponsors contract with pharmacies that do not meet reasonable and relevant requirements.

In particular, we emphasize that the requirements related to the deadline for responding to contract requests do not in any way preclude sponsors from applying to pharmacies requesting standard terms and conditions the same fraud prevention review protocols that they already use to evaluate other pharmacies seeking a Part D contract. As noted above, Part D plan sponsors may

conduct their regular fraud prevention review of a pharmacy prior to executing a standard contract and may decline to enter into the contract if the review indicates that the pharmacy poses a legitimate fraud risk.

Comment: Some commenters expressed concern that if Part D plan sponsors are not permitted to evaluate whether a pharmacy qualifies for a certain type of standard terms and conditions, sponsors may be required in some instances to disclose proprietary information to parties to whom it should not be shown. The commenters fear that some pharmacies might abuse this process by requesting sets of standard terms and conditions for which they know they are not qualified just to collect sets of such documents to share with other sponsors or pharmacies.

Response: We note in our proposed rule that Part D plan sponsors could require requesting pharmacies to enter into non-disclosure agreements prior to the delivery of standard terms and conditions. In that situation, the deadline for responding to the pharmacy would first apply to the delivery of the non-disclosure agreement. Once the pharmacy returned the executed agreement, the clock on the deadline would re-set, and the Part D plan sponsor would be required to deliver the terms and conditions to the pharmacy within the required timeframe. The use of appropriate non-disclosure agreements by sponsors should substantially reduce the risk that pharmacies would request contract terms just to develop a ''contract library'' to share with others.

As we noted above, Part D plan sponsors' use of questionnaires or other methods to evaluate a pharmacy's eligibility for a particular type of contract before the Part D plan sponsor provides the requested document is one of the specific issues we intended to address with this proposal. Therefore, to comply with this proposed timing requirement, Part D plan sponsors will be required to provide pharmacies with any set of standard terms and conditions a pharmacy requests. As we noted above, Part D plan sponsors may evaluate a pharmacy's eligibility for a particular contract during the period after the delivery of the requested document but before executing the contract. We expect both parties, Part D plan sponsors and pharmacies, to operate in good faith in carrying out the contracting process under the any willing pharmacy provisions. Therefore, pharmacies should only request contracts for the types of services they truly believe they are qualified to offer and to be forthcoming in describing their range of operations as part of their request. In turn, Part D plan sponsors will be expected to work cooperatively with pharmacies in identifying the types of Part D services the pharmacies can effectively provide to their plan enrollees.

Comment: A commenter noted that CMS was not proposing to establish a deadline by which a pharmacy and a Part D plan sponsor would need to execute a contract containing standard terms and conditions but that CMS's expectation is that Part D plan sponsors should not cause undue delay to completion of the contracting process.

Response: The commenter is correct. We did not propose to establish a deadline for the execution of a contract containing a set of standard terms and conditions. The appropriate timing in each instance would be influenced by the facts surrounding each request, including the type of requesting pharmacy, the complexity of its operations, and the regular process for conducting due diligence adopted by the relevant Part D plan sponsor.

After consideration of the public comments received, we are finalizing § 423.505(b)(18)(i) as proposed and finalizing a change to § 423.505(b)(18)(ii) by deleting ''2 business days'' and replacing it with ''7 business days.''

13. Changes to the Days' Supply Required by the Part D Transition Process (§ 423.120)

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). Section 423.120(b)(3) requires that a Part D sponsor provide certain enrollees access to a temporary supply of drugs within the first 90 days of a new plan enrollment 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. In the long-term care (LTC) setting, this supply must be for at least 91 days and may be up to 98 days, consistent with the 14-day-or-less dispensing increment for brand drugs required by our April 15, 2011 final rule (76 FR 21460 and 21526).

We proposed to make two changes to these regulations. First, we proposed 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 proposed a technical change to the current required days' transition supply in the outpatient setting to be a month's supply.

In discussing previous revisions to our transition regulations, we noted that in requiring multiple fills for the entire length of the 90-day transition period in our April 15, 2010 final rule, we had pointed out that the often complex needs of LTC residents frequently involved multiple drugs and necessitated longer periods in order to successfully transition to new drug regimens. (CMS–4085–F, 75 FR 19678).

However, in proposing to revise the transition days' supply in the LTC setting to be the same as for outpatient setting, we observed that, after more than 10 years of experience with Part D in LTC facilities, we had not seen the concerns that we expressed in the 2010 final rule materialize, and were 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 also observed that LTC facilities often contract with a single LTC pharmacy, as well staff or visiting physicians, and they would be readily available to address transition drug needs. Further, we noted that LTC facilities had many years' experience with the Medicare Part D program generally and transition specifically. Lastly, we stated that we had continuing concerns about drug waste and the costs associated with such waste in the LTC setting.

We also proposed to change the current requirement for a 30 days' transition supply to a ''month's supply'', currently codified for outpatient supply at § 423.120(b)(3)(iii)(A). We observed that we had 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, for drugs that typically are dispensed in 28-day packages, we noted that we historically required plans to dispense more than one package to comply with the 30 day requirement in the text of the regulation.) We noted that, if finalized, this change would mean that the regulation would require that a transition fill be for a supply of at least a month of medication, unless the prescription is written by the prescriber for less. We further noted the supply would be for at least the days' supply that the applicable Part D prescription drug plans has approved in its plan

benefit package submitted to CMS for the relevant plan year, unless the prescription was written by the prescriber for less.

We stated that 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. When the prescription is written by a prescriber for less than a month's supply the Part D sponsor must 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.

We received the following comments and our response follows:

Comment: Commenters offered support for the transition proposal on the basis that it would eliminate additional drug waste and costs, require minimal information technology effort, and make operations more efficient by providing uniformity across settings. A commenter suggested the impact on beneficiaries would be minimal. Another commenter noted that setting the LTC supply to the same required in outpatient and changing the supply to be a month's supply would provide easier explanations of rejected claims on CMS auditing and monitoring projects. A commenter suggested the extended LTC days supply was no longer necessary because CMS had additional beneficiary protections in place to handle the coverage of non-formulary drugs. A commenter requested that we include information about this change in the transition fill letter and Annual Notice of Change (ANOC) document, and another commenter encouraged CMS to conduct educational outreach to ensure successful implementation.

Response: We appreciate the commenters' support. We will update our model ANOC, Evidence of Coverage (EOC), formulary, and model transition letters to reflect that fact that Part D sponsors are now required to provide as a minimum (unless prescriptions are written for fewer days) an approved month's supply for enrollees in both the outpatient and LTC settings. We will also consider other ways to educate LTC facilities on the policy change.

Comment: Commenters opposed the proposal to reduce the transition supply for the LTC setting from 90 days to conform to the supply offered in the outpatient setting. Pointing to the complex needs of LTC beneficiaries who often have concurrent chronic diseases and take many drugs (10 or more), commenters expressed concern that changing formulary prescriptions for medical conditions could potentially harm LTC beneficiaries who are some of the most vulnerable patients in the Part D program. Other commenters pointed out that a month was not long enough because providers and pharmacists need to transition multiple formulary alternatives in a sequence rather than all at once in order to pinpoint which drugs caused adverse reactions. Commenters pointed to specific drug challenges, such as overdoses or the fact that changes to hypertension medications could lead to falls, as the cause for necessity of more gradual transitions for certain drugs or therapeutic drug classes. A commenter recommended that CMS require a 90 day supply of certain therapeutic drug classes (for instance, antidepressants, beta-blockers for cardiovascular disease; and Parkinson's disease) to reduce the risk of adverse events.

Another commenter stated a month's supply was not adequate because Part A nursing facility (NF) regulations on physician services at 42 CFR 483.30(b) require a physician to visit residents only a minimum of once every 60 to 70 days after the first 90 days of admission, while another commenter stated that LTC facilities needed to reach the same professionals who wrote the prescription for the medication no longer on formulary rather than any other prescriber. Some commenters provided specific examples and anecdotal experience with the LTC transition policy. A commenter stated that it took longer than 30 days to arrange for transition changes of beneficiaries typically on large numbers of drugs at times, such as when dual eligibles were reassigned to new zero-premium plans. Commenters expressed concern that delays in acquiring medications could result in increased healthcare expenses, such as emergency room visits, hospitalizations, or readmissions, and several commenters requested that we limit the transition supply to 60 days rather than a month's supply.

Response: We appreciate the commenters' concerns on ensuring and promoting health, but believe that a month's supply is adequate to achieve this goal. As to the comments that sequential introduction of medications would be necessary, we appreciate that beneficiaries in LTC facilities often take large numbers of drugs. However, we do not believe that beneficiaries would often require transition supplies for all the drugs they are taking. Rather, we believe that our robust formulary requirements make it unlikely that, for instance, a beneficiary taking 10 drugs who transitions to a new Part D plan would find all 10 of those drugs are now non-formulary drugs which would require a transition supply. We decline to carve out exceptions for drug classes to avoid creating further complications.

In addition, we also do not believe that only the prescriber who originates a prescription can address drug changes. And while Part A regulations only require physician visits every 60 to 70 days, we do not believe this would result in an inability to arrange for alternative prescriptions when necessary during a 30 day transition time frame. It is our understanding that LTC facilities frequently call physician offices to update prescriptions. And the regulation itself is not limited to specifying the frequency of physician visits, but requires that individuals admitted to facilities remain under the care of a physician. There is no time limit on 42 CFR 483.30(a), which requires NFs to ensure that the medical care of each resident is supervised by a physician—a service we believe would include prescribing drugs. Further, under § 483.30(d), facilities must provide physician services 24 hours a day in case of emergency. In the event that a beneficiary needed medication on an emergency basis, we believe these rules would require the physician to be available to prescribe it.

In response to comments on operational challenges, we note that in some cases LTC facilities will have the information to anticipate and plan for some transition changes ahead of time—for instance, beneficiaries are informed about prospective plan changes well in the advance of effective dates. Additionally, beneficiaries concerned about losing access to drugs formerly on their formularies may request coverage through the exception and appeals process. For these reasons, we decline to adopt the commenters' recommendations.

Comment: Several commenters suggested that the reason CMS had not seen evidence of problems in LTC facilities was partly because CMS had the appropriate longer transition fill policy in place. Commenters urged CMS not to finalize the proposal in the absence of new information indicating concerns CMS noted in 2010 no longer exist. A commenter noted it was likely

polypharmacy (which we interpret to mean the concurrent use of multiple medications) had increased among LTC beneficiaries over the last decade.

Response: Based on the maturity of the Part D program and increase in the knowledge and experience that health care professionals have gained over the decade managing medication prescribing with formulary adherence has led us to believe this change will not harm beneficiaries. Additionally, through our audit and monitoring processes CMS continues to oversee Part D sponsors adherence to the coverage determination process requirements for timeliness.

Comment: Some commenters suggested that changing the LTC transition fill to a month's supply would have a minimal impact on reducing drug cost and waste. A commenter noted that Part D sponsors do not receive the 90 day supply at once and are limited to dispensing 14 day (or less) increments in the LTC setting. Another commenter suggested there was no reason the current policy would create waste because substitutions typically occurred when the transition supply of the non-formulary drug was exhausted, with LTC beneficiaries' physicians generally substituting a new on-formulary drug for the non-formulary drug at the end of the transition period. Another commenter suggested that limiting the 90 day supply to three 30 day supplies could eliminate potential waste.

Response: We agree that Part D sponsors cannot dispense more than a 14 day supply at a time. However, we remain concerned that LTC facilities are relying on the provision of 90 day supplies rather than transitioning Part D beneficiaries to their new plan formularies sooner. This delay may lead to prolonged use of less cost effective formulary alternatives which may lead to an overall increase to program expenditures.

Comment: A commenter suggested that LTC pharmacies that bill on a ''post consumption'' method (in which the claims are submitted at the end of the month to reflect drugs actually taken by beneficiaries) would as a practical matter often receive much less than a month's notice that the transition supply was exhausted.

Response: The current transition period for new enrollees and continuing enrollees affected by negative new benefit year changes is 90 days post enrollment or the start of a new year. CMS expects that LTC pharmacies utilize processes currently in place for formulary and benefit adherence when medications are prescribed and provided outside of the transition period.

Comment: Commenters, including many who otherwise supported the proposal, suggested that referring to a ''month'' was vague and could create uncertainty for Part D sponsors and confuse beneficiaries—possibly leading to interruptions in coverage. To address their concerns, some commenters requested that CMS set a minimum number of days' supply that would constitute a month's transition supply. Other commenters requested that CMS add language to the regulatory text to clarify that a month's transition supply corresponds to the number of days the Part D sponsor designated as its applicable month's supply in its plan benefit package submitted to CMS for the relevant plan year. A commenter asserted that the policy to state that the month's supply will be what was submitted in the PBP or what the provider prescribes, whichever is less, is confusing.

Response: We agree with the commenters' suggestion that we clarify in the regulatory text at § 423.120(b)(3)(iii) that a month's supply means the month's supply approved in a plan's bid. Specifically, we refer to an ''approved month's supply'' at § 423.120(b)(3)(iii), which is the terminology also used in the daily cost sharing regulatory text at § 423.153 and the definition of daily cost sharing rate found in § 423.100.

This change to the regulatory text defines that a month's supply is what the Part D plan sponsor designates as the applicable month's supply in its plan benefit package (PBP) submitted to CMS for the relevant plan year. For example, if the Part D sponsor submitted ''30 days'' in the PBP as its month's supply at retail, and the transition supply is dispensed at retail, then 30 days is also considered the applicable month's supply for the transition supply. If the Part D sponsor had designated 31 days as its month supply at retail in the PBP, then the applicable month's supply for the retail transition supply would be 31 days. Similarly, if the Part D sponsor had designated 31 (or 32) days as its LTC month's supply in the PBP, then the applicable month's supply for the LTC transition supply would be 31 (or 32) days. We do not believe this will cause confusion. We note that this is how a month's supply is applied for Part D plans outside of the transition supply requirement; meaning, the days in a month's supply can vary from plan to plan and are included in plan documents that beneficiaries receive. (We additionally are conforming the requirements related to formulary changes to reflect an approved month's supply in § 423.120(b)(5). See Section II.A.14, Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes.)

In addition, transition policy currently found in § 423.120(b)(3)(iii)(A) provides that, among other things, the transition supply ''must be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days''. We so limit this supply because pharmacies cannot dispense more medication than the amount specified in the prescription by the prescriber. A pharmacy could not dispense more than a 10 day transition supply to an enrollee whose prescriber only writes a prescription for a 10 day supply of medication. The enrollee could only receive more medication if he or she received another prescription from a prescriber. Under the finalized regulation, the Part D sponsor would be required to provide at a minimum a total transition supply equal to the month's supply specified in the PBP.

Comment: Commenters submitted a number of questions about prepackaging, for example, a commenter suggested that CMS clarify that a month's supply would be considered 30 days unless packaging dictated. In another example, a commenter recommended that CMS confirm that a drug package in an unbreakable 28 day supply would meet the one month supply requirement for transition fill. Other commenters requested that CMS provide specific examples of how the transition policy would apply or confirm their understanding of the policy as set forth in the examples the commenters provided with different quantities (such as 17 or 21 day supplies) and types of drugs (such as insulin or creams).

Response: We appreciate the requests for more direction; however, the very nature of these disparate inquiries and suggestions has lead us to conclude that we cannot provide bright line guidance at this level of detail that could address all the different scenarios. Part D plans have been administering prepackaged drug supplies since 2006 outside of transition, and we believe they have established policies and procedures to determine what constitutes at least a month's supply of prepackaged drugs to be dispensed as a transition supply. For this reason, we believe the requested clarification is unnecessary.

Comment: A commenter suggested CMS permit the proposed changes to the transition policy only if patient costs would remain the same or less than previously. Another asserted that the

change to a month's supply would save money for Part D sponsors at the expense of beneficiaries.

Response: The proposal would not increase beneficiary costs because it provides a sufficient supply for beneficiaries and prescribers to transition to formulary alternatives or to request a formulary exception.

Comment: A commenter noted that the transition from the home to an LTC facility can be extremely stressful for elderly patients, which presents a risk to patient safety, for example due to the risk of falls from hypertension medication changes. This commenter asserted that rushing to change their drug regimens would heighten these concerns. Another commenter noted the need to wholesale switch multiple medications simultaneously to meet a new Part D formulary requirements when beneficiaries are transitioned into a nursing home or other LTC facility is fraught with danger, and risks overdosing of patients, which poses a significant health risk. A commenter urged CMS to instead increase the transition days' supply of medication from 90 to 120 days when an LTC patient's payer status transfers from Medicare Part A to Medicare Part D.

Response: CMS acknowledges the concerns of the commenters. Understanding these risks before the implementation of the Medicare Part D program led CMS to require that each Part D sponsor maintain a uniform formulary regardless of the treatment setting, for example, outpatient or LTC. Therefore, beneficiaries stabilized on certain medication regimens at home would be able to continue on the same regimen, without disruption, when admitted to an LTC facility. This proposal pertains to our transition policy which, as always, applies to situations involving either a new plan enrollee or continuing enrollee of a Part D plan affected by a negative formulary change in a new benefit year. Our specific proposal with regard to Part D beneficiaries in LTC facilities who qualify for a transition supply (that we did not propose to and are not changing) was to change the supply that Part D sponsors are required to dispense from 91–98 days' supply to a month's supply. We note that no change is being proposed to current policy addressing the need for at least a 31-day emergency supply for current enrollees in the LTC setting found in the Medicare Prescription Drug Benefit Manual, Chapter 6, § 30.4.6, as we believe that many of the commenters are referring to medication change issues in an LTC facility when a Part D beneficiary is discharged from a hospital or other skilled setting that was not dispensing medications under the beneficiary's Part D benefit.

Comment: A commenter suggested that there was no justification to require multiple fills to provide for up to a total month's supply of medication and that CMS use this opportunity to restate its proposed change to require that a transition fill in the outpatient setting be a one-time, temporary supply of a least a month of medication, unless the prescription is written by a prescriber for less than a month's supply.

Response: We did not propose to change our existing policy that requires multiple fills to provide for up to a full transition supply, and we therefore decline to adopt such a change in this final rule.

After consideration of the public comments received, we are finalizing our transition proposal with the modifications to the regulation text discussed below.

In § 423.120(b)(3)(iii), we are inserting reference to an ''approved month's supply'' to replace a ''month's supply'' in three places.

The transition fill policy is being finalized with modifications. To summarize, the final transition fill supply policy effective for plan year 2019 is to require Part D sponsors to provide as a minimum (unless prescriptions are written for fewer days) an approved month's supply for enrollees in both the outpatient and LTC settings. Please note that we also are finalizing a revision to § 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). See II.A.14 Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes.

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. Under § 423.128(d)(2)(iii), Part D sponsors must also have an internet website that provides 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).

In our proposed rule, we noted that while MedPAC had 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, the commission had also pointed out in the same report that, among other things, 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 (hereafter June 2106 MedPAC Report).)

We stated in our preamble that this proposed rule would implement MedPAC's recommendation by permitting generic substitutions without advance approval and discussed other ways we could better facilitate midyear changes. We described the specific changes listed below and explained how they would work with current requirements (in related areas such as beneficiary communications and the exceptions and appeals process) to maintain beneficiary protections.

Specifically, we proposed:

(1) Adding new paragraph (b)(5)(iv) to § 423.120 to 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) newly approved generics rated therapeutically equivalent by the Food and Drug Administration (FDA) to the brand name drug—rather than having to wait until the direct notice and formulary change request requirements have been met.

(2) Revising § 423.120(b)(6) to allow sponsors to make those specified generic substitutions at any time of the year rather than waiting for them to take effect two months after the start of the plan year.

(3) Adding § 423.120(b)(5)(iv)(C) through (E) to require advance general and retrospective direct notice to enrollees and notice to entities.

(4) Revising § 423.128(d)(2)(iii) to clarify the timing of online notice requirements.

(5) Revising § 423.120(b)(3)(i)(B) to except specified generic substitutions from our transition policy.

(6) Revising § 423.100 to clarify that our definition of ''affected enrollees'' applies to changes affecting enrollee access in the current plan year.

We further stated that we were addressing stakeholder requests for greater flexibility to make midyear formulary changes in general by proposing to change the § 423.120(b)(5)(i) notice requirement when (aside from expedited generic substitutions and drugs deemed unsafe or withdrawn from the market) drug removal or changes in cost-sharing would affect enrollees. Specifically, we proposed to change the minimum 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, to at least 30 days' notice to all entities prior to the effective date of changes and at least 30 days' direct notice to affected enrollees or a one month refill upon the request of an affected enrollee.

(We also noted that we were 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 II.A.13 of this proposed rule, Changes to the Days' Supply Required by the Part D Transition Process (§ 423.120) (hereafter referred to as section II.A.13. Transition Process).

We received the following comments and our responses follow:

a. Issues Related to Expediting Certain Generic Substitutions and Other Midyear Formulary Changes

Comment: Commenters voiced general support for the entire proposal and its flexibilities. Many commenters supported—often strongly—the proposal to permit certain immediate generic substitutions for a variety of reasons. They stated that increasing and accelerating access to generic medications could lead to greater competition, more options, and lower costs for Medicare beneficiaries and the program. They favored the proposal for aligning Part D policy to Medicaid and commercial insurance practices, and noted that the majority of State pharmacy boards supported mandatory generic substitution when available. Several observed that the proposal would decrease inventory carrying costs of brand name drugs for retail pharmacies.

While many commenters underscored their support for the general concept of generic substitutions, some provided support at a more granular level. We received specific support for permitting certain generic substitutions any time during the plan year; conforming the definition of an affected enrollee to mean enrollees taking the drug who will be affected during the current plan year; not requiring a transition for immediate generic substitutions; requiring advance general notice followed by retrospective direct notice; and encouraging, but not requiring, Part D sponsors to provide retrospective notice no later than by the end of the month after which the change becomes effective. A commenter recommended that we continue not to require Part D sponsors to implement generic substitutions in order to provide them flexibility so they can administer brand name drugs to patients who may medically require them.

A commenter specifically concurred that robust CMS requirements provided the necessary beneficiary protections and that 30 days provided enough time for the time for an enrollee to change to an alternative drug or obtain a formulary exception.

Response: We thank those commenters for their support of both our proposed policies.

Comment: While often stating that they supported the concept of providing Part D sponsors with more formulary flexibilities many commenters opposed—often strongly—the specifics of our proposal for various reasons bulleted below. The bulk of specific comments focused on the proposal to permit immediate generic substitutions under § 423.120(b)(5)(iv) and related proposals. However, many of the same—as applicable—points were directed towards our proposal to reduce the advance notice and refill supply for other midyear formulary changes required under § 423(b)(5)(i) from 60 to 30 days and from 60 days to a month. (For purposes of this preamble, we will refer to these changes as ''other midyear formulary changes''. This section a. of comments and responses discusses comments covering other midyear formulary changes in addition to comments focusing on immediate generic substitutions. Section b. covers comments that only discussed immediate generic substitutions and section c. covers an issue specific to other midyear formulary changes.)

- Commenters voiced concerns that beneficiaries with no (or less) advance notice would have no opportunity to discuss the transition and therapeutic options with their providers before taking a new medication. Commenters suggested that patients require quality information and that without such knowledge, beneficiaries might be confused to receive drugs at point of sale that did not have the same brand name, shape, or color as their earlier drug and possibly decide not to take them.
- Many observed that failure to adhere to a prescribed drug could adversely affect beneficiary health, and stated that this could also lead to increased costs elsewhere in the health care system.
- Some commenters professed concern that the changes would promote ''bait and switch'' situations in which beneficiaries enrolled in plans believing they would have access to certain medications only to find out midyear (with no or little notice) that the plan no longer covers those medications.
- Commenters contended that removing advance notice for generic substitutions (and reducing notice of other midyear formulary changes) eliminated an important beneficiary protection. They stated that advance general notice in the Evidence of Coverage (EOC) did not offer sufficient information to determine whether a change in medicine was appropriate and was ineffective given the increasingly complex and confusing nature of plan benefit designs and drug formularies. Commenters also opined that direct notice after the fact would be inadequate to satisfy the intent of the Part D statutory provisions concerning beneficiary access to medically necessary medications.
- Many commenters contended that generic drugs could not always substitute for brand name drugs because not all drugs are bioequivalent, and recommended that we provide beneficiaries with more time to speak to health care providers before switching certain medications to avoid adverse results including death. Commenters suggested that we except specific drugs or classes or types of drugs such as drugs treating hematologic diseases and disorders, epilepsy, and cancer and drugs with a narrow therapeutic range. Others noted that inactive ingredients could be harmful for patients with allergies or conditions such as certain autoimmune diseases and that switching medications could be antithetical to the overall treatment regimen for people taking a variety of drugs. A commenter requested that we acknowledge the unique differences of complex generic drugs as compared to simple generics as recognized under

existing FDA guidance, while another urged us not only to ensure that experts reviewing midyear changes for Part D sponsors had the expertise to understand molecular and genetic diagnostics and targeted precision medicine therapeutics but also to require that their credentials be provided to the public. Others generally objected to midyear formulary changes that, for instance, were not medically necessary.

Response: We appreciate concerns about beneficiary health and the importance of continuity of care. However, we believe that the policy as proposed strikes the right balance between providing beneficiaries with access to needed drugs and Part D sponsors with flexibility to administer their formularies. Given the context of strong Medicare beneficiary protections—including the availability of the formulary exceptions process—and the workings of the pharmacy market, we believe beneficiaries will not be harmed by these changes and possibly might benefit if the added formulary flexibility permits their plans to maintain high quality formularies with lower costs.

The policies we are finalizing in this rule provide more flexibility with respect to when certain formulary changes, including generic substitutions, can be made but do not change what formulary changes we permit. As noted in the information collection requirements section of this rule, our long-standing practice has been to approve all generic substitutions that would meet the requirements of this proposed provision—which again means that the proposed provisions will just permit the same allowable substitutions to take place sooner. And, rather than try to parse out the equivalency of specific drugs, as was discussed in the preamble to the proposed rule, we rely on Food and Drug Administration (FDA) determinations that the generic equivalents are interchangeable. Our proposal also does not change the types of other midyear formulary changes that we permit.

We also believe that consumers have a general familiarity with generic drugs that further mitigates against possible confusion. At this time, many people understand that generics are commonly substituted for brand name drugs and that they may look different from the drugs they are replacing. We do not believe that Medicare beneficiaries would be any more surprised by their different appearance or name or likely to stop taking the drug as a result than enrollees in commercial drug plans. We believe that Medicare beneficiaries generally would understand they could contact their pharmacists (who are trained to answer such questions) or their providers for assistance. Beneficiaries who have more recently transitioned from employer plans may, in fact, already be familiar with automatic generic substitutions, which may have occurred under their prior plans with no advance notice. Under our proposal, which we are finalizing in this final rule, all beneficiaries would receive advance general notice that such certain generic substitutions could take place immediately. Section 423.120(b)(5)(iv) requires the notice to appear in the formulary and other applicable beneficiary communication materials, which as discussed in the proposed rule, would include the EOC. Beneficiaries currently taking the drug would receive direct notice afterward.

Enrollees who are affected by other midyear formulary changes would receive 30 days' advance notice before the change takes effect, or as applicable, notice of the change and an approved month's refill. They could use that time before the change takes effect to contact their providers or request an exception.

Lastly, as we discussed in the proposed rule, we believe beneficiaries affected by either proposal will be sufficiently protected by the robust coverage determination and appeal process, including the right of an enrollee or his or her prescriber to request an exception to their plan's utilization management (UM) criteria, tiered cost-sharing structure, or formulary. We are not proposing to change our exceptions and appeals processes. Beneficiaries who, for instance, try a generic drug or other drug added as a result of other midyear formulary changes and find out the drug is less effective or causes adverse effects, have the right to request an exception to obtain coverage of another drug based on medical necessity.

Comment: Some commenters suggested that if we were to finalize the proposed changes, that we require at least some more notice—for instance, 45 or 30 days' notice before permitting generic substitutions. Commenters pointed out that the National Association of Insurance Commissioners (NAIC) model guidelines on Prescription Drug Benefit Management Model Act (#22) required a minimum 60-day advance notice for both generic and non-generic substitutions. (A commenter pointed out that an NAIC subgroup recently recommending revisions to the section did not change the 60 day notice.) Others noted that the June 2016 MedPAC report, which we cited for support in our preamble, did not recommend that we remove the advance notice for generic substitutions, but rather envisioned that the 60-day advance written notice to beneficiaries would stay in place along with any formulary flexibilities. (June 2016 MedPAC Report, page 195).

Response: We appreciate that the June 2016 MedPAC report assumed we would not change our beneficiary advance notice. And, we acknowledge that when we first finalized the 60 days advance notice in our January 2005 preamble, we referenced the NAIC model guidelines (January 28, 2005, 70 FR 4265). However, the fact that the NAIC subgroup did not recently recommend a change does not mean that a change is inappropriate. Not only has the pharmaceutical marketplace changed since 2005, but also our experience with the Part D program since then indicates that other beneficiary protections to address formulary changes including the exceptions process are sufficient.

Under the generic substitutions policies that we are finalizing, beneficiaries will receive advance general notice that certain generic substitutions may occur immediately, as well as direct notice thereafter. We released our proposed rule after the NAIC and MedPAC materials were published, which means that at the time they recommended 60 days' advance notice these entities could not have taken into account that we would require the additional beneficiary protection of advance general notice. We believe that this advance general notice for generic substitutions, for reasons stated elsewhere in this preamble, sufficiently balances beneficiaries' needs with the need for additional formulary flexibility. Regardless of when they receive their notices of formulary changes, beneficiaries have the right to request an exception. Again, we are mindful of beneficiary impact and take this step only with the knowledge that we would permit Part D sponsors to only substitute equivalent generic drug products that the FDA has determined to be interchangeable; that our program provides strong beneficiary protections; and we are not aware that this longstanding commercial practice has harmed patients.

We also believe that 30 days' notice, and an approved month's supply as required, are sufficient for other midyear formulary changes. In generally recommending a 60 day advance notice period, MedPAC and NAIC did not specifically analyze whether 30 days might provide enough notice for the

limited number of particular changes falling under the notice provisions of § 423.120(b)(5)(i). Furthermore, the same beneficiary protections that apply for permitted generic substitutions would apply in the case of other midyear formulary changes. As we noted in our proposed rule, the reduction to 30 days and an approved month's supply would align these requirements with the timeframes for transition fills, and we have seen no evidence to suggest that 30 days has been an insufficient days' supply for transition fills.

Comment: Several commenters requested that we consider more ways to provide formulary flexibility by, for instance, looking to employer practices or developing more midyear changes to prevent fraud, waste, and abuse. Another commenter suggested that requiring enrollee notifications when a drug becomes generically available could defeat the cost-savings potential.

Response: We believe that the flexibilities currently available (such as utilization management (UM) criteria) along with both our proposals (to permit immediate generic substitutions and expedite notice of other midyear formulary changes) include those flexibilities that would work best within the requirements of the current Part D program. To the extent not prohibited, Part D sponsors may also use strategies implemented by employers in the commercial world. As to fraud, waste, and abuse, we believe that permitting immediate generic substitutions as specified would assist Part D sponsors to preventing waste of unnecessary expenditures by allowing them to substitute less expensive generics for brand name drugs sooner. We did not intend to address fraud or abuse concerns with our proposal to expedite midyear formulary changes. Given that Part D sponsors are statutorily required to provide appropriate notice before removing a drug from its formulary or making any change in a drug's preferred or tiered cost-sharing status, we decline to dispense entirely with notice requirements for generic substitutions. Instead, the revised notice requirements that we are finalizing in this rule are intended to reduce burden and increase formulary flexibility within the confines of the statutory requirements.

Comment: Several commenters sought clarification regarding the relationship between our regulatory proposal and maintenance and non-maintenance formulary changes outlined in our guidance. A commenter requested that we identify the specific maintenance and non-maintenance other midyear formulary changes that do not fall within the requirements for immediate generic substitutions and that would require a 30 day prospective notice and a month's fill, as applicable, while another queried whether current timing limitations still applied to the other midyear formulary changes that did not fall within the requirements for immediate generic substitutions or if they could be implemented at any time of the year. A commenter encouraged us to consider modifying notice requirements depending on the application of our proposal to non-maintenance changes.

Response: Section 423.120(b)(5) did not, and with the changes we are finalizing in this rule, does not, differentiate between maintenance or non-maintenance formulary changes; rather, those terms are used in our formulary guidance to describe different types of midyear formulary changes. With our proposed revisions, the regulation establishes different notice requirements for three types of midyear changes: (i) Substitutions of newer generics that meet the requirements of § 423.120(b)(5)(iv) as proposed; (ii) drugs removed from formularies on the basis that they are deemed unsafe by the FDA or withdrawn by their manufacturer consistent with current § 423.120(b)(5)(iii); and (iii) all other midyear formulary changes that do not fall into one of the first two types, which are governed by § 423.120(b)(5)(i) and, as finalized, would require 30 days advance notice to affected enrollees (as defined in § 423.100) and, as applicable, an approved month's fill for affected enrollees (as defined in § 423.100).

While the changes we are finalizing to § 423.120(b)(5) reduce the number of days' direct advance notice required for other midyear formulary changes from 60 to 30 days, they do not otherwise change requirements or guidance applicable to these other midyear formulary changes. Thus, consistent with the changes we are finalizing in this rule, Part D sponsors are required, for example, to provide current and prospective Part D enrollees with at least 30 days' prior notice on their websites of other midyear formulary changes (§ 423.128(d)(2)(iii)).

Comment: Commenters expressed concerns that lack of advance direct notice for certain generic substitutions would harm pharmacies because, without sufficient opportunity to stock the new generics, they could be obligated to dispense brand name drugs without reimbursement from Part D sponsors. Some commenters expressed particular concerns about home infusion and LTC pharmacies by, for instance, pointing out that LTC pharmacies might not have access to wholesalers at night and during the weekend, and asking that we require Part D sponsors to notify network LTC pharmacies before implementing formulary changes. A commenter also pointed out that reducing the notice from 60 to 30 days for other midyear formulary changes would provide problems unique to LTC facilities. Because they do not always have immediate access to guardians or the ability to open resident mail, the time frame for making decisions about drugs or moving from plans would be very compressed.

Response: While we understand the commenters' concerns, we do not believe immediate generic substitution is unique to Medicare policy, and so therefore are not persuaded that we need special rules for Part D. Many commercial insurers and states require immediate generic substitutions, and we are not aware that this has posed significant problems for pharmacies serving commercial or Medicaid enrollees, and so we have no reason to believe the problems the commenters identify would be any more prevalent in Medicare. We assume manufacturers want to move their drugs to pharmacies as soon as possible. It is also our understanding that wholesalers send out alerts and literature about new generics to alert pharmacies that they are about to enter the market—which means it is less likely they will be caught unawares. As such, we do not see any reason that LTC pharmacies would merit a different approach. For the above reasons, we decline to adopt the commenters' suggestions. We encourage Part D sponsors to be mindful of drug availability when setting effective dates for generic substitutions.

As for other midyear formulary changes, we currently do not find it is necessary to carve out an exception for LTC facilities. Pharmacies—including LTC pharmacies–presumably will still receive notice timely and have the opportunity to reach out to beneficiaries, providers, and LTC facilities regarding those midyear formulary changes.

Comment: A commenter requested that we clarify that online postings would be considered sufficient notice for SPAPs, entities providing other coverage, authorized prescribers, network pharmacies, and pharmacists for all types of midyear negative formulary changes.

Response: Online postings that are otherwise consistent with our requirements for notice to specified entities may constitute sufficient notice of both immediate generic substitutions and other midyear formulary changes.

Comment: A commenter suggested that requiring errata sheets for generic substitutions could defeat the cost-savings potential, while another requested that we generally change the timing of errata sheet distributions.

Response: We did not make any proposals with respect to errata sheets, and therefore decline to make any policy changes with respect to them at this time.

b. Comments Specific to Immediate Generic Substitutions

Comment: A number of commenters urged us not to limit immediate substitutions of certain generics to those new to the market. They noted that Part D sponsors may not immediately place new drugs on formularies for a variety of reasons. For instance, there might only be a limited supply of drugs or the drug might not yet be available in all markets, such as in United States territories. A few noted that generic drugs may not initially be priced much lower than brand name drugs. Commenters suggested we permit immediate generic substitutions to occur any time within a year after a generic is available on the market or until the first day of the month following the end of patent challenge exclusivity. Another commenter stated it would be reasonable to require Part D sponsors to provide CMS with the reasons for the delay. Conversely, other commenters supported the proposal to permit Part D sponsors only to immediately substitute newly marketed generics.

Response: We are persuaded that we should not limit immediate substitutions to generic drugs based upon the availability of limited formulary update windows after initial formulary submission because there are many reasons that Part D sponsors might not make (or in some cases not be able to make) substitutions as soon as a generic drug is released. We appreciated and considered the different suggestions offered. However, we believe an approach that relies on tracking a generic approval or marketing date to this extent could be overly burdensome for us and plans, and confusing for beneficiaries. Additionally, implementing a policy that parses out detailed scenarios in which we would permit immediate generic substitutions would seem to defeat our goal of creating easier formulary flexibility, and requiring Part D sponsors to explain reasons for each delay they might make would increase burden.

Rather, to simplify policy and to encourage Part D sponsors to substitute generic drugs more often, we plan to limit market availability to the time of the initial formulary submission. Specifically, we are revising § 423.120(b)(5)(iv)(B) to provide that: A Part D sponsor that otherwise meets our requirements may immediately remove a brand name drug if it previously could not have included the brand name drug's therapeutically equivalent generic because the generic drug was not available on the market at the time the Part D sponsor submitted its initial formulary for approval. Part D sponsors that otherwise meet our requirements at § 423.120(b)(5)(iv) do not need to submit their formulary changes to CMS before they make a generic substitution. Part D sponsors can immediately substitute generic drugs for brand name drugs at the time that they submit their formulary changes to CMS, or alternatively, substitute generic drugs on their formularies and submit their changes to CMS during the next available update window that occurs after they have made any changes. Consistent with the policy we are finalizing in this rule, Part D sponsors that follow our requirements can substitute generic drugs released to market after their initial formulary submissions for the next year.

Comment: A few commenters suggested that failure to provide advance notice of generic drug substitutions might mean an unexpected change in copay or coinsurance could stress beneficiaries or cause them not to take their drugs. Noting that generics could have higher cost-sharing than brand products during the coverage gap, a commenter recommended that we amend the policy to ensure a beneficiary in the coverage gap who is prescribed a generic drug would not pay more than he or she would for the brand name drug.

Response: As we discussed earlier in these responses, this regulation is not changing the standards applied regarding generic substitutions, but rather changing notice requirements in order to permit the those substitutions to take place sooner. That said, we acknowledge that there could be an unexpected increase in cost sharing, but believe that such an occurrence generally would be limited to the coverage gap in 2019. Our intent was that Part D sponsors only be permitted to immediately substitute generic drugs if in addition to all other requirements (including application of the same or less restrictive UM criteria), the more recently released therapeutically equivalent generic drug is on the same or lower cost-sharing tier—not simply the same or lower cost-sharing. To make this clearer, are revising § 423.120(b)(5)(iv)(A) to require that Part D sponsors add a therapeutically equivalent generic drug to its formulary ''on the same or lower cost-sharing tier'' rather than ''with the same or lower cost-sharing''.

Beneficiaries will pay the same or less out of pocket in instances in which enrollees pay a set copay because § 423.120(b)(5)(iv)(A) would require that a generic drug appear on the same or a less costly tier than the brand name drug it replaces. In contrast, in cases of coinsurance, the amount paid out of pocket by an enrollee for a generic drug theoretically could increase if the negotiated price for the generic drug is more than the brand name drug. But, although generics might initially have negotiated prices that are not much lower than the brand name drug, we are not aware of situations in which such generic drugs actually have higher negotiated prices. Therefore, with the exception of the defined standard cost sharing in the coverage gap in 2019, we do not believe beneficiaries will pay higher cost sharing for these generic substitutions.

We acknowledge that because beneficiaries currently pay a larger percentage for generics than for brand name drugs during the coverage gap under the defined standard benefit, (up until 2020), the cost sharing for generics could be higher than that of brand name drugs during that benefit phase. However, this dynamic has existed since the beginning of the coverage gap closing in 2011 when beneficiaries began paying 50 percent for brand name drugs and 93 percent for generic drugs in the gap. The generic cost sharing percentage has been decreasing each year and will be the same 25 percent cost sharing as brand name drugs beginning in 2020.

Comment: A commenter requested that we confirm that the proposal to permit specified immediate generic substitutions would also apply to protected class generics, while another contended that because we did not consider the six protected classes, our proposal was contrary to the statutory requirement of section 1860D–4(b)(3)(G) of the Act requiring Part D sponsors to offer access to ''all'' drugs in those specified categories.

Response: We disagree that our proposal is contrary to section 1860D–4(b)(3)(G) of the Act, which expressly permits the Secretary to establish exceptions to permit Part D sponsors to exclude from their formularies, or otherwise limit access to, Part D drugs that are otherwise required to be included in the formulary as drugs of clinical concern. We established an

exception through rulemaking at § 423.120(b)(2)(vi)(A), which specifies that drug products rated as therapeutically equivalent by the FDA are excepted from the six classes of clinical concern specified in section 1860D–4(b)(3)(G)(iv) of the Act. Therefore, if a new generic in one of the protected classes enters the market, plan sponsors would be able to make an immediate generic substitution, consistent with the requirements we are finalizing at § 423.120(b)(5)(iv).

Comment: Noting, for instance, that it would create significant savings, commenters urged us to allow in the future, or even clarify that we currently meant to allow, Part D sponsors to substitute new to market biosimilars or at least interchangeable biological products. Conversely, others stated that they supported the fact that our proposal currently did not apply to biosimilar biologics. Several commenters, including one who was concerned that our provision would pave the way for such an expansion, requested that we ensure that biosimilars be excluded from future generic substitutions. They suggested, for instance, that they were not therapeutically equivalent and that applying this policy would result in third parties other than physicians taking beneficiaries off of stable medications. A number of commenters urged CMS to revisit treatment of biosimilar and interchangeable biological products with regard to mid-year formulary changes at such time as the FDA approves the first interchangeable biological product.

Response: Our proposal to permit certain immediate generic substitutions did not apply to biological products. Rather, § 423.120(b)(5)(iv)(A) permits these substitutions only when the new generic drug is therapeutically equivalent (as defined in § 423.100). That said, as interchangeable biological products become available, we would consider whether additional regulatory changes would be warranted.

Comment: Noting that we stated we did not believe that the transition policy is appropriate for immediate generic substitutions, a commenter requested that we clarify whether it would apply for generic substitutions that do not meet the requirements of § 423.120(b)(5)(iv). A commenter queried as to whether the exemption of immediate generic substitutions from the transition fill policy would only apply to those drugs removed based on this process, and whether new enrollees joining a plan during the plan year would be subject to the same requirement.

Response: We proposed to revise only the transition policy as regards immediate generic substitutions: under § 423.120(b)(3)(i)(B), the transition requirements do not apply for Part D sponsors that make such substitutions consistent with § 423.120(b)(5)(iv). The proposed regulation would not otherwise change the application of transition policy to other instances.

Comment: Commenters pointed out that there was no need to permit immediate generic substitutions because Part D sponsors had numerous other UM controls such as step therapy and prior authorization, which they had successfully used to influence beneficiary choices. A commenter also opined that there was no reason to eliminate advance notice aside from reducing plan administrative tasks because Part D sponsors know about the timing of generic releases well in advance.

Response: We agree that Part D sponsors currently have other UM controls that provide some flexibility; however, our goal is to provide even more flexibility in addition to those tools to promote and permit Part D sponsors to switch to generic drugs even sooner after their release date than we currently permit. And a central goal of this proposal is to reduce plan administrative tasks—albeit while still maintaining beneficiary protections.

Comment: A commenter recommended that CMS codify the requirement that plans must give direct notice to affected beneficiaries by the end of the month in which the changes take place. Another commenter recommended that we require Part D sponsors to notify enrollees of generic substitutions as soon as they occur including providing notice at the point of sale (POS) before prescriptions are filled if that is the earliest opportunity for notice.

Response: While we appreciate the idea, we do not currently have in place the means to provide this POS notice and believe implementing such a system would create a burden at odds with our goal of promoting more flexible formulary administration because of the resources and time required to build such a system. We also decline at this time to set hard deadlines because we believe that Part D sponsors have an incentive to provide beneficiaries with information on specific changes timely and, as noted earlier may, for generic substitutions that take place before the start of the next plan year, be able to provide notice before the change takes effect.

Comment: A few commenters suggested that if we were to still require direct notice, that we remove information from the direct notice about how to request exceptions to avoid creating the expectation that enrollees could qualify for exceptions without trying generics. Another commenter voiced concern about the fact that our preamble stated that enrollees could not be certain that they ''would be better served by taking no medication'' unless they first tried the generic equivalent. Noting that there could be sound medical reasons to believe alternatives could cause particular beneficiaries harm, the commenter requested that we clarify that no appeals standard applied to require an enrollee to try an alternative drug before an exception can or must be provided.

Response: We disagree that retaining information in the direct notice about the availability of the exceptions process would create undue expectations, particularly given that this information already is required at § 423.120(b)(5)(i)(E), which we did not propose to change. In discussing our reasoning for proposing to permit immediate generic substitutions without requiring that the plan provide a transition fill, we did not intend to suggest that the standards for exceptions (which are described in the statute) would change. Exceptions will remain subject to the standards set forth in § 423.578.

Comment: Suggesting that the direct notice repeats information already included in the EOB, a few commenters recommended that we remove the direct notice requirement for immediate generic substitutions. Another commenter requested that we confirm that we meant to apply the EOB timeframe when we encouraged Part D sponsors to provide retrospective direct notice of immediate generic substitutions ''no later than by the end of the month after which the change becomes effective'' such that a Part D sponsor making a generic substitution effective in April would have until the end of May to notify affected members.

Response: We did not propose to remove the direct notice requirements for specified generic substitutions but rather to remove the requirement that they be provided in advance of the permitted substitutions, and we therefore decline to eliminate them now. We did not intend to apply the EOB timeframe specified at § 423.128(e)(6) to the requirement to provide direct retrospective notice of immediate generic substitutions, but if Part D sponsors wish to include the direct retrospective notice in their EOBs, they could do so. Those so choosing must make sure the EOB

contents comply with the notice requirements of § 423.120(b)(5)(iv). (We intend to update our model EOB in this regard.) And while we currently intend to permit this flexibility, we continue to encourage Part D sponsors to provide direct and other notice as soon as possible. For instance, we see no impediments to providing online notice of changes if not before or on the effective date of a generic substitution, at least shortly thereafter.

Comment: A commenter noted that we had not proposed any requirements for Part D sponsors to update the content of formularies available to beneficiaries after making immediate generic substitutions.

Response: While we did not propose new beneficiary communications requirements specific to the content of formularies posted online or provided on paper, current regulations continue to apply. However, as noted in our proposed rule, we decided not to require a regulatory deadline because we anticipate that Part D sponsors will be promptly updating the formularies posted online. At a minimum, Part D sponsors must comply with § 423.128(d)(2)(ii) which still requires Part D sponsors to update their websites to reflect their current formularies at least monthly. Additionally, we are finalizing revisions to § 423.128(d)(2)(iii), which currently requires Part D sponsors to provide notice online to current and prospective enrollees regarding midyear formulary changes, to require that the notice be provided timely under § 423.120(b)(5).We further believe that Part D sponsors would have the incentive to update their formularies timely to encourage beneficiaries to move to the newly substituted drugs and to avoid beneficiary confusion.

Comment: A commenter queried: if a generic is released in October and the brand is on both the current year and the next year's formulary, could the sponsor remove the brand from following year's formulary, but leave the current year formulary unchanged?

Response: A Part D sponsor that met all requirements of § 423.120(b)(5)(iv) would be able to substitute the generic for the brand drug in the following year's formulary, but leave the brand drug on the current year's formulary. Alternatively, the Part D sponsor could substitute the generic for the brand name drug on both formularies at the same time, consistent with the requirements we are finalizing in this rule for immediate generic substitutions.

Comment: Characterizing the proposal as a major policy change, a commenter recommended that we test its implementation before shortening the notice provisions. Another commenter requested that we monitor the rate at which formularies are updated to reflect changes in coverage.

Response: We do not believe it is necessary for us to test implementation of this provision. We do not view it as a major policy change because, as discussed above, we have permitted Part D sponsors to make midyear formulary changes for some time and are merely changing the timing of implementation and notice rather than the kinds of changes that can be made. Lastly, given that we currently audit formulary administration and maintain a robust formulary monitoring program, we do not see the need to implement a model test.

Comment: A few commenters were concerned that generic drugs would not be timely added to our Formulary Reference File (FRF). We also received detailed questions regarding how the proposed change would affect operations related to matters such as pharmacy information systems, HPMS negative change requests, and FRF release dates and UM criteria.

Response: Part D sponsors are permitted to cover drugs that are not on the FRF, so long as they have determined that the drug product meets the definition of a Part D drug. We appreciated the operational inquiries and plan to update guidance as appropriate.

c. Issue Related to Other Midyear Formulary Changes

Comment: Commenters responding to another section of the proposed rule, II.A.13 Changes to the Days' Supply Required by the Part D Transition Process, suggested that referring to a ''month's'' supply rather than a ''30 day'' transition supply was vague and could create uncertainty for Part D sponsors and confuse beneficiaries—possibly leading to interruptions in coverage.

Response: To address the concerns, in finalizing the change to our transition requirements, we plan to revise § 423.120(b)(3)(iii) to refer to ''an approved month's supply'' rather than ''a month's supply'' so that it would be clear that we mean a month's supply in accordance with the month's supply approved in a plan's bid. (See section II.A.13 Transition Process for more discussion of that issue.) In our provision on notice of formulary changes, we originally proposed to revise the days' supply referenced in formulary changes to conform to that of the proposed transition provision, from a 30 day supply to a month's supply in § 423.120(b)(5)(i)(B). However, for the same reasons we noted with respect to the transition requirements, we believe it is appropriate to conform the reference to supply for notice of formulary changes to that used for transition supply. Therefore, in § 423.120(b)(5)(i)(B) rather than requiring ''a month's supply'' at the time an affected enrollee requests a refill of the Part D drug, we will require ''an approved month's supply''.

After consideration of the public comments received, we are finalizing our proposal on expedited substitutions of certain generics and other midyear formulary changes with the following modification as discussed and as follows:

In § 423.120(b)(3)(i)(B), we are removing an extraneous reference to ''and (b)(6)''.

In § 423.120(b)(5)(i)(B), we are removing the phrase ''a month's supply'' and adding in its place the phrase ''an approved month's supply''.

In § 423.120(b)(5)(iv)(A), we are removing the phrase ''formulary with the same or lower cost-sharing'' and adding in its place the phrase ''formulary on the same or lower-cost-sharing tier''.

In § 423.120(b)(5)(iv)(B), we are removing the phrase ''requested CMS formulary approval'' and replacing it with ''submitted its initial formulary for CMS approval''.

15. Similar Treatment of Biosimilar and Interchangeable Biological Products and Generic Drugs for Purposes of LIS Cost Sharing

Similar to the introduction of an abbreviated approval pathway for generic drugs provided by the Hatch-Waxman Amendments 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 PPACA amended section 351 of the Public Health Service Act (PHSA) (42 U.S.C. 262), adding a subsection (k) to create an abbreviated licensure pathway for 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/*) Biological products approved under section 351 of the PHSA (42 U.S.C. 262) 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 website for new biologics license application (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 individuals who do not receive the low-income subsidy (LIS) and are in the catastrophic phase of the benefit and for LIS-eligible individuals, respectively, 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. Because 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, biosimilar and interchangeable biological products are subject to the higher Part D maximum copayments for non-LIS Part D enrollees in the catastrophic portion of the benefit and for LIS eligible individuals in any phase of the benefit applicable to all other Part D drugs. Consequently, treatment of biosimilar and interchangeable biological products, which are generally high-cost, specialty drugs, as brands for the purposes of LIS cost sharing and non-LIS catastrophic cost sharing generated a great deal confusion and concern for Part D plan sponsors 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.

Consequently, we proposed to revise the definition of generic drug at § 423.4 to include biosimilar and interchangeable biological products approved under section 351(k) of the PHSA solely for purposes of cost-sharing under sections 1860D–2(b)(4) and 1860D–14(a)(1)(D)(ii–iii) of the Act by:

(1) Redesignating the existing definition as paragraph (i), and

(2) Adding 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 solicited comment on this proposed change to the definition of generic drug at § 423.4.

We received the following comments and our response follows:

Comment: A number of commenters expressed strong support for CMS' proposed change to the definition of generic drug, noting that it would spur greater price competition, expand access for Part D enrollees, help restrain growth in Part D program spending, reduce costs when medically appropriate, and improve the overall biologic marketplace. Some commenters expressed support of this proposal, contending that it would help non-LIS Part D enrollees in the coverage gap.

Response: We thank the commenters for their support. With regard to commenters who suggested the proposal would be beneficial to non-LIS Part D enrollees in the coverage gap since, we believe these commenters may have misunderstood our proposal. Our proposal would affect non-LIS cost sharing for enrollees who are in the catastrophic portion of the benefit. Further discussion of CMS treatment of biosimilar and interchangeable biological products during the coverage gap is discussed later in this comment and response.

Comment: A commenter requested clarification on whether CMS' usage of the term ''biosimilar'' means ''non-interchangeable biosimilar.''

Response: When CMS uses the term ''biosimilar'' or ''biosimilar biological product,'' we mean a biological product licensed under section 351(k) of the PHSA that has not been determined by the FDA to be ''interchangeable'' to the reference biological product. However, biological products licensed under section 351(k) of the PHSA are inclusive of biosimilar and interchangeable biological products. Consequently, because we proposed to apply our policy with regard to cost-sharing to biological products licensed under section 351(k) of the PHSA, it would apply equally to biosimilar and interchangeable biological products.

Comment: A commenter contended that CMS' proposal would require Part D plan sponsors to place biosimilar and interchangeable biological products within their generic tier. In contrast, other commenters suggested that because biosimilar biological products are usually specialty drugs, the proposal was not necessary because most Part D plan sponsors' formularies include a specialty tier. Other commenters suggested that CMS should work with Part D plan sponsors to address cost-sharing issues through their benefit design and cost-sharing structure. Finally, another commenter suggested that our policy would diminish the ability of Part D plans and manufacturers to negotiate.

Response: We disagree with commenters that the proposal would require plan sponsors to place biosimilar or interchangeable biological products on certain tiers. While biosimilar biological products are likely to be placed on a Part D plan sponsor's specialty tier, we explicitly stated in our proposed regulatory language that this change only applies to statutory cost-sharing for certain Part D enrollees and would not impact which tier Part D plan sponsors place a particular biosimilar biological product. Moreover, since the start of the Part D program, with few exceptions, CMS has generally left tiering assignments to Part D plan sponsors. Consequently, because the provision applies to statutory cost-sharing and not tier placement, we do not believe that Part D plan sponsors' or manufacturers' ability to negotiate preferable terms for formulary placement will be impacted.

Comment: A commenter suggested CMS exceeded its statutory authority to redefine generic drug in the manner we proposed, adding that the terms ''multiple source drug'' and ''generic

drug'' have specific meanings in the Part D statute that do not encompass biosimilar biological products.

Response: We disagree with the commenter. While the statute defines multiple-source drug at section 1927(k)(7) of the Act, the statute does not include a definition of generic drug for purposes of the Part D program. Consequently, through notice and comment rulemaking, CMS finalized the definition of generic drug at § 423.4 in the January 2005 final rule (70 FR 4194).

Comment: Although a number of commenters thanked us for resolving confusion relative to all LIS Part D enrollee cost-sharing and non-LIS catastrophic cost sharing, commenters opposed to our proposal uniformly contended that our policy would create confusion in the marketplace on a number of grounds, which they added could ultimately jeopardize Part D enrollee safety.

Commenters contended that our proposal inappropriately equates biosimilar biological products with generic drugs for purposes of their scientific and clinical applications. Commenters stated that biosimilar biological products are not interchangeable like therapeutically equivalent generic drugs, and that CMS should make clear that generic drugs are different from biosimilar biological products. A commenter requested clarification on how our proposal affects formulary requirements, specifically with regard to the requirement at § 423.120(b)(2)(i) that each formulary have at least two Part D drugs for each category and class submitted on the formulary file (except as noted in § 423.120(b)(2)(ii)).

In addition, commenters contended that it would contribute to confusion regarding variable rules for treatment of biosimilar biological products across CMS programs, including case-by-case determinations for formulary requirements, treatment as branded products for the Medicaid Drug Rebate program, treatment as multi-source generic drugs for purposes of Medicare Part B, and similar to generic drugs, treatment as non-applicable drugs for purposes of the Coverage Gap Discount Program (Discount Program). Similarly, a number of commenters urged CMS to categorize biosimilar and interchangeable biological products approved under section 351(k) of the PHSA as applicable drugs for purposes of the Discount Program. Some commenters suggested that CMS could accomplish this by using waiver authority under section 1860D–14A(g)(2)(A) to exempt biosimilar and interchangeable biological products from their statutory treatment as non-applicable drugs under the Discount Program.

Response: We stated in the proposed rule that this change would only apply to cost-sharing for certain Part D enrollees. This policy does not change or supersede our existing formulary requirements for biosimilar biological products that we addressed in the March 30, 2015 Health Plan Management (HPMS) memorandum entitled ''Part D Requirements for Biosimilar Follow-On Biological Products'' which is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Annual-Items/SysHPMS-Memo-Archive-%E2%80%93-2015-Qtr1.html.*

We appreciate the concerns about biosimilar and interchangeable biological products being treated differently under different CMS programs. However, to serve different purposes, CMS' statutory authority treats biosimilar and interchangeable biological products differently across CMS programs. Since the proposed rule was published, CMS notes that section 53113 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) amended section 1860D–14A(g)(2)(A) of the Act to sunset the exclusion of biological products approved under section 351(k) of the PHSA from the Discount Program. We further note that since the proposed rule was published, Medicare Part B policy changes for biosimilar biological products that were discussed in the CY 2018 PFS final rule (see CMS–1676–F, 82 FR 52976) took effect January 1, 2018. As a result, newly approved biosimilar biological products with a common reference product will no longer be grouped into the same Medicare Part B billing code. These two policy changes, when taken together with the policy we are finalizing now provide for greater alignment of biological products approved under section 351(k) of the PHSA across CMS programs and encourage the use and development of these products.

Although we attempted to clarify that we were not equating biosimilar and interchangeable biological products to generic drugs for any other purpose than cost sharing intended to encourage utilization of lower-cost alternatives, we are persuaded by comments that our proposed approach to include biosimilar and interchangeable biological products in our definition of generic drug still could be misinterpreted and create further confusion about the broader treatment of biosimilar and interchangeable biological products under the Part D program. In consideration of comments regarding the definition of generic drug, we are not finalizing our proposal at § 423.4 to revise the definition of generic drug.

Section 1860D–14(a)(1)(D)(ii)–(iii) of the Act establishes that the copayment amount cannot exceed the higher statutory threshold ($3 in 2006 as increased by Consumer Price Index percentage increase) for drugs other than generic drugs or preferred drugs that are multiple source (as defined in 1927(k)(7)(A)(i) of the Act). However, the statute does not prohibit CMS from establishing a lower maximum copay amount for other drugs since, by definition, such copay would not exceed the statutory maximum. By establishing a lower maximum copay for biosimilar and interchangeable biological products that is equivalent to the lower copay required for generic and preferred multiple source drugs, CMS achieves the same goal intended by our original proposal, but now does so without the confusion that would result from defining biosimilar and interchangeable biological products as generic drugs for this limited purpose. We believe this approach should avoid any confusion that would cause stakeholders to misinterpret this policy as applying more broadly.

While the statutory authority under section 1860D–14(a)(1)(D)(ii)–(iii) of the Act establishes a maximum statutory copay for LIS enrollees, thereby providing us with the flexibility to establish a lower copay amount for biosimilar and interchangeable biological products, section 1860D–2(b)(4) of the Act specifies a copayment threshold that is ''equal to'' the higher amount for any other drug that is not a generic drug or preferred drug that is a multiple source drug (as defined under section 1927(k)(7)(A)(i) of the Act). Therefore, CMS does not have the flexibility to establish a lower copay amount for biosimilar and interchangeable biological products for non-LIS enrollees that have reached the catastrophic phase of the benefit. Nevertheless, as illustrated by some comments below, we do not anticipate this will have any practical effect on non-LIS cost sharing in the catastrophic phase because such enrollees are required to pay cost sharing that is equal to the greater of the applicable copay amount ($3.35/$8.35 in 2018) or 5 percent. Given the high cost of biological products in general, the non-LIS catastrophic cost sharing will almost certainly be 5 percent.

In light of the comments, we now believe the better approach to encourage

utilization of biosimilar and interchangeable biological products via LIS cost sharing is to include them in § 423.782(a)(2)(iii)(A) and § 423.782(b)(3). The revised paragraphs will specify the following:

- A copayment amount of not more than $1 for a generic drug, biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved, or preferred drugs that are multiple source (as defined under section 1927(k)(7)(A)(i) of the Act) or $3 for any other drug in 2006, or for years after 2006 the amounts specified in this paragraph (a)(2)(iii)(A) for the percentage increase in the Consumer Price Index, rounded to the nearest multiple of 5 cents or 10 cents, respectively; or''
- For covered Part D drugs above the out-of-pocket limit (under § 423.104(d)(5)(iii)) in 2006, copayments not to exceed $2 for a generic drug, biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved, or preferred drugs that are multiple source drugs (as defined under section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug. For years beginning in 2007, the amounts specified in section (b)(3) for the previous years increased by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents, respectively.

Comment: Some commenters suggested that the cost-sharing reduction for LIS Part D enrollees ($1.25 versus $3.35 for dually eligible enrollees and $3.70 versus $8.35 for non-dually eligible enrollees) is insignificant and does not warrant the change.

Response: We disagree. While differences in cost-sharing of $1.10, and $4.65 may be inconsequential to many Part D enrollees, we believe this change promotes medication adherence in the LIS enrollee population, in addition to encouraging the use of biosimilar and interchangeable biological products in the market.

Comment: A commenter urged CMS to work with the FDA to create different approval pathways for biosimilar and interchangeable biological products. The commenter added approval of biosimilar and interchangeable biological products is fundamentally different from the FDA's distinct approval pathways for other types of drugs and biological products which address only one category of follow-on product compared to the reference product (for example, section 505(b)(1) versus section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), New Drug Application (NDA) versus Abbreviated New Drug Application (ANDA), whereas the approval pathway under section 351(k) of the PHSA addresses two different categories of biological products (that is, biosimilar and interchangeable biological products) when compared to a reference biological product approved under section 351(a) of the PHSA, and all three categories of biological products receive a Biologics License Application (BLA) approval.

Commenters stated that biological products currently approved through the pathway described by section 505(b)(2) of the FDCA are currently treated as applicable drugs for purposes of the Discount Program. In March 2020, an approved application for a biological product under section 505 of the FDCA will be deemed to be a license for the biological product under section 351 of the PHSA. FDA has not yet described whether an approved application for a biological product under section 505 of the FDCA will be deemed to be a license for the biological product under section 351(a) or 351(k) of the PHSA. As such, some commenters urged CMS to preemptively classify biological products approved under section 505(b)(2) of the FDCA as non-applicable drugs for the Discount Program, while other commenters urged CMS to take the position that they will remain classified as applicable drugs for purposes of the Discount Program.

Finally, some commenters suggested that, similar to generic utilization rate, CMS should begin to actively monitor usage of follow-on biological products across CMS programs by setting up appropriate infrastructure as a policy priority for the Agency.

Response: We thank the commenters. While we may consider them for future policy making, these comments are beyond the scope of this rule. However, CMS notes that since the proposed rule was published, section 53113 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) amended section 1860D–14A(g)(2)(A) of the Act to sunset the exclusion of biological products licensed under section 351(k) of the PHSA from the Discount Program.

In summary, in consideration of the comments received, we are not finalizing our proposal to revise the definition of generic drug. Instead, in this final rule, we are revising § 423.782(a)(2)(iii)(A) and § 423.782(b)(3) by adding '', biological products for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved,''.

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 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.

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 will result in the offering of a broad array of cost effective prescription drug coverage options for Medicare beneficiaries. 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. To that end, we have reconsidered the position 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 do however continue to believe 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 proposed 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.

We also announced 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 solicited 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.

We received the following comments and our responses follow:

Comment: Commenters opposed to this proposal expressed concerns that Medicare beneficiaries will be faced with even more plans to choose from, resulting in ''choice overload'' and beneficiary confusion when trying to distinguish between plan options. Several of these commenters were at least encouraged to see that CMS intends to maintain the meaningful difference requirement between basic and enhanced PDP offerings.

Response: We appreciate the concerns raised about potential beneficiary confusion. We believe that the tools CMS provides for beneficiaries to make decisions (for example, Medicare Plan Finder, Medicare and You Handbook, 1–800–MEDICARE) and our enforcement of communication and marketing requirements address these concerns. The current approach to define meaningful difference is based on a model tool that takes into account a cohort of Medicare beneficiaries in aggregate and is intended to identify a meaningful value between plan comparisons based on that cohort's utilization run through a plan's benefit design and formulary. An individual beneficiary's utilization may not mirror that of the model cohort, so we continue to strongly encourage individual beneficiaries to use the Medicare Plan Finder tool and the many other resources that CMS makes available to assist them in finding the plan that best meets their unique needs. In proposing to maintain the meaningful difference requirement between basic and enhanced plans, our intent is to ensure that a meaningful value continues to exist for those beneficiaries choosing an enhanced plan that has an associated supplemental Part D premium. We anticipate another positive outcome of this proposed change will be a potential reduction in Part D supplemental premiums, as sponsors will not be forced to make benefit changes to comply with a requirement that ultimately results in higher supplemental premiums for beneficiaries.

Comment: A subset of commenters who opposed this proposal stated that a quantifiable measure provides valuable information to beneficiaries and ensures substantial differences between plans. While the commenters believe using the OOPC model as the only measure of meaningful difference is a flawed approach, they believe CMS should maintain the requirement between enhanced plans but allow plan sponsors to seek waivers by providing alternate evidence of meaningful difference if the meaningful difference threshold is not met.

Response: We disagree with the commenter's suggested approach to maintain the PDP EA to EA meaningful difference requirement but allow sponsors to seek waivers if the meaningful difference threshold(s) are not met. The use of a waiver or justification process introduces additional subjectivity into the benefit review.

Comment: A commenter stated that it is crucial that CMS continue to limit plan sponsors to offering no more than two EA plans in each region.

Response: We agree and wish to clarify that the proposed changes to the meaningful difference requirement for PDP plan offerings does not change CMS's intention to use our bid negotiation authority to limit to three, the number of plans approved within a PDP region by a parent organization (one required basic plan and no more than two enhanced plans). The potential increase in plan offerings that we discuss takes into account only the addition of a second enhanced plan by any parent organization that currently offers a single enhanced plan within a PDP region. It is CMS's intent to maintain a balance with respect to encouraging competition and plan flexibilities while still providing PDP choices to beneficiaries that represent meaningful choices in benefit packages. To the extent that CMS finds the elimination of the EA to EA meaningful difference requirement results in potential beneficiary confusion or harm, CMS will consider reinstating the requirement between EA plans through future rulemaking or consider taking some other action.

Comment: A commenter urged CMS to share data that suggests the meaningful difference requirement is in fact preventing innovation by plans.

Response: We do not have data that this requirement specifically hinders innovation. However, for a number of years we have heard from plan sponsors their belief that this requirement is arbitrary, potentially harmful to the competitive Part D market, and results in plans that are becoming increasingly unaffordable for many beneficiaries. This proposal aims to combat these concerns, with the added benefit of allowing for flexibility in benefit design.

Comment: Several commenters supported the proposal to eliminate the PDP EA to EA meaningful difference requirement, applauding CMS efforts to increase innovation and plan flexibilities. In addition to those flexibilities, a few commenters noted the potential this proposal has to decrease total Part D premiums, due to lower supplemental Part D premiums associated with enhanced plans not needing to meet this requirement, and to increase beneficiaries' choice of coverage options. Comments supportive of the proposed change suggested it will eliminate unneeded disruption and provide more plan stability to beneficiaries currently enrolled in second EA plans, as sponsors will not be forced to adjust benefits to comply with changing requirements.

Response: We appreciate the comments received in support of this proposal to eliminate the PDP EA to EA meaningful difference requirement. The closure of the coverage gap has introduced challenges for plan sponsors to meet the EA to EA meaningful difference requirement, as the provision of additional coverage in the gap has been a key approach sponsors have used to meet the meaningful difference requirement. We agree with the concern that continued enforcement of this requirement could result in disruption and instability for beneficiaries as it may necessitate Part D sponsors to significantly modify their benefit structure from year-to-year or even require them to non-renew a plan if unable to attain the out-of-pocket threshold that has been set annually. The proposal could also result in plan offerings that are more competitive and market-driven within a less restrictive regulatory framework. We agree that

elimination of this requirement may offer plan sponsors additional flexibilities in terms of their plan benefit designs. As previously noted in the NPRM, we agree that it is possible for plan sponsors to offer unique benefit designs that attract different subsets of Medicare beneficiaries but have similar estimated out-of-pocket costs. Arguably, an EA plan that completely waives the deductible could be attractive to one subset of enrollees, while another EA plan that instead offers reduced cost-sharing or provides supplemental coverage of drugs that are excluded under Part D might attract a different subset of enrollees. While providing for different benefit designs, these two plans could have similar estimated out-of-pocket costs.

Comment: Some commenters urged the agency to eliminate the meaningful difference test in all instances for PDPs (that is, also between basic to EA plans), and pursue a suitable replacement that would provide more meaningful decision support for beneficiaries during open enrollment. A commenter claimed that the meaningful difference requirement may stifle innovation, reduce consumer choice, and impose additional costs on plans. The commenter further asserted that the current OOPC difference between basic and EA PDP offerings remains too high, which may make enhanced plans very expensive and cost prohibitive for many beneficiaries, further limiting consumer choice.

Response: We disagree with completely eliminating the meaningful difference requirement across all PDP offerings. While we support the flexibility and competition that this proposal to eliminate the meaningful difference requirement between enhanced plans will stimulate, we believe it is important to balance this with a need to ensure beneficiaries have a meaningful choice between plans, especially when some of those plans include an additional supplemental Part D premium. Eliminating the meaningful difference requirements between the basic and enhanced plan offerings could result in sponsor behaviors that adversely affect the program, such as the creation of enhanced plan options designed solely to engage in risk segmentation. Healthier beneficiaries may be increasingly incentivized to enroll in enhanced plans, leading to a higher risk pool in the basic plans. This could ultimately result in increasing bids and premiums for basic plans, given that LIS auto-enrollment is limited to basic plans. The fact that CMS pays most of the premium for LIS beneficiaries means that total government cost would likely increase.

Comment: A commenter suggested that the meaningful difference rules also be relaxed in the case of acquisitions/mergers so that multiple plan options can exist between the two merged entities for multiple years.

Response: Current regulations at § 423.272(b)(3)(ii) offer this flexibility, providing a two-year transition period following a new acquisition before a PDP plan sponsor will be held to the requirement that its bids be substantially different. Revisions to § 423.272(b)(3)(ii) will be made to better align the requirements with the proposed change for § 423.265(b)(2), specifically to remove the reference that benefit package or plan costs being substantially different from ANY (emphasis added) other bid submitted by the same Part D sponsor and to refer the reader to § 423.265(b)(2) that will reflect the provision change which identifies which plan benefit types are expected to be substantially different.

Comment: A commenter interpreted the proposal as rescinding CMS's policy that a second EA plan provide brand gap coverage, and noted that removing this policy also has the capability to increase plan flexibilities and increase beneficiary plan choice.

Response: As part of our application of the meaningful difference requirement to stand-alone PDPs, CMS reviewed additional enhanced PDPs within a service area with the expectation that they represent a higher value than the first enhanced plan and as such would include additional gap cost-sharing reductions for at least 10 percent of their formulary brand drugs. We confirm that elimination of the meaningful difference requirement between PDP enhanced plans would also eliminate this expectation.

Comment: With respect to our request for stakeholder input on how to redefine the meaningful difference requirement between basic and enhanced PDP offerings, we received very few detailed proposals, but many responses encouraged transparency and stakeholder input on any contemplated changes. With respect to potential modifications to the current OOPC model, two suggestions were received. One recommendation is for CMS to reconsider the approach to have non-formulary drugs be priced at the cost-sharing of the Part D sponsor's formulary exceptions tier rather than priced at the retail cash price. The other recommended that CMS set a consistent and reasonable OOPC differential that does not change from year to year, suggesting that this approach would afford sponsors more predictability and could reduce unnecessary changes, while still ensuring beneficiaries receive meaningful value.

With respect to potential alternatives to the OOPC model, two suggestions were received. One recommendation was for CMS to establish a minimum actuarial difference between basic and enhanced plans (for example, 20 percent average member cost-sharing for an enhanced plan vs. 25 percent average member cost-sharing for a basic plan). Another commenter suggested that CMS allow plans to demonstrate a meaningful difference between plan offerings by providing an actuarial attestation as to their actuarial value differences, while allowing actuaries to use a utilization profile that is representative of their population for quantifying differences in actuarial value (without the impact of selection effect or risk score differential).

Response: We appreciate the thoughtful input on how to redefine what constitutes a meaningful difference between basic and enhanced PDP offerings. Both the recommendations to improve upon the OOPC model and the alternative approaches will be carefully considered by CMS as we evaluate options moving forward. For CY 2019, CMS intends to maintain the current methodology to set a basic to enhanced OOPC differential threshold.

Comment: A significant number of commenters strongly believe that significant efforts need to be made to ensure beneficiary information tools are enhanced to improve upon the plan election experience. Some commenters recommended research focusing on understanding beneficiary perceptions of value and meaningful difference. Several commenters provided specific recommendations to enhance the Medicare Plan Finder (MPF); one such suggestion is to add flags within the system to highlight benefit enhancements, such as reduced cost sharing, additional coverage in the gap, reduced deductible or coverage of excluded Part D drugs. Another commenter suggested CMS modify the MPF to allow beneficiaries to filter and/or sort plans by enhanced features (for example, ''Show me plans in my area that offer no deductible''). Some commenters suggested that if CMS intends to finalize this proposal, it be postponed until those enhancements to beneficiary tools have been implemented.

Response: These recommendations are outside of the scope of this final rule provision. We do however agree with the need for clear and complete

information and intend to continue improving the MPF to make it as user friendly as possible. We encourage third party organizations that support beneficiaries in their decision-making to take advantage of existing resources (for example, public use files (PUF) available for the Part D program).

After consideration of all of the comments received, we are finalizing our proposal to revise § 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 are also modifying the language of § 423.272(b)(3)(ii) to make the provisions governing the meaningful difference transition period following a plan sponsor acquisition consistent with the new requirements stated at § 423.265(b)(2).

17. Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

In this proposed rule, we solicited comment on potential policy approaches for applying some manufacturer rebates and all pharmacy price concessions to drug prices at point of sale under Part D. We received over 1,400 responses to this request for information. We thank the commenters for the thought, time, and effort that went into developing these detailed responses. We will carefully review all input received from stakeholders as we continue our efforts to meaningfully address rising prescription drug costs for beneficiaries.

We further note that the President's Fiscal Year 2019 Budget included a proposal similar to the point-of-sale rebate policy considered in this request for information. As explained in the request for information, we believe the statute provides us with discretion to require that Part D sponsors apply at least a portion of the manufacturer rebates and all pharmacy price concessions they receive to the price of a Part D drug at the point of sale. Any new requirements regarding the application of rebates at the point of sale would be proposed through notice and comment rulemaking, in the future.

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 17005 of the 21st Century Cures Act (the Cures Act) modified section 1851(e)(2) of the Act to eliminate the Medicare Advantage Disenrollment Period (MADP) and to establish, beginning in 2019, a new open enrollment period (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), the 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.

Pursuant to the statute, newly eligible MA individuals can only use the OEP during the first 3 months in which they have both Part A and Part B. Under existing regulation (§ 422.68(c)), enrollments made using the OEP are effective the first of the month following the month in which the enrollment is made. 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.

The OEP, as enacted, permits changes to Part D coverage for individuals who, prior to the change in election during the OEP, were enrolled in an MA plan. As eligibility to use the 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 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 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 OEP to switch to: (1) Another MA–PD plan; (2) an MA-only plan; or (3) Original Medicare with or without a PDP. The OEP will 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 OEP to enroll in an MA plan, regardless of whether or not they have Part D. Furthermore, unsolicited marketing is prohibited by statute during this period, and is discussed in section II.B.5.c of this final rule.

To implement the changes required by the Cures Act, we proposed 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 are no longer in effect and renumber the enrollment periods which follow them. As such, we proposed 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 discussed in section II.B.5.c, §§ 422.2268 and 423.2268 will 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).

We received the following comments and our response follows:

Comment: We received a number of comments supporting the restoration of the Medicare Advantage OEP. Commenters noted that the OEP reflects the Administration's focus on consumer choice and competition, provides additional time for beneficiaries to make health plan decisions and ensures beneficiaries are enrolled in plans that best suits their needs and budgets, by affording an opportunity to make a change from the MA plan previously

chosen during the Annual Election Period (AEP).

Response: We thank commentators for their support of this proposal.

Comment: A couple of commenters requested clarification on the ability to use other election periods such as the 5-Star special enrollment period (SEP) or the SEP for individuals in the Program of All-inclusive Care for the Elderly (PACE) to make changes outside the OEP.

Response: We note that the OEP has no effect on other valid election periods, except that the Cures Act eliminates the Medicare Advantage Disenrollment Period (MADP) after 2018. The OEP is an additional statutory enrollment period that allows individuals enrolled in an MA plan to make a one-time election during the first 3 months of the calendar year.

Comment: A commenter asked whether the OEP was applicable to cost plans. The commenter further questioned if CMS intends to revise the current SEP to enroll in a PDP, or provide a corresponding SEP for cost plans with Part D to accept new enrollees.

Response: An individual enrolled in a cost plan may not use the OEP to make a change. Additionally, an individual cannot use the OEP to disenroll from an MA plan and enroll in a cost plan. As noted in statute, an individual is solely able to switch from one MA plan to another MA plan or from an MA plan to Original Medicare. As part of that enrollment change, the individual may add, drop, or keep Part D coverage; those enrolling in Original Medicare may enroll in a stand-alone Part D plan. If an individual makes a change from an MA plan to Original Medicare during the OEP, he or she can enroll in a cost plan if the cost plan is open for enrollment. They would not, however, be able to enroll in Part D without another valid enrollment period. Open enrollment periods for cost plans are outlined in § 417.426.

Comment: A commenter wanted to understand whether the OEP allowed only for changes from one contract to another, or if it allowed for changes within a contract (that is, from one Plan Benefit Package (PBP) to another PBP).

Response: The OEP permits individuals to switch to any MA plan in which they are eligible to join (that is, lives in service area, etc.). This includes switches from PBP to PBP, contract to contract under a MA organization, or from one MA organization to another.

Comment: We received a comment suggesting CMS exercise discretionary authority and expand the MA OEP to all beneficiaries.

Response: While the MA OEP, as enacted, provides a 3-month window for beneficiaries in an MA plan to make a change in their enrollment if they are dissatisfied with their choice during the AEP, we do not have the discretionary authority of expanding the scope to all beneficiaries. In our view, broadening the scope of this election period would contradict the intent of the statute.

Comment: A few commenters recommended CMS conduct robust beneficiary outreach and education on the OEP to ensure beneficiaries are aware of the enrollment changes, including their rights and responsibilities, in order to mitigate confusion and potential disruption.

Response: We appreciate the comments. We will take the necessary steps to ensure that beneficiaries are made aware of the new OEP and its timeframe. We believe that through education efforts directed to beneficiaries by CMS and plans (that is, 2019 Medicare & You handbook, *Medicare.gov*, member materials), beneficiaries will have sufficient notification to make their health plan decisions.

Comment: A couple commenters requested CMS issue clear expectations and guidance as soon as possible to detail the changes afforded by the MA OEP, including the ability to make changes to Part D coverage, and the effective dates for OEP elections to adequately prepare MA organizations for enrollees.

Response: CMS will issue guidance in a timely manner to provide plans time to implement. However, the discussion and regulation changes in this final rule should provide plans the information and guidance necessary to proceed and implement changes during the OEP.

Comment: Several commenters opposed the establishment of the OEP and requested narrowing those eligible to use it. A commenter indicated narrowing the eligibility requirements would prevent ''gaming'' (that is, allowing MA beneficiaries, already enrolled in an MA plan for the previous year, to use a secondary open enrollment period). Many commenters suggested limiting its use to only permit individuals to return to their prior plan or Original Medicare. They indicate such change would allow enrollees to ''correct'' coverage decisions with which the beneficiary may not be satisfied and would reduce the opportunity for agents to market coverage that may not meet the needs of the beneficiary. The commenters believe that allowing beneficiaries who are already enrolled in an MA plan for the entire previous year to use a secondary open enrollment period could result in inappropriate ''gaming''; the commenters urged CMS to consider a more narrow interpretation of the eligibility and/or mechanisms to monitor abuse of this provision.

Response: We thank the commenters for their suggestions. We disagree with narrowing the scope of those eligible or limiting the MA choices in the OEP to only the previous MA plan in which the beneficiary was enrolled, as the individual may have different needs than the previous year. In our view, Congress intended for enrollees to be able to select any MA plan that best meets their needs or select Original Medicare, if they prefer that healthcare option. Further, we believe the statute is clear on the scope of choices permitted to enrollees during the OEP.

Comment: A commenter opposed the restoration of the MA OEP to all MA enrollees. The commenter believed it would create a new special enrollment period for all MA–PD beneficiaries and offer an unlimited ability to switch MA plans or disenroll from MA, which conflicts with the proposed changes to limit SEP enrollments for those dually-eligible for Medicare and Medicaid. The commenter recommended CMS consider retaining the current MADP and offer the OEP through March 31 of each year solely for dually eligible individuals in conjunction with the proposed rule to limit Part D SEP for the remainder of the year.

Response: Under the new statutory provisions in section 1851(e)(2), individuals enrolled in MA plans may make one change during the first 3 months of the plan year to switch to another MA plan or select Original Medicare coverage. Individuals that use the OEP to make a change would generally retain that coverage for the remainder of the coverage year unless they qualify for another SEP. While we appreciate the commenter's suggestions, the statute mandates the establishment of the OEP and the discontinuation of the MADP.

Comment: Another commenter opposed the law change from the MADP to the OEP but acknowledged the requirements are set forth by Congress. The commenter asked for clarification on who is eligible for the new OEP and how this change affects a new enrollment in Part D if the beneficiary returns to FFS. The commenter further requested CMS clarify whether the OEP is open to all MA enrollees, including those who had an opportunity to make changes during the previous AEP and elected not to.

Response: The OEP is open to all MA enrollees, even if they chose to remain

in their current MA plan during the previous AEP. As noted earlier, during the OEP, individuals who disenroll from an MA plan and obtain coverage through Original Medicare may also enroll in stand-alone Part D coverage.

Comment: A few commenters stated that the OEP could inadvertently degrade the value of MA plans with 5-Star ratings as high-quality MA organizations are granted year-round enrollment. A commenter asked CMS to identify a comparable opportunity for plans achieving 5-Star status in order to maintain incentives for these plans.

Response: While the new MA OEP provides individuals with an opportunity to switch to another MA plan, it is limited to, the first 3 months of the year (or of the enrollment for newly eligible beneficiaries), unlike the year-round special enrollment period available to enroll in a 5-Star MA plan. As discussed in section II.B.5.c, plans may not conduct targeted marketing to those in the OEP. We believe that the benefit provided to a 5-Star MA plan—that they may market and enroll the rest of the year—is a valuable incentive to achieve a high quality rating. We note that the MA OEP provides an opportunity for individuals who may not be satisfied with their plan choice for the new year, regardless of the plan's rating, to find another MA plan that meets their needs or to select original Medicare. CMS continues to encourage plans to strive for the highest quality.

Comment: We received numerous comments related to the ability to conduct marketing during the OEP.

Response: We appreciate and acknowledge all comments. A discussion related to marketing during the OEP and responses to those specific comments can be found in section II.B.5.c.

We thank all the commenters for their feedback and suggestions. We note that there was a technical error in the language proposed in § 423.40(e). This new section should have been titled ''PDP enrollment period to coordinate with the MA open enrollment period.'' We have made this correction in this final rule.

After review and consideration of all comments on the restoration of the OEP, we are finalizing the revisions to §§ 422.60(a), 422.62(a), 422.68, 423.38(d) and (e), and 423.40(d) and (e) as proposed, with the technical modification noted above.

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 sponsoring 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 sponsoring 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. Current regulations require compliance programs for Part C and Part D sponsoring organizations that 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. In the May 23, 2014 final rule (79 FR 29853 and 29855)), we attempted to resolve this burden by developing our own web-based standardized compliance program training modules and establishing, that FDRs were required to complete the CMS training to satisfy the compliance training requirement. This requirement was applicable beginning January 1, 2016. The mandatory use of the CMS training by FDRs was designed to ensure that FDRs will 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 sponsoring organizations they served, hence, eliminating the prior duplication of effort that so many FDRs stated was creating a huge burden on their operation.

However, after implementation of the new CMS training, we continued 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 sponsoring organizations required their own plan specific training, as part of their contract with their FDRs, in addition to the CMS training. Also, sponsoring organizations were unwilling to identify which critical positions within the FDR were subject to the training requirement. As a result, FDRs were still being subjected to multiple sponsors' specific training programs. Furthermore, stakeholders have 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 efficiencies intended, we proposed to delete the provisions from the Part C and Part D regulations that require use of the CMS-developed compliance training.

In addition, we believe that the broader requirement that sponsoring organizations 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. Pursuant to § 422.504(i)(1) and § 423.505(i)(1), sponsoring organizations

maintain ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS. 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 of 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 sponsoring organizations 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 sponsoring organization's contract must specify that FDRs must comply with all applicable federal laws, regulations and CMS instructions. Additionally, we audit sponsoring organizations' 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 sponsoring organizations, so if they are non-compliant, it will come to light during the program audit and the sponsoring organization will ultimately be 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 stakeholders' 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 stakeholders' compliance operations, as well as our continuing requirements on sponsoring organizations for oversight and monitoring of FDRs, we no longer believe requiring sponsoring organizations to impose the compliance training requirements on their FDRs is the best way to achieve compliance. Specifically, we proposed 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*). Those proposed changes include restructuring § 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 proposed 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 were designed to 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 also believe these technical changes make the requirements easier to understand.

Compliance training will still be required of MA and Part D sponsoring organizations, their employees, chief executives or senior administrators, managers, and governing body members. The primary goal of deleting the compliance training requirement for FDRs is to reduce administrative burden on both sponsors and FDRs, but also allow MA and Part D sponsoring organizations the flexibility to oversee FDR compliance with Medicare Part C and D requirements in a way that is tailored to its organization, operations, resources and risks. We believe sponsoring organizations are in the best position to determine the most effective way to monitor and track compliance and fraud, waste and abuse (FWA) responsibilities and contractual obligations amongst their FDRs. We requested comments concerning these proposals and suggestions on other options we could implement to accomplish the desired outcome.

We received the following comments and our response follows:

Comment: A few commenters stated the current training requirements and process meet their needs because they had already invested resources to develop efficient systems for ensuring their FDRs satisfied the general compliance requirement. They expressed that eliminating the CMS compliance training for FDRs will add new administrative burden on sponsors to ensure CMS standards are met and holding FDRs accountable will be more challenging.

Response: While we recognize some sponsors were able to utilize our training requirements as a means to ensure FDRs at least completed compliance training, we believe by deleting this requirement we are affording sponsors much greater flexibility in designing an FDR oversight structure that best suits the needs of each sponsors' organization. Sponsoring organizations are free to choose the most effective and efficient method for ensuring that all their FDRs are in compliance with all applicable laws, rules, and regulations, and Medicare requirements (for example, training, attestations, reports, routine monitoring and auditing, and/or corrective actions). Additionally, sponsoring organizations should continue to evaluate their contractual arrangements with their FDRs to ensure appropriate levels of accountability for compliance are in place.

Comment: Several commenters suggested that FDRs should be held to the same compliance program training requirements as sponsoring organizations.

Response: CMS does not interfere in private contractual matters or written arrangements between sponsoring organizations and their FDRs. CMS' contract is with the sponsoring organization and sponsoring organizations are ultimately accountable for the performance of their FDRs compliance with applicable statutes, regulations and standards. Sponsoring organizations are required to develop an effective oversight structure for their FDRs. As part of routine monitoring activities, sponsoring organizations should evaluate whether regulatory requirements and accountability measures are included in contractual agreements. The burden of monitoring and documenting an FDR's compliance with applicable standards ultimately rests with the sponsoring organization.

Comment: A few commenters stated that sponsoring organizations and FDRs may incorrectly interpret the new proposed rule to mean compliance training is not required. A commenter suggested that not requiring training will lead to confusion, reduce provider compliance and increase compliance risks across the Medicare program.

Response: This change eliminates the *CMS* requirement for FDRs to complete compliance program training. However, FDRs are still required to comply with all statutes, regulations, and CMS program specific requirements. CMS recognizes that sponsoring organizations may continue to have requirements in

their contracts setting out their expectations with respect to oversight of FDRs' compliance with statutes, regulations, and CMS program specific requirements. If sponsors choose to include a compliance program training requirement as part of their contract with FDRs that is a private contractual matter between the FDR and sponsoring organization. Such training would not be prohibited by these rules as amended.

Comment: A commenter suggested that CMS create user-friendly compliance training content for FDRs.

Response: CMS did develop a generalized training that was available 24/7 on the CMS Medicare Learning Network Learning Management System. The overwhelming feedback we received was that the training content did not alleviate the large administrative burden associated with compliance training and, that the training was too generic to be helpful to most FDRs.

Comment: A commenter requested clarification on whether FDRs who are enrolled in Medicare will continue to receive the ''deemed'' status for FWA training. Commenters also requested clarification on who was deemed for purposes of the FWA training requirement (for example, whether deeming was limited to just the hospital participating in Medicare FFS or extends to their hospital's employees)?

Response: This provision eliminates Parts C and D compliance program and FWA training for FDRs. Therefore, deeming of these training requirements is no longer relevant for the Part C and D program.

Comment: A commenter questioned how this provision affects PACE organizations.

Response: This provision does not directly apply to all PACE organizations. However, PACE organizations that offer qualified prescription benefits are Part D plan sponsors that must comply Part D requirements and regulations in part 423 unless they are waived.

Comment: A commenter questioned how this provision affects agents and brokers.

Response: If FDRs, agents and brokers would be subject to the contract requirements sponsoring organizations have for FDRs. As this final rule would remove a specific CMS compliance training requirement for FDRs, agents and brokers would not be required to take this specific CMS compliance training either. Other regulations and requirements applicable to agents and brokers are outside of the scope of this proposal.

Comment: Several commenters inquired if FDR oversight requirements and expectations will be updated in Chapter 9 of Pub. 100–18, Medicare Prescription Drug Manual, and Chapter 21 of Pub. 100–16 of the Medicare Advantage Manual immediately following the implementation of the final rule. The commenters suggested that feedback should be solicited from sponsoring organizations to assist with providing industry best practices for communicating and monitoring FDR compliance.

Response: We always welcome feedback from sponsoring organizations and FDRs with respect to improving our sub-regulatory guidance and communicating expectations. We acknowledge that policy, technology and Medicare business practices continue to evolve. We intend to update Chapters 9 and 21, respectively and issue a draft to obtain public comment.

Comment: Multiple commenters recommended that CMS continue to maintain the CMS standardized training modules and make them available on the CMS Medicare Learning Network (MLN) as an acceptable form of training for situations where sponsoring organizations choose to require FDRs to complete compliance training or where FDRs found the CMS training to be more convenient to complete. Additionally, commenters stated that CMS should increase the MLN's tracking and reporting capabilities (that is to create a searchable database to confirm who has taken the training and reports that could be issued to sponsoring organizations) for compliance training requirements.

Response: CMS is unable, at this time, to provide the capacity for a searchable database of users who have completed training or a system that would allow reports to be sent to sponsoring organizations regarding the training status of various FDR organizations. We also believe that leaving the compliance training on the MLN website could create confusion among sponsoring organizations and FDRs. Therefore, this training course may be removed from the Medicare Learning Network website.

Comment: Sponsoring organizations, FDRs (that is, hospitals, physicians, pharmacies and health care providers) and other stakeholders wrote in support of the provision, agreeing that it would significantly reduce burden on FDRs.

Response: We thank the commenters for their support.

After careful consideration of all the comments received, we are finalizing this proposal without modification.

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 an 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 previously 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. 63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000. We proposed 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 request for 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).

We proposed to 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 proposed 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 proposed to delete all references to ''MA organizations'' in paragraph (b) to reflect our proposal that we will only review and approve waiver requests during the contract application process.

We also proposed 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 included 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.

We received the following comments, and our response follows:

Comment: We received several comments, primarily from plans, expressing support for the proposal to remove the requirement for MA organizations to resubmit the minimum enrollment waiver requests during the second and third year of a contract. These commenters also support the proposal to approve the minimum enrollment waiver for 3 years in year 1 of the contract as part of the initial application process. Several commenters noted that the requirement to resubmit the waiver in the second and third year of the contract created unnecessary burden on organizations, with a commenter noting that organizations already demonstrate their capacity to bear risk during the waiver submission for the first year in the application process. A commenter expressed support for this proposal because an approved 3-year minimum enrollment waiver encourages entry into the MA–PD market from smaller organizations that require more time to ramp up their operations.

Response: We appreciate the commenters' support for the proposal and agree that removing the resubmission of the minimum enrollment waiver in the second and third year of the contract eliminates an unnecessary burden for organizations. We also agree that approving the minimum enrollment waiver for organizations for a 3-year period supports market entry for smaller organizations.

Comment: A commenter expressed concern that the proposal to remove the requirement to resubmit the minimum enrollment waiver in the second and third years of the contract would discourage MA organizations from engaging in market strategies to increase their enrollment.

Response: We disagree that removing our requirement to re-submit the minimum enrollment waiver in the second and third year of the contract would discourage organizations from increasing their market share in the MA–PD program. As stated in our proposal, CMS monitors low enrollment at the plan benefit package (PBP) level. After the third contract year, the provision at § 422.506(b)(1)(iv) allows 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. We believe that our ability to terminate the contract or plan for low enrollment after the third year provides sufficient incentive for new organizations to market and grow their enrollment during years 2 and 3 of the contract.

Comment: A commenter expressed concern that low contract enrollment can impact an organization's financial capability and that financial problems could result in disruption of services to their enrollees. The commenter recommended that CMS retain the existing policy to review waiver requests on an annual basis to protect beneficiaries from disruptions in their care.

Response: We disagree that the review of waiver requests on an basis is necessary to monitor the financial stability of organizations or compliance with other MA requirements (such as benefit administration). CMS requires that organizations meet all applicable state licensure and fiscal soundness requirements or compliance with other MA requirements (such as benefit administration). According to §§ 422.504(a)(14) and 422.516(a)(5), CMS monitors an organization's compliance with fiscal soundness requirements, primarily through independently audited annual financial statements and other required documentation for the legal entity. All organizations must submit audited annual financial statements and some organizations may also be required or notified by CMS to submit quarterly financial statements in certain situations. CMS believes that these requirements provide adequate assurance that organizations contracting with CMS are financially viable while protecting Medicare beneficiaries from disrupted access to care.

After considering these comments, we are finalizing the revisions to § 422.514 as proposed.

4. Revisions to Timing and Method of Disclosure Requirements (§§ 417.427, 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.'' The Act specifies this detailed information in section 1852(c)(1), and also requires additional information specific to the Part D benefit under section 1860D–4(a)(1)(B). 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 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 § 422.111(b) is found in an MA plan's Evidence of Coverage (EOC), summary of benefits, and provider directory. The content listed in § 423.128(b) is found in a Part D Sponsor's EOC, summary of benefits, formulary, and pharmacy directory. Section 422.111(h)(2)(i) requires that plans must maintain an internet website 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 website ''does not relieve the MA organization of its responsibility under § 422.111(a) to provide hard copies to enrollees.''

We initially proposed, and will finalize, two changes to the disclosure requirements, but will also finalize a third change in response to comments received. First, we proposed to revise §§ 422.111(a)(3) and 423.128(a)(3) to require MA organizations 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. Second, we proposed to add the phrase ''in the manner specified by CMS'' to § 422.111(a) and to modify the sentence in § 422.111(h)(2)(ii) which states that posting documents on the plan's website does not relieve the plan of responsibility to provide hard copies to enrollees in order to provide authority for CMS to permit MA plans to provide these documents by directing enrollees to the website posting of the documents. We proposed to revise the sentence to 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 website (whether that document is the EOC, directory information or other materials) does not relieve the MA organization of the responsibility to deliver hard copies upon request. Finally, in response to a comment we received with which we agreed, we intend to further revise § 422.111(h)(2)(ii) and to add new § 422.111(h)(2)(iii) to make explicit that the Summary of Benefits be provided in hard copy when directed to do so by CMS. We intend the final rule to authorize CMS to direct the manner in which plans provide the documents and information subject to paragraph (a) to enrollees; as discussed in the proposed rule, we intend to use that authority to provide MAOs the flexibility to deliver certain required documents—such as the EOC and provider directory but not the Summary of Benefits—through electronic delivery or posting on the website in conjunction with delivery of a hard copy notice (describing how the information and materials are available) and provision of a hard copy upon request. We believe this final rule will allow 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 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. Current 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 did not propose 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 proposed 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 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 must be adequately described in the ANOC (per § 422.111(d)), which is provided at least 15 days before the AEP.

This change will 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 of errors that plans self-identify in the document through errata sheets they submit to CMS and mail to beneficiaries. In late-2016 and early-2017 for the 2017 plan year, MA and Part D plans overall submitted 166 ANOC/EOC errata, which identified 221 ANOC errors and 553 EOC errors in the 2017 plan materials. 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 proposed that we would use the authority to direct the manner of delivery under paragraph (a) to give plans more flexibility to provide certain 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)(2). At that time, MA plans were not required to maintain a website, but if they chose to they were required to include the EOC, Summary of Benefits, and provider network information on the website. 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 website at § 422.111(h)(2) and moved the requirement that posting documents on the plan website 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 website 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 proposed regulatory text for § 422.111(a) will permit delivery by notifying enrollees of the internet posting of the documents, subject to the right to request hard copies.[71] As explained in the proposed rule regarding the changes to § 422.111, we intend to use the authority provided by this rule to give plans the flexibility to provide certain documents such as the EOC and the provider network information in an electronic manner and 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 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 believe 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.[72] 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, online 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.[73] 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, we believe allowing plans the option to use a similar strategy for additional materials is appropriate. In addition, we believe that it is appropriate to codify the authority to permit this flexibility in the applicable regulation.

We intend to issue sub-regulatory guidance to identify permissible manners of disclosure under this final rule; we expect such guidance will be similar to the current guidance for the provider directory, pharmacy directory, and formulary regarding dissemination of the EOC. Importantly, neither the proposal nor this final rule 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 Section 1557, 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 and Section 1557.

To create the flexibility for delivery of required materials, CMS proposed to modify § 422.111(h)(2)(ii) and to revise § 422.111(a). The proposed 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. 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.

We received the following comments on our proposals regarding the time and manner of delivery of required materials to MA and Part D plan enrollees, and our response follows:

Comment: Many commenters indicated unequivocal support for the provision as proposed.

Response: We appreciate the support of the proposed change.

Comment: Many commenters indicated that they did not support the proposal to allow plans to deliver certain required documents electronically and only provide hard copy versions of those required documents upon request. These commenters expressed concern that there are still many beneficiaries who do not have easy access to electronic documents, especially those in rural areas and those who are of advanced age.

Response: We appreciate the concern that these commenters have about Medicare beneficiaries' ability to access electronic documents. We believe that the hard copy notification of the ability to request a hard copy as well as the

[71] 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.*

[72] Pew Research Center, May 2017, ''Tech Adoption Climbs Among Older Adults'', *http://www.pewinternet.org/2017/05/17/tech-adoption-climbs-among-older-adults/.*

[73] 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.*

electronic status and availability of the documents should mitigate this as enrollees who want or need hard copies will be able to call the plan to request them. Additionally, we know from our experience administering the program that many of these beneficiaries rely on family members and friends to review important documents for them, and that these family members and friends will be more likely to have access to electronic versions of the required documents. As an additional measure, we intend to suggest in our subregulatory guidance regarding use of electronic delivery, that when a beneficiary requests hard copy delivery of a required document in place of electronic delivery, the plan may wish to continue to provide hard copies to that beneficiary on an ongoing basis, so that the beneficiary does not have to request hard copy format again. Finally, as we indicated earlier, the number of beneficiaries who have access to electronic mediums such as broadband internet access is growing every year. We believe we have placed sufficient protections in place and have addressed the growing desire for electronic versions of required documents.

Comment: A commenter requested that we exclude the Summary of Benefits from electronic delivery citing the importance of hard copy for this document in the beneficiary's process of choosing to remain in a current plan or choose a new plan.

Response: We agree with this comment and are finalizing additional revisions to § 422.111(h)(2)(ii) and new text in § 422.111(h)(2)(iii). The new paragraph (h)(2)(iii) provides that posting the Summary of Benefits does not relieve the obligation to provide hard copies of the document to enrollees when CMS determines that it is in the best interest of the beneficiary. CMS considers the Summary of Benefits, unlike the EOC, to be a marketing material because its primary purpose is to influence a prospective enrollee's decision to enroll in a plan. For example, agents use the Summary of Benefits as a tool to help sell plans to prospective enrollees. It indicates key benefits in a standardized arrangement, providing the beneficiary with a safeguard to confirm what the agent has presented. On the other hand, the EOC is a document delivered after a beneficiary has made an enrollment decision and is, in essence, a contract between a current enrollee and the plan, articulating rights and responsibilities, as well as detailed guidance on how to interact with the plan. CMS believes that enrollees should not have to take an extra step to find the Summary of Benefits when enrolling in a plan. Because plans provide the Summary of Benefits with an enrollment mechanism, to avoid an extra step, the Summary of Benefits must be available in the same format as the enrollment mechanism. To that end, when plans provide a paper application to a prospective enrollee, CMS instructs the plan to also provide a paper Summary of Benefits along with the paper application.

Comment: Many commenters indicated support for the proposed changes, but also requested additional considerations that mainly fell into two areas: (1) A request to allow plans the option to include the hard copy notification about electronic posting of the EOC and provider directories along with the ANOC; and (2) a request to allow plans the option to include other information with the ANOC, especially additional benefit information (for example, supplemental benefits) as, while CMS requires plans to provide this information, CMS currently prohibits plans from providing this information with the ANOC.

Response: We also agree with both suggestions regarding the ANOC. We are revisiting our prior guidance (section 60.6 in the 2018 Medicare Marketing Guidelines document) prohibiting plans from providing other materials along with the ANOC as we make the changes to align our subregulatory guidance with this final rule.

As discussed earlier, we are finalizing as proposed revisions to § 422.111(a)(3) and § 423.128(a)(3) to require delivery by the beginning of the Annual Coordinated Election Period of the Evidence of Coverage and other materials and information described in paragraph (b) of each regulation. In addition, we are finalizing revisions to the regulation text as follows:

—In § 422.111(a), the proposed revision to add ''in the manner specified by CMS'' at the end of the introductory sentence;

—in § 422.111(h)(2)(ii), the proposed revision to specify that posting of the EOC and provider directory—but not the summary of benefits—on the plan's website does not relieve the plan of the obligation to provide hard copies of those materials upon request under paragraph (a) when requested by the beneficiary;

—in § 422.111(h)(2)(iii), new text to move the requirement to post the Summary of Benefits on the plan's website from paragraph (h)(2)(ii) to this new paragraph and a provision clarifying that posting does not relieve the plan of the obligation to deliver hard copies of the Summary of Benefits when CMS determines that it is in the best interest of beneficiaries.

These revisions authorize CMS to specify the manner of delivery of materials described in paragraph (b) of both §§ 422.111 and 423.128, and to clarify that posting of certain information or materials on the MA organization's website does not relieve the organization of the obligation to provide information in hard copy when beneficiaries request hard copy.

5. Revisions to Parts 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 will qualify as marketing or promotional information and materials. 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 prohibitions and requirements. Throughout this proposal, the changes discussed for MA organizations/MA plans and prescription drug plan (PDP) sponsors/Part D plans apply 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 proposed 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: (a) Including ''communication requirements'' in the scope of Subpart V or parts 422 and 423, which will include new definitions for ''communications'' and ''communication materials'' in §§ 422.2260 and 423.2260; (b) amending §§ 422.2260 and 423.2260 to add a definition of ''marketing'' in place of the current definition of ''marketing materials'' and to provide lists identifying marketing materials and non-marketing materials; (c) adding new regulation text to prohibit marketing during the Open Enrollment Period proposed in section II.B.1 of this proposed rule; (d) 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. In addition, section 1876(c)(3)(C) authorizes CMS to adopt conditions and procedures under which a cost plan informs potential enrollees about the cost plan, which would clearly cover the scope of regulations proposed in this section that will be applicable to cost plans. 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 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 proposed changing the title of each Subpart V by replacing the term ''Marketing'' with ''Communication.'' We proposed to define in §§ 422.2260 and 423.2260 the terms ''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 enrollees). We proposed that marketing materials (discussed later in this section) will 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 will include both mandatory disclosures that are primarily informative and materials that are primarily geared to encourage enrollment.

In addition to these proposals related to defined terms and revising the scope of Subparts V in parts 422 and 423, we proposed 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.

CMS proposed, 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 will be subject to the more stringent requirements, including the need for submission to and review by CMS. Under this proposal, we stated in the proposed rule, those materials that are not considered marketing, per the proposed definition of marketing, will fall under the less stringent communication requirements.

With regard to §§ 422.2264 and 423.2264, we specifically proposed 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 will 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 proposed 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 proposed 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 also proposed revisions. First, we proposed to revise the text so that it is stated as a prohibition on sponsoring organizations: Sponsoring organizations may not, for markets with a significant non-English speaking population, provide materials, as defined by CMS, *unless* in the language of these individuals. We proposed adding the statement of ''as defined by CMS'' to allow the agency the ability to define the significant materials that will require translation. We proposed 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 proposed 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 proposed 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 will 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 did not propose to expand the list of prohibitions, but proposed to notate which prohibitions are applicable to which category. The only substantive change proposed is in connection with paragraph (a)(7), which we discuss earlier in this section. We solicited 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 proposed a definition of ''marketing'' to be codified in §§ 422.2260 and 423.2260. We proposed to 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'' was proposed 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 for prior CMS review and approval 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 and are 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 scope of materials that fall under the scope of marketing, we stated that the proposal would allow us to better focus review on those materials that present the greatest likelihood for a negative beneficiary experience.

We proposed 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 providing factual 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 will no longer fall within the definition of marketing under the 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 will be excluded from the marketing definition will fall under the proposed definition of communication materials, with what we believe are more appropriate requirements. 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 proposed 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 and 423.2260. The current list of examples includes: Brochures; advertisements in newspapers and magazines, and on television, billboards, radio, or the internet; 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 proposed 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 did not 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 will be considered marketing.

Third, we proposed 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 and 423.2260 to identify the types of materials that will 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, will also be excluded from marketing. We also proposed, in the preamble, that required materials in § 422.111 and § 423.128 not be considered marketing, unless otherwise specified, and, separately, materials specifically designated by us as not meeting the definition of the proposed marketing definition based on their use or purpose; however, the proposed regulation text (82 FR 56505–06 and 52525) combined these categories inadvertently so that the proposed regulation text excluded from the definition of marketing materials those that are required by §§ 422.111 or 423.128 unless CMS specified otherwise because of the use or purpose of the materials. We proposed to revise the list of exclusions from marketing materials to maintain the current beneficiary protections that apply to marketing materials but to narrow the scope of CMS's review and approval responsibilities to exclude materials that are unlikely to lead to or influence an enrollment decision.

Our proposal was intended to exclude from marketing any 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 will not be used to make an enrollment decision in a specific Medicare plan, rather they will be used to drive beneficiaries to request additional information that will 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; we therefore proposed to exclude materials that do not have such rankings or measurements from marketing. In addition, we proposed to exclude materials that mention benefits or cost sharing but do not otherwise 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, proposed to exclude 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 proposed 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. Elsewhere in this final rule (section II.B.1 (Restoration of the Medicare Advantage Open Enrollment Period (§§ 422.60, 422.62, 422.68, 423.38 and 423.40)), we finalize that revision to the MA regulations. 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 proposed to add a new paragraph (b)(10) [74] to both proposed §§ 422.2268 and 423.2268 to apply this prohibition on marketing. We also requested comment on how the agency could implement the statutory requirement. The new OEP is not available for enrollees in Medicare cost plans; therefore, these limitations apply to MA enrollees and to any PDP enrollee who was enrolled in an MA plan the prior year. CMS expressed concern in the proposed rule 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. We noted that one mechanism could be to limit marketing entirely during that period, but were concerned that such a prohibition would be too broad. We proposed a ''knowing'' standard instead, believing that it would both effectuate the statutory provision and avoid against overly broad

[74] The proposed rule, at 82 FR 56436, mistakenly referred to paragraph (b)(9) as the location of this new proposed text.

implementation. We solicited 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 became synonymous with communications from the plan to enrollees or potential enrollees. As a result of our proposal to define both ''marketing'' and ''communications,'' we proposed a number of technical changes that we believe are necessary to update regulation text that uses the term marketing throughout parts 422 and 423. Accordingly, we proposed the following technical changes in Part C:

- In § 422.54, we proposed to update paragraphs (c)(1)(i) and (d)(4)(ii) to replace ''marketing materials'' with ''communication materials.''
- In § 422.62, we proposed 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 proposed to use ''supplemental benefits packaging'' instead of ''marketing of supplemental benefits.''
- In § 422.206(b)(2)(i), we proposed 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 proposed to replace the term ''marketing'' with the term ''communication.''
- In § 422.510(a)(4)(iii), we proposed 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 proposed to replace the term ''marketing'' with ''communications'' in § 422.750 and 422.752 to reflect its proposal for Subpart V. The proposal to change the terminology was not intended or designed to expand the scope of CMS's authority with respect to sanction regulations. Rather, CMS sought to preserve the existing reach of the 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 proposed the following changes to §§ 422.750 and 422.752:

- In § 422.750, we proposed to revise paragraph (a)(3) to refer to suspension of ''communication activities.''
- In § 422.752, we proposed to replace the term ''marketing'' in paragraph (a)(11) and the heading for paragraph (b) with the term ''communications.''

We did not propose 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 proposed the following technical changes in Part D:

- In § 423.38(c)(8)(i)(C), we proposed 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 proposed to replace ''marketing'' with ''communications'' to reflect the change to Subpart V.
- In § 423.505(b)(25), we proposed to replace ''marketing'' with ''communications'' to reflect the change to Subpart V.
- In § 423.509(a)(4)(V)(A), we proposed to delete the word ''marketing'' and instead simply refer to Subpart V.

For the reasons explained in connection with our proposal to revise the Part C sanction regulations, we also proposed the following changes: [75]

- In § 423.750, we proposed to revise paragraph (a)(3) to refer to suspension of ''communication activities.''
- In § 423.752, we proposed to replace the term ''marketing'' in paragraph (a)(9) and the heading for paragraph (b) with the term ''communications.''

We did not propose 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 solicited comment on the proposed technical changes, particularly whether a proposed revision 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 stated our belief that our proposals would maintain the appropriate level of beneficiary protection and 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 would allow CMS 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 solicited comment on these proposals and whether the appropriate balance is achieved with the proposed regulation text.

e. Comments and Reponses on Proposals Related to Communications and Marketing

CMS was pleased to see a large number of comments in support of using the narrower definition for ''marketing,'' and the new term ''communications'' in Subpart V. Commenters in favor of the proposed changes indicated that the proposed new definitions appropriately safeguard prospective and current enrollees, while not placing an undue burden on MA plans and Part D plan sponsors. In that same vein, commenters expressed that the proposed changes allow for a less burdensome approach to communicating with beneficiaries. Other commenters said that the new definition of marketing was logical and aligns with the layman's definition of ''marketing.''

We received the following comments, and our response follows:

Comment: Many commenters in favor of the proposed changes to Subpart V asked CMS to provide more information on what materials would fall under the definition of marketing and what materials would fall under the definition of communications, but not marketing. Moreover, commenters requested additional information on

[75] We note that the proposed rule preamble (82 FR 56437) mistakenly did not include a discussion of the specific Part D regulation sections that we proposed to revise in connection with CMS sanction authority; however, the proposed regulation text (82 FR 56524) did include the proposed change.

whether or not communication materials that are not marketing materials would still be submitted to CMS for review. Several commenters suggested materials, such as standardized models, be considered communications, but not marketing. Many of these comments acknowledged that they expected such detail to be captured in sub-regulatory guidance, such as the MMG. Additionally, a subset of commenters reiterated the importance of CMS working with industry to develop updated sub-regulatory guidance for marketing and communications.

Response: CMS agrees that sub-regulatory guidance is the more appropriate vehicle for applying the definitions and identifying what types of materials are marketing and what types are communications. As such, we intend to develop a successor to the current MMG that will include guidance for both communications and marketing. CMS will seek comment as a part of the development of the new guidelines.

Comment: A commenter who supported the updates to Subpart V urged CMS to further refine the definition of marketing to include materials or activities targeting ''prospects'' and not current enrollees.

Response: CMS disagrees with this suggestion and believes that the definition of marketing, as proposed and finalized, correctly focuses on all beneficiaries, including existing, new and potential enrollees of a plan, when the intent is to draw attention to the plan and influence the individual's plan selection. Plans market to their current members for the purposes of ''upselling'' or retention and such efforts are appropriately subject to our marketing oversight and regulations. Additionally, we note that this final rule includes a provision (in finalized § 422.2260 and § 423.2260) that authorizes CMS to characterize materials that fall under § 422.111 and § 423.128 as not marketing materials based on their use and purpose; therefore, many required materials will fall under the broad communication definition.

We generally agree with the commenter(s) that required and standardized materials, such as the EOC, directories, and materials required under §§ 422.111 and 423.128, should generally fall under communications rather than marketing materials under the definition we proposed and are finalizing here. We are finalizing an exclusion from marketing materials that provides that unless CMS provides otherwise, materials required under §§ 422.111 and 423.128 are not marketing materials. To the extent that a document (or materials) required by those regulations appears to serve a marketing purpose, meaning that it is promotional materials or designed to influence an enrollment decision instead of providing factual information that is required to be disclosed under the Medicare program, we believe it is important that the regulation text provide CMS the authority to designate the document as a marketing material subject to the higher level of scrutiny.

Comment: Several commenters were not in favor of the changes to Subpart V and expressed concern that CMS is reducing oversight of important plan materials while proposing to give plans more flexibility on plan design and in the types of benefits that can be offered. The majority of these comments focused on concerns regarding CMS's proposal to no longer designate and review the EOC as a marketing material. These commenters believed this proposal suggested CMS was stepping back from its oversight responsibilities.

Response: CMS understands the concern and assures the commenters that our oversight of the EOC will not change for a few reasons. First, the EOC is based on a model material created by CMS and therefore is a document over which CMS already has a high level of oversight and monitoring. Second, the benefits information used to populate the EOC is derived from the plan's bid submission, which goes through its own CMS-based review.

Third, for over 10 years, EOCs have been submitted to CMS as a marketing material under ''File and Use.'' As a result, the EOCs have not been prospectively reviewed upon submission but CMS has historically exercised oversight of the accuracy of EOCs through retrospective reviews, timeliness monitoring studies, and by collecting and analyzing EOC-based errata reported by the plans. The vast majority of EOC errors have been identified through these retrospective processes. We do not expect these oversight and enforcement processes to change with the regulation changes in this final rule. In addition, with this regulatory change, CMS will retain oversight authority over any current marketing material that will become a communication material as a result of the changes to Subpart V, principally the changes to §§ 422.2262, 422.2264, 422.2268, 423.2262, 423.2264 and 423.2268. In particular, we proposed and are finalizing, with slight grammatical revisions, text to §§ 422.2262(d) and 423.2262(d) to provide authority for CMS to review materials—whether communications or marketing—after release and use of the materials by the sponsoring organization. The regulation authorizes CMS to direct modification or stopped use of the materials to clarify that CMS's ability to oversee and enforce compliance with the limits on communications and marketing is not limited to the pre-use review and approval required for marketing materials.

Comment: Some commenters expressing concern with the changes to Subpart V asked that CMS monitor the impact of this change and revisit or reverse course if there is clear evidence that beneficiaries are receiving inaccurate or incomplete plan materials.

Response: CMS agrees that monitoring and evaluation are critical parts of the oversight process and that protection of beneficiaries is a primary goal. The authority outlined earlier will keep CMS well-equipped to monitor any communication issues and to act as needed without additional regulatory changes. In addition to the more formal processes, CMS may act on any information received from Medicare beneficiaries, typically through our Complaints Tracking Module (CTM), as well as complaints received from competing plans.

Comment: CMS received several comments asking how the changes to Subpart V will impact D–SNPs whose materials are also reviewed by the state. A reviewer suggested that CMS work with the states to develop joint guidance.

Response: In general, CMS does not believe that the changes to Subpart V will have an impact on D–SNPs that is different from the impact on other MA plans and Part D plan sponsors. Currently, most marketing reviews are conducted separately by both CMS and the states for materials used by D–SNPs. The changes to Subpart V will result in some materials currently defined as marketing not being subject to prior review and approval by CMS. This, however, should have no bearing on any state requirements that may necessitate state review. Additionally, states retain authority to control and supervise Medicaid managed care plans, even if those plans also have Part C or Part D contracts. State Medicaid agencies also may establish or modify requirements with respect to review of D–SNP materials as part of the contract required under § 422.107.

Comment: CMS also received several provider-focused comments expressing an overarching concern with how the restriction of marketing in the health care setting impacts a provider's ability

to counsel patients about coverage options, particularly if a patient can benefit from coordinated, accountable care in MA. A commenter suggested that CMS exclude from the definition of marketing materials under section 422.2260 any communications from providers or MAOs to their patients regarding their care, including communications regarding cost-sharing responsibilities or listing the plans in which a provider participates. The same commenter noted that CMS does not generally require providers to seek CMS's approval for communications with patients who are enrolled in traditional Medicare. Further, they expressed that as long as the provider-patient or MAO-patient communication does not serve to ''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,'' then such communications regarding cost-sharing obligations should not be subject to CMS review simply because the patient receives Medicare benefits through an MAO.

Response: CMS's restrictions on sales and marketing in the health care setting, which are required by section 1851(j)(1)(D) of the Act, were never intended to preclude a doctor from discussing MA with patients. Rather, the requirements prohibit a sponsoring organization (including its officials, employees, contractors, participating providers, the agents, brokers, and other third parties representing such organization) from *marketing* to a Medicare beneficiary in the health care setting. Based on the examples provided, combined with the changes made to Subpart V, CMS does not believe that discussions about cost-sharing responsibilities of a patient, identifying the plans with which a provider participates, or about patient care are considered marketing. As the commenter points out, such discussions are intended to educate a beneficiary about the merits of the MA program and the respective responsibilities of the patient and the provider under MA coverage, not to influence a beneficiary's decision-making process. However, certain activities or discussions undertaken by a provider could be marketing, such as distribution of brochures or appointment forms for specific plans or attempting to persuade a beneficiary to select a specific plan. Based on the comments received, we will clarify this distinction in sub-regulatory guidance.

Comment: Another commenter stated that any attempts to use information to intentionally mislead beneficiaries when selecting a plan or choosing to utilize a specific pharmacy (including the use of the term ''preferred'') should be expressly prohibited. The commenter continued that all information provided to beneficiaries should be inclusive, complete, and accurate to allow the beneficiary to make their own decisions regarding which plan to select and which pharmacy to use.

Response: CMS agrees with the commenter that all information provided to beneficiaries should be inclusive, complete, and accurate to allow the beneficiary to make their own decisions regarding which plan to select and which pharmacy to use. The regulations finalized today, as do the current regulations, explicitly prohibit the provision or information or other activities that mislead beneficiaries at paragraphs (a)(1) and (2) of §§ 422.2268 and 423.2268. However, we disagree with the commenter's suggestion that the use of the term ''preferred'' should not be allowed. CMS allows for preferred pharmacies where the copay may be lower for the beneficiary (§ 423.120(a)(9)) and we believe that conveying this potential cost savings to enrollees is important.

Comment: CMS received a comment outlining the unique challenges of ESRD beneficiaries and that treatment area is an ideal location for clinical and non-clinical staff to help beneficiaries assess their coverage choices.

Response: CMS appreciates the real-world insight that this example provides. However, the restriction on marketing in the health care setting is statutory. By contrast, any activities that would fall under the new definition of communications, but not marketing, are allowed in the health care setting, so long as the communication activity complies with new §§ 422.2268(a) and 423.2268(a). Plan-specific materials that are still considered marketing may not be distributed in areas where care is delivered. But a provider may discuss the MA program with the patient and make the plan's marketing materials available in common areas.

CMS received overwhelming support for extending the translation requirement proposed at §§ 422.2268(a)(7) and 423.2268(a)(7).

Comment: Several commenters expressed that they were pleased that CMS proposed to extend its current document translation requirement to ''communications'' designated by CMS rather than limiting it to certain marketing documents. The commenters asked that CMS adopt this change and, in implementation, expand the list of specific documents that are subject to translation rules. The commenters continued that, currently, many important documents are not translated, such as notices that beneficiaries are being denied services or will be disenrolled for failure to pay premiums.

Response: CMS appreciates the supportive feedback. We are finalizing the regulatory language at § 422.2268(a)(7) and § 423.2268(a)(7) to require translation of ''vital materials'' as opposed to materials ''as defined by CMS''. We believe that this standard will provide sufficient flexibility to sponsoring organizations in connection with mere marketing materials as well as provide beneficiaries with access to the information and materials that are vital to coverage. In conjunction with the final regulation, CMS intends to develop a successor to the current MMG that will include guidance for both communications and marketing. In this sub-regulatory guidance, we intend to provide additional guidance explaining which documents and materials are vital materials that must be translated. We also remind commenters and plans that this regulation is not the only legal obligation for MA organizations and Part D sponsors with regard to Medicare beneficiaries who have limited English proficiencies. 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 Section 1557, 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 and Section 1557. Guidance about obligations under these other statutes is available from the Office for Civil Rights. Further, we note that § 422.111(h)(1)(iii) and § 423.128(d)(1)(iii) require the call centers of sponsoring organizations to provide interpreters to enrollees who are LEP or do not speak English, without limitation based on the number of enrollees in a service area that are LEP or do not speak English.

Comment: Several commenters asked that CMS change the current translation standard, which only covers languages spoken by five percent or more of the population in the service area. The commenters expressed concern that the current rule means that, except for a couple small pockets, the only required language for translation is Spanish.

Response: CMS uses U.S. Census Bureau's American Community Survey data to determine which PBPs must provide translated materials and has determined that five percent of a language spoken in service area is an

appropriate threshold for translation requirements. We reiterate that other laws also apply to sponsoring organizations and this marketing and communication regulation is not the only applicable provision for ensuring access for beneficiaries with limited English proficiency. For example, as recipients of federal financial assistance, MA plans and Part D prescription drug plans are subject to the nondiscrimination requirements under Title VI of the Civil Rights Act of 1964 and Section 1557 and their implementing regulations (45 CFR parts 80 and 92).

Comment: A commenter asked if the language used in §§ 422.2268(a)(7) and 423.2268(a)(7) was error in the wording, as the commenter found it unclear.

Response: The language is correct. It is written in the context of what plans cannot do. Paragraph (a)(7), as proposed and finalized, prohibits plans from providing materials in markets with significant non-English speaking populations *unless* the communications are in the language of the non-English speaking populations. We believe that this is a clear statement of the intended prohibition.

We received a number of comments based on the updates to §§ 422.2268 and 423.2268 to address section 1851(e)(2) of The 21st Century Cures Act (the Cures Act). Overall, comments were evenly split among those in favor of CMS's proposed language and those commenters who suggested alternative methods of addressing the Cures Act prohibition on marketing during the new OEP. There were no commenters in favor of a broader prohibition on marketing during the OEP.

Comment: Several commenters were in favor of CMS's use of the term ''knowingly'' stating that it would protect a plan from the marketing prohibition when the plan does not know that the beneficiary is enrolled in an MA plan at the time.

Response: CMS appreciates feedback and concurrence.

Comment: Some commenters suggested that, during the OEP, marketing could be acceptable if it did not include any reference to the OEP.

Response: CMS appreciates the suggestion; however, using the term ''knowingly'' takes into account the recipient as well as the content of the message so we believe that a prohibition that only addressed the term ''OEP'' would be too narrow to satisfy the statute. For example, if a plan were to send messaging specifically calling out the OEP, that would be knowingly targeting. Likewise, if a plan was aware that an individual had already made an enrollment decision during the AEP, sending unsolicited marketing materials to that individual, even if the OEP was not mentioned, would be considered ''knowingly targeting''. To that point, as finalized, the regulation accomplishes what the commenters have suggested, as well as addresses marketing to specific individuals that are able to make a plan selection during the OEP.

Comment: Another commenter stated that marketing often takes the form of educating beneficiaries about their options and their rights to change plans, or remain in their plan if they are satisfied. Restricting such marketing will effectively undo much of the ''good'' that was established under OEP, discouraging beneficiaries from exploring various plan options and selecting the plan that is best for them, and their families. The commenter supported a policy which would allow marketing to all beneficiaries during OEP, including those beneficiaries eligible for OEP. In particular, the commenter asserted that it would be largely unworkable to limit marketing only to a subset of individuals who have not yet enrolled in a plan during OEP. The commenter offered that one potential option is to only prohibit direct marketing communications to OEP beneficiaries, but permit broader communications including: Television ads, general mailing campaigns, internet marketing, and radio ads during the OEP.

Response: The statute prohibits unsolicited marketing and the final regulation has been updated to reflect this. Neither the statute nor regulation restricts a plan from providing educational materials or marketing materials if and when the beneficiary proactively reach out looking for OEP help. To that end, CMS supports each plan's ability to reactively respond to beneficiaries when it comes to the OEP. CMS disagrees that plans should be able to market its coverage under the guise of help.

CMS believes that the intent of Congress was to allow beneficiaries to make an enrollment decision during the OEP, but not for it to be a second opportunity for plans to proactively persuade or attempt to persuade beneficiaries to switch plans. Prohibiting plans from knowingly targeting beneficiaries during the OEP addresses Congress's intent while affording plans with the flexibility to still conduct marketing to other potential enrollees, such as age-ins. Upon review of the proposed rule, in light of these comments, we are finalizing the proposed regulation text with the addition of the word ''unsolicited'' to modify ''marketing materials'' to be consistent with the statute and to clarify that responses to inquiries from beneficiaries is not prohibited.

Comment: A commenter suggested the ''knowing'' standard would unfairly disadvantage MA plans where a beneficiary might already be enrolled, since that plan would be more likely to know that the enrollee was enrolled in an MA plan during the previous year. If another MA plan does not know that enrollees are already enrolled, that MA plan could market to those enrollees, potentially influencing enrollees to switch plans. This standard would not be in the best interest of beneficiaries and could cause market disruption. The commenter recommended that CMS create a standard where marketing during OEP is not targeted to specific enrollees, thus plans would be permitted to run general marketing campaigns (plan-specific or on the MA and/or Part D program). This type of standard would satisfy statutory requirements, would reduce beneficiary confusion, and would ensure that plans are on a level playing field.

Response: CMS appreciates the commenter sharing this concern. Our goal is to implement the Congressional intent without creating an additional undue burden to plans. In addition, the OEP does not impact those beneficiaries who are aging into the Medicare program and have not yet made an enrollment decision, as they are still in their the Initial Coverage Election Period (ICEP). We believe that tying the marketing prohibition to a ''knowingly'' standard implements the statute while avoiding an unnecessary burden on plans and sponsoring organizations. It is true that a plan that just processed an enrollment may have more knowledge of the status of a beneficiary, yet we believe that ''knowingly'' also address the content of the message, which should mitigate the concern by not permitting other organizations to specifically target such individuals with marketing that touts the ability to make another plan choice via the OEP.

Comment: A commenter stated that implementing these marketing limitations could prevent a plan from sending marketing mailings to individuals who are not enrolled in a plan, but would otherwise be eligible (for example, age-ins). The commenter states that it is important to note that a purchased mail list could not accurately exclude individuals already enrolled in a Medicare Advantage plan. The commenter also asked if there could be exceptions to such a prohibition for marketing mailings intended to reach

individuals eligible to enroll in an MA plan outside of using the OEP election period (for example, a targeted age-in mailing).

Response: The intent of the guidance is not to restrict plans' ability to use mailings or other marketing aimed at individuals aging into the Medicare program who have not yet made an enrollment decision. Such marketing would focused on the fact that these age-ins are a entering (or have entered) the Initial Coverage Election Period. In this instance, if a plan buys a list of age-ins and sends general marketing mailers to all on the list, but some of those on the list have already selected an MA plan during their Initial Coverage Election Period, CMS would not consider it knowingly targeting based on the content of the message combined with the fact that the plan would have no way of knowing that an enrollment decision had already been made. In this instance, the content of the marketing must not address or include a reference to the OEP or the opportunity to make an additional enrollment change during their first 3 months of coverage.

Comment: A commenter asked how OEP marketing restrictions will impact access for dually-eligible members who want to move during that time to a FIDE or other highly integrated D–SNP. The commenter stated that CMS should also allow marketing to dually eligible beneficiaries for integrated FIDE and D–SNPs during the OEP.

Response: CMS does not intend the restriction of OEP marketing to impact any D–SNP marketing. Barring information to the contrary, such marketing appears aimed at dually eligible individuals who are using the Part D SEP that is available to dually-eligible beneficiaries other LIS eligible individuals, rather than use of the OEP, for changing enrollment. This would indicate that the plan is not knowingly targeting those in the OEP, which is what the rule, as proposed and finalized, prohibits.

Comment: A commenter expressed concern that an organization could use their Medigap line of business using a generic marketing line of, ''not happy with your plan, change now'' to generate leads. This would generate inquiries from those in a MA plan, at which point the company can steer the conversation to their MA products. The commenter suggested that, if CMS is going to offer the open enrollment window, CMS should allow marketing in order to keep the playing field equal.

Response: While veiled by the use of Medigap, CMS would still consider the situation described by the commenter as targeted marketing performed by the MA organization, if the intent is to get those in the OEP to switch MA plans rather than actually marketing a Medigap plan. CMS does not believe the answer is to allow marketing across the board, as that would only exacerbate the concern and conflict with the statute.

Comment: A commenter asked if it is possible that during the Open Enrollment Period a beneficiary may request marketing materials from different plans if they were unhappy with their plan and wanted to switch. This information would inform them about their choices.

Response: The statute clearly prohibits unsolicited marketing. CMS agrees that providing marketing materials and other information in response to a request from a beneficiary is allowed under this final rule as it is at the beneficiary's request and hence not unsolicited. To address this, we have updated the regulatory language in the final rule to specifically state unsolicited.

Comment: A commenter requested a clarification if this also includes marketing to beneficiaries aging into Medicare.

Response: The exclusion is directed to those eligible for the OEP, including newly eligible enrollees. For more information about the OEP, we direct readers to section II.B.1 of this final rule.

Comment: A commenter asked if Medicare Advantage plans that have achieved a 5-Star plan rating are allowed to market to beneficiaries all year round. The commenter also asked if CMS will be allowing an exception to the statutory requirements of The 21st Century Cures Act to allow 5-Star plans year round marketing.

Response: With the exception of targeted marketing to those in the OEP and marketing prior to October 1 for the next contract year, all plans may market year round. What distinguishes 5-Star plans is that they may also enroll year round pursuant to the SEP we have adopted under our authority at §§ 422.64(b)(4) and 423.38(c), which could make marketing year round more advantageous and effective. However, 5-Star plans may not target those in the OEP; we believe that 5-star plans would not need to target enrollees in the OEP, however, because the beneficiary could enroll in a 5-star plan at any time during the year as a result of the plan's 5-Star status. To that point, CMS believes that a 5-Star plan marketing its 5-Star status and the ability to enroll year round does not prove that the MA organization is knowingly targeting those who may also be eligible for the OEP.

Comment: Several commenters expressed concern with brokers' activities, with a commenter stating the OEP should not be a time for aggressive marketing tactics or a time in which brokers are incentivized to promote beneficiaries to switch plans. Several commenters suggested that CMS should consider monitoring for churn of beneficiaries among multiple plans and possible beneficiary confusion during the OEP. Similarly, another commenter asked how this will be enforced and where a beneficiary should report marketing abuse.

Response: CMS agrees with the commenter that the OEP should not be a time for plans and brokers to aggressively market. Further, CMS believes this very concern is what prompted Congress to include the OEP marketing restrictions in the statute. CMS will monitor for violations of the prohibition of knowingly marketing to beneficiaries in the OEP and take appropriate compliance or enforcement action. CMS encourages beneficiaries to report any abusive, confusing or misleading marketing practices by plans, agents and brokers by contacting contact 1–800–Medicare. In addition, we encourage reports of potential violations of this requirement.

Comment: A commenter asked that education about this prohibition to be targeted to all related industries and interest groups so that all entities that may target this vulnerable population will understand the law and the consequences for knowing violations.

Response: CMS agrees that compliance with this provision is the responsibility of plans and their first tier, related and downstream entities, including agents and brokers. CMS will include additional sub-regulatory guidance on this change in the law and reminds plans that they are responsible for the activities of their downstream entities, including agents and brokers.

Comment: CMS received a number of comments requesting the agency to define ''unsolicited marketing'' as it appears in the statute.

Response: We do not believe that is necessary and do not adopt a definition of the phrase in this final rule. CMS believes the intent of Congress was for plain and ordinary meaning of those words to apply, consistent with CMS's existing guidance on the prohibition on unsolicited direct contact required by section 1851(j)(1)(A) of the Act.

After considering these comments, we are finalizing the proposed changes related to marketing and communications requirements as proposed with some modifications:

We are finalizing the new definitions proposed at §§ 422.2260 and 423.2260 with corrections to the list of exclusions from marketing materials (as noted in section II.B.5.b) to exclude disclosures required by §§ 422.111 and 423.128 unless CMS directs otherwise and to exclude materials specifically designated by CMS as not meeting the definition of the proposed marketing definition based on their use or purpose. We are also finalizing technical and editorial corrections to the text, including the removal of the incorrect paragraph designations in § 423.2260 and alignment of the text in §§ 422.2260 and 423.2260.

We are finalizing the amendment to §§ 422.2262(d) and 423.2262(d), the revisions to §§ 422.2264 and 423.2264, and the revisions to §§ 422.2268 and 423.2268 as substantially as proposed, with modifications in paragraph (a)(7) that the translation provision is applicable to ''vital documents'' instead of to documents specified by CMS and in paragraph (b)(10) to add the modifier ''unsolicited'' before the phrase ''marketing materials.''

We are finalizing as proposed the technical amendments described in section II.B.5.d of this final rule with modifications in §§ 422.62(b)(3)(B)(ii) and § 423.38(c)(8)(i)(C) to clarify that the special enrollment period is available when the sponsoring organization ''(or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communications as outlined in subpart V of this part.'' These technical amendments are necessary because after we published the proposed rule, we discovered that our proposed change limited this authority to only written communications. This was not our intent. In addition, among the minor edits to improve the regulation text in subpart V of parts 422 and 423, we are finalizing a correction to the internal cross-reference in §§ 422.2274 and 423.2274 to cite to paragraph ''(b)(2)(iii)'' instead of ''(b)(3)(iii)'' in newly redesignated paragraph (b)(2)(ii)(A).

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 proposed 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 proposed 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 will also apply to the IRE reconsideration pursuant to § 423.600(d). We did not propose 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.

We received the following comments and our responses follow:

Comment: We received many comments, primarily from plans, expressing support for the proposed change to the payment adjudication timeframe from 7 to 14 calendar days at the redetermination and reconsideration levels. Commenters noted that, because payment requests involve an enrollee who has already received the medication, allowing the plan 14 calendar days (instead of 7 calendar days) to process the payment request would allow the plan to prioritize requests for coverage where the enrollee has not yet accessed the prescription drug, particularly during times when the plan sponsor is experiencing a high volume of requests. Commenters noted that this would ensure adequate resources are directed to processing more time-sensitive pre-service requests where the beneficiary has not yet obtained the drug. Commenters also expressed support for this proposal for the reason that it could reduce the number of unfavorable decisions made due to insufficient information to support the request. Some of these commenters requested that CMS consider lengthening the timeframe for other decisions, such as coverage determinations.

Response: We appreciate the commenters' support for the proposal and agree that allowing an additional 7 calendar days to process payment requests will result in a more thorough review of the payment request which may lead to fewer unfavorable decisions due to insufficient information to support the request. We also agree that affording more time for payment requests will permit plan sponsors to better prioritize requests for coverage; this will help plan sponsors efficiently allocate resources to more time-sensitive pre-service requests where the beneficiary has not yet obtained the drug.

Comment: Several commenters expressed concern about the effect of this proposed change on beneficiaries and encouraged CMS to keep the existing adjudication deadline for plan sponsors and the IRE. Some commenters noted concern about the increased financial burden this proposal would place on enrollees given that many Medicare beneficiaries are on limited budgets. A commenter noted that enrollees who wait up to a month to learn that their case has been decided against them would have to either pay for the drug out of pocket again or get a prescription for an alternative drug within a short time period. Commenters believed these options jeopardize enrollees' access to needed drugs. A commenter asked for clarification on when payment must be made to an enrollee if a favorable decision is issued.

Response: We'd like to clarify that, contrary to the statement of a commenter, enrollees will not have to wait ''up to a month'' to receive a plan sponsor's redetermination decision on a request for payment. Our proposal was to extend the adjudication timeframe for payment cases from 7 to 14 calendar days. While we acknowledge that extending the adjudication timeframe for 7 calendar days at the redetermination and IRE level increases the length of time the enrollee will wait for a decision, we do not believe that an additional 7 calendar days to receive notice on a payment request will create access issues for enrollees, given that the enrollee has already received the drug. We believe the additional 7 calendar days plan sponsors and the IRE will have to gather information and process these requests could be beneficial to enrollees because decisions are likely to be informed which, in turn, will potentially result in fewer payment decisions being denied and subject to further appeal.

The change we proposed is limited to payment requests where the enrollee has already received the drug, so we believe there is minimal to no risk that an additional 7 calendar days to process these requests will adversely affect the health of an enrollee who has requested

reimbursement. As we noted in the proposed rule, when coverage is approved, the plan must make payment to the affected enrollee no later than 30 calendar days after the date the plan sponsor receives the redetermination request. In other words, the change to a 14 calendar day adjudication timeframe will not change the time in which the plan sponsor has to issue payment to the enrollee.

We believe the proposed change to a 14 calendar day timeframe is an appropriate balance between plan sponsors' need to obtain information to thoroughly evaluate a payment request and the interest of enrollees in receiving prompt notice on a payment request. We believe the proposed change will enhance efficiency in the adjudication of these types of cases, reduce adverse payment decisions, and reduce the number of late cases that have to be auto-forwarded to the IRE. As previously noted, the proposed change to a 14-calendar day adjudication timeframe will also apply to payment requests processed by the Part D IRE. Because the enrollee has received the prescription drug that is subject to the payment request, we disagree with commenters who believe the additional time will needlessly delay access to treatment. We believe that allowing plan sponsors and the IRE additional time to obtain necessary documentation and thoroughly review the case will be beneficial overall and that the advantages offset the additional 7 calendar days an enrollee may have to wait for a decision on a payment request.

Comment: A commenter noted that there's no evidence to support the proposed change and that, instead of increasing the timeframe, CMS should enforce current timeframes and delay implementation of this change until the extended timeframe can be tied to specific enhanced performance standards, with substandard performance resulting in financial consequences for plans. Another commenter noted that new protocols will need to be issued and that timeliness calculations for data universe fields will need to be adjusted.

Response: CMS has received significant feedback from plan sponsors regarding the difficulties encountered with receiving information necessary to process requests in a timely manner. CMS has also received feedback that there should be greater consistency in the appeals process. As noted in the proposed rule, implementing a 14 calendar day timeframe for redeterminations and IRE reconsiderations involving payment requests will establish consistency with the timeframe for coverage determinations that involve a request for payment. Since these are cases where the enrollee has already obtained the drug, we believe it's reasonable to afford plan sponsors and the IRE additional time to obtain the documentation necessary to support a favorable decision on the request. We acknowledge that audit protocols and related materials will need to be modified to comport with the new 14 calendar day payment timeframe for redeterminations in order to measure plan performance in meeting this timeframe. We agree with the commenter that plan sponsors' performance in meeting this new timeframe for payment redeterminations should be evaluated, but disagree that implementation of the new timeframe should be delayed.

Comment: A commenter that expressed support for the proposal noted that CMS should align the coverage determination payment timeline with the existing redetermination timeline of 30 calendar days.

Response: We appreciate the commenter's support for the proposal, but wish to clarify that the existing redetermination timeframe is 72 hours for expedited requests and 7 calendar days for standard redetermination requests.

After consideration of the public comments received, we are finalizing this provision as proposed.

7. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE (§ 422.590)

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) contracted with CMS to review plan-level appeals. Pursuant to § 422.590(f), MA plans must notify enrollees upon forwarding cases to the IRE.

We proposed to revise § 422.590 to remove paragraph (f) to delete the requirement for plans to notify enrollees upon forwarding cases to the IRE. The Part C IRE will continue to be contractually responsible for notifying enrollees upon receipt of cases from MA plans. We proposed this change to ease burden on MA plans without compromising notice to the enrollee (or other party) of the progress of the appeal and to allow MA plans to redirect resources to time-sensitive activities, such as review of coverage requests and improved efficiency in appeals processing and provision of health benefits.

We received the following comments and our responses follow:

Comment: We received many comments expressing strong support for our proposal to eliminate the MA notice when plans forward cases to the Part C IRE. A majority of commenters agreed that the current MA plan notice requirement is duplicative and unnecessary, as the Part C IRE also is responsible for notifying an enrollee that it has received the case. These commenters indicated that the redundant notice is costly, elimination of this unnecessary notice will reduce beneficiary confusion, and the proposed change is in line with current paperwork reduction initiatives.

Response: We agree with the commenters that this proposal will ease unnecessary administrative burden on MA plans while favorably impacting enrollees. We expect this change to increase beneficiary understanding and allow plans to redirect resources previously allocated to issuing this notice to more patient-care related, time-sensitive activities. We appreciate the comment that this proposal is consistent with the agency's *Patients Over Paperwork* initiative to reduce paperwork and agree the change will benefit beneficiaries, plans and providers.

Comment: A few commenters suggested CMS implement additional measures related to the proposal—such as setting a timeframe by which the IRE must acknowledge receipt of a member's case (for example, within 5 days).

Response: CMS agrees an enrollee must receive timely notice when his or her case is forwarded to the Part C IRE. We will continue analyzing notification timeframes as we endeavor to ensure the IRE's notification process is timely and efficient. We note that a regulatory change would not be necessary as CMS contracts with the Part C IRE and may implement changes to certain parts of the IRE's workload and deadlines through that contract.

Comment: Some commenters recommended other programmatic improvements—including issuance of new protocols used during program audits or the timeliness monitoring project to delete the applicable timeliness calculations for this notice. Other commenters recommended we consider electronic issuance of IRE notifications to enrollees.

Response: While the commenter's suggestions are outside the scope of this rule, we appreciate these comments and will ensure the suggestions are appropriately conveyed.

Comment: Some commenters generally support this change, but requested additional clarification. For example, a few commenters inquired whether MA plans may voluntarily continue the current practice of notifying their members upon forwarding cases to the IRE. These commenters indicated providing notices to members on an optional basis could prevent increased member inquiries. Another commenter sought clarification regarding Appendix 10 of Chapter 13 of the Medicare Managed Care manual—a sample (model) notice (''Notice of Appeal Status'') provided to plans for the purpose of informing enrollees whose cases are forwarded to the IRE for review. Another commenter indicated Appendix 10 includes redundant information the IRE is expected to provide. While another commenter inquired whether MA plans would continue to have the full adjudication timeframe to forward the denied case to the IRE or if the MAO's processing timeframe would be reduced.

Response: We would like to clarify that this change does not preclude plans from continuing to notify enrollees upon forwarding cases to the IRE; plans are permitted to continue the current practice of notifying members upon forwarding case files to the IRE if they choose to do so. We will no longer expect plans to use CMS' Model Notice of Appeal Status (Appendix 10 of Chapter 13 of the Medicare Managed Care manual) after the end of the 2018 plan year. By removing the requirement that MA plans must notify beneficiaries upon forwarding cases to the Part C IRE, we no longer expect plans to use CMS' Model Notice of Appeal Status; thus, inclusion of duplicative language on the model notice is unnecessary as well as moot. While plans opting to notify members upon forwarding cases to the IRE may continue using CMS' model notice, CMS will no longer expect MA plans to utilize the current model notice. Changes to processing timeframes are outside the scope of this rule but we note that § 422.590(a), (b) and (d), which control the timeframe for service, payment and expedited reconsiderations, are not being amended in this rule; those provisions require that an MA plan prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than the timeframe specific to the type of reconsideration.

Comment: A few commenters objected to this proposal, indicating that MA enrollees expect to receive notices from their plans and would find notices from the IRE confusing. Another commenter asserted the provision of this notice is not a burden on MA plans. A commenter anticipated the Part C IRE's notification would not be as timely as plan notification and some asked CMS to eliminate IRE notice instead of eliminating MA plan notice.

Response: We disagree with the commenters. While MA enrollees expect to receive material from their plans, we believe that enrollees who are awaiting appeals decisions anticipate notification from the Medicare IRE to confirm the IRE has actually received the case and what the beneficiary can expect next. Mandatory materials sent by MA plans to enrollees, such as Medicare's integrated denial notice, describe the IRE-level of review following denial at the MA plan reconsideration stage. Additionally, even before this change was proposed, the IRE was required to provide a notice to enrollees. We also believe beneficiaries welcome knowing an independent, outside entity, under contract with Medicare, is reviewing their health plan's initial coverage denial. As set forth in our regulatory impact analysis, we believe that providing this notice is a burden for MA plans and an unnecessary one at that. Eliminating this duplicative notice will relieve an unnecessary burden on MA plans. We will continue to work closely with the IRE—through CMS' contract oversight and evaluation efforts and by promulgating additional contractor guidance, as needed—to ensure Medicare beneficiaries nationwide receive timely notice in a consistent form and manner.

After consideration of the public comments received, we are finalizing this amendment to delete paragraph (f) and redesignate the subsequent paragraphs of § 422.590 as proposed.

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 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, it noted that notice and comment rulemaking could be waived, and 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 18,918) 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

We proposed to adopt the NCPDP SCRIPT 2017071 as the official Part D e-prescribing standard for certain specified transactions, and to retire the current standard (NCPDP SCRIPT version 10.6). Unlike past updates to the part D e-prescribing standards, as version 2017071 is not fully backward compatible with version 10.6, we were unable to propose a transition period in which 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**. While moving directly from one version to another may present challenges, we believe that the new version provides the opportunity to standardize additional transactions over what was possible with the current version, and, as noted in our proposed rule, we believe that those added transactions and the improvements to the existing transactions would, among other things, improve communications between the prescriber and dispensers.

Specifically, 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 proposed to require use of NCPDP SCRIPT 2017071 for the following new 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.

To implement these proposed policies, we proposed 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). As amended, the requirement at § 423.160(b)(1)(v) would identify the standards that will be in effect for the named transactions on or after January 1, 2019.

We also proposed adoption of NCPDP SCRIPT 2017071 as the official Part D e-prescribing standard for the medication history transaction at § 423.160(b)(4) and proposed to retire NCPDP SCRIPT versions 8.1 and 10.6 for medication history transactions transmitted on or after January 1, 2019. Furthermore, we proposed 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, and proposed to add § 423.160(b)(1)(v) to require use of NCPDP SCRIPT Version 2017071 on or after January 1, 2019. Furthermore, we proposed 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 proposed to incorporate NCPDP SCRIPT version 2017071 by reference in our regulations at 42 CFR 423.160(c)(1)(vii).

We also solicited comments regarding the impact of these proposed effective dates on industry and other interested stakeholders, and proposed a technical correction of a prior regulation. On July 30, 2012, we published a regulation (CMS–1590–P), which established version 10.6 as the Part D e prescribing standard effective March 1, 2015 for the electronic transactions listed in § 423.160(b)(2)(iii). However, despite the preamble discussion's clear 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) of the regulation text erroneously cross-referenced the standard named in (b)(2)(ii) (NCPDP SCRIPT 8.1), rather than that named in (b)(2)(iii) (NCPDP SCRIPT 10.6). We proposed 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).

We received the following comments and our response follows:

Comment: Many commenters urged CMS to adopt the NCPDP SCRIPT electronic Prior Authorization (ePA) transaction for the Part D program. They note that ePA is more efficient for prescribers, pharmacies, plans, and patients.

Response: We understand that Part D plans are anxious to adopt the NCPDP SCRIPT ePA standard. However, the HIPAA standard transaction for prior authorization does not accept the NCPDP SCRIPT ePA standard. In order for CMS to adopt the 2017071 for use in the Part D e-prescribing program, the HIPAA standard transaction would need to be modified to allow for use of an NCPDP SCRIPT ePA standard. Such HIPAA changes will need to occur in a Departmental regulation, and cannot be effectuated in a CMS regulation. If the HIPAA regulations are modified, CMS will be able to propose adoption of the NCPDP SCRIPT ePA for use in the Part D e-prescribing program.

Comment: We received a variety of comments concerning the amount of lead time needed to adopt a new standard. Some commenters requested that CMS' proposed time frame for implementing the new NCPDP SCRIPT version be extended. Several commenters expressed the desire to begin using the new standard immediately after the rule is finalized but wanted to accommodate other plans who were not ready to adopt the standard. These commenters favored a gradual transition whereby plans could opt to adopt Version 2017017 voluntarily when the final rule is published or be permitted to use Version 10.6 for 18 to 24 months thereafter. A commenter asked CMS not to require implementation of the new NCPDP SCRIPT version on a Federal holiday or in January, since plans would be in the midst of open season.

Response: Comments have persuaded us that it will take some plans more time to update the standard than we had previously anticipated. We also appreciate that many plans would like to begin using the new standard immediately. Given these two viewpoints we would have liked to have proposed a phased-in transition for plans to use when implementing the new NCPDP SCRIPT version. However, because we understand that Version 2017017 is not backwards compatible to Version 10.6, this is not a feasible option, necessitating a hard cut off point. We also understand that some industry partners would prefer not to

implement the new NCPDP SCRIPT version on January 1 however, Section 1860D–12(f)(2) prohibits the implementation of ''significant'' regulatory requirements on a prescription drug plan other than at the beginning of the year. Therefore, in order to ensure that all Part D plans, prescribers and dispensers are able to make a successful transition to the new part D e-prescribing standard, and that the transition is compliant with statutory requirements, we are delaying the implementation date until January 1, 2020 subject to the additional conditions regarding certain ONC standards discussed infra. This will provide affected organizations additional time to develop and test the new requirements.

Comment: A few commenters noted that the use of medication history transactions would help the industry address opioid overuse and asked that CMS add them to the list of named transactions.

Response: The adoption of the 2017071 version of the NCPDP SCRIPT medication history transaction was proposed in the final rule, but, as was done historically, we proposed to codify it separately from the other transactions at § 423.160(c)(1)(vii). Furthermore, we proposed to incorporate the 2017071 proposed transactions at § 423.160(b)(4)(ii), which we believe would include RxHistory Request and RxHistory Response. As a result of positive feedback to these proposals, subject to the additional conditions regarding certain ONC standards discussed infra, we do intend to finalize these proposals effective January 1, 2020.

Comment: A commenter stated that although the Password Change Transaction remains in the 2017017 NCPDP SCRIPT Standard, its use is not universally supported and that some payers have replaced these transactions with alternative enhanced security authentication measures. The commenter asked CMS to remove the Password Change Transaction from the final rule.

Response: We appreciate the comment, and understand that some industry partners are exploring different procedures for processing password resets which may obviate the need for the NCPDP SCRIPT standard Password Change Transaction. Given the evolution of these processes and the importance of ensuring up-to-date security processes for sensitive health information, we have removed the Password Change Transaction from the final rule pending further review.

Comment: A commenter correctly noted that the proposed rule mentions some of the changes in the new standard, but it doesn't mention all of them. Specifically, the commenter asked whether a new field for language access is included in the transactions we are adopting from version 2017071.

Response: The language field was added to a prior NCPDP SCRIPT standard, Version 10.11, and has not been removed in any subsequent updates. Therefore the language field continues to be included in all versions after 10.11 including Version 2017017. That said, we did not propose to adopt NCPDP SCRIPT 2017071 for that transaction in the context of the part D e-prescribing program, so the public is free absent other program standards to the contrary to convey such content using whatever standard or means they wish to use.

Comment: A few commenters noted that this NPRM proposed use of a different version of the NCPDP SCRIPT standard in Part D than is used in other programs managed by HHS. These commenters expressed concern that this may create confusion in the industry. Specifically, commenters noted ONC's Electronic Health Record Certification Program which currently utilizes the NCPDP SCRIPT Version 10.6.

Response: HHS has a history of harmonizing NCPDP SCRIPT versions across the various programs which it manages. For example, please see the final rule titled, ''Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology'' (77 FR 54163, 54198–54200), in which HHS aligned its programs to prior versions of the part D e-prescribing standard. We anticipate similar action in this context, and are confident that the necessary proposals are currently under development. Each Agency and Office within the Department adheres to a different regulatory schedule so that regulations are published at different intervals. Nevertheless, with the adoption of this version of the NCPDP SCRIPT standard for Part D prescribing, HHS remains committed to continued agency coordination to ensure alignment, interoperability, and the adoption of the most appropriate standard and version for each use case. We are therefore modifying our proposal to adopt NCPDP SCRIPT 20170171 by conditioning the effective date of our adoption of the proposed on corresponding regulatory action being taken to update the Health IT Certification Criteria to NCPDP SCRIPT 2017071 for the named transactions effective the January 1, 2020 implementation date.

Comment: A commenter asked whether stakeholders are required to adopt all transactions within the NCPDP SCRIPT standard or only those which are applicable to their business purpose.

Response: PDP sponsors and MA organizations offering MA–PD are required to establish electronic prescription drug programs that comply with adopted e-prescribing standards. Other organizations such as prescribers or dispensers only need to implement the adopted transactions under that standard that they use in their part D e-prescribing operations. If there are any questions on which transactions apply to a business case, organizations should consult the Business process descriptions documented within the version 2017071 NCPDP SCRIPT standard implementation guide.

Comment: A commenter pointed out that the named transactions are inconsistent with the current implementation guide Version 20170171. The commenter asked that CMS reflect the updated nomenclature and transaction types throughout.

Response: We appreciate this comment, and acknowledge that NCPDP made what we understand to be non-substantive changes to their nomenclature. The final regulatory text therefore reflects those non-substantive changes to the names of the transactions from those which appeared in our proposed regulation. We have amended the regulatory text in the final rule to adopt the updated names.

Comment: A commenter suggested that we defer naming the REMS-related transactions until the Risk Evaluation and Mitigation Strategies (REMS) program transactions are proven compared to other standards before mandating the 2017071 version of the NCPDP SCRIPT standard for REMS usage.

Response: We disagree, and have included the REMS-related transactions in our final rule. The FDA designed the REMS program to mitigate serious drug-related risks associated with the some medications, a goal which CMS whole heartedly supports. Use of the REMS transactions will allow REMS requirements to be completed within existing healthcare workflows, which will be critical as the REMS program includes more medications. Absent these transactions the successful management of the REMS would require manual intervention for pharmacists and prescribers. Manual maintenance of REMS program data would be

particularly difficult because each REMS has specific safety measures unique to the risks associated with a particular drug. For these reasons CMS strongly supports using electronic processes to support this important drug safety initiative.

Comment: A commenter recommended that CMS immediately adopt the updated NCPDP Telecommunication Standard D.0 which allows the conditional use of the field ''Quantity Prescribed'' to communicate the actual quantity prescribed by the provider. The commenter stated that adoption of the field would promote more appropriate beneficiary access to controlled substances, reduce the industry's administrative burden, and eliminate the misidentification of partially-filled prescriptions as refills.

Response: CMS is aware of the concerns noted. The NCPDP Telecommunications Standard D.0 was adopted to include specific implementation guides, and it is a HIPAA standard, so we'd need to await the HIPAA standard changing. As noted above, proposals to modify HIPAA transactions are promulgated by the Department, not CMS, under a different rule-making authority. This suggestion is therefore outside the scope of this rule.

We received broad support for updating the NCPDP SCRIPT standard to Version 2017071, along with concerns about the implementation date and technical concerns about the transactions named. Based on comments received we are finalizing this provision with modifications and have conditionally moved the effective date to January 1, 2020, to give ONC time to update its Electronic Health Record certification program to the NCPDP SCRIPT 2017071 standard.

Summary and Availability of Incorporation by Reference Material

The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. For a final 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 final 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 updates 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.ncpdp.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.

This regulation codifies adoption of the NDPDP 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.

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 updated NCPDP SCRIPT standards have been requested by the industry and include electronic standards for transactions that are commonly used such as the transmittal of new prescriptions, changes to existing prescriptions, requests for renewals, and transfers of prescriptions between pharmacies. These enhancements will provide a number of efficiencies which the industry and CMS supports.

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. 75 FR 19677. As part of that rulemaking, we established, at § 422.502(b)(1) and § 423.503(b)(1), that we will 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 year;[76] to the methodology scores each applicant's performance by assigning weights based on the severity of its non-compliance in several performance categories. Under the annual contract qualification application submission and review process we conduct, applicants and renewing organizations must submit the application by a date, usually in mid-February, announced by us. We proposed to reduce the past performance review period from 14 months to 12 months after consideration of our experience.

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 its 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. When we established the 14-month review period, we did so based in part on the belief that it was necessary to include in the period a full contract year (that is, January through December) of performance to be certain that our review captured an applicant's most recent full cycle of performance in order to capture all relevant aspects of an organization's performance. As we have implemented the 14-month review

[76] *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.*

period, we have learned that the contract year, as a unit of measure, adds little value to our annual analysis. The January-through-December period is most significant because it covers the period during which the organization must provide approved benefits to its enrollees, but it does not truly reflect the schedule under which we make the contract compliance and performance determinations that we have adopted as factors in the past performance methodology. For example, compliance notices, audit reports and star ratings are often by necessity issued following the conclusion of a particular contract year. Therefore, an accurate review of a contract's past performance, conducted as part of the annual application review cycle, does not depend on our being certain that the review period covers a full contract year that begins two Januarys before an application deadline. As part of an annual process, the period need cover only 12 months.

We continue to believe that an applicant's most recent contract performance is important to consider in each review cycle. Therefore, we proposed to revise § 422.502(b)(1) and § 423.503(b)(1) to reduce the review period from 14 to 12 months. This will 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 will eliminate the counting of instances of non-compliance in January and February of each year in 2 separate application cycles. We also proposed to have this review period change reflected consistently in the Part C and D regulation by revising both § 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 clarified in the proposed rule that our proposal would not change any other aspect of our consideration of past performance in the application process.

We received the following comments and our response follows:

Comment: All commenters expressed support for the reduction of the past performance review period from 14 to 12 months.

Response: We appreciate the statements of support for our proposal.

Comment: Some commenters urged that the proposed 12-month period cover a calendar year (that is, January through December) rather than the March through February period that immediately precedes the application. These commenters noted that the calendar year review period would allow CMS to let potential contract applicants know whether CMS would deny their applications based on poor past performance before they committed resources to preparing and submitting applications.

Response: As we discussed when we proposed this change, we believe it is critical that CMS consider an applicant's most recent record of contract performance at the time of the submission of the application to CMS in February. The adoption of a calendar year past performance period would create an unacceptable gap between the end of the review period and the application deadline. Therefore, we will not accept this recommendation.

While we cannot accommodate the recommendation that we adopt a calendar year review period, we note that CMS makes past performance resources available to organizations that they can use in making the decision to invest resources in preparing an application. Each year, CMS conducts mid-year performance reviews of contracting organizations and share those results with the organizations. While the results of such reviews are not final, they give organizations a real sense of how CMS views their contract performance to that point in the year. We also draft the annual past performance methodology in a way that allows organizations to track their own past performance scores throughout the year, allowing the organizations to determine, as the year goes on, the likelihood that CMS will deny their planned application.

Comment: A commenter provided a series of recommendations for modifications to the methodology CMS adopts each year to evaluate applicants' past performance record (for example, changes in weights assigned to certain areas of performance, evaluation of performance at the contract, rather than organization, level).

Response: Since these comments do not address the duration of the past performance review period, they are outside the scope of our proposal. We will take the comments under consideration for review of the methodology in the future.

Based on our review of comments expressing broad support for the reduction of the past performance review period, we are finalizing the amendments to §§ 422.502(b)(1) and (2) and 423.503(b)(1) and (2) as proposed.

10. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE

a. Part D Provisions

(1) Background

(a) 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.

(b) 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.

Second, we revised paragraph § 423.120(c)(6)(ii) to address a gap in § 423.120(c)(6) regarding certain types of prescribers. 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.

(c) 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. Numerous prescribers have, in preparation for the enforcement of § 423.120(c)(6), enrolled in or opted out of Medicare. However, we noted in the November 28, 2017 proposed rule that 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. Several provider organizations, moreover, expressed concerns about the enrollment requirements. They 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, was 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. However, the concerns of these provider organizations remained.

Recognizing these concerns, and wanting to reduce as much burden as possible for providers without compromising our program integrity objectives, we proposed in the November 28, 2017 proposed rule several changes to § 423.120(c)(6) as well as to several other provisions, which we describe below.

(2) 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 were to finalize the proposals described in the November 28, 2017 proposed rule, we would not finalize the provisions of the IFC. Instead, the regulations contained in this final rule would supersede our earlier rulemaking.

We proposed an effective date for our proposed provisions in § 423.120(c)(5) of 60 days after the publication of a final rule. We proposed an effective date of our proposed revisions to § 423.120(c)(6) of January 1, 2019.

(a) Prescriber NPI Validation on Part D Claims

In the May 6, 2015 IFC, we revised § 423.120(c)(5), which addresses the submission and validation of National Provider Identifiers (NPIs) of Part D prescribers, to state that before January 1, 2016, the following are applicable:

- In paragraph (c)(5)(i), we stated 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 stated 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 stated 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 stated 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 stated 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 stated 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 stated 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.

We noted in the November 28, 2017 proposed rule that these provisions, which focused on NPI submission and validation, were no longer effective because the January 1, 2016 end-date for their applicability had passed. We further explained that prior to the January 1, 2016 date, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was signed into law on April 16, 2015 (shortly before the IFC was finalized). Section 507 of MACRA amended 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, we issued a guidance memo on June 1, 2015 titled, ''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 published, but that its several of its provisions reflected certain existing Part D claims procedures established by the Secretary that would comply with section 507 of MACRA. The provisions in § 423.120(c)(5) that reflected the procedures that would comply with section 507 were the following:

- Paragraph (c)(5)(iii).
- Paragraph (c)(5)(iii)(A).
- Paragraph (c)(5)(iii)(B)(*1*).

(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 proposed in the November 28, 2017 proposed rule to include these provisions in new paragraph (c)(5). They were to be enumerated as, respectively, new paragraphs (c)(5)(ii), (c)(5)(ii)(A), (c)(5)(ii)(B), (c)(5)(iii), and (c)(5)(iv). Paragraphs (c)(5)(i), (c)(5)(ii), and (c)(5)(iii)(B)(*2*) were not to be included in new paragraph (c)(5). We also noted in the November 28, 2017 proposed rule 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 contained the NPI of the prescriber who prescribed the drug. This provision, too, reflected existing Part D claims procedures and policies that comply with section 507 of MACRA. We therefore proposed to retain this provision and sought comment on associated burdens or unintended consequences and alternative approaches. However, we proposed to move it from paragraph (c)(6) to paragraph (c)(5) so that most of the NPI provisions in § 423.120 were included in one paragraph. We stated in the proposed rule that these new provisions would not only effectively implement section 507 of MACRA but also enhance Part D program integrity by streamlining and strengthening procedures for ensuring the identity of prescribers of Part D drugs.

(b) Targeted Approach to Part D Prescribers and Provisional Supply

We outlined in the proposed rule our belief 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 taxpayer-funded Trust Funds. In other words, rather than require the enrollment of Part D prescribers regardless of the possible level of risk posed, we proposed to focus on preventing payment for Part D drugs prescribed by demonstrably problematic prescribers. We therefore proposed to establish a ''preclusion list'' that would include such individuals and would deny payment for Part D drugs they prescribe. That is, we proposed to replace the prescriber enrollment requirement outlined in § 423.120(c)(6) with a claims payment-oriented approach. The specific provisions we proposed are as follows:

• In § 423.100, we proposed to delete the definition of ''other authorized prescriber'' and add the following:

++ Preclusion List means a CMS compiled list of prescribers who:

++ Meet all of the following requirements:

++ The prescriber is currently revoked from the Medicare program under § 424.535.

++ The prescriber is currently under a reenrollment bar under § 424.535(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: (1) The seriousness of the conduct underlying the prescriber's revocation; (2) the degree to which the prescriber's conduct could affect the integrity of the Part D program; and (3) any other evidence that CMS deems relevant to its determination; or

++ Meet both of the following requirements:

++ 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.

++ CMS determines that the underlying conduct that would have 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: (1) The seriousness of the conduct involved; (2) the degree to which the prescriber's conduct could affect the integrity of the Part D program; and (3) any other evidence that CMS deems relevant to its determination

• In paragraph (c)(6)(i), we proposed 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 will 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 proposed 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 will 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 proposed 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 proposed to address the provisional coverage period and notice provisions, which we previously referred to, as follows:

++ A Part D sponsor or its PBM must not reject a pharmacy claim for a Part D drug under paragraph (c)(6)(i) or deny a request for reimbursement under paragraph (c)(6)(ii) unless the sponsor has provided the provisional coverage of the drug and written notice to the beneficiary required by paragraph (c)(6)(iv)(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), a Part D sponsor or its PBM must do the following:

—Provide the beneficiary with the following, subject to all other Part D rules and plan coverage requirements:

—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.

—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.

—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).

• In new § 423.120(c)(6)(v), we proposed 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 proposed 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 will 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.

We also stated in the proposed rule the following:

• We proposed 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.

• 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 also solicited comment on the following:

• 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 that are not prescribing to Part D beneficiaries. We anticipated that this could create delays in our ability to screen providers due to data lags and may introduce some program integrity risks. We were 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.

• 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.

• 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.

• 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.

(c) Appeals

In our revisions to § 423.120(c)(6), we proposed to permit prescribers who are on the preclusion list to appeal their inclusion on this list in accordance with 42 CFR part 498. We believed that given the aforementioned pharmacy claim rejections that would be associated with a prescriber's appearance on the preclusion list, due process warranted 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 was 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 proposed to update several other regulatory provisions regarding appeals:

• We proposed 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 proposed to add a new paragraph (n) that would state as follows:

++ In paragraph (n)(1), we proposed 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 proposed 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 proposed 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.

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.

We also solicited comment on whether a different appeals process is warranted and, if so, what its components should be.

b. Part C/Medicare Advantage Cost Plan and PACE Provisions

(1) Background

(a) 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, foremost of which was the addition of 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 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. Other provisions were also added or revised to reflect the requirements in § 422.222.

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 they would, as with the previously mentioned Part D requirement, 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) required 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 will 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.

(b) 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, as of April 2017, roughly 120,000 MA-only providers and suppliers remain unenrolled in Medicare. This is approximately 11% of all MA providers and suppliers. While there may be overlap between the Part C and D provider and prescriber populations, it is minor at approximately 25,000 providers. 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 recognized and shared these concerns. We believed that the Medicare enrollment requirement could result in a duplication of effort and, consequently, impose a burden on MA providers and suppliers. While we maintained 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 proposed in the November 28, 2017, to utilize the same ''preclusion list'' concept in MA that we are proposing for Part D and to eliminate the current enrollment

requirement in § 422.222. We believe this approach will 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.

To this end, we proposed the following provisions, which included those permitting provider and beneficiary appeals similar those we previously mentioned for Part D.

(2) Specific Regulatory Changes

Given the foregoing discussion, we proposed the following regulatory changes. We note that many of the revisions below merely involved changing references to ''enrollment'' to ''preclusion list'' to reflect the proposed replacement of the former requirement with the latter. We also proposed the deletion of several sections that we believed were no longer needed because of our proposed preclusion list policy.

• In § 417.478, we proposed to revise paragraph (e) as follows:

++ In new paragraph (e)(1), we proposed 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 proposed 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 proposed 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 proposed to add a definition of ''preclusion list'' that reads as follows:

++ Preclusion list means a CMS compiled list of individuals and entities that:

++ Meet all of the following requirements:

++ The individual or entity is currently revoked from Medicare under § 424.535.

++ The individual or entity is currently under a reenrollment bar under § 424.535(c).

++ 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 will consider the following factors: (1) The seriousness of the conduct underlying the individual's or entity's revocation; (2) the degree to which the individual's or entity's conduct could affect the integrity of the Medicare program; (3) any other evidence that CMS deems relevant to its determination; or

++ Meet both of the following requirements:

++ 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.

++ 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: (1) The seriousness of the conduct involved; (2) the degree to which the individual's or entity's conduct could affect the integrity of the Medicare program; and (3) any other evidence that CMS deems relevant to its determination.

• We proposed to delete § 422.204(b)(5).

• We proposed to establish a new § 422.204(c) that will require MA organizations to follow a documented process that ensures compliance with the preclusion list provisions in § 422.222.

• We proposed to delete the existing version of § 422.222(a) and replace it with the following:

++ In § 422.222, we proposed to change the title thereof to ''Preclusion list''.

++ In paragraph (a)(1), we proposed 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 proposed to replace the existing language therein with a provision stating that CMS will send written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice will contain the reason for the inclusion and will 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 proposed 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 proposed 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 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 included on the preclusion list, defined in § 422.2''.

++ Revise paragraph (b) to state that 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 § 422.501(c), we proposed to do the following:

++ 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 § 422.504, we proposed to do the following:

++ 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed to delete § 460.68(a)(4).

• We proposed to delete § 460.70(b)(1)(iv).

• We proposed to delete § 460.71(b)(7).

• In § 460.86, we proposed to revise paragraphs (a) and (b) to state as follows:

++ Paragraph (a) would specify 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 OIG or is included on the preclusion list, defined in § 422.2.

++ Paragraph (b) will specify that if a PACE organization receives a request for payment by, or on behalf of, an individual or entity excluded by the OIG or on the preclusion list, the organization must notify the enrollee that is included on the preclusion list in writing, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity excluded by the OIG or is included on the preclusion list.

++ We also proposed 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 proposed 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 proposed to add a new paragraph (n) that would state as follows:

++ In paragraph (n)(1), we proposed 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 proposed 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 would be entitled to a hearing before an ALJ.

++ In paragraph (n)(3), we proposed 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.

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 believed the beneficiary should be permitted to appeal alleged errors in applying the preclusion list. We solicited 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.

• We proposed 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. 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 also proposed 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.

• We also proposed that both basic and supplemental benefits should be subject to the payment prohibition that is tied to the preclusion list. We believed that restricting the payment prohibition to only one of these two categories will undercut the effectiveness of our preclusion list proposal.

• We noted 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 included all affected individuals and entities. Having one joint list, we believed, will make the preclusion list process easier to administer.

We also solicited comment on the following matters:

• An alternative by which CMS would first identify through encounter data those providers or suppliers furnishing services or items to Medicare beneficiaries.

• 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.

c. Comments Received

We received 74 comments and our responses follows. We note that many comments concerning the overall preclusion list did not clearly distinguish between the Part D and MA provisions of the proposed rule. We are therefore grouping these comments together without delineating between the two programs. Comments concerning other topics, however, such as provisional supply and appeals, are clearly denoted as such.

(1) General Comments Concerning the Preclusion List Concept

Comment: A number of commenters expressed support for our preclusion list proposal. Some commenters stated that the proposal will accomplish CMS' objective of ensuring that only qualified providers and suppliers provide services to Medicare beneficiaries, but in a significantly less burdensome way. Other commenters stated that basing prescription coverage on Medicare enrollment added duplicative and burdensome requirements on physicians and providers, leading to more waste and cost.

Response: We appreciate the commenters' support.

Comment: A number of commenters opposed our proposed preclusion list requirement. A commenter stated that while the proposed rule described the preclusion list as an effort to reduce the

burden on providers, the commenter believed it would actually be more inefficient to maintain two systems—specifically, the preclusion list and the traditional Medicare enrollment system—than to simply require all providers that seek to serve Medicare beneficiaries to enroll in traditional Medicare. The commenter believed this would be particularly onerous on CMS and providers given that nearly half of providers who serve MA enrollees are already enrolled in traditional Medicare. The commenter, as well as others, urged CMS to retain the current enrollment requirement, believing it to be, as stated in the proposed rule, 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. Commenters added that Medicare enrollment remains the most effective way to protect all Medicare beneficiaries.

Response: We recognize the commenters' concerns about the removal of the Part D and MA enrollment requirements and whether CMS would, consequently, remain able to confirm a prescriber's or provider's compliance with Medicare requirements. However, we respectfully decline to adopt the commenters' recommendation that we retain these enrollment requirements. We continue to believe that the most effective means of reducing the burden of the Part D and MA enrollment requirement on prescribers and providers 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, and preventing MA payment for items and services furnished by providers and suppliers who pose an elevated risk to Medicare beneficiaries and the Trust Funds. Such an approach enables CMS to focus on prescribers and providers who pose threats to the Medicare program and its beneficiaries, while minimizing the burden on those who do not. We believe the criteria warranting a prescriber's or provider's addition to the preclusion list are sufficiently comprehensive such that this approach will effectively protect Medicare from making payments associated with Part D drugs prescribed by, or MA services provided by, problematic parties and prohibit such problematic parties from directing the care of program beneficiaries.

While enrolling such prescribers and providers gives Medicare a greater degree of scrutiny in determining a prescriber's or provider's qualifications, we note that the perceived burden associated with this process could cause some prescribers and providers not to enroll in Medicare, thus possibly leading to access to care issues. For instance, according to a CMS analysis of prescriber enrollment trends, as of January 2017 there are close to 340,000 active Part D prescribers based on 2016 PDE data who are not enrolled in or opted-out of Medicare. The number of prescribers who are unenrolled constitutes an estimated 25 percent of all identified Medicare prescribers nationwide in 2016. Further data suggests that an additional 18,000 new non-enrolled prescribers are identified each month. This amount of incoming prescribers, coupled with the 120,000 unenrolled MA providers referenced above, creates operational challenges that have led to delays in CMS' implementation of such an enrollment requirement.

Also, we are unclear as to what the commenter means by provider burden. There is no provider burden associated with the preclusion list, except to the extent that we place a prescriber or provider on the preclusion list and the provider wishes to challenge that designation.

Comment: A commenter noted that, according to a Government Accountability Office (GAO) study published in 2015, CMS currently furnishes insufficient oversight of MA provider networks. The commenter stated that there is no mechanism in place to assess the accuracy of the information submitted by or about MA plans to CMS and that CMS does not require MA plans to routinely submit updated network information for review. The commenter stated that FFS provider enrollment may provide a mechanism to assist CMS with ensuring the important beneficiary protection of network adequacy.

Response: We appreciate the commenter's feedback. We clarify, however, that the MA program does have network adequacy requirements to ensure that network based MA plans have adequate providers under contract to furnish Part A and B services. Detailed information on the MA network adequacy requirements can be found in the health service delivery reference file located at the bottom of the CMS web page at the web link below: *https://www.cms.gov/Medicare/Medicare-dvantage/MedicareAdvantageApps/index.html. We do not believe it would be appropriate to add an enrollment requirement for network providers merely for CMS to oversee the accuracy of network directories or to monitor network adequacy. CMS has developed other systems for those purposes.*

Comment: A commenter stated that based on CMS's estimates, approximately 10 percent of MA providers would be negatively impacted by a requirement to be enrolled in FFS Medicare. The commenter contended that CMS in the proposed rule did not (1) disclose in the proposed rule if losing 10 percent of providers would cause an access issue for Medicare beneficiaries, or (2) include additional rationale and justification for eliminating the requirement for enrollment. Without such additional justification, the commenter stated, it would be inappropriate to remove the enrollment requirement at this time.

Response: We appreciate the commenter's feedback on the clarification needed in the final rule. With an estimated 1,053,000 providers currently furnishing services and items to beneficiaries through MA plans, we currently estimate that at least 120,000 remain unenrolled in Medicare. While this may not seem significant on a national scale, it could negatively impact areas where the current provider-to-beneficiary ratio is disproportionate, especially noting the results of CMS' Part D enrollment efforts, as mentioned earlier. We would expect similar results if we were to undertake efforts to enroll Part C providers and suppliers. Considering the number of prescribers and providers that have not yet enrolled across both Part C and D and our concerns regarding the potential for access to care issues, we disagree with the commenter's suggestion that we continue the enrollment requirement and we decline to adopt changes to the proposal based on this feedback.

Comment: A commenter stated that requiring providers to enroll in Medicare in order to serve MA plan enrollees ensures that all Medicare beneficiaries are served by providers that satisfy CMS's rigorous criteria. The commenter stated that removing the requirement that providers enroll in traditional Medicare in order to serve MA plan enrollees would eliminate a strong incentive for providers that serve MA enrollees to indeed enroll in traditional Medicare. The commenter believed that enrolling in traditional Medicare is an effective tool for protecting Medicare beneficiaries and saw no reason for CMS to abandon it. If, the commenter added, CMS decides to finalize the preclusion list requirement, the commenter urged that CMS make clear that any provider that is currently enrolled in traditional Medicare could not be placed on the

preclusion list. This guarantee, the commenter explained, would not apply to any providers that are revoked from Medicare or under a reenrollment bar; rather, it would simply establish that participation in traditional Medicare is sufficient for a provider to serve MA plan enrollees.

Response: While we appreciate the commenter's concern, we reiterate our view that the criteria warranting a prescriber's or provider's addition to the preclusion list are comprehensive enough that this approach will provide sufficient program safeguards.

Prescribers and providers currently enrolled in Medicare (and, therefore, not revoked) cannot also be included on the preclusion list because they would not meet the applicable criteria under, respectively, §§ 423.100 and 422.2.

Comment: Several commenters stated that the preclusion list would not protect beneficiaries to the extent that the current enrollment requirement would. The commenters explained that the enrollment process, through investigating applicants and preventing problems before they occur, ensures that Part D drugs are prescribed only by qualified prescribers. With the preclusion list, however, CMS would be relying on a retroactive approach such that it is only after a prescriber has already engaged in inappropriate activities that he or she would be put on the preclusion list. Reactive provisions such as the preclusion list, the commenters contended, must by their very nature lag behind proactive provisions such as enrollment requirements. The preclusion list proposal, therefore, may put beneficiaries at risk for inappropriate prescribing practices from physicians and eligible professionals who would not have successfully completed the enrollment process. Another commenter expressed serious concerns about implementing the preclusion list proposal in lieu of the current enrollment requirement. The commenter believed that the careful screening involved with the enrollment process is the best means of: (1) Ensuring that providers and suppliers are qualified to furnish services and are fully compliant with Medicare rules; and (2) preventing fraud, waste, and abuse.

Response: We appreciate the commenters' concerns. While enrollment may provide more robust data we believe the preclusion list approach provides sufficient program safeguards to balance program integrity initiatives, provider burden, and our concerns regarding a potential access to care issue. Specifically, we will not limit our review or screening to only those prescribers present on PDE data but will also include those who potentially could prescribe based on other data in our internal systems. Therefore, we are not restricting our ability to preclude only those parties that are currently furnishing items and services for program beneficiaries. Under § 423.120(c)(6), for instance, we will have the ability to preclude any prescriber, even prior to the prescriber showing up on PDE data, who meets the criteria for being placed on the preclusion list.

Comment: A commenter stated that, according to the proposed rule, approximately 65 percent of those who were required to enroll or opt-out under the May 23, 2014 final rule have done so. The commenter believed that this is an impressive figure and that, rather than eliminating the enrollment requirement altogether and relying on the complaints of those prescribers who found the process burdensome, CMS should proceed with the enrollment requirements and provide additional outreach regarding the enrollment process.

Response: We appreciate the commenter's recommendation. As mentioned previously, however, and even after CMS undertook vigorous outreach activities after the May 23, 2014 final rule regarding the need to enroll, approximately 340,000 active Part D prescribers have neither enrolled in nor opted-out of Medicare. The loss of 340,000 prescribers could potentially prove troublesome in areas where the prescriber population is already low and access to care is a serious concern. More specifically, even with a provisional fill option approximately 2.5 million Part D beneficiaries (based on analysis performed on 2015 and 2016 PDE data) could lose access to needed prescriptions if full enforcement of the enrollment requirement were to take effect on the scheduled date. Based on these figures, and our concerns for potential access issues we believe the preclusion approach would be more appropriate. We note again that an additional 18,000 new prescribers are identified each month. These incoming prescribers, coupled with the previously mentioned 340,000 unenrolled prescribers and 120,000 unenrolled MA providers, creates a significant workload.

Comment: A commenter stated that in proposing to eliminate the enrollment requirement, CMS failed to consider or address continuity of and access to care issues. The commenter stated that the choice of Medicare options has serious consequences for access to services and physicians, and it is important that the impact on beneficiaries be considered. Not requiring MA providers to be enrolled in Medicare is particularly problematic for MA enrolled beneficiaries who are patients of a provider not enrolled in Medicare and who disenroll from the MA plan and elect traditional Medicare. Those beneficiaries, the commenter stated, would no longer be able to receive services from their regular physician and have them billed to fee-for-service Medicare. Another commenter, too, stated that not requiring MA providers to enroll in Medicare can create problems for beneficiaries who disenroll from a MA plan and elect traditional FFS Medicare.

Response: We appreciate the commenter's feedback. In regard to beneficiaries leaving the MA program and defaulting to traditional Medicare, we are not aware of this as a significant issue nor was it a part of our rationale for the enrollment requirement. MA enrollees in particular are aware of the need to assess whether their health care providers are in a network of available providers when selecting among Medicare coverage options and therefore we expect them to able to ask the necessary questions of a treating provider when contemplating whether to switch to original FFS Medicare for coverage. In addition, we have already expressed our concerns regarding the number of unenrolled prescribers and providers and the access to care issues that could result if the Part D and MA enrollment requirements remain. We do not agree with the commenters that this issue arises with the frequency or scope to outweigh the policies we have articulated for our proposal and decision in this final rule about the enrollment requirement and preclusion list.

Comment: Several commenters stated that while CMS gave adequate justification for why all applicable Part D prescribers and MA providers and suppliers should be enrolled in Medicare, CMS failed in the proposed rule to explain why earlier justifications are now wrong; specifically, that enrollment: (1) Ensures that Medicare enrollees receive items or services from providers and suppliers that are fully compliant with the requirements for Medicare enrollment; (2) assists in efforts to prevent fraud, waste, and abuse and to protect Medicare enrollees by allowing CMS to carefully screen all providers and suppliers to confirm that they were qualified to furnish Medicare items and services; (3) in addition to the existing MA credentialing requirements, permits ''a closer review'' of MA

providers and suppliers; and (4) is necessary due to the fact that CMS has access to information and data not available to MA organizations. Commenters also requested that CMS articulate meaningful arguments in favor of overturning the current enrollment policies.

Response: The agency is updating its policy to reflect its experiences meeting the requirement of the aforementioned final rules, updated data analysis, and continued stakeholder engagement. CMS has worked diligently to enroll providers and suppliers in order to meet the requirements of the May 23, 2014 and November 15, 2016 final rules. As mentioned previously, enrollment can permit a greater degree of scrutiny in determining a prescriber or provider's qualifications. However, we are concerned that the perceived burden associated with enrollment may cause some providers to not enroll for purposes of furnishing items and services under Part C or to prescribe Part D drugs, which could potentially lead to access to care issues. Indeed, the significant number of prescribers and providers that remain unenrolled bear this out. Such a serious loss of prescribers and providers, should the enrollment requirements be enforced, could potentially impact patient care, especially for beneficiaries located in areas already experiencing access to care issues. Also, we reiterate our belief that the criteria warranting a prescriber's or provider's addition to the preclusion list are comprehensive enough to prohibit problematic prescribers and providers from receiving program dollars or directing the care of Medicare beneficiaries. In short, given the data analysis CMS has conducted regarding the number of prescribers and providers that remain unenrolled even after a vigorous outreach campaign, coupled with potential access to care concerns, we believe the preclusion list approach is a sufficient alternative to screening prescribers and providers given the concerns regarding a lack of providers enrolling to meet the enrollment requirement.

Comment: Noting our concerns in the proposed rule about the potential burden of the enrollment process, a commenter stated that elimination of the enrollment requirement will merely transfer, rather than eliminate, this burden. The commenter explained that removing the enrollment requirement will deny MAOs a valuable and reliable data source when considering provider credentialing and network participation, meaning that MAOs may need to invest additional resources in developing fraud, waste, and abuse (FWA) investigations. The loss of prospective MA plan review of providers will only make the nature of credentialing and FWA programs even more cumbersome, and will create new incentives for plans to fill the oversight void left by the loss of MA program enrollment. As a result, the commenter stated, the MA program is likely to see little or no reduction in total administrative burden; to the contrary, a diversity of efforts among plans seeking to compensate for the loss of enrollment data may make program participation more burdensome for providers, who could be subject to new and unique review or verification requirements by plans. The commenter (1) concluded that the risks associated with elimination of current enrollment requirements outweigh any modest reduction to provider burden that may result and (2) urged CMS to retain the enrollment requirement.

Response: We appreciate the commenter's feedback. However, we do not believe the preclusion list approach will require the plans to invest more heavily in developing resources to combat fraud, waste, and abuse, as the plans would continue utilizing their current resources and processes for credentialing network providers and fighting fraud, waste and abuse. We note that the MA and Part D programs have compliance and fraud, waste and abuse monitoring requirements that exist separate from the preclusion list (and provider enrollment) policy; those requirements are not being increased under this final rule. Nor does this final rule increase the burdens on MA plans related to provider credentialing. If the requirement to enroll were to remain, Medicare health and drug plans would adjudicate claims based on review of Medicare's enrollment data. Under the preclusion list approach, plans are completing the same task using preclusion data in place of enrollment data. The plans are not subject to any more burden than they would have been under the previous rule. CMS will maintain the responsibility of reviewing each provider and making the determination to place them on the list or not. Upon implementation of the preclusion list, there may be an increase in notification by plans to beneficiaries regarding the preclusion status of a provider they have received prescriptions or services from within the past 12-months. However, we believe this is only minimally more than the burden plans would have been subject to under the previous rule.

Further, the preclusion list approach will place no burden on providers or prescribers as they will not need to take any action, unless they choose to appeal being added to the preclusion list. If any provider is concerned about burden for themselves or beneficiaries, they retain the option to enroll, and CMS is continuing to allow plans to require enrollment if they so choose. As long as the provider's enrollment is in good standing, he or she will not appear on the preclusion list.

Comment: A commenter expressed concern that the proposed rule would, in actuality, result in increased regulation contrary to (1) Presidential Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs and (2) Presidential Executive Order 13777 on Enforcing the Regulatory Reform Agenda. The commenter asked CMS to reconsider the preclusion list provisions in light of these executive orders.

Response: We believe that the preclusion list concept complies with these Executive Orders because it reduces the burden on prescribers, providers, and plans.

Comment: A commenter stated that CMS did not consider the effect of its preclusion list proposal on the protection of Qualified Medicare Beneficiaries (QMBs) from improper billing by in-network providers. The commenter stated that a provider's enrollment in Medicare gives CMS a direct path to enforcement against a provider that improperly bills a QMB. While recognizing that, by regulation, CMS requires plans to include billing protections in a provider contract, the commenter stated that this provision does not afford the beneficiary the same level of protection that is afforded by CMS's ability to enforce the Medicare provider's contract with the agency.

Response We believe the contract provisions required between the MA plan and a network provider pursuant to § 422.504(g)(1)(iii) are binding on providers; such agreements specify that QMBs must not be charged cost sharing when the state is responsible for paying such amounts under the Medicaid program. Further, the regulation at § 422.504(g) contains broader beneficiary protection requirements for MA organizations, including a requirement that the plan must indemnify the beneficiary from any fees that are the legal obligation of the MA organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the MA organization, to provide services to the organization's enrollees.

Comment: A commenter recommended that CMS not eliminate its enrollment requirement but instead ascertain and attempt to address any

problems with the enrollment process. As an illustration, the commenter suggested that CMS inquire more deeply into the facts behind the 120,000 MA providers that are not enrolled, such as determining whether non-enrollment is concentrated among particular provider types or specialties, particular geographic regions, or particular plan sponsors. If such concentrations exist, the commenter stated, CMS could consider extending the 2019 deadline and undertaking a more targeted outreach. Another commenter stated that in eliminating the proactive enrollment process that best protects beneficiaries and the Medicare program from fraud and abuse, CMS is proposing to take a step back in time, rather than a step forward. The commenter urged CMS to keep the enrollment requirements in place and to step up outreach to those who could have enrolled but have not.

Response: We appreciate the commenters' recommendations. However, we disagree that more targeted outreach would further reduce the number of prescribers and providers not yet enrolled. This is because CMS, as previously stated, has already completed a vigorous Part D and MA enrollment campaign (including targeted outreach), yet the number of unenrolled prescribers and providers remains comparatively high, thus potentially creating significant access to care issues. Moreover, it would be inefficient to continue to pursue the enrollment approach given the current data and results from our Part D outreach efforts.

Comment: A commenter urged CMS to examine whether the enrollment requirement has any substantial effect on a plan's ability to develop adequate provider networks. The commenter's experience is that plans are narrowing their networks as part of delivery strategies and not because there are not enough providers available. The commenter stated that the trend toward narrower networks increases the importance of having participating providers in those networks subject to the Medicare enrollment process. The commenter envisioned circumstances where highly specialized providers are needed and few within a specialty choose to enroll in Medicare, and stated that there may be other unique circumstances that would merit an exception to the general rule of Medicare enrollment. The commenter contended that CMS could develop an authorization process that allows for those special circumstances and permits plans to bring providers into their networks so that beneficiaries have adequate access. This narrower approach, the commenter believed, would be preferable to the preclusion list proposal.

Response: We disagree with the commenter that the problems and concerns we articulated about implementation of the provider enrollment requirements are incorrect. It is our hope that by adopting a replacement for the provider enrollment requirements, a broader population of highly specialized providers will be able to provide services to MA beneficiaries, while prohibiting payment to providers that would typically be revoked from the program based on our authorities at § 424.535. We believe the preclusion list approach broadens the provider population as we are no longer limiting beneficiaries to providers who would be Medicare enrolled and either in or out of network, but are limiting the population to only those who are not precluded.

Further, with 120,000 MA network providers not currently enrolled, we feel the trend to narrower networks is not so prevalent that such a high volume could be explained as ''network attrition.''

Comment: A commenter stated that CMS should take into account, in further consultation with states, how its proposed change from the enrollment requirement to a preclusion list may impact states given that: (1) State Medicaid programs use Medicare provider registration data as part of their respective Medicaid provider database and registration requirements; (2) various agencies in the states use Medicare certification of particular provider types as part of their respective provider licensure and registration requirements (for example, home health agencies, hospices); (3) states do not provisionally address provider circumstances of behavior that could result in revocations (as stated in proposed § 423.100) and how such circumstances may be addressed differently by provider type; and (4) provider registration with state Medicaid agencies may be considered to be sufficient in representing effective and valid Medicare program registration by proxy, outside of any additional CMS provider preclusion list development, which also may be coordinated with the states.

Response: We appreciate this recommendation and note that the impact on state Medicaid programs was contemplated when we formulated our preclusion list proposal. Concerning those providers that would no longer be required to enroll if the proposal is finalized—specifically, those that are not currently enrolled in Medicare fee-for-service—we believe that not requiring enrollment will have little to no impact on state Medicaid programs that require Medicare enrollment as a prerequisite to Medicaid enrollment because their reluctance to enroll in Medicare would extend to Medicaid as well based on our experience. Regarding providers that obtain Medicare certification, they typically do so in order to provide services in the Medicare fee for service program; thus, not requiring enrollment will have minimal impact on those providers that furnish covered services in states that require Medicare certification in their licensure or registration process. Finally, reliance on Medicaid registration would most likely pose a similar issue given that, in CMS' experience, providers who do not enroll with Medicare are most likely not enrolled or willing to enroll with Medicaid.

(2) Operational Matters Pertaining to the Preclusion List

Comment: Many commenters expressed concern about the operational complexities of the preclusion list proposals and the lack of details thus far given. They urged CMS to provide as many operational details about how the preclusion list will be tested, accessed, updated, formatted, downloaded, etc., as early as possible to give all affected parties sufficient time to implement new processes.

Response: We appreciate the commenter's concern. However, we believe these details would be best addressed outside of rulemaking, though we note our view that the preclusion list will be simpler to operationalize than an enrollment requirement because far fewer service and prescription claims will be impacted under Parts C and D. The list will be available via a secure server from which plans will be able to download the file.

Comment: A commenter stated that it is not clear whether CMS proposed to create two preclusions lists, one for Part C and one for Part D. If CMS intends to create two preclusion lists, the commenter asked CMS (1) how it will reconcile the appearance of a provider on one list and not the other, and (2) whether one list will take precedence over the other.

Response: There will be only one preclusion list, which both the Part D and MA programs will utilize.

Comment: A number of commenters sought clarification on the relationship between the OIG exclusion list and the CMS preclusion list. The principal issues raised were as follows: (1)

Whether all parties on the OIG list would be included on the preclusion list; (2) coordination between the preclusion list, the OIG list, and other lists similar to the OIG exclusion list, such as the System for Award Management (SAM); (3) how plans should address situations where a prescriber or provider is on one list but not the other; (4) the hierarchical order of processing when a prescriber or provider appears on multiple lists (for example, whether the preclusion list or the OIG list takes precedence if a provider appears on both lists); and (5) whether the preclusion list criteria will differ from the OIG exclusion list criteria so as to ensure that prescribers and providers are not included on both lists.

In addition, several commenters recommended that the preclusion list be combined with the OIG exclusion list so as to enhance efficiency and simplicity. A commenter stated that combining the lists would streamline implementation of the preclusion list requirement by allowing plans to leverage the current OIG exclusion list process, while another commenter expressed concern that two different notices would have to be sent to the beneficiary if the provider appeared on the preclusion and OIG lists, thus likely causing beneficiary confusion. Another commenter stated that if a provider were on both the preclusion list and the OIG exclusion list, this would present difficulties from a plan sponsor's operational standpoint, for provider remittances and beneficiary explanations of benefits can only report a single denial reason; this commenter recommended that CMS consider not including OIG excluded providers on the CMS preclusion list so that providers and beneficiaries have a singular reason for claims payment denial. Another commenter, however, recommended that the preclusion and OIG exclusion lists remain separate and distinct from one another with no overlap; if this recommendation cannot be realized, the commenter suggested that the OIG exclusion list take precedence over the preclusion list.

Response: As stated in the proposed rule, the preclusion list will include those prescribers and providers that have engaged in behavior for which CMS could have revoked the prescriber or provider to the extent applicable if they had been enrolled in Medicare. A CMS revocation is based on § 424.535, which includes the authority at § 424.535(a)(2)(i) to revoke an enrolled party that is excluded or debarred (per the SAM) from the Medicare program. Therefore, if a prescriber or provider is placed on the OIG exclusion list or the SAM list, they will also be placed on the preclusion list. The only circumstance in which a prescriber or provider would show up on either one of the above-mentioned lists and not the preclusion list is if a delay occurs in including that prescriber or provider on the preclusion list after the party was added to the OIG list or SAM; in that instance, the plan should process in accordance with existing procedures.

With respect to the commenter's concerns regarding notices, plans would only need to send one notice to beneficiaries notifying them of the prescriber's or provider's exclusion or preclusion.

In determining which list will take precedence for the purpose of notifying the beneficiary and/or provider/supplier in the event of a payment denial, we will address this issue in guidance outside of rulemaking; in this guidance, we will take into account the fact that the plans do not currently check the SAM list. CMS is unable to combine both lists as they are implemented under different statutory and regulatory authorities. Plans will continue to check the OIG list as they have done in the past as the rule proposed no changes to that process. A provider or prescriber could be either excluded, precluded, or both. In any event, the claim must deny according to the procedures for each list.

Comment: While expressing concerns regarding the operational challenges of enrolling prescribers that are not ''typical'' Medicare providers, a commenter expressed even greater concern about the preclusion list concept. The commenter believed that the preclusion list would overlap and include additional providers not on the OIG exclusion or SAM lists, thus creating additional operational and administrative challenges. The commenter added that most beneficiaries understand that if a provider or supplier has been excluded from receiving payment from all federal programs, their services cannot be covered by Medicare. Explaining to a beneficiary that a case-by-case determination has been made that his or her provider is not eligible for Medicare payment, the commenter contended, is very confusing and more likely to result in a beneficiary not receiving necessary treatment than to result in the prevention of fraud.

Response: While we appreciate the commenter's concerns, we do not believe that administering the preclusion list would be any more difficult than the process currently used in rejecting claims for services from providers that are on the OIG exclusion list. Further, we do not believe that payment denials due to a party's inclusion on the preclusion list will cause confusion among beneficiaries; beneficiaries are currently aware that excluded provider claims will be denied, and the preclusion list is a similar concept.

Comment: In raising the question of whether the preclusion list will be independent of the OIG exclusion list or if the OIG exclusion list will be incorporated by reference, a commenter also asked CMS to clarify whether the process for reinstatement and waiver applications will be identical for the two lists.

Response: As already mentioned: (1) If a prescriber or provider is placed on the OIG exclusion list, they will also be placed on the preclusion list; and (2) we will address which list will take precedence for the purpose of notifying the beneficiary and/or provider/supplier in the event of a payment denial in guidance outside of rulemaking. CMS is unable to combine both lists as they are implemented under different statutory and regulatory authorities.

The preclusion list will not employ a waiver process in contrast to the OIG list. In the case a provider or supplier that was excluded and is subsequently reinstated, unless enrolled in Medicare and concurrently revoked for the exclusion, the provider or supplier would remain on the preclusion list until the end of the enrollment bar period or until they enroll with Medicare. Medicare would not be made aware of the reinstatement until the provider attempted to enroll, at which point, if successfully enrolled, would be removed from the preclusion list.

Comment: A commenter urged that CMS include precluded and excluded prescribers in a single file that is made available to the industry on a regular basis, rather than maintain a two-file approach.

Response: We appreciate the commenter's recommendation. From an operational perspective, however, we are unable to combine the two files, for both are maintained under different regulatory authorities. We will address which list will take precedence for the purpose of notifying the beneficiary and/or provider/supplier in the event of a payment denial in guidance outside of rulemaking.

Comment: A commenter asked whether the proposed preclusion list would eliminate the requirement to review the regional Medicare opt-out lists for practitioners.

Response: The preclusion list concept will not alter this requirement.

Comment: A commenter asked whether the proposed preclusion list will include the entire country.

Response: We believe the commenter is seeking clarification as to the population of prescribers and providers that will be subject to the screening that would determine if a provider is placed on the preclusion list. Using CMS' internal data and systems, which includes but is not limited to, PECOS and National Plan and Provider Enumeration System (NPPES), we will screen any prescriber or provider that may or could potentially prescribe Part D drugs or furnish MA services or items to a Medicare beneficiary, through the fee-for-service program or a Medicare Advantage plan. The screening process will include providers and suppliers from the entire country.

Comment: A commenter stated that while the preclusion list could help CMS combat fraud, waste, and abuse, the Part D preclusion list appears to only apply to prescribers, not to pharmacists or pharmacies. The commenter added that some pharmacies have been involved in fraud schemes and that, in the current opioid epidemic, pharmacies have occasionally been integral to many schemes where these medications are prescribed without legitimate medical use. Similar to the MA preclusion list provisions, the commenter recommended that the Part D preclusion list provisions apply to both individuals and entities (such as pharmacies).

Response: We appreciate this recommendation and clarify that this is our intent. The preclusion list will prevent any individual or entity that is able to prescribe or provide services under the Medicare Part C and D programs from prescribing or providing those services, assuming they meet the criteria for inclusion on the preclusion list.

Comment: A commenter asked whether (1) the preclusion list file will include termination dates as well as effective reinstatement dates, and (2) the prescriber will be removed from the file upon reinstatement.

Response: The preclusion list will be updated once every 30 days. It is not necessary for the update to include the removal of any prescriber or provider's NPI whose reenrollment bar has expired, for the file will contain time periods for which each prescriber provider is precluded (an expiration date per se), similar to the OIG exclusion list. The time period for preclusion will be determined by CMS' current reenrollment bar criteria and will be applied to currently enrolled revoked providers and those providers who would have been revoked had they been enrolled in Medicare. Further, prescriptions ordered, or claims for reimbursement submitted, by a precluded provider will be denied based upon the effective date indicated in the list.

Comment: With respect to PDE editing, a commenter asked whether CMS will use the creation date of the preclusion file or whether it will be based on the active preclusion file when the PDE is processed.

Response: We believe these dates are insignificant given that claims will be edited based on the time period for which a provider is precluded as indicated in the preclusion list file.

Comment: A commenter stated that CMS must ensure that the preclusion list is updated frequently and on a regular basis to minimize the lag time between when a provider is placed on said list to the time that information is available to health plans and other providers; the greater the lag time between preclusion and disclosure, the greater the potential of unknowingly filling a prescription written by such a provider. The commenter added that CMS must also ensure the preclusion list contains the vital information needed to properly identify a precluded prescriber, such as an NPI and the current practice address of the provider; the commenter stated that lack of a current address increases the difficulty in finding a provider on the preclusion list, especially when a provider has a common name that yields many search results.

Response: As already mentioned, the preclusion list will be updated once every 30 days, and prescriptions ordered, or claims for reimbursement submitted, by a precluded provider will be denied according to the date specified on the preclusion list. The list will indicate the period for which the provider is precluded. Additionally, CMS will include the address data it has available from its internal data sources. We will also include the prescriber's or provider's NPI, name, and tax identification number, which will be sufficient to confirm that a particular prescriber or provider is on the preclusion list.

Comment: Several commenters sought clarification on how the preclusion list information would be shared with health plans. A commenter asked whether the preclusion list will be published on a public site or a restricted site that only plan sponsors can access. Another commenter requested that CMS clarify when the file layout and location of the preclusion list of prescribers will be available.

Response: The preclusion list will be available on a monthly basis via a secure website. As for making the file publicly available, CMS does not intend to make this information available to the public except as required by law. CMS notes that if the file were made public, the information in it could be used in an inappropriate manner and not for its intended purpose. Plans will be expected to download the monthly file, which we intend to make available to the plans by January 1, 2019. We will address further operational details concerning the preclusion list in sub-regulatory guidance.

Comment: Several commenters asked whether beneficiary notices would be required if the beneficiary's provider ended up on the preclusion list shortly after the beneficiary had been assigned or received care from the provider. If beneficiary notice is required, commenters asked whether distribution of the notice is the responsibility of the health plan or CMS.

Response: Notice will be provided to beneficiaries at least 60 days prior to the prescriber or provider being added to the list. Whether the notice originates from CMS or plans will be addressed in guidance outside of rulemaking.

Comment: A commenter asked whether a prescriber will be precluded immediately after it is included on the preclusion list or if CMS will permit different dates of preclusion effectiveness on a case-by-case basis.

Response: As stated in the proposed rule, a prescriber's or provider's claims will be denied based on the effective date indicated in the preclusion list file.

Comment: A commenter asked whether the preclusion list can be integrated into pharmacy software systems to ensure that medications are not dispensed if the prescriber is on the list.

Response: We believe plans will integrate the list into their claims adjudication process in order to appropriately adjudicate pharmacy claims in real-time at the point of sale. We foresee this process as being similar to how plans currently use the OIG exclusion list.

Comment: A commenter asked that CMS have specific administrative procedures in place to ensure that prescriptions dispensed without the pharmacy knowing a prescriber is on the preclusion list are adjudicated appropriately.

Response: If a sponsor pays a pharmacy claim involving a prescription written by a precluded prescriber in error, we would expect that the sponsor would not recoup the payment from the pharmacy since the

pharmacy will not have access to the preclusion list.

Comment: A commenter urged CMS to consider updating the preclusion list more frequently than monthly. The commenter expressed concern that only updating the preclusion list monthly could lead to situations where CMS may be aware that an individual should be removed from the preclusion list (such as the revocation ends on a day at the beginning of the month but they will not get off the preclusion list for an additional month, therefore essentially prolonging the revocation for longer than permitted by current regulation), but Part D sponsors have not yet been notified and, as a result, claims will reject and beneficiaries may not have access to their Part D prescriptions.

Response: While we appreciate the commenter's recommendation, we note, for the purpose of comparison, that any enrolled provider revoked from Medicare does not have their billing privileges automatically restored upon the expiration of their enrollment bar; reinstated providers are required to submit an application for initial enrollment and are subject to the enrollment and screening requirements in 42 CFR part 424, subpart P as if they were initially enrolling. If the provider was not previously enrolled and does not wish to enroll, the time period the provider would have to wait for the list to be updated—30 days or less—is comparable to the time it may take a previously enrolled but revoked provider to re-enroll. Further, the OIG exclusion list works in a similar manner and is only updated once every 30 days. If an excluded provider were reinstated on the first of the month, the provider would have to wait until the updated OIG list is released. Ultimately, our intent is to operationalize the preclusion list similar to how the OIG exclusion list is operationalized currently. We also note the notification to providers that they are on the preclusion list will communicate the date on which the provider's reenrollment bar will end and he or she will be eligible to begin prescribing or furnishing services.

Comment: A commenter recommended that CMS publish the preclusion list in the same format and record layout as the current OIG exclusion list and, more specifically, to include the prescriber's NPI number on the preclusion list file so that the individual prescriber is accurately identified and appropriately included in the claims adjudication systems. The commenter also suggested the following: (1) The file should include the file extension (in other words, .csv); (2) the file should be placed on a public domain for download capability; and (3) CMS should maintain a file that tracks the history for those individuals and entities that are reinstated on the cumulative file, for this facilitates a more efficient process for updating provider records and processing claims.

Response: We appreciate this feedback and will take it into consideration. We will provide a file extension upon making the file available. As for making the file publicly available, CMS does not intend to make this information available to the public except as required by law. CMS notes that if the file were made public, the information in it could be used in an inappropriate manner and not for its intended purpose.

Further, we do not believe it will be necessary to create a historic tracking file as the preclusion list will be cumulative and as such will contain the time period for which a provider is precluded.

Comment: A commenter recommended that each updated preclusion list file be effective at least five (5) business days after Part D sponsors receive it to allow them time to configure their claims adjudication systems with the most current version.

Response: We appreciate the commenter's feedback and are finalizing the rule to include a period of at least 30 calendar days with which the plan will have to intake into their system the most current preclusion data.

Comment: A commenter asked whether, if a claim for reimbursement is received several months after the date of service, CMS will require Part D sponsors to go back and review the preclusion list in effect at the time of the date of service. Another commenter sought clarification as to whether CMS will maintain an archive of the preclusion list files with the dates of enforcement.

Response: We plan to make the preclusion list a cumulative file that will contain periods for which claims should be denied, meaning the list will contain start and end dates for preclusion periods. Accordingly, we believe that referring back to archived files will not be necessary.

Comment: A commenter supported CMS' recommendation to leverage the PDE data as the initial data source for precluded provider analysis. The commenter stated, however, that any changes to the PDE layout to support these efforts will need to be outlined in technical guidance to ensure efficient and effective data exchanges.

Response: We appreciate the commenter's support and agree any changes to PDE layout will need to be outlined in technical guidance issued outside of this rule.

Comment: A commenter requested that all technical guidance related to ''other authorized prescribers'' be removed.

Response: We appreciate the commenter's feedback. All provider types, including those that are not eligible to enroll but who are eligible to prescribe, will be subject to screening for placement on the preclusion list.

Comment: A number of commenters sought clarification as to who notifies the beneficiary that their provider is on the preclusion list.

Response: Plans will be responsible for notifying beneficiaries of their prescribers being placed on the preclusion list as stated at § 423.120(c)(6). As for Part C beneficiaries whose provider is precluded, whether the notice originates from CMS or plans will be addressed in guidance outside of rulemaking.

Comment: Several commenters asked for clarification on how to handle situations where a claim for a dual-eligible beneficiary comes from a prescriber who is on the preclusion list but is not excluded by Medicaid. Other commenters also requested that CMS explain how claims for dual-eligible beneficiaries should be handled.

Response: If a Part D drug claim is rejected by the Part D plan because the prescriber is included on the preclusion list, the drug cannot be covered by Medicaid and eligible for federal financial participation (FFP) under Medicaid for dual eligible beneficiaries.

Comment: A commenter stated that with new admissions, long-term care pharmacies often dispense the medication(s) without entering a claim in real-time because the relevant information received from the long-term care facility on the patient is incomplete. Should this occur with a provider on the preclusion list, a long-term care pharmacy would either have to spend resources to contest the denial of payment or bear the cost. To avoid undue costs and to prevent the pharmacy in this situation from inadvertently filling such prescriptions, the commenter requested that there be a standard process by which the plans or CMS inform long-term care pharmacies of providers included on the preclusion list.

Response: We believe this is best addressed by the contract between the plan and the pharmacy.

Comment: A commenter recommended that the final rule maintain the proposed language that payment denials would apply only to health care items or services furnished

on or after the date the individual or entity was added to the preclusion list.

Response: We appreciate the commenter's recommendation and agree. We are maintaining the language in the proposed rule that payment denials or claim rejections occur only after the date on which a provider is placed on the preclusion list and are effective the date indicated on the preclusion list file. To clarify, the preclusion list will include the prospective specified time period for which the provider is precluded.

Comment: With regard to beneficiary notification, a commenter urged CMS to consider permitting MA plans to follow existing processes, including, but not limited to, the termination of a contracted MA plan provider and subsequent notification to the beneficiary. Upon submission of a claim from an individual or entity that is on the preclusion list, the commenter explained, the claim would be denied and the beneficiary would not have any liability for the claim, yet the beneficiary would receive an explanation of benefits notifying the beneficiary of the claim denial and reason; if the claim is related to a contracted provider who was then terminated from a MA plan's network, the beneficiary would be notified of that status and the reason.

Response: With respect to the process that occurs upon a claim being submitted for services furnished by a contracting provider, if the MA plan determines through its periodic review of provider credentialing that a contracting provider is no longer eligible to treat Medicare beneficiaries the MA plan will ensure that the provider does not furnish services for plan enrollees until such time as the provider is either terminated by the plan or the provider resolves the reason for being on the preclusion list. If a contracted precluded provider has treated plan enrollees, the enrollee will only be responsible for the plan allowed cost sharing and will be notified that the contracted provider is no longer available.

Comment: A commenter requested that CMS clarify how ''entities'' would be identified on the preclusion list file and whether individual providers furnishing services under that entity would also be precluded (for example, if the individual providers under the entity are also precluded, the affiliated Type 1 NPIs will also be listed on precluded provider file).

Response: Entities that provide health care services will be eligible to be placed on the preclusion list. Whether or not the individuals providing services under the entity depends on if the individual met the criteria for being placed on the list. Individuals under precluded entities will not automatically be precluded based on their association with a precluded entity.

Comment: A commenter stated that, regardless of who furnishes notice to the beneficiary, CMS will need procedures in place to address beneficiary questions. If plan sponsors must notify the beneficiary, the commenter explained, the plan sponsor will have no access to the reason for the preclusion to be able to answer beneficiary questions.

Response: We appreciate the commenter's feedback and will take into consideration that the plan will not have the specific reason. However, we believe this is an operational detail best addressed outside of rulemaking.

Comment: A commenter stated that CMS should clarify whether the preclusion list will be shared with state Medicaid programs for inclusion in the state's Medicaid exclusion list. Another commenter stated that the preclusion list policies should apply to both the Medicare and Medicaid benefits where coordination occurs between these programs under Medicare/Medicaid Plans and Special Needs Plans. Another commenter expressed concern that the preclusion list will not be aligned with state lists and that the impact on the beneficiary at the point of sale will not be aligned between state and federal processes; the commenter stated that this would be particularly relevant for an MMP beneficiary. Another commenter recommended that for Medicare-Medicaid Plans and Special Needs Plans involving situations where the prescriber is listed on the preclusion list, the beneficiary should not be eligible for coverage under both plans. The commenter believed that this would eliminate confusion for beneficiaries who have multiple prescriptions that could apply to either the Medicare benefit or the Medicaid benefit. Another commenter asked whether, for dual-eligible or Medicare-Medicaid Program beneficiaries, the drug can be covered under Medicaid or whether the final rule applies to both lines of business.

Response: We appreciate the feedback of these commenters. In our experience, State Medicaid agencies do currently construct their own exclusion lists based on state-specific criteria. The criteria they use may or may not be consistent with the criteria used to determine if a provider should be placed on the preclusion list. At this time, we are not requiring states to utilize the preclusion as a means of excluding providers in the Medicaid program but we intend to make the preclusion list available to State Medicaid programs in the future and are exploring how best to share this information with states. Also, for dual eligible beneficiaries, if a Part D drug claim is rejected by the Part D plan because the prescriber is included on the preclusion list, the drug cannot be covered by Medicaid and eligible for federal financial participation (FFP) under Medicaid for dual eligible beneficiaries.

Comment: A commenter urged CMS to work closely with industry stakeholders to define the minimum necessary attributes of the preclusion list file layout.

Response: We appreciate the commenter's suggestion and will take this into consideration as we work to operationalize these requirements.

Comment: A commenter asked that CMS confirm that, similar to the OIG excluded provider guidance, plan sponsors will not return reject code 569 (''Provide Notice: Medicare Prescription Drug Coverage and Your Rights'') on claims that reject as a result of a precluded provider.

Response: We appreciate the commenter's question and will take this into consideration. However, we believe this is an operational detail best addressed outside of rulemaking.

Comment: A commenter urged CMS to ensure that the list is available to prescribers so they are able to confirm their inclusion on the list independent of notification by a plan sponsor.

Response: Prescribers will be notified in advance of being placed on the preclusion list as required by § 423.120(c)(6). The notification would explain that the provider has met the criteria for preclusion and has the right to appeal that determination within 60 days. Once a provider has exhausted their first level appeal process or has not submitted an appeal within 60 days, an additional 90-day period will lapse prior to their addition to the preclusion list. The 90-day period allows the plans 30-days to intake the preclusion data and a 60-day beneficiary notification period. Subsequent updates to the list will provide any newly added provider with a 60-day appeals window but will not provide a 90-day period as discussed above, thus after implementation beneficiaries may not be notified that they may have received a prescription or services from a provider that is now precluded.

We therefore believe it is unnecessary to provide the list to prescribers. As for making the file publicly available, CMS does not intend to make this

information available to the public except as required by law. CMS notes that if the file were made public, the information in it could be used in an inappropriate manner and not for its intended purpose.

Comment: A commenter stated that CMS must notify prescribers when they are placed on the preclusion list. The commenter did not believe this administrative function should be the plan sponsors' responsibility.

Response: We agree with the commenter. As written in the regulation text at § 423.120(c)(6)(v)(A), ''CMS sends written notice to the prescriber via letter of his or her inclusion on the preclusion list.''

Comment: A commenter stated that CMS should not duplicate exclusion efforts already administered via the OIG.

Response: While we appreciate the commenter's feedback, we do not believe we are duplicating efforts currently undertaken by the OIG. We note that the preclusion list uses exclusion data from the OIG along with other provider data to create an alternative to enrollment. As previously stated, the preclusion list will include prescribers and providers who have engaged in behavior for which CMS has or could have revoked the prescriber or provider to the extent applicable if he or she had been enrolled in Medicare. Further, the intent of the preclusion list is to be broader than the OIG exclusion list, for it can include prescribers and providers who may not be excluded but still pose a threat to the program and/or beneficiaries.

Comment: In response to our solicitation of comments, a commenter did not recommend any opioid-specific criteria for inclusion on the preclusion list. The commenter believed that the end result (for example, suspension/termination of medical and/or DEA license) should serve as the preclusion criteria.

Response: We appreciate the commenter's feedback. We note that Medicare has the authority to revoke for improper prescribing practices (42 CFR 424.535(a)(14)), which includes a pattern or practice that is abusive or represents a threat to the health and safety of our beneficiaries. In screening nonenrolled providers, we would apply this authority in determining their inclusion on the list. Further, CMS has the ability to revoke providers for suspension or revocation of their DEA certification or registration, or loss of prescribing authority (42 CFR 424.535(a)(13)).

Comment: A number of commenters stated that monthly updates of the preclusion list would be inadequate and that the list should be updated weekly or no less than bi-monthly; a commenter stated that a reasonable timeframe for incorporating the preclusion list into its claims adjudication system would be within four (4) business days of the file's posting This commenter explained that upon removal or resolution of a provider's preclusion, the industry will need to be able to begin paying the claims as soon as possible in order to prevent beneficiary access issues. Even if a new override mechanism for data delays is created, the commenter continued, most pharmacies will be unwilling to override the rejection for fear of audit risk and/or payment recoupment. The commenter expressed concern that claims would be rejected for up to a month for prescribers whose preclusion statuses have been resolved. The same situation could happen with newly precluded prescribers; if an event occurs that warrants the prescriber's inclusion on the preclusion list, the commenter expressed concern over the prospect of paying claims for these prescribers for up to a full month, particularly if the prescriber's behavior places beneficiaries at risk. Other commenters shared these concerns.

Response: We appreciate the commenter's concerns. We note, however, that the OIG list is posted every 30 days and plans are able to integrate that file into their systems in a reasonable amount of time. The preclusion list will be designed to be integrated in a similar manner and claims adjudicated in a similar process. We therefore believe that posting the list once every 30 days is sufficient. Further, the specific time period for which a provider is precluded will be identified on the file shared with plans.

Comment: A commenter requested technical guidance for any PDE changes that will be needed to support the preclusion list process. Among the specific questions the commenter raised were: (1) Whether CMS could confirm that plans will no longer need to identify an exception for ''other authorized prescribers'' on the PDE, and that this field should be submitted with spaces or blanks; and (2) whether CMS anticipates any other changes to the PDE file layout and/or processes related to the preclusion list.

Response: We will issue any necessary PDE guidance outside the regulatory process. We note that the regulatory text no longer refers to other authorized prescribers. Such a designation was necessary to identify which claims should be paid under an enrollment requirement since other authorized prescribers could not enroll. However, under the preclusion list requirement, only claims thatmust be rejected need to be identified.

Comment: A commenter asked CMS to clarify the conduct that would lead to non-Medicare providers being included on the preclusion list.

Response: As we stated in the proposed rule, the preclusion list will include those prescribers and providers that have engaged in behavior for which CMS could have revoked the prescriber or provider to the extent applicable if he or she had been enrolled in Medicare. CMS revokes providers based on the authorities located at 42 CFR 424.535. If it is determined that a prescriber or provider meets the criteria that would cause them to be revoked if he or she were enrolled in the program and the underlying cause for revocation is considered to be detrimental to the program, the prescriber or provider will be placed on the preclusion list. CMS would not have the authority outside of those listed at 42 CFR 424.535 to revoke a provider or therefore add them to the preclusion list.

Comment: A commenter recommended that CMS provide sponsors with clarifications on the process of creating and maintaining the preclusion list, followed by an opportunity to submit comments and feedback.

Response: We appreciate the commenter's question and will take this into consideration.

Comment: A commenter recommended that CMS require plan sponsors to treat all precluded provider claims in the same manner regardless of the drug. If the CMS preclusion warrants a discretionary effective date based on the preclusion reason, the commenter stated that this should be managed by CMS.

Response: We appreciate the commenter's recommendation and believe that it is consistent with our proposal. If a provider is placed on the preclusion list, any prescription drug claims submitted with the provider listed as the prescriber must be denied or rejected regardless of the drug or medication being prescribed.

Comment: A commenter asked whether the range of providers defined as ''in scope'' for purposes of complying with the preclusion list requirement will be made clear for purposes of implementing the adjudication logic. As an illustration, the commenter asked whether providers (such as pharmacies) under MAOs would be designated as ''in scope'' for this requirement. If so, the commenter stated, CMS must provide clear instructions for sponsors to adjudicate claims (or not) involving situations where a pharmacy on the

preclusion list is in a position to fill a prescription for a non-precluded prescriber.

Response: We appreciate this comment and clarify that the preclusion list will include any prescriber or provider that falls within the preclusion list definition in, respectively, §§ 423.100 and 422.2.

Comment: A commenter urged CMS to define how individuals/entities would be identified by CMS to add to the preclusion list and how the list will be created and maintained, followed by a comment opportunity for the industry to provide feedback.

Response: As already mentioned, the preclusion list will include those prescribers and providers that have engaged in behavior for which CMS has or could have revoked the prescriber or provider to the extent applicable if the prescriber or provider was or had been enrolled in Medicare. CMS revokes prescribers and providers based on the authorities located at § 424.535. If it is determined that a prescriber or provider has met the criteria that would cause the prescriber or provider to be revoked if they were enrolled with the program, or is revoked, and the underlying cause for revocation is considered detrimental to the Medicare program, the prescriber or provider will be placed on the preclusion list.

Comment: A commenter recommended that CMS clarify how and in what instances CMS would apply sanctions to a plan that pays an individual/entity on the preclusion list.

Response: CMS will determine appropriate compliance action on a case-by-case basis. In doing so, CMS will weigh key factors such as beneficiary harm, and duration and extent of compliance failure.

Comment: A commenter stated that a pharmacy often needs to send out medications for nursing home beneficiaries. If the preclusion list is not made readily available electronically, the commenter sought clarification as to which party would be responsible for payment of these medications.

Response: As already mentioned, CMS will make the preclusion list available every 30 days via a secure server from which plans will be able to download the most up to date list. If the plan fails to utilize the most up-to-date version of the list, the plan is at risk of paying for prescriptions written by precluded prescribers.

Comment: A commenter stated according to chapter 18, section 40.3.1 of CMS' Prescription Drug Benefit Manual and in previous technical guidance, plans do not have to provide beneficiaries s with the standardized pharmacy notice (CMS–10147—Medicare Prescription Drug Coverage and Your Rights) if the reason for the reject is due to a provider who has been excluded from participation in the Medicare program. The commenter sought clarification that this policy will also apply to claims rejected due to a prescriber being on the preclusion list.

Response: Regarding this particular technical guidance, it applies only to those prescribers who have been excluded by the OIG. Thus, if a beneficiary's prescribing provider is both excluded and is on the preclusion list, CMS will provide guidance on which list should take precedence in regard to how notification should be made to beneficiaries.

(3) Miscellaneous Payment Issues

Comment: A number of commenters urged CMS to: (1) Include language to clearly identify the scope of the payment prohibition to individuals/entities on the preclusion list; and (2) clarify which payments to individuals/entities are permissible and which are not (for example, health care services only; administrative services also).

Response: Payment for covered services or items furnished by a precluded prescriber or provider is prohibited under this rule, and the screening process for the preclusion list will apply to any prescriber or provider and not those conducting administrative services. However, we note that urgent and emergency services as defined in § 422.113, are excluded as indicated in the regulatory text at § 460.86(a) for Part C covered services and § 422.224(a) for Part D covered drugs.

Comment: A commenter noted that proposed § 422.222(a) would prohibit payment for health care items and services. The commenter asked whether a person or entity could still be paid for administrative services furnished to the sponsor. If the person or entity can be paid for such services, the commenter suggested that this be made clear throughout the proposed preclusion list provisions, for some provisions refer to a general prohibition against ''payments'' while others reference a prohibition against payment for ''health care items and services.'' In this vein, the commenter also cited § 422.224(a), which the commenter stated, appears to combine the payment prohibitions arising from an OIG exclusion with a party's inclusion on the preclusion list. The commenter found this confusing because a sponsor is precluded from paying a person who is excluded by the OIG for both health care services and administrative services, whereas CMS seemingly intends for the preclusion list prohibition to only apply to health care items and services. The commenter urged CMS to explain this distinction in § 422.224.

Response: As mentioned in our previous response, payment for covered services or items furnished by a precluded prescriber or provider is prohibited under this rule, and the screening process for the preclusion list will apply to any prescriber or provider and not those conducting administrative services. Further, administrative services may not be reimbursed via the claims process and therefore may not be subject to payment denials due to preclusion.

Additionally, we note that urgent and emergency services as defined in § 422.113, are excluded as indicated in the regulatory text at § 460.86(a) for Part C covered services and § 422.224(a) for Part D covered drugs.

Comment: A commenter stated that the proposed provision to § 422.224(a) does not appear to exclude emergency or urgently needed services from the payment prohibition therein. The commenter recommended that CMS make clearer that such services are indeed excluded from § 422.224(a)'s purview.

Response: Ultimately, we do not believe that even emergency or urgent situations would warrant subjecting beneficiaries to care provided by providers who meet the preclusion list criteria and therefore, decline to adopt the commenter's recommendation in finalizing the rule.

Comment: A commenter noted that § 422.224(a) applies the preclusion list payment prohibition to Medicare enrollees of the MAO/Medicare cost plan. An MAO or Medicare cost plan, the commenter explained, commonly offers other product lines besides the MA program or Medicare cost plan program that will cover Medicare enrollees; an example is the offering of commercial health plan coverage where an enrollee is covered under Medicare either as primary or secondary payer. The commenter stated that the OIG exclusion payment prohibitions extend to payments for these persons as well and asked whether CMS intended to extend the preclusion list payment prohibition to non-MA/cost enrollees of an MAO or a Medicare cost plan.

Response: We do not believe we have the authority to regulate commercial health plans or other non-Medicare product lines offered by the MAO.

(4) Application to Other Parties

Comment: Since PACE organizations provide Medicare and Medicaid covered services, a commenter asked how the

preclusion list requirement will apply to staff and contractual individuals and entities that are not eligible to enroll in Medicare (for example, nurses, recreational therapists, drivers). The commenter sought clarification that such individuals and entities will not be vetted for inclusion on the preclusion list and that it will not be necessary to check these individuals and entities against the preclusion list. Another commenter interpreted the proposed preclusion list requirement (as well as the OIG exclusion list) to apply to: (1) The staff of the PACE organization (whether employed directly by or under contract with the organization); and (2) entities with which a PACE organization may contract to furnish care, such as inpatient hospitals, nursing homes, and post-acute care settings. The commenter did not, however, believe that the preclusion list proposal required the PACE organization to verify whether employees or contracted staff of a hospital or other provider entity with which the PACE organization contracts are included on the preclusion list. Likewise, the commenter did not believe the preclusion list policy included staff members of the PACE interdisciplinary team who are not eligible for Medicare provider or supplier enrollment, such as nurses, recreational therapists, and drivers. The commenter urged that CMS clarify these issues.

Response: PACE would follow the same approach as MA organizations; that is, PACE would verify that contracted providers that furnish Part A and B services and items are not on the preclusion list. This would include those providers that are not otherwise eligible to enroll in Medicare. To address the specific points raised by the commenter, the administrative staff of the PACE organization would not be subject to the preclusion list requirements. Further, to the extent a PACE program contracts with a precluded provider, the requirements could only be applied if that entity or provider is visible on the claim. Regarding application of the preclusion list, we will hold PACE organizations to the same requirements as MAOs.

Comment: A commenter asked whether CMS expects PACE organizations to hold contracted entities responsible for confirming that their staffs (whether employed or contracted) are not on the CMS preclusion list. The commenter recommended that the preclusion list requirements not extend beyond those individuals and entities with whom PACE organizations contract directly unless a similar requirement is implemented in fee-for-service Medicare such that hospitals, nursing homes, home health agencies, etc. are required to check their staff against the preclusion list. The commenter's concern is that by imposing an additional contractual requirement on PACE organizations, their ability to secure contracts may be negatively impacted. Also, the commenter urged that any requirement on PACE organizations for employees of contracted entities to be vetted against the CMS preclusion list be delayed until such a requirement for these employees exists in fee-for-service, at which time such a requirement would be universal and not applied distinctively by PACE (and MA) organizations.

Response: As mentioned in our previous response, PACE would follow the same approach as MA organizations; specifically, PACE would verify that contracted providers that furnish Part A and B services and items are not on the preclusion list. This would include those providers that are not otherwise eligible to enroll in Medicare.

Comment: Regarding the requirement to provide notice to PACE participants if a PACE organization receives a request for payment by an individual or entity excluded by the OIG or included on the preclusion list, a commenter asked CMS to consider the differences between PACE organizations and MA plans in implementing the notice requirement.

Response: We appreciate the commenter's recommendation and will take this into consideration as we work to operationalize this requirement.

(5) Preclusion List Criteria

Comment: Several commenters believed that some of the criteria to be used to make preclusion list determinations lack objectivity. A commenter cited the following examples: (1) The seriousness of the conduct underlying the prescriber's revocation; (2) the degree to which the [physician's] conduct could affect the integrity of the Part D/MA program; and (3) any other evidence that CMS deems relevant to its determination. The commenter stated that such criteria hurts the program by potentially limiting the pool of available clinicians for Medicare beneficiaries and puts the professional reputation of the physician in jeopardy; the commenter stated that once a clinician has been placed on the list, there will be professional consequences for him or her. The commenter did not believe that CMS' proposed appeals process is enough to address this concern. The commenter urged CMS to remove criteria that are subjective in nature in the final rule.

Response: We appreciate the commenter's suggestion and believe the appeals process addresses this concern as no provider will be added to the preclusion list until they have exhausted their first level of CMS appeal or if they fail to appeal their addition to the list. Specifically, beneficiaries and Part C and D plans will not be notified of the provider's preclusion status until after this period in order to avoid negative consequences for a provider whose preclusion status is not yet final. In regard to the subjectivity of the preclusion list standards, we believe it is necessary to maintain this subjectivity given some providers are revoked for reasons that may not be considered detrimental to the program. For example, a provider may have failed to update an expired license.

Ultimately, we believe the preclusion list approach will broaden the pool of available clinicians as they are no longer restricted by the requirement that they be enrolled in order to furnish items or services.

Comment: A commenter expressed concern that the requirements for putting a prescriber on the preclusion list are too narrow. The commenter supported a means of including physicians or other prescribers on the preclusion list who have a history of problematic opioid prescriptions, or at least to flag such prescriptions if they would meet the requirements under the Plan Sponsor Drug Management Plan and do not meet any exemption.

Response: We appreciate the commenter's recommendation and will take this into consideration in any future regulatory revisions of the preclusion list provisions. At this time, however, we are unable to adopt these recommendations in this final rule as such data is not readily accessible to make such a determination.

Comment: A commenter recommended that Medicare revocation reasons § 424.535(a)(6), (9), and (10) be excluded as reasons for a provider to be included on the preclusion list, for these reasons only apply to those that are enrolled in Medicare.

Response: We agree that the revocation authorities at § 424.535(a)(6), (9), and (10) would not be applicable to prescribers and providers that are not Medicare enrolled but are evaluated for inclusion on the list. However, these revocation authorities will apply to prescribers and providers that are Medicare enrolled and are under review for inclusion on the list. Logically, we would not be able to evaluate non-Medicare enrolled providers against this criteria, and do not believe it is

necessary to specifically exclude these revocation authorities from the preclusion list criteria. To illustrate, the revocation authority at § 424.535(a)(4) is based upon the provider indicating as true information that is in fact false or misleading on the enrollment application. The providers who will be precluded may not have enrolled with Medicare and therefore would not be subject to this revocation authority. We therefore decline to adopt the commenter's recommendation in finalizing the rule.

Comment: A commenter recommended that CMS develop prescriber preclusion list criteria that focuses on beneficiary safety and mitigates the risks of opioid prescribing.

Response: We believe that by utilizing Medicare's current revocation authorities as criteria to evaluate a prescriber's inclusion on the preclusion list, we are, in fact, safeguarding beneficiaries against overprescribing of opioids. The current revocation reasons at § 424.535 allow CMS to exclude or remove from the program those prescribers who may prove to be a detriment to Medicare. The preclusion list expands CMS' authority by allowing the application of these revocation authorities to not only Medicare-enrolled prescribers and providers but also to any prescriber or provider that could potentially provide care to our beneficiaries, thus further broadening our ability to keep out problematic providers. We also reiterate that Medicare has two revocation authorities at § 424.535(a)(13) and (14) that specifically focus on a prescriber's prescribing practices. The authority at (a)(14), for instance, gives Medicare the ability to revoke if a prescriber shows a pattern or practice of abusive prescribing that CMS determines is a threat to the health and safety of Medicare beneficiaries. Given this clarification, we respectfully decline to adopt the commenter's recommendation.

(6) NPI Issues

Comment: Several commenters expressed support for our proposed changes to § 423.120(c)(5).

Response: We thank the commenters for their support.

Comment: A commenter stated that § 423.120(c) is among the sections of this rule that are listed as waived for PACE organizations. The commenter asked whether CMS intended to impose the requirements in proposed § 423.120(c)(5) and § 423.120(c)(6) on PACE organizations. If, the commenter asked, the requirements under proposed § 423.120(c)(5) for an active and valid NPI on all pharmacy claims apply to PACE organizations, the commenter requested a waiver for PACE organizations of the requirement in proposed § 423.120(c)(5)(ii) for Part D sponsors to communicate at point-of-sale if an NPI is active and valid. The commenter stated that such a waiver would be consistent with CMS' recognition of differences in how Part D may be implemented by PACE organizations and the way PACE organizations interact with their contracted pharmacies to obtain Part D drugs on behalf of their participants.

Response: Section 423.120(c) is waived for PACE organizations, and no waiver is necessary. However, to the extent a PACE organization adjudicates claims electronically or contracts with a pharmacy to fill prescriptions on their behalf and such pharmacy adjudicates beneficiary claims electronically on behalf of PACE enrollees, PACE organizations must comply with the requirements of § 423.120(c).

Comment: A commenter sought confirmation that the NPI is intended for encounter data submitted to CMS via the Encounter Data System (EDS), and not the abbreviated format via the Risk Adjustment Processing System. The commenter also suggested that the proposed change to § 422.310(d)(5) be revised to state as follows: ''(5) 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 submitted to CMS via the Encounter Data System (EDS), MA Plans must submit a NPI in a billing provider field on each MA encounter data record, per CMS guidance.''

Response: The proposed provision at § 422.310(d)(5) does refer only to encounter data. The record layout for Risk Adjustment Processing System (RAPS) data has not changed and is not addressed in this rule-making. Finally, we decline to accept the commenter's suggested revision to the regulation text, because the name of a system such as the EDS could change over time, and we believe it is clear that this provision applies to MA encounter data. Thus, we are finalizing paragraph (d)(5) as proposed.

Comment: With respect to the requirement for a valid NPI on drug claims, a commenter stated that the beneficiary should not be held responsible for the price of the drug in the event of an invalid NPI.

Response: We refer the commenter to § 423.120(c)(5)(iv), which generally states that a sponsor may not make payment to a beneficiary dependent upon the sponsor's acquisition of an active and valid prescriber NPI in the case of a beneficiary request for reimbursement.

Comment: A commenter noted that the MACRA legislation, which included the valid NPI requirement, was signed into law on April 16, 2015 and became effective January 1, 2016. Accordingly, the commenter stated that it, alongside other major PBMs, has been enforcing the active NPI requirement at the point of sale since January 1, 2016. The commenter thus expressed confusion about the modifications to (c)(5) and the request for comments, and sought clarification from CMS regarding the intent of this modified guidance.

Response: The modifications to (c)(5) are to comply with MACRA. In this regard, CMS previously issued guidance on June 1, 2015 [77] that existing procedures to comply with the previous requirement at § 423.120(c)(5)(iii)(B)(*2*) which stated that a Part D sponsor must pay a claim even when the pharmacy does not correct the NPI or confirm that it is active and valid will no longer apply as of January 1, 2016. Thus, the modifications to (c)(5) are intended to remove this regulatory language because it does not comply with MACRA. Sponsors in compliance with the June 1, 2015 guidance should not have to change any existing claims procedures due to these modifications.

Comment: A commenter expressed support for the proposed amended requirements for risk adjustment data, but urged that CMS consider two related issues prior to final rulemaking. First, while standard claims transactions (which represent the vast majority of claims) include provider NPI data, a provider that submits a manual, paper claim may not have an NPI on file with the plan. Plans may engage in efforts to obtain an NPI, but responses to these efforts from an unaffiliated provider is not always timely. The commenter recommended that CMS adopt a limited exception to its proposed NPI requirement where a provider submits a paper claim and does not have an NPI on file with the receiving plan. Second, the commenter stated that a number of providers, including rehabilitation centers and durable medical equipment (DME) suppliers, are contracted by and bill plans under a group or ''Type 2'' NPI. The commenter stated that the proposed rule was not clear regarding whether CMS will accept a Type 2 NPI in satisfaction of the proposed encounter data standard. For plans that

[77] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/HPMS-Memo-Prescriber-Enrollment-Enforcement-v06012015.pdf.*

currently accept and use Type 2 NPIs, capturing individual NPIs would likely require changes to both credentialing policies and contracting standards; the administrative burden of making these changes would be considerable. The commenter added that while the use of exclusively Type 1 NPIs could represent a very significant burden for some plans, the commenter did not believe that use of a Type 2 NPI would provide any less support for CMS' program integrity efforts than that provided by a Type 1 NPI. The commenter requested that the final rule provide allowances for submission of either Type 1 or Type 2 NPIs in risk adjustment encounter data.

Response: MA organizations and other submitters of MA encounter data should follow 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),* including the TR3 guidance for use of Type 1 and Type 2 NPIs. Submitters should also follow CMS' existing guidance regarding NPIs that is specific to encounter data submissions. For example, CMS released a December 21, 2017 memo ''*Encounter Data Record Submissions—NPI Submission Guidance—Frequently Asked Questions (FAQ),*'' released through CMS' Health Plan Management System (HPMS), which discusses situations under which default NPIs may be used. As noted in this memo, CMS expects the number of encounter data records (EDRs) with default NPIs for providers who would otherwise have an NPI (that is, not atypical providers) to be a very small percentage of an MAO's total EDR submissions. CMS is monitoring the level of default NPI use.

Comment: A commenter urged CMS to enforce Section 507 of MACRA as effectively and efficiently as possible, taking into account the burdens that may be imposed on plans and providers, as well as on beneficiary access to needed medications. For example, the commenter cautioned that the proposed enforcement mechanism could prove problematic with respect to certain providers in limited contexts—such as teaching hospitals with residents and interns who may use the NPI of their attending physician. As such, the commenter encouraged CMS to provide additional clarity about how the final policy will be implemented to account for these and similar situations that may arise, in order to maintain beneficiary access.

Response: Section 507 of MACRA amends section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) by requiring that pharmacy claims for covered Part D drugs include prescriber NPIs beginning January 1, 2016 that are determined to be valid under procedures established by the Secretary in consultation with appropriate stakeholders. MACRA does not address the issue of which NPI a pharmacy must use on a claim for a prescription written by a resident—only that is be active and valid. In addition, the modifications to (c)(5) are technical to make the regulatory text consistent with exiting law and guidance.

Comment: A commenter urged CMS to consider how to mitigate potential access challenges created for patients when claims with invalid NPIs are submitted in error.

Response: As already stated, section 507 of MACRA amends Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) by requiring that pharmacy claims for covered Part D drugs include prescriber NPIs beginning January 1, 2016 that are determined to be valid under procedures established by the Secretary in consultation with appropriate stakeholders. The modifications to (c)(5) are technical to make the regulatory text consistent with existing law and guidance.

Comment: With the revisions to § 423.120(c)(5) and based on section 507 of MACRA, a commenter sought clarification as to whether the 24-hour follow-up for the plan sponsor to work with the pharmacy to identify the prescriber NPI and resubmit the claim is no longer applicable. Another commenter asked whether, in instances when a pharmacy encounters an issue with a prescriber NPI and the pharmacy either cannot or does not correct the NPI, plans are still required to outreach to network pharmacies within 24 hours in an attempt to obtain a valid NPI.

Response: Such outreach is no longer required. CMS' previous guidance in this regard was based upon the prior requirement—which the modifications to § 423.120(c)(5) are removing—for sponsors to pay pharmacy claims with inactive and invalid NPIs when the pharmacy either could not or did not correct the prescriber NPI and then obtain the active and valid ones afterward.

Comment: A commenter urged CMS to make two modifications to § 423.120(c)(5). First, the commenter suggested changes to new § 423.120(c)(5)(ii), which, as proposed, would require the sponsor at the point of sale to communicate whether a submitted NPI is active and valid to accommodate for long-term care (LTC) pharmacies where there is no point of sale. The commenter stated that this provision must contain a blanket exception for LTC pharmacies prohibiting the PDP or PBM from denying any claim by an LTC pharmacy. Second, the commenter sought revisions to new § 423.120(c)(5)(iii)(B), which, as proposed, would permit a PDP or its PBM to deny reimbursement to a pharmacy that dispensed a drug prescribed by a physician without an NPI number under certain conditions; the commenter stated that this provision must contain a similar blanket exception prohibiting the denial of LTC pharmacy claims in all circumstances, given other regulatory requirements mandating that the prescription be filled. The commenter stated that the aforementioned changes must also be made to the proposed MA regulations. By making these changes, the commenter contended, CMS can ensure that LTC pharmacies are able to meet beneficiary needs as well as comply with other legal requirements mandating the dispensing of medications to nursing home residents.

Response: Section 507 of MACRA requires that for plan year 2016 and thereafter, claims for covered Part D drugs must include an active and valid prescriber NPI. MACRA did not provide an exemption for pharmacy claims submitted by long-term care pharmacies. Therefore, we decline to create one in the technical change we are making to 423.120(c)(5) to comply with MACRA.

(7) Effective Date

Comment: Many commenters expressed concern about the January 1, 2019 effective date of the preclusion list requirement. Aside from the need for CMS to address all of the operational complexities of the requirement (for example, regarding file layouts, frequency of updates, interaction with other lists, types of payments affected) and to issue appropriate guidance to affected stakeholders, commenters noted several other reasons for the unworkability of the January 1, 2019 date. First, and most generally, stakeholders need enough time to adapt to and implement the new requirements. Second, plans may need to make system changes, with several commenters noting that some code values specific to prescriber enrollment will need to be sunsetted and potentially new values created. Third, plan sponsors will need sufficient opportunity and guidance to clearly understand, test, and use the new file layout, including how each field is to be

interpreted, and how the file may change over a given time period. Adhering to a January 1, 2019 date, some commenters cautioned, would lead to beneficiary confusion and delays in getting needed medications. Various commenters suggested an effective date of no earlier than January 1, 2020. Others recommended the following effective dates: (1) 12 months after the preclusion list provisions are finalized or published; (2) at least twelve (12) months after CMS releases its final guidance, with all of the specifications, to have the preclusion list fully incorporated into its claims adjudication systems; or (3) a minimum of 18 months after the publication of necessary technical guidance and confirmed file layouts. Another commenter urged that the deadline for full incorporation should be a mid-year date (for example, July 1), as opposed to January 1. A mid-year deadline would allow Part D sponsors to focus more exclusively on this important system modification, while being able to adequately prepare for annual readiness implementation activities at the beginning of the calendar year. Another commenter stated that with a January 1, 2019 effective date, a fully functional production file is not likely to be provided to plan sponsors in time for full testing across various scenarios, such as transition periods and coverage reviews, by that date. The commenter asked whether CMS will acknowledge that flexibility on full implementation may be necessary.

Response: We appreciate the commenters' concerns and recommendations. We recognize that operationalizing these changes across the Part D and MA programs will require effort and resources for plans and for CMS. However, we believe this approach is similar to how plans currently utilize the OIG exclusion list and should be operationalized in the same manner. We therefore believe that a significant amount of additional work will not be necessary. Although, the enrollment requirement may have been delayed various times, due to the decrease in burden under the preclusion list approach, we do not believe a delay is necessary and that the January 1, 2019 timeline is sufficient.

Comment: Responding to our solicitation for comment regarding a reasonable time period for Part D sponsors and PBMs to incorporate the preclusion list into claims adjudication systems, a commenter suggested a 180-day period. This would give Part D sponsors and PBMs sufficient time to prepare their systems and operationalize the changes. The commenter added that after the initial incorporation, CMS should post the preclusion list by the 15th of every month and require Part D sponsors to utilize the list beginning on the first day of the following month.

Response: We understand the commenter's concerns. As stated in our previous response, however, we believe that January 1, 2019 is the appropriate date. Further, we do not believe making the list available on the 15th of each month allows the plan enough time to properly ingest preclusion data into their claims adjudication systems.

(8) Provisional Supply

Comment: A number of commenters opposed the provisional supply requirement and recommended its removal from the final rule for several reasons.

First, they contended that the preclusion list is akin to the OIG exclusion list, for which there is no concomitant supply requirement. They explained that beneficiaries generally understand that prescriptions written by excluded parties will not be covered. They saw no reason for a provisional supply requirement for the preclusion list when there is none for the OIG exclusion list.

Second, they stated that a problematic prescriber, especially one prescribing opioids or other potentially dangerous drugs, should not be entitled to payment, nor enable receipt of a medication for such a long period of time that may negatively impact a beneficiary. Indeed, several commenters specifically noted that the provisional fill requirement could harm beneficiaries. A commenter explained that prescribers on the preclusion list would likely have already been notified by CMS of that status, potentially several times. In this scenario, the precluded provider is aware of their status yet will continue to see Medicare patients and issue prescriptions for them. This places beneficiaries at risk, especially if the prescription issued involves controlled substances/opioids or other high-risk drugs.

Third, concerns were expressed about the length of the provisional supply period, specifically with respect to cost and overutilization; particular concern was expressed about the burdens on plan sponsors of operating and administering the provisional fill requirement. A commenter, stating that the provisional supply requirement is highly complex, urged CMS to eliminate it. The commenter contended that if the preclusion list aims to identify problematic prescribers who, through their prescribing activity, pose a risk to beneficiaries, then CMS can manage patient access to care based on the post-dated preclusion effective date that is applied to the file. The commenter stated that: (1) This approach could address CMS' objective of preventing problematic prescribers from continuing to prescribe opioids; (2) supporting a 90-day or any other discretionary period determined by CMS before adding a prescriber to the preclusion list (post-beneficiary notification) would eliminate the need to provide provisional coverage at point of service; and (3) this would also solve the complexities that plans face in programming systems to track provisional supply and ensuring the program works in conjunction with other Medicare requirements, such as the transition fill program.

Fourth, commenters outlined the difference between the original provisional fill policy, which was designed to minimize potential disruptions in access to needed drugs while prescribers were enrolling into Medicare, and the newly proposed requirement, which would apply to demonstrably problematic prescribers. Noting, again, that provisional fills are not available for prescriptions written by OIG excluded prescribers, commenters stated that there is no policy justification for having provisional fills for prescribers who have engaged in improper behavior.

We note that a commenter recommended that CMS provide outreach to the prescriber and the beneficiary prior to including the prescriber on the preclusion list; specifically, once the appeal period ends and CMS adds the prescriber to the preclusion list, CMS would then notify the beneficiary. The prescriber would be added to the precluded list 90 days after the beneficiary notification date. This, the commenter stated, would help eliminate the complexities of implementing the provisional supply process, as the 90-day period would be built into the effective date; CMS could add the end-date based on reenrollment bar criteria. The commenter added that its recommendation that the provisional supply requirement be eliminated would streamline point-of-sale edits and avoid potential overlaps or conflicts with other programs, such as transition fill. The commenter also contended that this would deal with the immediate need to address opioid prescribing risks as well as reduces the likelihood of beneficiary disruption at point-of-sale.

Response: We appreciate the commenters' concerns and recommendations. Given the commenter's points, we agree that the preclusion list will be operationalized

in the same manner as the OIG exclusion list and allowing a provisional fill for the preclusion list and not the exclusion list will cause confusion among beneficiaries. Second, we share the commenter's concern regarding problematic prescribers and their ability to continue prescribing controlled substances. Finally, we agree that the provisional fill requirement is highly complex and would represent additional burden for plans to implement as evidenced by many of the comments we received.

Based on the large number of comments we received urging us to eliminate the provisional fill based on the concerns mentioned earlier CMS will not finalize the provisional supply requirement at § 423.120(c)(6)(v) and will not finalize the provisional fill as proposed in the interim final rule expiring in mid-May. Instead, CMS will only place a prescriber and their applicable preclusion period on the preclusion list after the prescriber has exhausted the appeals process (described in more detail below), plus an additional 90-day period, including a 60-day period for plans to ingest preclusion data and a 30-day beneficiary notice period.

Comment: A commenter asked whether the preclusion list will be on a per script basis or whether the plan can preliminarily notify the beneficiary that all scripts prescribed by a particular doctor on the preclusion list will be rejected.

Response: Section 423.120(c)(6) requires the beneficiary to be notified within 3 days of adjudication of a claim written by a prescriber on the preclusion list. However, because we are not finalizing the provisional supply requirement, we are modifying the language to require the sponsors to send an advance notice to any beneficiary who has received a prescription from a precluded provider as soon as possible but that the beneficiary must receive such notice no later than 30 days prior to the initial publication of the preclusion list.

Comment: Expressing concern that the proposed rule places the responsibility of managing provisional coverage on the industry, a commenter requested that CMS consider the numerous risks associated with the proposed provisional coverage period and support an alternate approach that allows CMS to manage patient access to care concerns with the use of post-dated preclusion effective dates. The commenter cited several risks. First, the commenter stated that unique provisional coverage rules based on the drug class will create beneficiary and prescriber confusion, as well as compromise existing claim adjudication hierarchical rules. Second, the commenter noted industry confusion as to whether a remaining days' supply would apply to the 90-day provisional coverage period, where prescriptions could require a shortened days' supply or the beneficiary could obtain up to 180 days' supply of a medication. The commenter cited the following scenario: (1) A prescriber's preclusion effective date is January 1, 2020; (2) the beneficiary obtains a 90-day supply of medication on January 1, 2020; (3) a provisional coverage period of January 1, 2020 through April 1, 2020 is set at the beneficiary/prescriber level; and (4) on March 20, 2020, the beneficiary requests a prescription refill for a 90-day supply. The commenter asked which of the following rules would apply: (a) The 90-day supply is covered, for the March 20 claim date of service is within the provisional coverage period; or (b) a 13-day supply is covered because there are only 13 days remaining (March 20 through April 1) in the provisional coverage period.

Response: We appreciate the commenters' concerns and recommendations. As already stated, however, we are not finalizing our proposed provisional fill policy.

Comment: A commenter stated that although provisional fills would likely reduce such access disruptions for beneficiaries, potential beneficiary confusion associated with the conflicting messages (specifically, the message that prescriptions from the precluded provider cannot be filled in the future, with the exception of this one time) may only delay the disruption until the beneficiary seeks to refill the prescription at issue. At this point, the commenter stated, the disruption may be greater to the beneficiary because the delay in addressing the invalid prescription at the outset potentially risks non-adherence to the necessary medication while seeking a non-excluded prescriber to issue a substitute order.

Response: We understand the commenter's concerns. However, as already mentioned, we are not finalizing our proposed provisional fill policy.

Comment: For claims submitted after the provisional coverage period, a commenter asked whether these claims receive NCPDP Reject Code 569 (Provide Notice: Medicare Prescription Drug Coverage and Your Rights) or Reject Code 829 (Pharmacy Must Notify Beneficiary: Claim Not Covered Due To Failure To Meet Medicare Part D Active, Valid Prescriber NPI Requirements).

Response: If payment is denied because the prescriber or provider is on the preclusion list, the beneficiary will not have the right to appeal. Therefore, it will not be necessary to use the NCPDP Reject code '569.

Comment: A commenter asked whether the type of fill and prescriber type need to be included in the PDE.

Response: We will issue any necessary PDE guidance outside of the regulatory process.

Comment: A number of commenters supported our proposed provisional supply requirement, believing that it would ensure that beneficiaries continue to receive needed prescriptions while they find another prescriber.

Response: While we appreciate the commenters' support, we have decided not to finalize our proposed provisional supply requirements for the reasons stated above. We believe a 60-day notification period for beneficiaries will provide ample time for those impacted individuals to locate a new provider. Any beneficiary who received services furnished by a precluded provider within the past 12 months of the implementation date of the preclusion list will be notified that they have 30 days to locate a new provider.

Comment: Supporting the provisional supply requirement, a commenter encouraged CMS to ensure that information on the provisional supply requirement is provided to beneficiaries in advance to minimize confusion and disruption. The commenter added that CMS should carefully align the policies it finalizes with respect to the implementation of CARA in the context of the proposed prescriber preclusion list; this should include policies to ensure that enrollees with medical needs for pain medication will have appropriate access to that medication should a physician or other prescriber that prescribed pain medications for that enrollee be placed on the preclusion list. The commenter also stated that CMS should ensure that the provisional supply requirement is implemented in an administratively feasible manner, such that it is easily incorporated into prescription claims systems.

Response: Given that we are not finalizing our proposed provisional supply requirements, we believe that these comments are moot.

Comment: A commenter stated that in cases where timely access to needed opioids is medically appropriate, CMS should take steps to require Part D sponsors to provide timely transfer to a new prescriber when the first prescriber is on the preclusion list. Such an

approach will ensure that patients can obtain timely access to pain management while also allowing for an appropriate assessment for any substance use disorder and referral to treatment as needed.

Response: We believe that the 60 day notification period (as mentioned above) will provide ample time for a patient to seek care from another prescriber.

Comment: Several commenters noted that a provider could appear on both the Medicare Exclusion Database (MED) (which contains OIG exclusions) and the proposed preclusion list. This scenario, a commenter stated, could present operational challenges for plan sponsors, for while provisional fills do not apply to drugs prescribed by providers on the MED, they would apply to prescribers on the preclusion list. The commenter suggested that CMS consider not including providers on the MED on the CMS preclusion list; this would eliminate duplication and help ensure that plan sponsors have more clarity surrounding whether a provisional fill is required.

Response: We recognize the commenters' concerns regarding the interaction between the MED and the preclusion list and its relationship to the provisional fill requirement. As already mentioned, however, we (1) are not finalizing our proposed provisional supply requirements and (2) will provide plans with guidance on which list should take precedence, in regard to beneficiary notification, when a provider appears on both lists.

Comment: A commenter suggested that as an alternative to providing beneficiaries with a 90-day provisional supply of a drug, CMS could provide advance notice of a prescriber's placement on a preclusion list and make it effective 30 days after receipt; this way, Part D sponsors have time to run a report to identify affected beneficiaries and provide them with notice that they may obtain only one (1) additional prescription fill from the precluded prescriber.

Response: We appreciate the commenter's suggestion, and note this is similar to the process we are finalizing as outlined above.

Comment: A commenter asked whether CMS will use the claim processing date (as opposed to the date of service) to apply the provisional coverage rule. The commenter cited a scenario in which a drug is dispensed to a beneficiary (according to the date of service) prior to his or her prescriber's inclusion on the preclusion list but the pharmacy processes the claim after the date of inclusion; the commenter asked whether the 90-day provisional coverage period would begin on the date of service or on the date the claim is processed by the pharmacy. The commenter recommended that CMS use the claim processing date to apply the provisional coverage requirement.

Response: While we appreciate the commenter's suggestion, we note that we are not finalizing our proposed provisional fill requirement.

Comment: A commenter understood the provisional coverage policy to require that once the 90-day period commences, the beneficiary will be able to: (1) Fill any and all prescriptions from the precluded prescriber during this period; and (2) take multiple fills during the 90-day provisional coverage period (for example, one 30-day fill, then another 30-day fill, and then a 90-day fill). The commenter sought clarification as to whether this is CMS' intention.

Response: Given that we are not finalizing our proposed provisional supply requirements, we believe that this comment is moot.

Comment: A commenter stated that if CMS is unable to eliminate the provisional supply requirement, CMS should furnish clarification regarding several issues. First, the commenter stated that previous technical guidance provided details around provisional supply being a lifetime edit; specifically, for medications prescribed by a precluded prescriber, this guidance clarified that beneficiaries who change pharmacies during a provisional supply period would still only receive one provisional supply of medication. Similarly, for beneficiaries who change plans within the same contract, if the plan sponsor or its PBM can determine via claims history that the beneficiary has already received a provisional supply, then the provisional supply requirement has been satisfied. The commenter asked CMS to confirm that these details from previous technical guidance still apply for provisional coverage. Second, if a single claim involves both a provisional supply and a transition supply, the commenter asked CMS to specify whether there will be a combination letter for the beneficiary notice. The commenter recommended that the notification process be kept separate for the two programs. The provisional supply notice would be less frequent than a transition letter, for only the initial dispensing event would trigger a letter advising the beneficiary of the issue with the prescriber. The transition notification should remain status quo and address the medication in question and educate the beneficiary about his/her appeal rights. Third, the proposed rule states that reasonable efforts must be made by the plan to the prescriber notifying them of a beneficiary who was sent a notice that the prescriber is being precluded. The commenter asked CMS to clarify whether this outreach is necessary given that CMS would have previously reached out to the prescriber prior to placement on the preclusion list. The commenter stated that CMS notes its intention to allow the normal Part D rules to apply for safety edits, prior authorization, quantity limits, etc., during the provisional coverage period. The commenter: (1) Contended that all appropriate edits for opioids should also apply during the provisional coverage period, as these are designed to prevent serious adverse events; and (2) recommended that all safety and utilization management edits remain the same during the provisional fill period, regardless of medication type (that is, opioids versus non-opioids).

Response: We appreciate the commenter's concerns and recommendations and reiterate that we have decided not to finalize our proposed provisional supply requirement. Further, we will provide beneficiaries with a 30 day advance notice prior to prescriptions being rejected due to their prescriber being precluded.

Comment: Several commenters stated that if the provisional supply requirement is retained, plan sponsors will require at least 12 months for its implementation. A commenter stated that plan sponsors will, during the 12-month period, need (1) CMS to release the specific provisional fill requirements, (2) model beneficiary notice letters, (3) guidance to better understand how provisional fills work when a prescriber is on both the preclusion and OIG lists, and (4) information on how provisional fills function in relation to the existing transitional fill requirements. Another commenter, noting the time and resources that will be required to make necessary updates required to sponsors' (and their contracted PBMs') IT systems, procedures, and operational policies, urged that the implementation date of the provisional supply requirement be delayed to a date determined to be feasible after consultation with sponsors and their contracted PBMs. Another commenter urged that CMS continue dialogue with industry partners on implementing the provisional fill functionality, including the establishment of an ''active date'' no sooner than 8 months *after* a production file is made available and the functional assumptions around the file are communicated to the industry.

Response: While we appreciate the commenters' concerns and recommendations, we reiterate that we are not finalizing our proposed provisional supply provisions.

Comment: Regarding the provisional supply requirement, a commenter stated the following: (1) Placing edits on opioids contradicts CMS' proposal that the definition of a drug is no longer needed; (2) the provisional supply provisions as stated lack clarity on the use of a ''preclusion reason'' to be able to identify when a different provisional coverage period would apply; (3) it is unclear if the revised provisional coverage period applies across a beneficiary's lifetime (for example, changing plans, changing pharmacies) as was outlined in the prescriber enrollment provisional coverage technical guidance; (4) claims that meet both transitional fill and provisional coverage criteria will result in the beneficiary receiving two different notices; and (5) it is unclear how plan sponsors would coordinate the provisional coverage period and adhere to § 423.120(c)(6)(iii), which would state that a Part D plan sponsor may not submit a 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 for the date of service.

Response: We recognize the commenter's concerns and reiterate that we are not finalizing our proposed provisional supply provisions.

Comment: A commenter expressed concern regarding the provisional supply language in § 423.120(c)(6) that reads, ''. . . and if allowed by applicable law.'' The commenter believed that this implies a requirement to validate state-by-state prescriptive authority at the point of sale. The previous technical guidance, the commenter stated, made clear that this was not a point of sale requirement. The commenter asked that CMS confirm whether or not this is still true.

Response: Given that we are not finalizing our proposed provisional supply requirements, we believe that this comment is moot.

Comment: A commenter stated that stand-alone prescription drug plans (PDPs) and PBMs have no contractual relationship with network prescribers; only an MAPD with a contracted provider network could manage a requirement to transfer the beneficiary to a new provider upon preclusion. A commenter suggested that this could be managed through the provisional fill notification to the beneficiary, whereby the beneficiary is instructed that coverage will not continue after the 90-day provisional period ends; also, MAPDs should be instructed to remove precluded prescribers from their provider network.

Response: While we appreciate the commenter's suggestion, we reiterate that we are not finalizing our proposed provisional fill requirement. In addition, and with respect to the removal of precluded prescribers from an MAPD's network, we decline to make the commenter's recommendation as removing the provider seems redundant given they are already precluded.

Comment: A commenter stated that the proposed provisional supply requirement failed to consider the way LTC pharmacies actually operate, particularly legal and regulatory requirements unique to LTC pharmacies. Unlike retail pharmacies that have access to real time adjudication at the pharmacy counter, LTC pharmacies often must dispense first, and adjudicate afterwards. The commenter stated that while the 90-day supply of medications permitted under (current and proposed) § 423.120(c)(6) is appropriate, the proposed ''three-day fill'' exception for retail pharmacy is insufficient for an LTC pharmacy. The commenter stated that CMS must address this issue and prohibit PDPs/PBMs from denying claims that LTC pharmacies had to dispense before being able to verify an NPI number or a preclusion list listing.

Response: With respect to NPIs, Section 507 of MACRA requires that for plan year 2016 and thereafter, claims for covered Part D drugs must include a valid prescriber NPI. MACRA did not provide an exemption for pharmacy claims submitted by long-term care pharmacies. Therefore, we decline to create one in the technical change we are making to 423.120(c)(5) to comply with MACRA. With respect to the preclusion list, under the requirements we are finalizing, Part D sponsors are required to provide impacted beneficiaries with a 60 day advance notice which would sufficiently alert LTC facilities that there will be an upcoming issue with coverage for the beneficiaries' prescriptions under Part D.

(9) Appeals

Comment: Several commenters contended that the administrative burden on both providers and payers could be reduced by allowing providers to appeal before being included on the preclusion list. A commenter suggested that once the initial determination is made, CMS should immediately send notice of the initial determination and the reasoning for inclusion. The notice should include a grace period of a length that CMS deems sufficient to file an appeal. During this grace period, CMS should not place the provider on the preclusion list. If, the commenter continued, the provider does not file an appeal by the end of the grace period, CMS should then add the provider on the preclusion list. If the provider does file an appeal, the provider should not be included on the preclusion list until the provider's appeal is upheld or the provider can no longer exercise the appeal options, whether due to lack of timely filing or because the appeals opportunity has been exhausted. The commenter contended that by forgoing immediate inclusion on the preclusion list when the initial determination has been made, CMS will reduce potential provider burden by limiting the number of appeals a provider has to file; as an illustration, the commenter stated that if the provider was accidentally included on the preclusion list, the provider would have sufficient time to correct the issue without suffering from a loss of revenue due to preclusion list-related denials. The commenter added that MA plans would also benefit from not having to manually overturn denials due to the provider's mistaken inclusion on the preclusion list; such a manual process, the commenter stated, only extends for a longer time the period between services rendered and reimbursement for those services.

Another commenter stated that the approach described by the previous commenter would minimize beneficiary confusion and eliminate the need for a provisional fill requirement. Another commenter suggested that claims not be denied until the provider's appeal is completed and, if the provider loses their appeal, the provider then would be listed on the preclusion list. Another commenter, noting that our proposal that the preclusion list would be updated monthly, asked whether, if a prescriber appeals its inclusion on the preclusion list, it will require a month for the prescriber to be removed from the list in the event of a successful appeal.

Response: We appreciate these comments and generally agree with them. Concerning appealing one's placement on the preclusion list, our proposal includes the right for providers or prescribers to appeal their inclusion on the preclusion list in accordance with the appeals process at 42 CFR part 498 that we had proposed in the November 28, 2017 proposed rule.

Prescribers and providers will only be placed on the list upon exhausting their first level appeal plus an additional 90-

day period. The 90-day period allows the plans 30-days to intake the preclusion data and a 60-day beneficiary notification period (That is, claims will not begin to be denied until the expiration of this additional 60-day beneficiary notification period.). Subsequent updates to the list will provide any newly added provider with a 60-day appeals window but will not provide a 90-day period as discussed above, thus after implementation beneficiaries may not be notified that they may have received a prescription or services from a provider that is now precluded. We note, however, that the appeals process is intended to permit a prescriber or provider to challenge CMS' placement of the prescriber or provider on the list and not to challenge the underlying reason for the revocation, OIG exclusion, or other adverse action that led to the preclusion list inclusion. Indeed, the preclusion appeals process would neither include nor affect appeals of payment denials or enrollment revocations, for there are separate appeals processes for these actions. Any appeal under this proposed provision will be limited strictly to the individual's inclusion on the preclusion list. In addition, CMS will send written notice to the provider of his or her inclusion on the preclusion list. The notice would contain the reason for the inclusion and would inform the providers of his or her appeal rights. This is to ensure that the prescriber or provider is duly notified of the action, why it was taken, and their ability to challenge CMS' determination.

Comment: A commenter asked CMS to clarify how the appeal process would work and when reinstatements would occur. In the case of reinstatements, the commenter recommends that reinstatements take place when the next file is released, rather than mid-term, and that CMS not allow retroactive reinstatements.

Response: As already mentioned, prescribers and providers will be afforded appeal rights based on the process at 42 CFR part 498. Concerning reinstatement, the preclusion list will include periods for which the prescriber or provider is unable to receive Medicare reimbursement or submit prescriptions reimbursable by the Medicare program; if a prescriber or provider is reinstated after further appeal, the list will be adjusted to remove the prescriber or provider's period of preclusion and the provider would no longer be subject to the payment prohibition. The removal would be applied retroactively. However, a provider or prescriber would need to resubmit any claims denied as a result of the preclusion.

Comment: A commenter stated that CMS should handle any appeals. The commenter did not believe this administrative function should be the responsibility of plan sponsors.

Response: We agree with the commenter. Appeals from precluded providers due to placement on the list, will be handled by CMS.

Comment: A commenter requested clarification regarding a beneficiary's appeal rights for alleged errors in applying the preclusion list. The commenter stated that under existing CMS regulations, the denial of access to a Part D drug on the basis that the provider is excluded is not a coverage determination and does not trigger appeal or grievance rights. The commenter contended it therefore follows that if a beneficiary does not have access to a Part D drug because the prescriber is on the preclusion list, it is not a coverage determination and no appeal or grievance rights are triggered. Accordingly, the commenter recommended that CMS follow processes applicable in situations involving an excluded/sanctioned prescriber and not provide any appeal rights. The commenter also suggested that any beneficiary complaint about a denial due to an individual or entity included on the preclusion list be treated via the grievance process, as there is no beneficiary liability and, as such, nothing for the beneficiary to appeal. The commenter supported CMS' proposal of a separate appeals process for parties on the preclusion list should the latter disagree with CMS' decision to include them on the list. Another commenter recommended that in order to keep the preclusion list and OIG exclusion list processes aligned, CMS should not allow beneficiaries to appeal a prescriber preclusion. The commenter stated that CMS should either allow or disallow beneficiary appeals in both instances for consistency and to prevent beneficiary confusion; this is because beneficiaries, according to the commenter, will not understand the difference between an exclusion and a preclusion.

Response: We agree with the commenters. We believe that the denial of access to a Part D drug on the basis that the provider is excluded by the OIG does not currently grant the beneficiary appeal rights, and we are finalizing a similar policy to a prescriber or provider being on the preclusion list.

Comment: A commenter stated that if CMS allows beneficiaries to appeal a preclusion only, CMS should confirm whether the point of sale appeal notice (NCPDP Reject Code '569') requirement applies.

Response: If payment is denied because the prescriber or provider is on the preclusion list, the beneficiary will not have the right to appeal. Therefore, it will not be necessary to use the NCPDP Reject code '569.'

Comment: A commenter asked CMS to confirm that, prior to adding a prescriber to the preclusion list, the appeals timeframe must be exhausted. If CMS adds the prescriber to the preclusion list while the appeals timeframe is still in effect, the commenter stated that this could cause beneficiary disruption due to inappropriate rejects, especially if the prescriber's appeal is approved. Another commenter stated that plans will not have any authority over the preclusion list; therefore, they will not be able to address or resolve the beneficiary's appeal. The commenter stated that there will need to be a process in place to address beneficiary appeals, concerns, and questions about why their prescriber is being added to the preclusion list; plan sponsors will not have access to the reason for the preclusion to answer such questions.

Response: As already mentioned, providers will be afforded appeal rights in accordance with the appeal process at 42 CFR part 498. With respect to the plans' ability to respond to beneficiary questions concerning a provider's inclusion on the preclusion, CMS will furnish guidance on this matter outside of rulemaking.

Comment: A commenter asked CMS to align the appeals process with the provisional supply period so that an initial appeals determination would be rendered prior to the end of the provisional supply period. The commenter believed that this would help reduce patient care disruption when clinicians are incorrectly placed on the preclusion list.

Response: As already stated, we are not finalizing our provisional supply proposal and will place a prescriber or provider on the preclusion list only after the prescriber or provider has exhausted their first level of appeal plus an additional 90-day period. The 90-day period allows the plans 30-days to intake the preclusion data and a 60-day beneficiary notification period. Subsequent updates to the list will provide any newly added provider with a 60-day appeals window but will not provide a 90-day period as discussed above, thus after implementation beneficiaries may not be notified that they may have received a prescription or services from a provider that is now precluded.

Comment: A commenter stated that the proposed rule did not clarify what happens to a clinician who wins his or her initial redetermination but CMS challenges the redetermination. The commenter asked whether a provider is taken off the preclusion list if they are initially successful in their appeal but CMS challenged the decision.

Response: As mentioned previously, prescribers and providers that are notified of their meeting the criteria for placement on the preclusion list will be afforded the formal appeals process at 42 CFR part 498 that as we proposed in the November 28, 2017 proposed rule. Prescribers and providers will only be placed on the list upon exhausting their first level appeal.

Comment: A commenter agreed with CMS' proposal that individuals who are on the preclusion list should be permitted to appeal their inclusion on the list. However, the commenter asked CMS to issue additional operational guidance on the appeals process and, in particular, to provide additional detail about (1) the communications process if a prescriber's appeal was successful, and (2) the timeline for removing the prescriber from the preclusion list. Another commenter urged that CMS: (1) Clarify for plan sponsors and prescribers that CMS will handle any appeal requests directly rather than through plans, given that CMS gathered and acted on the information that placed the prescriber on the preclusion list; and (2) implement a process for notifying prescribers of a date after which adjudicators will stop their prescription claim processing.

Response: As mentioned previously, prescribers and providers that are notified of their meeting the criteria for placement on the preclusion list will be afforded the formal appeals process at 42 CFR part 498 that as we proposed in the November 28, 2017 proposed rule. Prescribers and providers will only be placed on the list upon exhausting their first level appeal.

(10) Additional Comments

Comment: A commenter stated that in CMS' implementation of the preclusion list, the beneficiary should be held harmless (unless the beneficiary has engaged in some manner of fraud).

Response: We believe the contract provisions required between the MA plan and a network provider pursuant to § 422.504(g)(1)(iii) are binding on providers; such agreements specify that QMBs must not be charged cost sharing when the state is responsible for paying such amounts under the Medicaid program. Further, the regulation at § 422.504(g) contains broader beneficiary protection requirements for MA organizations, including a requirement that the plan must indemnify the beneficiary from any fees that are the legal obligation of the MA organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the MA organization, to provide services to the organization's enrollees

Comment: A commenter stated that if CMS removes the enrollment requirement, which the commenter opposed, CMS should (1) enact protections so that a beneficiary who disenrolls from an MA plan can continue to see a provider who did not enroll in Medicare and that the provider can be allowed to submit a claim to Medicare on behalf of the beneficiary, and (2) allow some flexibility for MA coverage of services of providers that are highly specialized and do not typically accept Medicare.

Response: We appreciate the commenter's recommendation. In regard to beneficiaries leaving the MA program and defaulting to traditional Medicare, we are not aware of this as a significant issue nor was it a part of our rationale for the enrollment requirement. We also believe that the preclusion list approach will support the need for highly specialized providers. No longer needing to enroll, highly specialized providers can provide services to MA beneficiaries, while the preclusion list will prohibit those providers that would typically be revoked from the program based on our authorities at § 424.535 from servicing MA beneficiaries.

Comment: A commenter stated that the distribution of the preclusion list should include basic hold harmless and indemnification language in favor of the MAOs.

Response: Response under development and will be furnished in the next round of clearance.

Comment: A commenter urged CMS to expand efforts to coordinate and increase the sharing of information with other federal public programs, state medical boards, and other entities on potentially problematic prescribing to help inform the identification of prescribers who should appear on the preclusion list.

Response: We appreciate the commenter's recommendation and will consider it as we work to operationalize the preclusion list requirement.

Commenter: To ensure that MA plans have appropriate processes in place to screen providers, suppliers, and prescribers against the preclusion list, a commenter recommended including review as part of CMS' ongoing audit and monitoring activities, potentially as part of the Program Audits or the Industry Wide Timeliness Monitoring. Alternatively, the commenter stated, prescription drug events and/or risk adjustment data might be used as a means to confirm that plans are not paying providers and suppliers on the prelusion list.

Response: We agree with the commenter. We will work to build such review processes into the already existing program audits as we operationalize this requirement.

Comment: Several commenters asked CMS to confirm that, with the proposed removal of the enrollment requirement, MAOs will retain the right to require providers and suppliers offering services to beneficiaries to be enrolled in Medicare per their contracts.

Response: MAOs can establish enrollment in Medicare as a contracting condition.

Comment: A commenter stated that the proposed rule did not specifically mention how CMS will implement the exception for emergency and urgently needed services furnished by a provider on the preclusion list. The commenter suggested that CMS create a Healthcare Common Procedure Coding System (HCPCS) modifier for this exception to allow for timely, automated processing of claims. The commenter explained that if a provider on the preclusion list furnishes a service that meets the definition under § 422.113 for emergency or urgently needed services, the provider should be required to include the assigned modifier on a claim; the modifier would alleviate the need for payers to manually review every claim in case a rare urgently needed or emergency service exception might apply. The commenter stated that CMS has this same processing mechanism in place for providers who have opted-out of Medicare; those providers must submit claims using HCPCS modifier GJ to signal that an urgently needed or emergency exception applies, and the commenter contended that CMS should create a separate and distinct modifier for preclusion list providers. If, the commenter stated, the scarcity of HCPCS modifiers warrants sufficient merit to outweigh the creation of a new modifier, the commenter recommended that CMS edit the GJ modifier so that it is required to be used by providers on the preclusion list in addition to Medicare opt-out providers.

Response: We are not requiring that MAOs reference the preclusion list when paying non-contract providers though we believe it would be a best practice for MAOs to do so. However, if an MAO determines that a non-contract

provider is on the preclusion list and not eligible for Medicare payment the MAO should also not pay that provider consistent with the requirement that MAOs pay non-contract providers the same as Original Medicare as required under the MA regulations at § 422.214. MAOs are required to ensure that their contracted providers are properly credentialed and not on the preclusion list. When periodically re-validating credentialed providers the MAO should also re-verify that their contracted providers are not on the preclusion list.

Comment: A commenter stated that a challenge associated with FFS provider enrollment for MA-only providers is the CMS policy that would terminate a provider's enrollment in FFS Medicare if at least one claim is not submitted within a 12-month period. If a provider has no intention of treating FFS Medicare beneficiaries, the provider would have to undertake the administrative burden of re-enrolling with FFS Medicare on an annual basis. The commenter recommended that CMS address this issue, specifically suggesting that the CMS–855 enrollment form be modified to allow a provider to indicate that he or she only intends to treat MA beneficiaries, thus eliminating the need for the provider to reenroll.

Response: In finalizing this rule, we will no longer be requiring enrollment in Medicare FFS in order for providers to participate with MA plans. Even if we made the commenter's suggested change to the CMS–855 forms, we still believe that this does not accurately address the large volume of prescribers and providers that have yet to enroll with the program. As already mentioned, there are close to 340,000 active Part D prescribers who are not enrolled in or opted-out of Medicare and 120,000 MA providers that would require outreach and would need to enroll. We believe the success rate for enrollment of MA providers would be similar to that experienced with the Part D population. Based on these figures and our concerns for potential access to care issues, we again believe that this outweighs the benefits gained from requiring enrollment.

Comment: A commenter contended that the proposed rule did not address the exemption from credentialing for ordering and referring dentists through PECOS, the Part D enrollment portal, or the paper CMS–855O form. Also, the commenter asked how the proposed rule would affect the credentialing of ordering and referring dentists who refer oral biopsies for interpretation to a pathology lab.

Response: The final rule will not apply to the existing enrollment requirement for ordering and referring providers at 42 CFR 424.507, which has been enforced since January 6, 2014. Thus, providers who order or refer would continue to need to enroll for certain ordered or referred services to be reimbursed.

Comment: Several commenters noted that sections 6405(a) and (b) of the Affordable Care require physicians and eligible professionals who (1) order durable medical equipment, prosthetics, orthotics, and supplies or (2) certify home health services must be enrolled in Medicare or validly opted-out for the item or service to be covered. These requirements are currently codified in § 424.507, are in effect, and are also applicable to physicians and eligible professionals who order imaging and clinical laboratory services. The commenters suggested that CMS (1) replace this current enrollment requirement with a preclusion list requirement akin to that described in this rule, and (2) work to seek legislative relief from section 6405 of the Affordable Care Act.

Response: We believe that the subject matter addressed by the commenter pertains to a different regulatory provision (§ 424.507) and is therefore outside the scope of this rule.

Comment: With respect to the current version of § 423.120(c)(5)(v), a commenter stated that the U.S. Drug Enforcement Administration's 2010 Rule for Electronically Prescribing Controlled Substances defines identity proofing requirements for DEA Registrants (providers), which includes in-person identity proofing that involves checking identity documents such as a driver's license and/passport. Additionally, providers could be identity-proofed remotely by answering a series of questions that should be known only to them, typically based on information contained in one's credit report. This is known as knowledge-based verification (KBV). The commenter stated that KBV was not an optimal solution since: (1) Passing the questions is based on a combination of accuracy and timing; (2) the credit reporting agencies do not have data on 100 percent of health care providers; and (3) there have been cyber-attacks across healthcare industries, compromising personally identifiable data on Americans. Should CMS continue to use KBV, it should be augmented with other means as part of a risk based approach.

Response: We appreciate this comment but believe it is outside the scope of this rule.

Comment: A commenter stated that the Healthcare Information and Management Systems Society (HIMSS) formed the Identity Management Task Force that focused on policy and technical challenges relating to identity, attribute, and role-based access management, as it pertained to patient identity, provider identity and IT asset identities. The Task Force published: (1) ''Patient Portal Identity Proofing and Authentication'' in 2016; and (2) identity proofing and authentication recommendations for patients accessing their health information electronically. The commenter stated that while the paper defines best practices for patients, it leverages existing National Institute of Standards and Technology (NIST) guidance for identity proofing and authentication, and many of the cases are applicable to providers; the commenter recommended that CMS review them. The commenter also noted that NIST updated its Digital Identity Guidelines in July 2017 (NIST Special Publication 800–63A, ''Digital Identity Guidelines: Enrollment and Identity Proofing'') and that CMS should consider them as they relate to identity proofing providers.

Response: We appreciate this comment but believe it is outside the scope of this rule.

Comment: Several commenters stated that some dentists who opted out in order to comply with the Part D enrollment requirements did not realize that they would consequently be unable to furnish Part C items and services until after the initial 90-day period for withdrawing his or her opt-out affidavit had expired. The commenters urged CMS to permit its MACs to contact each dentist who has opted out and allow him or her to withdraw his or her affidavit even if the initial 90-day period has passed.

Response: The November 28, 2017 proposed rule did not propose changes to current opt-out policy. We note that, as stated in chapter 15 of the Medicare Benefit Policy Manual, if a physician or practitioner who has not previously opted out changes his or her mind after the Medicare contractor has approved the affidavit, the opt-out may be terminated within 90 days of the effective date of the affidavit. If the physician or practitioner has previously opted out, the physician or practitioner may cancel his or her opt-out by submitting a written notice to each Medicare enrollment contractor to which he or she would file claims absent the opt-out, not later than 30 days before the end of the current 2-year opt-out period, indicating that the physician or practitioner does not want to extend the application of the opt-out affidavit for a subsequent 2-year period.

Comment: A commenter stated that prescribing authority is already tied to a physician having a DEA number and not an NPI. Since physicians must already establish a relationship with the federal government through the DEA in order to prescribe, the commenter encouraged CMS to explore implementation of these policies though closer coordination with the DEA.

Response: We appreciate this comment but believe it is outside the scope of this rule.

Comment: In response to our solicitation of comments concerning additional solutions for beneficiaries who try to fill an opioid prescription from a provider on the preclusion list, a commenter stated that requiring a Part D sponsor to transfer beneficiaries from one medical provider to another is not feasible; the commenter explained that Part D sponsors do not have contracts with medical providers. The commenter also stated that any drug-specific carve out within the program at this time would add significant complexity in administering the preclusion list. The commenter thus made two recommendations. First, CMS should not pursue drug-specific solutions but should allow the flexibility to make decisions based on the totality of a prescriber's activity. Second, to the extent that CMS will require Part D sponsors to transfer beneficiaries to new prescribers, CMS should provide Part D sponsors with at least a 30-day notice to effectively assist the beneficiaries in the transition.

Response: We appreciate the commenter's recommendation. We agree that a notice period is necessary to effectively transition beneficiaries. Accordingly, and as mentioned previously, we are specifying that after the prescriber or provider has exhausted their first level appeal, there will be a 90-day period, during which time the plan can begin working to transition the beneficiary to a new prescriber or provider. The 90-day period allows the plans 30-days to intake the preclusion data and a 60-day beneficiary notification period. Subsequent updates to the list will provide any newly added provider with a 60-day appeals window but will not provide a 90-day period as discussed above, thus after implementation beneficiaries may not be notified that they may have received a prescription or services from a provider that is now precluded.

Comment: In response to our solicitation of comments on limits that should be set with respect to doses for opioid prescriptions, a commenter stated that CMS should manage the opioid epidemic outside of these proposed provisions. The commenter stated that creating separate policies for opioid and non-opioid medications: (1) Is extremely burdensome; and (2) introduces additional and unnecessary complexities into a new process when there are already better clinical programs in place to manage this crisis. The commenter encouraged CMS to issue uniform regulations regarding provisional fills and to utilize Part D sponsors' clinical programs to combat the opioid epidemic.

Response: We appreciate the commenter's recommendation and note that we are not finalizing our proposed provisional supply policy. Further, the preclusion list approach will apply to prescribers of prescription drugs, including opioids.

Comment: In response to our request for comment regarding whether additional beneficiary protections are necessary, a commenter made two recommendations. First, CMS should consider having notice requirements to ensure that all beneficiaries receiving care from an individual or entity placed on the preclusion list will be notified well in advance so that they can seek care and treatment elsewhere. Second, an exception should be made for those in the middle of a course of previously covered treatment so that their care is not interrupted.

Response: As mentioned previously, we have proposed that after the prescriber or provider has exhausted their first level appeal, there will be a 90-day period The 90-day period allows the plans 30-days to intake the preclusion data and a 60-day beneficiary notification period, during which time we believe the plan will have adequate time to transition the beneficiary to a new prescriber or provider. Subsequent updates to the list will provide any newly added provider with a 60-day appeals window but will not provide a 90-day period as discussed above, thus after implementation beneficiaries may not be notified that they may have received a prescription or services from a provider that is now precluded. Finally, we decline to adopt additional requirements for beneficiary notice or exceptions to the preclusion list consequences in this final rule.

Comment: While supportive of the preclusion list concept, a commenter expressed concern that the preclusion list requirement could (1) unnecessarily increase complexity in the Part D program, (2) expose Medicare beneficiaries to problematic prescribers, and (3) perpetuate a cycle where there is insufficient time to implement complex new requirements that have substantial operational challenges. To mitigate some of these issues, the commenter recommended that CMS create and manage a single prescriber preclusion list that is modeled after the OIG exclusion list so that the two files can be handled in a similar manner.

Response: We agree with this recommendation and believe that the preclusion list concept would align with the OIG list and the process that Medicare health and drug plans use to handle prescribers and providers on that list. As already mentioned, we are not finalizing the 90-day provisional supply period. CMS instead will place a prescriber or provider on the preclusion list after the prescriber or provider has exhausted their first level appeal plus an additional 90-day period, including a 60-day period for plans to ingest preclusion data and a 30 day-beneficiary notice period.

Comment: A commenter suggested that CMS adopt the following operational steps before a precluded provider edit occurs at the point of sale: (1) CMS conducts analysis and identifies the specific prescriber; (2) CMS notifies the prescriber of the pending precluded status and outlines the appeal process; (3) once the appeal period has concluded, CMS notifies the impacted beneficiaries; and (4) CMS adds the prescriber to the precluded provider file with a future effective date of 90 days after beneficiary notification, with CMS to add the precluded provider end-date based on reenrollment bar criteria. (The commenter contended that the failure to sufficiently post-date effective dates may create additional risks where CMS may need to support point-of-service override processes due to timing delays associated with monthly file updates.) The commenter believed that these steps would allow CMS to manage the provisional fill period and any variances across preclusion types or beneficiary risk levels (for example, opioids). Several other commenters recommended that CMS adopt this approach.

Response: We appreciate the commenter's feedback and believe our approach allows ample notification time for beneficiaries and prescribers or providers. A prescriber or provider will only be placed on the preclusion list upon exhausting their first level appeal. However, before claims are impacted there will be a 90-day period. The 90-day period allows the plans 30-days to intake the preclusion data and a 60-day beneficiary notification period, during which time the plan can begin working to transition the beneficiary to a new prescriber or provider. Subsequent updates to the list will provide any newly added provider with a 60-day

appeals window but will not provide a 90-day period as discussed above, thus after implementation beneficiaries may not be notified that they may have received a prescription or services from a provider that is now precluded.

Comment: A commenter recommended that CMS provide MA plans with a 30-day advance notice of the addition of individuals or entities to the preclusion list in order to (1) align with provider termination notification requirements and (2) assist MA plans in identifying and notifying beneficiaries of the individual's or entity's preclusion status.

Response: We appreciate the commenter's feedback and, as stated earlier, agree that a 30-day period is necessary after the exhaustion of the provider or prescriber's first level appeal for adequate notice to be provided to MA plans. In addition, we believe that an additional 60-day period is appropriate during which notification will be provided to the beneficiary. We are therefore finalizing a 90-day period between the end of the first level appeal and the placement of the provider or prescriber on the preclusion list. However, we will not finalize the provisional fill requirement.

Subsequent updates to the list will provide any newly added provider with a 60-day appeals window but will not provide a 90-day period as discussed above, thus after implementation beneficiaries may not be notified that they may have received a prescription or services from a provider that is now precluded.

(d) Final Provisions

Given the foregoing, we are finalizing as proposed all of the provisions we identified in section 10(a) and (b) above except as follows:

- We are changing § 423.120(c)(6)(iv) to remove the provisional supply requirement and to revise the notice requirement as follows:

++ Paragraph (iv)(A) will state that 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 written notice to the beneficiary required by paragraph (c)(6)(iv)(B) of this section.

++ Paragraph (iv)(B)(1) will be revised to read as follows: ''Subject to all other Part D rules and plan coverage requirements, provide an advance written notice to any beneficiary who has received a prescription from a prescriber on the preclusion list as soon as possible but to ensure that the beneficiary receives the notice no later than 30 days after publication of the most recent preclusion list.''

++ We are deleting paragraphs (iv)(B)(1)(i) and (ii). Paragraph (iv)(B)(1)(i), which deals with provisional drug supply, is no longer needed, while the language in paragraph (iv)(B)(1)(ii) will be merged into revised paragraph (iv)(B)(1).

++ In paragraph (iv)(B)(2), we are changing the reference to (c)(6)(iv)(B)(1)(ii) to (c)(6)(iv)(B)(1). This is because, as already mentioned, paragraph (c)(6)(iv)(B)(1)(ii) is being deleted and the language therein merged into paragraph (c)(6)(iv)(B)(1).

- Revise § 422.222(a) to state: ''An MA organization may not pay, directly or indirectly, on any basis, for items or services 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''. We note that the language that excluded emergency and urgently needed services from the scope of § 422.222(a) has been removed. § 422.222(a)

- Beneficiaries will not be permitted to appeal the application of the preclusion list to a particular prescriber, individual, or entity.

11. 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 that final rule, we specified in § 422.152 that MA organizations must have ongoing QI Programs, which include chronic care programs, but CMS generally 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 and that some MA 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 also amended 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 reported and 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.

Through annual review of QIP and CCIP reporting submissions, CMS found its implementation of the QIP and CCIP requirements had become burdensome and complex, rather than streamlined and conformed to MA organizations' implementation of QIPs and CCIPs. 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. For example, many MA organizations merely re-iterated the CMS reporting requirements and did not provide quantitative data or demonstrate that they were meeting their intended project goals. Often, the results data lacked clarity and context and were difficult to interpret and validate. MA organizations cited numerous studies but did not indicate how they would use the information to improve enrollee outcomes.

We gained little value from the information reported. 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. Over the years, we have modified the reporting requirements in an attempt to gain specific and quantifiable project goals, clear and concise results data, a favorable effect on enrollee health outcomes, and meaningful descriptions of how the MA organization will disseminate those results amongst the industry to promote best practices.

However, we also found that the scaled down 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 mandated 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 Part C 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 MA 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), 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, perhaps by using different means than a QIP.

Based on this, we concluded that 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 proposed to delete §§ 422.152(a)(3) and 422.152(d), which outline the QIP requirements. In addition, in order to ensure any references for other provisions in this section remain accurate, we proposed to reserve paragraphs (a)(3) and (d). The removal of these requirements will reduce burden on both MA organizations and CMS.

We explained in the proposed rule that even with this proposed removal of the QIP requirements, the MA requirements for QI Programs will 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 will 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 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. As explained in the proposed rule, the proposed amendments do 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 continue to believe that these other 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.

We solicited comments on our proposal, including whether additional revision to § 422.152 is necessary to eliminate redundancies CMS has identified in this preamble.

We received the following comments, and our response follows:

Comment: Most commenters expressed strong support for this proposal to remove the QIP requirement for MA organizations. A few supportive commenters suggested that CMS also remove the CCIP requirement for MA organizations. Specifically, the Medicare Payment Advisory Commission (MedPAC) encouraged CMS to remove as well the duplicative CCIP attestation because measures around prevalent chronic conditions are already measured in the star rating program (for example, diabetes, hypertension).

Response: We appreciate the significant support for this proposal. We acknowledge the suggestion to also remove the CCIP requirement for MA organizations, and believe MedPAC has a valid concern that chronic condition measures are already measured in the star rating program. However, section 1852(e) of the Act requires that each MA organization include a CCIP as part of its required overall QI Program. Therefore, we will continue to require that MA organizations attest annually to having an ongoing CCIP and that the CCIP comply with the requirements issued by CMS under § 422.152(a)(2) and (c).

Comment: Another commenter expressed appreciation for CMS's interim sub-regulatory steps to streamline QIP and CCIP reporting requirements and reduce burden on both MA organizations and CMS (that is, for reporting associated with 2018 QIPs and CCIPs); the commenter encouraged CMS to continue to evaluate whether any additional steps can be taken for 2018 QIPs and CCIPs to further streamline reporting and reduce burden. Similarly, a commenter requested that

CMS make a decision on this proposal so as to limit the resources invested in developing a new 2018 QIP.

Response: We would like to clarify that the required attestations for 2018 QIPs and CCIPs were already completed at the end of December 2017. Therefore, all organizations should have already developed their 2018 QIP plan and implemented it beginning on January 1, 2018. This final rule, making the proposed changes, will be applicable for the 2019 MA plan requirements.

Comment: Another commenter recommended that CMS take into account the impact on state external quality review organization (EQRO) evaluation activities that currently implement the optional use of MA organizations' QIP reports as part of annual reviews for Medicaid managed care plans, citing 42 CFR 438.360.

Response: CMS's removal of the QIP requirement for MA organizations at § 422.152(a)(3) and (d) does not alter the Medicaid managed care plan requirements at § 438.360. If review of an MA organization's CCIP does not produce information that meets the conditions specified in § 438.360(a), then this information could not be used to satisfy that regulation. Guidance on part 438 requirements is outside of the scope of this rule, but we appreciate the comment. We will consider how the QIP removal may impact state EQRO evaluation activities and may issue guidance as necessary to state Medicaid agencies.

Comment: A commenter questioned whether CMS has intentions to make Medicare quality initiatives (that is, MA QI requirements) and Program of All-Inclusive Care for the Elderly (PACE) quality initiatives (that is, Quality Assessment and Performance Improvement or QAPI program) more comparable.

Response: Although there are some similarities in the required quality initiatives for MA and PACE, the PACE QAPI program requirements are outside the scope of this rule. Due to the unique nature of the PACE model, we do not currently intend to align the requirements between the QIP and the QAPI program. However, we may consider doing so in the future.

Comment: A few commenters opposed this proposal, believing that it is premature to eliminate the QIPs without careful evaluation and consideration of where overlaps occur and which QIPs lead to the greatest improvements. Instead of eliminating the QIPs for MA organizations, they suggested that CMS, when issuing mandatory topics for QIPs, take into account any relevant overlap to ensure QIPs are addressing the most important areas and taking into account other related activities.

Response: We disagree with the suggestion that CMS retain the QIP and consider any relevant overlap and other related activities when issuing mandatory QIP topics instead of finalizing the removal of the QIP requirements in § 422.152. Although we are eliminating the QIP requirement, MA organizations must still have a CCIP (section 1852(e) of the Act; 422.152(a)(2) and (c)). Through the CCIP, MA organizations must address chronically ill populations identified by CMS through a list of chronic conditions. However, MA organizations are not required to choose from this list and may choose other chronic conditions as appropriate to meet the needs of their enrollee population. We believe that this flexibility allows MA organizations to identify a focus area that does not overlap or duplicate other related activities, including star rating metrics. Alternatively, an MA organization may choose to design a CCIP that intentionally relates to other activities. We do not prohibit correlated quality activities, and MA organizations may take advantage of this flexibility.

Comment: Another commenter expressing opposition for this proposal stated that the QIP requirements dovetail with existing Medicaid quality requirements and integrated programs have a unique opportunity to pursue joint Medicare and Medicaid QIPs. They feared that the lessening of CMS expectations in this area will result in less attention on such activities by dual eligible special needs plans (D–SNPs).

Response: We understand the commenter's concerns regarding joint Medicare and Medicaid quality initiatives. However, we believe that MA organizations offering integrated D–SNPs may still achieve this by connecting the Medicaid quality project with the required CCIP for MA. States may also strengthen quality requirements through State Medicaid Agency Contracts.

After consideration of the public comments we received, we are finalizing our proposal to remove the QIP requirements for MA organizations in § 422.152(a)(3) and (d), as proposed. We are reserving those paragraphs.

12. Reducing Provider Burden—Comment Solicitation

In the proposed rule, we solicited comment on the nature and extent of the burden faced by providers pursuant to MA organizations' requests for medical records and for ideas to address the burden. We thank the over 40 commenters who responded. We plan to carefully review the information received, including ideas for continued conversations with stakeholders.

C. Implementing Other Changes

1. Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements (§§ 422.2410, 422.2420, 422.2430, 422.2460, 422.2480, 422.2490, 423.2410, 423.2420, 423.2430, 423.2460, 423.2480, and 423.2490)

a. Overview of Proposed Rule

In the November 28, 2017 proposed rule (82 FR 56366), we proposed certain modifications to the medical loss ratio (MLR) requirements in the Medicare Part C and Part D programs. Briefly, we proposed to change the MLR calculation by including in the MLR numerator, as QIA, all expenditures for fraud reduction activities or for Medication Therapy Management (MTM) programs that meet the requirements of § 423.153(d). As explained in the proposed rule, we believe that the proposed inclusion of all fraud reduction activities in the MLR numerator as QIA renders extraneous the provision that provides an adjustment to incurred claims for amounts recovered through fraud recovery efforts, up to the amount of fraud reduction expenses. We also proposed to revise the MLR reporting requirements to significantly reduce the amount of MLR data that MA organizations and Part D sponsors submit to CMS on an annual basis. Finally, we proposed certain conforming and technical amendments, which are described in greater detail in section II.C.1.e. of this final rule.

b. Background

The proposed rule provided background on the Part C and Part D medical loss ratio (MLR) requirements, including the statutory and regulatory authority. 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. In the May 23, 2013 **Federal Register** (78 FR 31284), we published a final rule that codified the MLR requirements for 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). Section 1857(e)(4) of the Act 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, which is incorporated by reference in section 1860D–12(b)(3)(D) 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 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.

c. Changes to the Calculation of the Medical Loss Ratio (§§ 422.2420, 422.2430, 423.2420, and 423.2430)

(1) Fraud Reduction Activities

In the proposed rule, we explained that our general approach in developing the Medicare MLR rules has been to align with the commercial MLR rules in order to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes, including by Medicare beneficiaries. However, we also recognized in the original MLR rule (78 FR 12429) 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 where we initially aligned the commercial and Medicare MLR rules was the treatment of expenditures related to fraud reduction efforts, which we defined to include both fraud prevention and fraud recovery (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 (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 a positive adjustment to incurred claims. The initial Medicare MLR proposed rule, published February 22, 2013 (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.

In the November 28, 2017 proposed rule, we explained that we had reconsidered our policy regarding the treatment of fraud reduction expenses in the Medicare MLR numerator based on the specific characteristics of the MA and Part D programs. We noted that limiting or excluding amounts invested in fraud reduction undermines the federal government's efforts to combat fraud in the Medicare program; such action also reduces the potential savings to the government, taxpayers, and beneficiaries that robust fraud prevention efforts in the MA and Part D programs can provide. We also stated that fraud prevention activities can improve patient safety and deter the use of medically unnecessary services, which is part of the reason we require such activities as a condition of participation in the MA and Part D programs.

For these reasons, we proposed certain changes to the treatment of expenses for fraud reduction activities in the Medicare MLR calculation. First, we proposed 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 proposed 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, given the proposed revisions of the QIA definitions surrounding the treatment of fraud reduction activities, we proposed 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 noted that 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 an additional incentive for 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 the Medicare statute 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 and drug 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 will 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.

As we explained in the proposed rule, we believe that the inclusion of expenditures for fraud reduction activities in the QIA portion of the MLR numerator, as proposed, makes it unnecessary to include in incurred claims the amount of claim payments recovered through fraud reduction efforts, up to the amount of fraud reduction expenses. 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 as a result of fraud, rather than in preventing payment of fraudulent claims. Under our proposal, claim payments recovered through fraud reduction efforts will no longer be included in the MLR numerator as a limited adjustment to incurred claims. Instead, all expenditures for fraud reduction activities will 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 the same level of incentive to just pursue recovery of paid fraudulent claims, and may now be further incented to invest in fraud prevention. We believe that effective fraud reduction strategies will include efforts to prevent payment of fraudulent claims, and that the 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 proposed 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.
- Redesignate the introductory text of §§ 422.2430(a) and 423.2430(a) as paragraphs (a)(1), and revise these newly designated paragraphs (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 solicited comment on these proposed changes, particularly whether our proposal was 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 solicited comment on the types of activities that should be included in, or excluded from, fraud reduction activities. In addition, we solicited comment on alternative approaches to accounting for fraud reduction activities in the MLR calculation. In particular, we were interested in receiving input on the following:

- 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; and
- Whether fraud reduction activities should be subject to any or all of the exclusions from QIA at §§ 422.2430(b) and 422.2430(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 will 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).)

We received 43 comments pertaining to the proposed changes to the treatment of expenses for fraud reduction activities in the Medicare MLR calculation. The following is a summary of the comments we received on these proposals and our responses:

Comment: A majority of the commenters supported the proposal to designate all fraud reduction activities as activities that improve healthcare quality, or QIA. A number of commenters noted that fraud prevention can improve patient safety, deter the use of medically unnecessary services, and can lead to higher levels of health care quality. Several commenters noted that they agreed with our conclusion that the MLR regulations' limited adjustment to incurred claims for fraud recoveries, up to the amount of fraud reduction expenditures, curtailed the incentive to invest in fraud prevention.

Response: We appreciate the support.

Comment: Several commenters opposed our proposal to include all expenditures for fraud reduction activities in the MLR numerator as expenditures for QIA. Some commenters that opposed our proposal argued that the MLR is supposed to represent the proportion of revenue that is spent on medical costs or improving healthcare quality, whereas amounts spent on fraud prevention, detection, and recovery provide little value to beneficiaries and represent administrative expenses that are part of a plan sponsor's cost of doing business. As such, the commenters argued the costs were not appropriate for inclusion in the numerator. Other commenters expressed concern that the proposal would encourage plans to adopt aggressive practices to reduce fraud, such as claim audits, that would ultimately increase provider burden.

Response: We appreciate the concerns raised by the commenters. We respectfully disagree with the argument that fraud reduction expenses do not provide significant value to beneficiaries. We believe, and a number of commenters on the proposed rule noted, that fraud prevention can improve health care quality by ensuring that patients receive care that is legitimate and appropriate, and that providers have the appropriate credentials for the services they perform. In addition, as explained in the proposed rule, we believe that fraud reduction activities can lower the cost of care and reduce trust fund expenditures and thereby potentially provide value to beneficiaries, the government, and taxpayers.

We acknowledge that the proposed inclusion of fraud reduction activities in the MLR numerator could encourage MA organizations and Part D sponsors to implement new practices for combatting fraud and that these may involve new administrative

requirements for providers. However, we note that MA organizations and Part D sponsors would no longer have the same level of incentive to ''pay and chase'' claims in order to account for fraud reduction expenditures in the MLR numerator under the proposed rule; they would instead be further incented to implement pre-payment fraud prevention efforts, as they would now be able to include expenditures related to these efforts in their MLR numerator, regardless of whether they have recovered any claims payments through fraud reduction efforts. We believe that any increase in provider burden as a result of newly-implemented pre-payment fraud prevention practices could potentially be offset by a reduction in the provider's burden associated with the need to contest efforts from health plans to recover claims already paid, as is necessary under the current rules for health plans' fraud reduction expenditures to have a positive impact on their MLR.

Comment: A commenter requested that we amend the regulations for the commercial and Medicaid markets to align with the proposed changes to the treatment of fraud reduction expenditures in the Medicare MLR regulations.

Response: The commercial and Medicaid MLR regulations are outside the scope of this final rule but we will take these comments under advisement.

Comment: We received several comments that requested that we expand the proposal to include in QIA all efforts to reduce fraud, waste, and abuse.

Response: We did not propose in this regulation to designate efforts to reduce waste and abuse as QIA for MLR purposes. We appreciate the comments we received on these issues, however, and will consider whether adding these activities to the QIA category of the MLR numerator should be incorporated into future rulemaking.

Comment: We received one comment that directly addressed our solicitation in the proposed rule concerning the establishment of a new category in the MLR numerator for fraud reduction expenses. The commenter argued that treating fraud reduction expenses separately might encourage plan sponsors to pay more attention to fraud reduction activities and would make it easier to track, measure, and audit expenses that were allocated to this category. Many commenters supported the inclusion of fraud reduction activities in the QIA category of the MLR numerator, without expressing an opinion on whether we should instead create a new numerator category for fraud reduction expenses.

Response: We thank the commenter for responding to our solicitation. We note that MA organizations and Part D sponsors are expected to keep track of any expenses they intend to include in the MLR numerator, regardless of how the expenses are categorized in the underlying analysis and data. Given that the majority of commenters indicated a preference for the proposed inclusion of fraud reduction activities in the QIA category of the MLR numerator, we have decided against establishing a separate numerator category for fraud reduction expenditures. We believe, as noted earlier and in the proposed rule, that fraud reduction is sufficiently related to and supports QIA to consider it properly part of that category.

Comment: Several commenters responded to our solicitation for feedback on whether fraud reduction activities should be subject to any or all of the exclusions at §§ 422.2430(b) and 422.2430(b). Several commenters recommended that we amend §§ 422.2430(b)(1) and 423.2430(b)(1), which exclude from QIA any activities that are designed primarily to control or contain costs, to create an exception for fraud reduction activities. The commenters contended that fraud reduction activities could arguably be described as cost-control activities and expressed concern that a particular fraud reduction activity could (or would) be excluded from QIA due to concerns or confusion regarding this section of the regulation, thereby discouraging investment in such activities by some health plans that may be concerned about being out of compliance if they attempted to incorporate these expenses as QIA. A few commenters recommended that CMS remove the regulatory language at §§ 422.2430(b)(5) and 423.2430(b)(5) that excludes from QIA ''costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities,'' as this would exclude investments in health IT that could be used to reduce the incidence of fraud, such as claims code auditing, pre-pay coding, physician-profiling, and audit/recovery operations. The commenters noted that this change to the regulatory language should retain the exclusion for costs related to claims adjudication systems.

Response: We agree with the commenters that maintaining the current exclusion of cost-control activities without creating an exception for fraud reduction activities could cause confusion regarding which fraud reduction activities could be included in QIA. As explained earlier, one of the reasons we proposed to depart from the commercial MLR rules in our treatment of fraud reduction efforts is to encourage MA organizations and Part D sponsors to pay fewer fraudulent claims, which we believe will lower the overall cost of providing coverage to MA and Part D enrollees and potentially produce savings for beneficiaries, taxpayers, and the federal government. We believe that excluding from QIA fraud reduction activities that are designed primarily to control or contain costs would undermine the incentive to engage in fraud reduction activities.

We also agree that the current exclusion of costs directly related to health IT that are designed primarily or solely to improve claims payment capabilities could be construed to exclude investments in technology solutions that are designed to enhance MA organizations' and Part D sponsors' ability to reduce the incidence of fraud. In order to avoid creating uncertainty about whether investments in health IT as a means of reducing fraud may be included in QIA, we believe it is appropriate that we revise §§ 422.2430(b)(5) and 423.2430(b)(5) to specify that the exclusion of costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities does not apply to costs that are related to fraud reduction activities under §§ 422.2430(a)(4)(ii) and 423.2430(a)(4)(ii).

After consideration of the public comments received, we are finalizing the regulatory changes to paragraphs (a) of §§ 422.2430 and 423.2430 as proposed, with the following modifications. We are revising §§ 422.2430(b)(1) and 423.2430(b)(1), which exclude from QIA activities that are designed primarily to control or contain costs, to provide an exception for fraud reduction activities. We are also revising the §§ 422.2430(b)(5) and 423.2430(b)(5) to provide that costs related to fraud reduction activities under §§ 422.2430(a)(4)(ii) and 423.2430(a)(4)(ii) are not subject to the exclusion that applies to costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities.

(2) Medication Therapy Management (MTM) (§§ 422.2430 and 423.2430)

In the May 23, 2013 final rule (78 FR 31294), we provided guidance 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 be for a purpose identified in paragraph (a)(1) and: (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) will 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 received numerous inquiries seeking clarification whether MTM programs are QIA. To address those questions and resolve any ambiguities or uncertainties, we proposed to specifically address MTM programs in the MLR regulations.

We proposed 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. We believe that the MTM programs that we require under the Part D regulations 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 will 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 solicited comment on these proposed changes.

We received 39 comments pertaining to our proposal to amend the MLR regulations to specify that all MTM programs that comply with § 423.153(d) are QIA.

Comment: Nearly all of the comments supported the proposal to explicitly designate MTM programs that comply with § 423.153(d) as QIA for MLR purposes. A number of commenters noted that MTM programs promote medication adherence and care coordination, which contribute to improved health outcomes and a reduction in health care costs. Several commenters argued that eliminating uncertainty with respect to whether MTM expenditures will be included in the MLR numerator will encourage sponsors to expand access to MTM programs to include greater numbers of enrollees who may benefit from participation.

Response: We appreciate the support.

Comment: A commenter requested that we clarify that the Center for Medicare & Medicaid Innovation's (CMMI) Part D Enhanced MTM models are also QIA, thereby incentivizing participation in these models.

Response: We have waived the MLR requirements to the extent necessary to permit all prospective payments for approved and permissible MTM services under the Part D Enhanced MTM model to be treated as QIA for purposes of MLR reporting. See ''Announcement of Part D Enhanced Medication Therapy Management Model Test'' (September 28, 2015), available at *https://innovation.cms.gov/Files/x/mtm-announcement.pdf*.

Comment: A commenter requested that we take steps to ensure that any required MTM programs established by plan sponsors do not create an undue administrative burden for prescribing physicians or medication denials and delays for patients.

Response: We acknowledge the commenter's concerns about possible increases to physician burden or medication denials and delays for beneficiaries. However, this final rule addresses the designation of MTM programs that meet the requirements of § 423.153(d) as QIA for MLR purposes; we believe that rules and requirements pertaining to the administration of MTM programs are outside the scope of this final rule.

Comment: A commenter recommended that we only include MTM programs in QIA if the sponsor utilizes pharmacists at qualified long-term care pharmacies.

Response: As noted earlier, one of the reasons we proposed to explicitly designate MTM programs that comply with § 423.153(d) as QIA is to encourage sponsors to expand access to these programs. We do not believe that it is necessary to create additional requirements for MTM programs to qualify as QIA, beyond the requirements already present in § 423.153(d).

After consideration of the public comments received, we are finalizing without substantive our proposal to amend §§ 422.2430(a) and 423.2430(a) to specify that all MTM programs that comply with § 423.153(d) are QIA.

(3) Additional Technical Changes to Calculation of the Medical Loss Ratio (§§ 422.2420 and 423.2420)

We also proposed 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 proposed 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).

We received no comments on the proposed technical changes and therefore are finalizing the proposed changes to §§ 422.2420(d) and 423.2420(d) without modification.

d. Proposed Regulatory Changes to Medicare MLR Reporting Requirements (§§ 422.2460 and 423.2460)

We proposed to reduce the MLR reporting burden by requiring MA organizations and Part D sponsors to submit the minimum amount of information that CMS needs in order to determine whether an MA or Part D contract has satisfied the minimum MLR requirement with respect to a

contract year, and whether the contract must remit funds to CMS or face additional sanctions.

As we explained in the November 28, 2017 proposed rule (82 FR 56459), our general approach when initially developing the Medicare MLR regulations was to align the Medicare MLR requirements with the commercial MLR requirements to the greatest extent possible. Consistent with this policy, when we originally developed the Medicare MLR reporting format, we attempted to model it on the tools used to report commercial MLR data. We believed at the time that this would limit the burden on organizations that participate in both markets. However, it was not possible to make these forms and reports identical due to differences in the types of data collected for purposes of commercial MLR reporting versus Medicare MLR reporting. We explained in the November 2017 proposed rule that we had become concerned that requiring health insurance issuers to complete what was ultimately a substantially different set of forms for Medicare MLR purposes had created an unnecessary additional burden. We noted that our proposal to reduce the burden of MLR reporting for the MA and Part D programs 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.

Specifically, we proposed that the Medicare MLR reporting requirements will be limited to the following data fields, as shown in Table E1:

- Organization name
- Contract number
- Adjusted MLR (which will be populated as ''Not Applicable'' or ''N/A'' for non-credible contracts as determined in accordance with §§ 422.2440(d) and 423.2440(d))
- Remittance amount

TABLE 10—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 noted in the proposed rule that although we were proposing a significant reduction in the amount of MLR data that MA organizations and Part D sponsors must report to CMS on an annual basis, we did not propose 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 for purposes of determining 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 will continue to be required to retain documentation supporting the MLR data 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.

We also proposed 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 proposed 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 Adjusted 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.

We received 33 public comments, some in support and some in opposition to our proposal to reduce the amount of MLR data that MA organizations and Part D sponsors submit to CMS on an annual basis. We received the following comments and our response follows:

Comment: Most of the commenters supported our proposed changes to the MLR reporting requirements. Several commenters that supported the proposal expressed concern that the audit burden would increase once we started relying solely on audits to monitor compliance. Other commenters stated that although they supported the proposed reduction in the amount of MLR data they would be required to submit to us on an annual basis, they did not expect their MLR reporting burden to be significantly reduced since they would still be required to collect and analyze the same information in order to calculate the MLR percentage and remittance amount. A commenter asked that we issue guidance on how we will facilitate the current desk review in light of the proposed changes.

Response: We appreciate the support. We do not expect that the proposed changes to the MLR reporting requirements would cause MLR audits to be more burdensome than the MLR audits that we have conducted in previous years. We acknowledge that MA organizations and Part D sponsors will continue to collect the same

information in order to calculate the MLR percentage and remittance amount. However, as we explained in section II.B.9 of the proposed rule (82 FR 56472), in estimating the reduction to the MLR reporting burden that would result from the proposed changes to the reporting requirements, we assumed that MA organizations and Part D sponsors would spend eleven fewer hours per contract performing the following tasks: (1) Reviewing 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) drafting narrative descriptions of methodologies used to allocate expenses; (3) performing an internal review of the MLR report form prior to submission; (4) uploading and submitting the MLR report and attestation; and (5) correcting or providing explanations for any suspected errors or omissions discovered by CMS or our contractor during initial review of the submitted MLR report. We believe that the aggregate savings to MA organizations and Part D sponsors as a result of the proposed changes meaningfully reduce the burden of the MLR reporting requirements. The changes to the MLR reporting requirements in this final rule will not affect MLR reporting until MLR data for contract year 2018 is submitted in 2019. The desk reviews of MLR data submitted for contract years 2016 and 2017 will not be affected by the changes to the reporting requirements.

Comment: Several commenters objected to the proposal to reduce the amount of MLR data that MA organizations and Part D sponsors submit to CMS on an annual basis. Several commenters contended that we cannot conduct meaningful compliance oversight with the minimal amount of MLR data that we proposed to collect. Several commenters noted that it is important that we continue to have access to detailed data on spending for health care services and quality improvement activities by MA organizations and Part D sponsors. A few commenters argued that the lack of transparency into how an MLR is calculated will result in more ''gaming'' of the MLR by MA organizations and Part D sponsors.

Response: As noted earlier, we did not propose 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, which includes the capability to request detailed data regarding the QIA expenditures included in the Medicare MLR, in order to determine that the MLR and remittance amounts were calculated and reported accurately, and that sanctions were appropriately applied. MA organizations and Part D sponsors will still be required to submit an attestation regarding the MLR data submitted, as they currently do. We believe that we can continue to effectively oversee MA organizations' and Part D sponsors' compliance with the MLR requirements by relying solely on audits. In addition, we note that MA organizations and Part D sponsors are required to submit and attest to the data that details their spending on enrollee health care services as part of their annual bids.

Comment: A commenter indicated no objection to the proposed reduction in the amount of MLR data reported to CMS by MA organizations and Part D sponsors, but noted that, in order to monitor the financial performance of Medicare-Medicaid Plans, states would need to maintain their ability to specify and require detailed reporting of financial and MLR data through MIPAA contracting authority, Financial Alignment Initiatives, and other coordinated and integrated mechanisms.

Response: We appreciate the commenter's interest in maintaining access to MLR data for Medicare-Medicaid Plans and other integrated care products. This final rule does not diminish states' existing authority to collect MLR data from such plans under state law, MIPAA contracting, or Medicaid managed care regulations, or terms of three-way contracts for MMPs.

Comment: A commenter recommended the mandatory retention period that applies to documents and records that support MAOs' and Part D sponsors' MLR calculations be shortened from 10 years to 3 years.

Response: In their contracts with CMS, MA organizations and Part D sponsors agree to maintain for 10 years books, records, documents, and other records of accounting procedures and practices that are sufficient for CMS to conduct various reviews, audits, and inspections. §§ 422.504(d) and 423.505(d). We are not persuaded that a shorter record retention period is appropriate for documents that support the MLR calculation.

Comment: A commenter requested that we similarly reduce the amount of MLR data that is reported by commercial health insurance plans.

Response: The MLR reporting requirements for commercial health insurance plans are outside the scope of this rule, but we will take these comments under advisement.

Comment: A few commenters requested that we continue to develop and make available the reporting template as a tool to assist in calculating the MLR.

Response: In section V.C.16 of the proposed rule (82 FR 56488), we explained that, if our proposed reduction in the amount of MLR data reported to CMS were to be finalized, we would reduce the amount we currently pay to contractors for software development, data management, and technical support related to MLR reporting. We intend to discontinue development of the more detailed MA and Part D reporting template after we collect the MLR reports for contract year 2017. We intend to continue to make available the prior years' more detailed MLR reporting templates (used in contract years 2014 through 2017) on the CMS website (CMS.gov) as well as in the Health Plan Management System (HPMS). Therefore, commenters can continue to utilize the prior years' more detailed MLR reporting templates to assist with their MLR calculations.

Comment: A commenter requested that we provide instructions to aid MA organizations and Part D sponsors in the preparation of their simplified MLR data submissions, similar to the instructions that we provided to instruct MA organizations and Part D sponsors on how to complete the more detailed MLR reporting template.

Response: As explained in the Supporting Statement accompanying the PRA listing for CMS Form Number CMS–10476 (published November 28, 2017), respondents can continue to use the current instructions to familiarize themselves with the guidance specific to the calculation of the MLR, and we expect that the revised instructions (for contract year 2018 and thereafter) will make minimal changes to address the simplified reporting requirements. We intend to make the revised MLR Data Submission Instructions available in subregulatory guidance for contract year 2018 MLR reporting. For more information, we refer readers to the Supporting Statement, which is available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10476.html.*

After consideration of the public comments received, we are finalizing the changes to the MLR reporting requirements in §§ 422.2460 and 423.2460 as proposed.

e. 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 proposed 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. The proposed technical changes bring these provisions into conformity with the more substantive regulatory text changes being proposed herein. The 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 to conform to 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.

We received no comments on these aspects of our proposal and therefore are finalizing the proposed technical changes to §§ 422.2410, 422.2480, 422.2490, 423.2410, 423.2480, and 423.2490 without modification.

2. Medicare Advantage Contract Provisions (§ 422.504)

Under section 1857 of the Act, CMS enters 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. We proposed 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) states that compliance with paragraphs (1) through ((13)) is material to the performance of the MA contract; in addition, § 422.504(a)(16) states that compliance with paragraphs (a)(1) through (a)(15) is material to the contract. Neither provision addresses paragraphs (a)(17) or (a)(18). These inconsistencies could cause confusion on the part of MA organizations and complicate CMS enforcement of the regulations.

We proposed 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 proposed to renumber current paragraphs §§ 422.504(a)(17) and (a)(18). The proposed revision to the paragraph (a) introductory text was to provide that compliance with all contract terms listed in paragraph (a) is material.

We received no comments on this proposal and therefore are finalizing these changes to § 422.504(a) as proposed without modification.

3. Late Contract Non-Renewal Notifications (§§ 422.506, 422.508, and 423.508)

According 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 for this 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 proposed to clarify our 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 one-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 (and we did not propose to add one).

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 and, as applicable, 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 proposed to modify § 422.506(a)(3) to remove language that indicates late non-renewals may be permitted by CMS so that there will only be one process—mutual termination under §§ 422.508—that is applicable if CMS or the organization is not taking action under § 422.506(b) (Nonrenewal of contract) or § 422.510 (Termination of contract by CMS). Also, we proposed to amend §§ 422.508(a)(3) and 423.508(a) 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.

We received the following comments, and our response follows:

Comment: A commenter expressed support for our clarification that CMS considers MA organization non-renewal requests received after the first Monday in June as a request for mutual termination covered under § 422.508. The commenter requested that CMS clarify any differences in the notification requirements and other processes for contracts that non-renew under § 422.506 and contracts that mutually terminate under § 422.508.

Response: We appreciate the commenter's support for our proposal clarifying that CMS treats non-renewal requests received after the first Monday in June as a request to mutually terminate the contract. The provisions under §§ 422.506(a)(2)(ii) and 422.508(a)(1) outline the notification requirements for contracts that non-renew and mutually terminate; CMS has provided guidance on these provisions in the Medicare Managed Care Manual, Chapter 11 and annual non-renewal and contract closeout guidance released in our Health Plan Management System.

After considering this comment, we are finalizing our proposal to remove § 422.506(a)(3) and to revise §§ 422.508(a)(3) and 423.508(a) without amendment.

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 subpart K of 42 CFR part

422. 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 42 CFR parts 422 and 423. We proposed 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 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. 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 proposed 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.

We received no comments on this proposal and therefore are finalizing the amendments to §§ 422.664(b)(1) and 423.652(b)(1) without modification.

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 assure that adequate and appropriate stop-loss insurance is provided 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); that regulation was adopted in 2000, and was based on a similar rule adopted for section 1876 risk plans pursuant to the similar physician incentive plan requirements under section 1876(i)(8). In recent years, CMS has received a number of requests to update the stop-loss insurance limits in § 422.208 associated with physician incentive plan (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).

We proposed to change the existing regulation in three substantive ways:

- 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 the large variety of potential risk arrangements.
- 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 received comments from 9 stakeholders regarding our proposal to update the physician incentive plan (PIP) rule. In this final rule we are finalizing the stop loss limits substantially as proposed but with modifications to adopt definitions and streamline the regulation text. The heart of our proposal—to adopt a methodology that can be applied to updated claims information in order to create tables that associate minimum attachment points for stop-loss coverage based on the panel size of the physician or physician groups that are at risk of substantial financial loss—is being finalized as proposed. Also, as we discuss below, we are considering future rulemaking to implement a more extensive update of the PIP regulation. Additionally, based on the comments we received on the proposed rule and our own review of the proposal, we are clarifying the methodology we proposed in determining when physicians and physician groups are at substantial financial risk and the resulting stop-loss insurance requirements. We are adopting limited changes to the regulation text (compared to the proposed regulation text) to clarify these changes and improve the readability of the text at § 422.208; we are also adopting definitions for terms used in the final rule. This final rule also includes a correction to a typo in the Panel Size row 16,100, Net Benefit Premium column of the Combined Stop-Loss Insurance Deductible table (Table PIP–11), which we discovered in our review for purposes of finalizing the proposed rule. As proposed, we will apply the methodology in the final regulation to provide sub-regulatory guidance (for example, in the annual CMS Call Letter) based on changes to medical costs and health care utilization patterns; these updates are anticipated to be in the form of a combined stop-loss insurance deductible table and a separate stop-loss insurance deductible table. As noted in the proposed rule, we believe this update to the regulation governing the stop loss insurance requirements is needed at this time given the changes in underlying medical costs since the tables were originally established. However, we are also aware that approaches to risk sharing have evolved since the physician incentive regulation was first established. Because of these health care contracting developments, we are considering more extensive changes to the physician incentive rule in the future. To that end, CMS will seek further dialogue with stakeholders on this topic to inform future rulemaking.

a. Determination of Substantial Financial Risk and Stop-Loss Insurance Requirements for Physicians and Physician Groups

Under the current PIP regulation at § 422.208, aggregate stop-loss protection must cover 90 percent of the costs of referral services that exceed 25 percent of potential payments. Per patient stop-loss protection must cover 90 percent of the cost of referral services that exceed the per-patient deductible limit. The current stop-loss insurance deductible

limits are identified in a table codified at § 422.208(f)(2)(iii). 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. There is no requirement for stop-loss protection when the physician or physician group has a panel of risk patients of more than 25,000; we did not propose to change this requirement or the general rule that aggregate stop-loss protection must cover 90 percent of the costs of referral services that exceed 25 percent of potential payments. We noted in the proposed rule our belief that the general provisions in the current regulation—for example, the determination of substantial financial risk (see § 422.208(d)(2))—do not need to be updated. We did seek comment about 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.

We received the following comments and our responses follow:

Comment: We received a question asking if a bonus based on both quality and utilization counts towards substantial financial risk.

Response: The statute mandates protection for physicians and physician groups when risk of substantial financial loss is tied to referrals; therefore we must include incentives that are triggered by the level of referrals. This condition is not changed if quality is an additional trigger for the *same* referral based payment. However, we do exclude quality-only bonuses from determinations of substantial financial risk.

Comment: We received two comments asking if bonus-only risk arrangements would be subject to the rule.

Response: Bonus-only arrangements can tie part of physician compensation to reductions or limits in services and referrals. We interpret the statutory direction to include bonus-only risk arrangements in determining when a physician or physician group is at risk of substantial financial loss. Thus, an excessive bonus-only risk arrangement that exceeds the risk threshold and is payable due to a reduction in physician referrals for services, would be subject to the rule. This would be particularly true if the base payment before bonuses was a relatively low amount.

Comment: Some commenters were concerned that the physician incentive rules could apply to payments made to physicians related to the quality of their care and patient satisfaction.

Response: The Medicare statute at section 1852(j)(4) of the Social Security Act, which established the physician incentive regulation, requires that financial incentives related to referrals a physician makes are subject to the physician incentive rule. However, bonus payments or other payments to physicians for the quality of care furnished or patient satisfaction that are not tied to the referrals a physician makes are not subject to this rule.

Comment: A commenter asked us to clarify the ''substantial financial risk'' test when an independent practice association (IPA), a management services organization (MSO), or any other type of intermediary negotiates with the MAO on behalf of physicians/physician groups.

Response: The regulation provides that a physician/physician group is placed at substantial financial risk when the physician/physician group may lose (or fail to receive) 25% or more of potential payments as a result of use and cost of referral services. Payments based on other factors, such as quality of care furnished, are not considered in this determination. The substantial financial risk test is always focused on the potential payments to physicians/physician groups. The regulation provides, at paragraph (b), that it applies to an MA organization and any of its subcontracting arrangements that utilize a physician incentive plan in their payment arrangements with individual physicians or physician groups.

If stop-loss protection is required, it is to be determined at either the physician/physician group level or the intermediary level as illustrated in the following cases.

Case 1: In this case, the physicians/physician groups have an agreement with the intermediary for payments which are not influenced by the financial outcome of the intermediary. The intermediary does not share any additional payments with or reduce payments to the physician/physician group based on use and costs of referral services. Withholds, bonuses, capitation, or any other similar arrangements are applied to payments only at the intermediary level and not to payments to those who provide health care services. If the physician/physician group will earn the same income regardless of their referral practices, there is no risk of substantial financial loss and stop-loss protection is not required by this regulation.

Case 2: The intermediary shares additional payments based on use and costs of referral services with the contracted physicians/physician groups. The amount of the additional payment paid to each physician/physician group is related to the referral services associated with that individual physician/physician group. In this case, the physicians/physician groups are at financial risk based on their referral patterns. The analysis must be performed at the physician/physician group level to evaluate whether that risk is a substantial financial risk of 25% or more of potential payments for each physician/physician group.

Case 3: The intermediary shares additional payments based on use and costs of referral services with the contracted physicians/physician groups, but the amount of additional payments per physician/physician group are not related to the referral services of the individual physician/physician group. The additional payments are shared equally by all physicians/physician groups contracted with the intermediary based on the financial outcome of the intermediary. In this case, determination of substantial financial risk may be done at the intermediary level because the risk is evenly shared among all contracted physicians/physician groups. That is, the physicians/physician groups may pool their membership to determine if they are at substantial financial risk.

Case 4: The physicians/physician groups have an ownership stake in the intermediary. The intermediary shares additional payments based on use and costs of referral services with the contracted physicians/physician groups. The amount of the additional payment paid to each physician/physician group is related to the referral services associated with that individual physician/physician group. In this case, the physicians/physician groups are at financial risk based on their referral patterns. The analysis must be performed at the physician/physician group level to evaluate whether that risk is a substantial financial risk of 25% or more of potential payments for each physician/physician group.

Case 5: The physicians/physician groups have an ownership stake in the intermediary. The intermediary shares additional payments based on use and costs of referral services with the contracted physicians/physician groups, but the amount of additional payments per physician/physician group are not related the referral services of the individual physician/physician group.

The additional payments are shared equally by all physicians/physician groups contracted with the intermediary based on the financial outcome of the intermediary. In this case, determination of substantial financial risk may be done at the intermediary level because the risk is evenly shared among all contracted physicians/physician groups. That is, the physicians/physician groups may pool their membership to determine if they are at substantial financial risk.

Comment: A few commenters asked if MA plans are required to pay for the stop loss coverage.

Response: MA organizations are responsible for assuring that the coverage is in place. The regulation does not require MA organizations to pay for this coverage. Payment for the coverage may be negotiated between the MA organization and its network providers that participate in the physician incentive plan.

Comment: We received one comment with regard to ensuring that MA plans have incentive programs that are open to all providers, including nurse practitioners, and not just physicians.

Response: This comment is outside the scope of this regulation.

We are not finalizing any changes to the definition of substantial financial risk or risk threshold.

b. Update Deductible Limits and Codify Methodology

Our proposal to 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 was the most significant proposed change. We explained in the preamble that medical cost increases and changes in utilization that have occurred since adoption of the current rule raised concerns that the current regulation requires stop-loss insurance that is more conservative and more expensive than is necessary. The statute provides us with the authority to adopt standards identifying the adequate and appropriate amount of stop-loss coverage, taking into account patient panel size and other factors. In developing the new attachment points for the stop-loss protection required under the statute, we stated our belief that it is appropriate to furnish more flexibility for MA organizations and the physicians and physician groups that participate in PIPs to select between single combined stop-loss insurance and separate stop-loss insurance for institutional services and professional services.

We explained in the proposed rule the analysis we went through to develop tables that could be used to identify the specific deductibles for the required stop-loss protection. To develop the specific attachment points, we used a data-driven analysis using Medicare Part A and B claims data from 340,000 randomly selected beneficiaries. We believe that this sample size provided a statistically significant sample for purposes of the analysis. We assumed a multi-specialty practice, and estimated medical group income based on FFS claims, including payments for all Part A and B services. We used projections of net income based on services provided personally by individual physicians and directly by physician groups because that is how we have determined ''potential payments'' as defined in the existing regulation. We then 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 percent confidence, the point at which a multi-specialty group of a given panel size that engaged in a global capitation arrangement would, through referral services, lose more than 25 percent of its potential payments. We set that point—the threshold for loss of 25 percent of potential payments—as the single combined per patient deductible as illustrated in the Combined Stop-Loss Insurance Deductible Table (Table PIP–11), which was included in the preamble of the proposed rule. We performed an analysis for multiple panel sizes, which are also listed on Table PIP–11. We proposed to describe the methodology used for calculating Table PIP–11 in the regulation, at paragraphs (f)(2)(iii) and (iv), but did not propose to codify the table itself so that CMS could update the table in the future as necessary using the methodology and updated data. We proposed that the new rule (including the published Table PIP–11) would apply for contract years beginning on or after January 1, 2019 and until CMS published an update through the annual Call Letter or through other sub-regulatory guidance to MAOs.

TABLE PIP–11—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
1,400	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	28
16,800	1,000,000	12
17,400–25,000	2,000,000	4
>25,000	No Stop Loss	0

We proposed at § 422.208(f)(2)(iii)(A) that Table 1 be used to determine the maximum attachment point/maximum deductible for per-patient-combined stop-loss insurance coverage that must be provided for 90 percent of the costs

above the deductible or an actuarial equivalent deductible limit can be determined. The methodology for developing the table was described in proposed § 422.208(f)(2)(iv). For panel sizes that fall between the table values, proposed § 422.208(f)(2)(iii)(A) directed use of linear interpolation to identify the required deductible. In addition, our proposed § 422.208(f)(2)(iii)(B) provided for use of Table 1 when using non-risk patients equivalents in determining the panel size.

In addition to the maximum deductible permitted for per-patient combined stop-loss protection, proposed Table 1 included a ''net benefit premium'' (NBP) column. We explained in the proposed rule how the NBP would be used to identify the attachment points for separate stop-loss insurance for institutional services and professional services when using the Separate Stop-Loss Insurance Deductibles Table (Table PIP–12). We explained how the NBP column would not be used when combined insurance was used to satisfy the stop-loss protection requirements in § 422.208. 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. We also explained how Table PIP–12 was calculated using a methodology similar to the calculation of Table PIP–11 and proposed to codify the methodology for developing Table PIP–12 in proposed § 422.208(f)(2)(v) and (vi). Similar to our approach in Table PIP–11, we used Fee-For-Service Medicare Part A and Part B claims data to develop Table PIP–12. We estimated professional potential payments and institutional potential payments using the same data set as was used for populating Table PIP–11. The central limit theorem was used to obtain the distribution of claim means, and deductibles were obtained at the 98 percent confidence level. The methodology and assumptions for Table PIP–12 were proposed to be codified in § 422.208(f)(2)(vi) as the standards for developing and updating Table PIP–12 in the future as necessary.

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TABLE PIP-12: SEPARATE STOP-LOSS INSURANCE DEDUCTIBLES

Professional Deductible (in thousands)	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

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We also explained how our proposal would use Table PIP–12. The NBP would be identified from the third column of Table PIP–11, based on the

panel size for the applicable physician or physician group. Our proposal permitted use of linear interpolation for panel sizes that did not appear on Table PIP–11. The cell in Table PIP–12 with a numerical entry that is greater than or equal to the NBP would be selected; the associated combination of professional and institutional deductible levels for that NBP would be the maximum deductibles for the required stop-loss protection for each of those respective claims. The coverage identified using Table PIP–12 this way was proposed as the required stop-loss protection for separate per-patient coverage pursuant to proposed § 422.208(f)(2). We proposed to codify the use of Table PIP–12 for deductibles for separate stop-loss insurance professional services and institutional services based on the NBP in paragraph (f)(2)(v).

We solicited specific comments on the proposed regulation, as follows:

- Whether the methodology for developing Tables PIP–1 and PIP–2 as codified in proposed paragraphs (f)(2)(iv), (vi), and (vii) provided sufficient detail;
- Whether the proposed regulation text clearly identified how the tables should be used; and
- 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.

We received the following comments and our responses follow:

Comment: We received several comments in favor of CMS updating the deductible amounts.

Response: We thank the commenters for the support. We are updating the deducible amounts and finalizing this regulation as proposed with clarifications and changes described in this final rule.

Comment: Several commenters agreed with CMS that the stop loss tables should be regularly updated for cost and utilization. Some suggested a 2- to 3-year cycle.

Response: We concur with this comment, will monitor cost and utilization every 2 to 3 years, and will implement future updates to the stop loss tables when CMS determines that changes in medical costs and changes in patterns of health care utilization justify an update.

Comment: Some commenters stated that CMS should consider changes to the physician incentive plan rule to better reflect changes in the incentive arrangements that are currently being used. These commenters also asked that CMS consider a broad update to the rule and its underlying methodology and allow for greater stakeholder input. They also stated that the changes being proposed further complicate an already complicated regulation and add technical jargon.

Response: CMS will seek further dialogue with stakeholders on this topic to inform future rulemaking. We are mindful of the need to minimize complexity and make our rules as transparent as possible. However, a degree of complication cannot be avoided in our attempt to add the flexibility needed to handle the many variations in risk sharing arrangements between MA plans and physicians. We replaced the term ''DGCP'' with the term ''risk patients,'' which we believe is clearer.

Comment: A commenter requested that CMS add the following language to the regulation at § 422.208(f)(2)(iii)(A) ''Stop-loss protection must cover 90 percent of costs of referral services 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 of referral services above the deductible.''

Response: We agree and have made this change to the regulation. We are finalizing paragraph (f)(2)(iii) with this statement. We are also finalizing the text to refer more consistently to ''the required stop-loss protection'' to be clear that the protection described in this statement with the deductibles identified in the tables is required.

Comment: Several commenters questioned CMS' interpretation of the definition of potential payments to physicians.

Response: It is not our intention to change the definition of potential payments in the current regulation. Per the regulation, potential payments means the maximum payments possible to physicians or physician groups including payments for services they furnish directly, and additional payments based on use and costs of referral services such as withholds, bonuses, capitation or any other compensation to the physician or physician group. It does not include payments that ''pass through'' the physician or physician group to compensate other health care providers for referred services. In the development of Tables PIP–11 and PIP–12, potential payments were derived from payments for Parts A and B services provided directly by the physician in the sample claims data. Our interpretation of potential payments is a reasonable approximation of what portion of the full global capitation amount can be expected to be earned by the physician or physician group including withholds and bonuses. We use this amount to trigger substantial financial risk in the determination of the maximum deductible in the Tables.

Comment: Commenters requested that CMS to clarify how it defines ''global capitation''.

Response: We are finalizing a definition for the term ''Global capitation'' in § 422.208(a) to avoid ambiguity. Global capitation means a specific type of ''capitation'' that includes both professional and institutional services. Services covered by global capitation may also include prescription drug benefits and supplemental benefits as well as basic benefits (as those terms are defined in § 422.100(c)). For purposes of Tables PIP–11 and PIP–12 global capitation includes all Parts A and B services except hospice. If the capitation for a physician group is different from all Parts A and B services except hospice, the group must use an actuarially equivalent amount of stop loss coverage.

Comment: A commenter asked for more detail with respect to the description of the methodology including a detailed calculation for one of the cells in the table.

Response: The methodology and calculation of the panel size for the Single Combined Deductible of $100,000 in the Combined Stop-Loss Insurance Deductible Table (Table PIP–11) is presented here and the parameters for the methodology for this table is finalized in paragraph (f)(2)(iv). Per the PIP regulation, if the physician incentive plan places a physician or physician group at substantial financial risk for services the physician or physician group does not furnish itself the MA organization must assure that the physician or physician group has stop loss protection. Substantial financial risk is defined to be 25 percent of potential payments.

We used the central limit theorem to determine the required panel size for each deductible level in Table PIP–11 and Table PIP–12. Our goal is to determine the number of individuals required for each deductible so that there is a 98 percent probability that actual referral claims net of deductible are less than the sum of expected referral claims net of deductible plus 25 percent of potential payments.

We model the distribution of claim amounts using the following statistical formula and the Central Limit Theorem: Aggregate referral claims for a group of n individuals

$$\sum_{i=1}^{n} X_i \xrightarrow{d} \mathrm{N}(n \times \mu, n \times \sigma^2),$$

Where

Xi is the annual referral claim amount net of deductible paid by the physicians with mean (μ) and variance (σ^2) for an individual, calculated on a per capita basis. Xi is assumed to be independently and identically distributed for each individual. Statistics are calculated using a sample of 340,000 randomly selected beneficiaries from the Medicare Part A and B claims data excluding hospice,

μ is the population mean for physician paid referral claims net of the deductible,

σ is the standard deviation for physician paid referral claims net of the deductible level.

For this example, the standard deviation for an attachment point of $100,000 is $17,158, r is our estimate of potential payments which does not vary relative to the deductible and is calculated to be $1,400 PMPY, n is the panel size, and $N(n \times \mu, n \times \sigma^2)$ denotes the Normal distribution with mean, $n \times \mu$, and variance, $n \times \sigma^2$.

Given the definitions and assumptions above, we solve for the following probability:

$$\text{Probability}\left[\sum_{i=1}^{n} X_i \leq n \times (\mu + 0.25r)\right] = 98\%$$

Standardizing and solving for the Z value we attain the formula

$(n\mu + n0.25r - n\mu) / (\sigma\sqrt{n}) = Z_{0.98} = 2.05$

(Note that this is a one-tail test)

$$\text{Which simplifies to } n = \left(\frac{2.05\sigma}{0.25r}\right)^2 = \left(\frac{2.05 \times 17{,}158}{0.25 \times 1{,}400}\right)^2 = 10{,}100$$

Therefore, the cell on the combined table with a deductible of $100,000 corresponds to at least 10,100 patients.

The net premium is then calculated as 90% of the sum of the claims above $100,000, divided by the number of patients.

Comment: We received a comment recommending that CMS consult with stop loss coverage experts in developing this regulation. We believe that this regulation, as finalized, is consistent with the applicable actuarial principles and practices.

Response: Over the years, CMS has had numerous discussions with qualified actuaries regarding our method of determining stop-loss insurance requirements.

After consideration of the comments, we are finalizing changes to the regulation text at § 422.208(f)(2)(iii) through (vi) substantially as proposed. We are finalizing the five new definitions; the codification of the methodology CMS would use to update the stop-loss deductible limits; and the requirements for using the tables to identify the stop-loss protection required when a multi-specialty physician practice in a global capitation arrangement is at risk for substantial financial loss; and regulation text reiterating that stop-loss protection must cover at least 90 percent of the costs of referral services above the deductible or an actuarially equivalent amount of the costs of referral services that exceed the per-patient deductible limit. We are finalizing definitions for the terms ''Combined Stop-Loss Insurance Deductible Table (Table PIP–11)'' and the ''Separate Stop-Loss Insurance Deductible Table (Table PIP–12)'' to refer to the tables developed using the methodologies codified at paragraphs (f)(2)(iv) and (vi). We are also finalizing definitions for the terms ''global capitation,'' ''net benefit premium,'' and ''non-risk patient equivalents'' as those terms are discussed above. Finally, we are also finalizing changes to the regulation compared to the proposal to better organize and clarify the requirements.

c. Actuarially Equivalent Arrangements

We stated in the proposed rule that, over the past several years, MA organizations have requested that CMS update the tables as well as provide additional flexibilities around protection arrangements. We noted our belief 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 we provided where actuarially equivalent modifications might be necessary included: Global capitation arrangements that include some, but not all Part A and B services; global capitation arrangements that include supplemental benefits and/or drug benefits; capitation arrangements that include only physician services; stop-loss policies with different coinsurances; stop-loss policies that use medical loss ratios (MLRs), 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. We proposed to amend § 422.208 to provide, as a new paragraph (f)(3), that stop-loss protection would comply with the requirements so long as it were certified as actuarially equivalent to the coverage described in paragraph (2), meaning the coverage described in the tables developed using the methodology codified in paragraph (f)(2). We proposed that certification of the actuarially equivalent protection must be done by an actuary who meets the qualification standards established by the American Academy of Actuaries, follows the standards of the Actuarial Standards Board, develops the deductibles of the alternate coverage to be actuarially equivalent to the coverage in the tables, and makes the computations in accordance with generally accepted actuarial principles and practices.

We received the following comments and our responses follow:

Comment: We received many comments in favor of and two against allowing actuarial equivalent arrangements. Supporters welcome the flexibility for compliance with the PIP regulation. A commenter was concerned with added complexity and administrative burden, the other commenter pointed out a typographical error.

Response: CMS is finalizing as proposed to allow actuarial equivalent arrangements. Given that the finalized tables address only multi-specialty provider groups selecting per-person stop-loss insurance, allowing actuarial equivalence is critical to meeting the requirements of this regulation. The typographical error referring to stop-loss protection for non-capitated

arrangements has been corrected in the final regulation text. We are finalizing § 422.208(f)(3) as proposed to permit MA organizations to use other stop-loss protection arrangements so long as the following conditions are met: The deductibles for the alternate coverage are actuarially equivalent to the coverage described in paragraph (f)(2); the actuary makes the computations in accordance with generally accepted actuarial principles and practices; and the actuary is 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.

After consideration of the comments, we are finalizing the regulation text in § 422.208(f)(3) substantively as proposed with revisions to correct grammatical errors and to refer to the defined tables as appropriate.

d. Non-Risk Patient Equivalents Included in Panel Size

We stated in the proposed rule that we believe the number of a physician's or physician group's non-risk patients should be taken into account when determining the stop-loss deductible(s) for risk arrangements. 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 proposed, at § 422.208(f)(2)(iii) and (v), to allow Non-risk patient equivalents (NPEs), such as Medicare FFS patients or commercial FFS 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, both Medicare and non-Medicare, divided by an estimate of what the average capitation per member per year (PMPY) would be for all non-global risk patients. Both the numerator and denominator are for physician services that are rendered by the physician or physician group. We proposed that the deductible for the stop-loss insurance that is required under this regulation will be the lesser of: (1) The deductible for globally capitated patients plus $100,000; or (2) the deductible calculated for globally capitated patients plus NPEs. The deductible for these groups will be separately calculated using the tables and requirements in our proposed regulation at paragraphs (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 proposed the same flexibility for combined per-patient stop-loss insurance and the separate stop-loss insurances. We are finalizing this as proposed.

We received the following comments and our responses follow:

Comment: Several commenters asked CMS to clarify how non-risk patient equivalents (NPEs) are calculated and used.

Response: NPEs are a measure of the number of non-risk patients, both Medicare and non-Medicare. To calculate NPEs, estimate the annual claims for physician rendered services for non-risk patients. Then estimate what a PMPY capitation for physician rendered services would be if non-risk patients were capitated for physician rendered services. The quotient is the number of NPEs. As noted above, we are finalizing a definition for the term to avoid ambiguity.

For example, assume that the physician claims for non-risk patients is expected to be roughly $22 million. Assume that the average capitation for physician rendered services is $2,000. The number of NPEs would be $22 million divided by $2,000, which is 11,000 non-risk patient equivalents. This calculation provides a standard cost level for non-risk patients regardless of their utilization.

To use, assume that the physician medical practice has 7,000 risk patients. One would first look up the deductible (or attachment point) for combined coverage using 7,000 patients. Then, look up the attachment point using 18,000 = (7,000 + 11,000) patients. The final attachment point is the lesser of the attachment point with 18,000 patients, or $100,000 plus the attachment point with 7,000 patients. Therefore the NPEs can add a maximum of $100,000 to the combined attachment point.

Comment: A commenter asked for clarification about how CMS, in its stop-loss methodology, determines what is a risk pool and how it affects the number of risk patients. Another commenter asked about the pooling level.

Response: It is not our intent to alter the authority to pool patients provided in § 422.208(g), which allows a physician or physician group to pool, under certain circumstances, the Medicare and Non-Medicare patients for whom they accept capitation risk to determine panel size. Stated differently, pooling allows at-risk commercial, at-risk Medicare, and at-risk Medicaid patients to be considered in the determination of the panel size. With the amendment we are finalizing in § 422.208(f)(2), we are authorizing the use of Non-risk Patient Equivalents (NPE) so that the panel size includes non-risk patients served by the physician or physician group. With regard to the level of pooling, if there is an intermediary involved, the pooling may be accomplished at the physician/physician group level or the intermediary level. See the response to the question regarding how the PIP regulation is applied when an intermediary is involved for guidance in section II.C.5.a of this final rule.

Comment: Some commenters questioned how MA plans can satisfy their regulatory obligation given the situation in which physicians or physician groups will not share sufficient patient income information for the MA plan to determine NPE. Some suggested other measurements.

Response: CMS will allow MA plan sponsors to accept attestations regarding the calculation of NPE from physicians or physician groups.

Comment: A commenter recommended that CMS amend the regulation at (f) by adding a dollar sign when using the term DGCP + 100,000 so that it states DGCP + $100,000, and is therefore clear what unit is being applied. (See (f)(2)(iii)(B) and (f)(2)(v)(B).)

Response: We agree and have made the change to the physician incentive regulation as proposed in the comment. We have also removed the reference to DGCP and replaced it with the phrase ''risk patients'' for continuity with the original regulation.

We are finalizing amendments to § 422.208 to permit use of the non-risk patient panel size in identifying the required stop-loss protection in paragraph (f)(2)(iii).

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. 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 54226).

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. This language is no longer relevant, as the current compensation structure is not based on the initial payment, but having the language in the regulations has created confusion with plans and brokers.

We proposed to make a technical correction to the existing regulatory language at §§ 422.2274(b) and 423.2274(b). We 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). Additionally, we proposed to renumber the existing provisions under §§ 422.2274(b) and 423.2274(b) for clarity.

Although not summarized in the preamble of the proposed rule, we also proposed to correct the language in the newly redesignated § 423.2274(b)(2)(iii). The current regulation text reads, ''When a beneficiary disenrolls from an MA plan. . . .'' Because the reference is within the Part D regulations (section 423), the regulation should refer to Part D sponsors. We proposed regulation text to correct the text so that the reference to ''an MA plan'' instead refers to ''a Part D sponsor.'' (82 FR 56526)

We received the following comments, and our response follows:

Comment: A few commenters indicated support for the proposed change citing decreased burden on plans and requested that we adopt the change as proposed.

Response: We appreciate the support for this provision.

Comment: A commenter indicated support for the provision but also requested that CMS investigate current compensation and administrative fees charged by field marketing organizations (FMO) for exchanges.

Response: We appreciate the support for the provision. The request to investigate the compensation and administrative fees of exchange FMOs is outside the scope of this regulation but we will take it under consideration.

All of the comments we received were generally supportive, and therefore we are finalizing the proposal to redesignate paragraphs (b)(1)(iii) as (b)(1)(iv); redesignate paragraphs (b)(2)(iii) as (b)(1)(iii); remove paragraphs (b)(2)(i) and (ii); and redesignate paragraphs (b)(3) as paragraphs (b)(2) in §§ 422.2274 and 423.2274, without modification. In addition, we are finalizing the technical correction to newly redesignated paragraph § 423.2274(b)(2)(iii) to replace the reference to an MA plan with a reference to a Part D sponsor.

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.

As discussed in the proposed rule, we have become aware since implementation of the provision in §§ 422.2272(e) and 423.2272(e) that the regulation does not allow latitude for punitive action by the sponsoring organization 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), that requires 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 proposed to delete §§ 422.2272(e) and 423.2272(e), the provisions that limit what MA organizations and Part D sponsors can do upon discovery 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).

We received the following comments, and our response follows:

Comment: We received ten comments supporting the change as proposed.

Response: We appreciate the support from industry of this proposed change.

Upon consideration of the comments, we are finalizing the removal of paragraphs (e) from §§ 422.2272 and 423.2272 as proposed.

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; and 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 and 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 proposed 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.

We received the following comments and our response follows:

Comment: A few commenters stated that they believed this proposal would only minimally impact plans.

Response: We agree that this change to § 405.924(a) will minimally impact plans since these premium adjustments are already considered initial determinations.

After consideration of the public comments, we are finalizing the change to § 405.924(a) as proposed.

9. Eliminate Use of the Term ''Nonrenewal'' 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 bases and procedures for contract termination versus those for nonrenewal of 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 nonrenewals 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 nonrenewal authority. We proposed to revise our use of terminology such that that the term ''nonrenewal'' only refers to timely elections by contracting organizations to discontinue their contracts at the end of a given year. We

proposed to remove the CMS initiated nonrenewal authority codified 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 nonrenewals 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 MA or Part D contract.

The similarities between CMS-initiated nonrenewal and termination are demonstrated by the extensive but not complete overlap in bases for CMS action under both processes. For example, both 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. Further, 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 proposed striking these provisions from the nonrenewal portion of the regulation and adding them to the list of bases for CMS-initiated contract terminations in §§ 422.510 and 423.509.

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 proposed 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 proposed 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.

We received the following comments and our response follows:

Comment: CMS received only a few comments on this proposal, all expressing general support. The commenters expressed particular appreciation for our proposal to preserve the requirement that affected beneficiaries receive notice of a CMS-initiated termination at least 90 days prior to the December 31 effective date when CMS makes such a determination on or before August 1. The commenters noted that the 90-day notice deadline enables affected beneficiaries to make a needed plan election during the annual coordinated election period.

Response: CMS appreciates the expressions of support for the proposal. We note that in the event of a CMS-initiated contract termination, the contracting organization has administrative appeal rights that, if exercised, could prevent affected beneficiaries from receiving plan termination notices during the annual coordinated election period. When CMS terminates an MA organization or Part D plan sponsor contract under §§ 422.510 or 423.509, the organization may request a review of the decision by a hearing officer under §§ 422.660 and 423.650. Generally, a request for a hearing generally postpones the effective date of the termination (except, for example, in instances such as financial insolvency or imminent threats to beneficiary health and safety), meaning that beneficiary notices would be delayed until after the completion of the hearing process. So, while we intended to establish beneficiary notification deadlines that align with the annual coordinated plan election period, we recognize that in some instances, the exercise of administrative appeal rights by terminated organizations may prevent that outcome for beneficiaries.

Comment: Some commenters asked CMS to clarify whether the proposed change would prohibit MAOs from expanding or marketing other plans in the service area in which one of its plans was terminated or non-renewed.

Response: The proposal would make no changes to rules that govern an MA organization's or Part D plan sponsor's ability to offer or market other plans in the same service area affected by the CMS-initiated termination. CMS' decision to terminate an organization's MA or Part D contract would have no impact on the status of any other type of MA or Part D contract the organization may operate in the same service area as the terminated contract. A CMS-initiated termination may affect the contacting organization's ability to qualify for a new or expanded contract covering the same service area as the terminated contract. Under §§ 422.502(b)(3) and 423.503(b)(3), CMS may deny applications from organizations for which CMS has terminated a contract within the 38 months preceding the contract qualification application deadline. Our proposal does nothing to change that authority. As is currently the case, CMS' application of this authority depends on the facts associated with each case, including the type of contract (for example, MA coordinated care plan, MA private fee-for-service) and the

service areas associated with the terminated contract and the new application.

Comment: Some commenters asked CMS to clarify how the proposed change would affect the plan information displayed on *Medicare.gov*.

Response: CMS proposed eliminating the category of CMS-initiated nonrenewals primarily to reduce confusion among sponsoring organizations and different CMS staff concerning the authority under which CMS or a contracting organization may end a Medicare contract and the instructions that apply to each process (for example, timing of contract decision, beneficiary notice requirements). In implementing a termination or nonrenewal, it is critical for the party taking the step to end the contract to be clearly identified so that the end of the contract can be properly implemented. Generally, enrollees need only know when their plan will no longer be available, not the party responsible for the decision to discontinue the plan. Therefore, we do not expect the proposed regulatory change to have an impact on how and what plan information is displayed on *Medicare.gov*, since it is a tool designed for use primarily by beneficiaries. Nevertheless, CMS will keep this proposed change in mind when considering any updates to the *Medicare.gov* website.

Based on our consideration of the comments and the expressions of support for this primarily technical change to the regulations governing the MA and Part D contract termination processes, we are finalizing the amendments to §§ 422.506(b), 422.510(a), 422.510(b), 423.507(b), 423.509(a) and 423.509(b) as proposed with two minor modifications to §§ 422.510(b) and 423.509(b). In reviewing the proposed regulation text, we found that the provisions directing organizations with contracts terminated prior to August 1 to issue beneficiary notices at least 90 days prior to the end of the current contract year should have been added to §§ 422.510(b)(1) and 423.509(b)(1), which govern ordinary terminations, not §§ 422.510(b)(2) and 423.509(b)(2), which govern immediate contract terminations. Therefore, we have deleted the references in the regulation text to §§ 422.510(b)(2)(v) and 423.509(b)(2)(v) and placed the relevant language at §§ 422.510(b)(1)(iv) and 423.509(b)(1)(v).

We also identified a grammatical error in the proposed § 422.510(b)(2) and an inconsistency with the language of § 423.509(b)(2)(v) which we are correcting in the finalized text. As a result we are making the necessary grammatical correction in the new § 422.510(b)(1)(iv) and making it consistent with § 423.510(b)(1)(v).

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 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the November 28, 2017 (82 FR 56336) proposed rule, we solicited public comment on each of these issues for the following sections of the rule containing information collection requirements (ICRs). We received comments and we provide a summary of the comments and our responses under the respective ICR section.

A. Wage Data

While we did not receive comments related to any of the private sector or individual occupations or wage estimates, we are revising our wage estimates for individuals. To derive average costs for individual respondents, the proposed rule used the federal minimum wage of $7.27/hour as set out under the Fair Labor Standards Act (29 U.S.C. 206(a)). Based on internal review, we are now adopting a rate of $23.86/hour from the U.S. Bureau of Labor Statistics (BLS).

1. Private Sector Wages

To derive average costs, we used data from 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, Table F1 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 13—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.

2. Wages for Individuals

To derive average costs for individuals, we used data from the May 2016 National Occupational Employment and Wage Estimates for our salary estimate. We believe that the burden will be addressed under All Occupations (occupation code 00–0000) at $23.86/hour since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment, etc.

Unlike our private sector adjustment to the respondent hourly wage, we are not adjusting this figure for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding the Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions (§ 423.153(f))

Excluding beneficiary appeals, the following requirements and burden will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). We did not receive any public comments pertaining to our proposed burden estimates, therefore we are finalizing them as proposed.

As discussed in section II.A. of this rule, § 423.153(f) implements 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. The rule stipulates that Part D plan sponsors are 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 (currently approved under OMB control number 0938–0964 (CMS–10141). However, the approval only accounts for the notice that is currently sent to beneficiaries who have a POS edit put in place to monitor opioid access (which will count as the initial notice described in the preamble of this final rule and defined in § 423.153(f)(4)) and does not capture the second notice that at-risk beneficiaries will receive confirming their determination as such or the alternate second notice that potentially at-risk beneficiaries will 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 are using an average of 923 edits per year (4,617 POS edits/5 years) to assess the burden under § 423.153(f). If we assume that the number of edits or access to coverage limitations will likely double due to the addition of pharmacy and prescriber ''lock-in'' to OMS by this rulemaking, to approximately 1,846 such limitations, we then estimate a total of 3,693 initial and second notices (1,846 limitations × 2) corresponding to such edits/limitations. We estimate it will 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 hours × $39.22/hour) or $3.26 per notice ($12,040.54/3,693 notices).

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) 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 all of the notices into their claims systems. This results in a total one-time burden of 1,095 hours (5 hours per sponsor × 219 sponsors) at a cost of $89,680.50 (1,095 hours × $81.90/hour) or $409.50 per sponsor ($89,680.50/219 sponsors).

In aggregate, the burden to upload and prepare the additional second notice is 1,402 hours (307 hours + 1,095 hours) at a cost of $101,722 ($12,041 + $89,681).

Revisions to § 423.38(c)(4) will 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 codified in § 423.38(c)(4), this SEP is extended to include ''other subsidy-eligible individuals'' so that both full and partial subsidy individuals are treated uniformly. As such, the SEP limitation in this final rule will also be extended to include both full and partial subsidy individuals. 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 until such identification is terminated in accordance with § 423.153(f).

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 initial notice to the beneficiary that he or she has been identified as a potential at-risk beneficiary.

As explained previously, 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 to monitor opioid access. This notice is covered under currently approved OMB control number 0938–0964 (CMS–10141), and will count as the initial notice described in the preamble of this final rule and defined in § 423.153(f)(4)). This initial notice will include language to notify an individual of the inability to use the duals' SEP. Therefore, the burden associated with the notification of the inability to use the duals' SEP is currently approved under OMB control number 0938–0964 (CMS–10141).

This final rule also codifies an existing provision whereby an individual can make an election within 3 months of a gain, loss, or change to Medicaid or LIS eligibility, or notification of such a change, whichever is later.

An individual who is determined to be a potential at-risk or an at-risk individual will be able to use this SEP to change plans. Also, if a potential at-risk or at-risk individual is eligible for another election period (for example, AEP, OEP, or other SEP), this SEP limitation will not prohibit the individual from making an election. Providing a limitation for dually- and other LIS-eligible at-risk beneficiaries after the initial notification will decrease sponsor burden in processing disenrollment and enrollment requests for dual- and LIS-eligible beneficiaries who wish to change plans as outlined later in this section.

We estimate that 1,846 beneficiaries will meet the criteria 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 (1,403 = 1,846 beneficiaries × 0.76). Approximately 10 percent of LIS-eligible enrollees use the duals' SEP to make changes annually (140 = 1,403 × 0.10). Thus we estimate, at most, 140 changes per year will no longer take place because of the duals' SEP enrollment 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 million 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.

This final rule also provides that the review 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 will 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 will have rights to an expedited redetermination. 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 of the PRA; however, the burden for appeals is included in the regulatory impact analysis of this final rule.

In aggregate, these components of this provision will result in an annual net cost of $101,722 (see Tables F2 and F3).

TABLE 14—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

* This rule does not impose any new or revised information collection requirements/burden.
** Exempt from the PRA.

TABLE 15—ESTIMATED BURDEN FOR THE CARA PROVISIONS

[In hours]

	2019	2020	2021	3-year average
Preparation and Upload Notices	$101,722	0	0	$33,907.3
SEP Limitation *	0	0	0	0
Appeals **	N/A	N/A	N/A	N/A
Total	101,722	0	0	33,907.3

* This rule does not impose any new or revised information collection requirements/burden.
** Exempt from the PRA.

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

Enrollment requirements and burden are currently approved by OMB under control number 0938–0753 (CMS–R–267). Since this rule will not impose any new or revised requirements/burden and we did not receive any public comments pertaining to the burden discussion that was set out in our proposed rule, we are not making any changes under the 0938–0753 control number. (*Note:* While CMS–R–267 has expired, we are proposing to reinstate the collection through this final rule.) We acknowledge that the establishment, through subregulatory guidance, of a new and simplified positive (that is, ''opt in'') election process that would be available to all MA organizations for their commercial, Medicaid or other non-Medicare plan members, may result in a minimal reduction in burden; however, this potential reduction is not quantifiable, and therefore, de minimus.

We note that this enrollment mechanism is optional and that it existed prior to this regulation. As outlined in the proposed rule, we are codifying an existing process that has been in place for more than a decade. In terms of enrollment operations, the default enrollment process has elements similar to beneficiary-initiated enrollments (determining eligibility, processing the enrollment transaction and notifying the beneficiary) and, as such, the overall burden for enrollment processing is not changing and is captured in our existing PRA package. With regard to the default enrollment notice, we note that there is not a standardized notice that previously existed, nor is a new standardized notice being created; this enrollment notice serves the same purpose as the notice required for beneficiary-initiated enrollments, in that it informs the beneficiary of the enrollment start date and of other information necessary to access plan benefits and services.

As is the case currently for the seamless conversion enrollment process, MA organizations choosing to offer a default enrollment process will request approval from CMS and, if approved, implement a process with notification and processing elements similar to those carried out for beneficiary initiated enrollments, including issuance of a plan-developed notice to inform individuals of the

enrollment and of other important plan information.

As discussed in section II.A.7. of this rule, we are finalizing our proposal to revise §§ 422.66 and 422.68 by: Codifying the requirements for default enrollment that are currently set out in subregulatory guidance,[78] revising current practice to limit the use of this type of enrollment mechanism, and clarifying the effective date for ICEP elections. This will 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 the provision 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 will not change. For those MA organizations that want to use this enrollment mechanism and request and obtain CMS approval, the administrative requirements will remain unchanged from the current practice.

As indicated in the preamble to this final rule, we are finalizing the proposed changes with the following modifications, none of which we believe will result in any impact to the Medicare Trust Funds.

- Section 422.66(c)(2)(i) is revised to clarify that we will allow default enrollment into a FIDE–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.
- Section 422.66(c)(2)(i) is revised to clarify that, for an organization to be approved for default enrollment, it must have an overall quality rating, from the most recently issued ratings, under the rating system described in §§ 422.160 through 422.166, of at least 3 stars or is a low enrollment contract or new MA plan as defined in § 422.252. In addition, the MA organization must not be under an enrollment suspension.
- Section 422.66(c)(2)(ii) is revised to include an approval period not to exceed 5 years, subject to CMS authority to rescind or suspend approval if the plan is non-compliant.
- Section 422.66(c)(2)(iv) is revised to state that the notice issued by the MA organization will include information on the differences in premium, benefits and cost sharing between the individual's current Medicaid managed care plan and the dual eligible MA special needs plan and the process for accessing care under the MA plan; an explanation of 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 MA plan; and a general description of alternative Medicare health and drug coverage options available to an individual in his or her Initial Coverage Election Period.
- Section 422.66(c)(2)(iv) is revised to clarify that the mandatory notice is in addition to the information and documents required to be provided to new enrollees under § 422.111.

[78] Chapter 2 of the Medicare Managed Care Manual found at *https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html?redirect=/MedicareMangCareEligEnrol/*.

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

As discussed in section II.A.7. of this rule, we are finalizing a limited expansion of passive enrollment authority under § 422.60(g). More specifically, the new provisions at § 422.60(g) will allow CMS, in consultation with a state Medicaid agency, to implement passive enrollment procedures in situations where criteria identified in § 422.60(g)(1)(iii) and (g)(2) are met. We are finalizing these provisions as proposed, with one exception. Specifically, we are modifying § 422.60(g)(4) to require, under new § 422.60(g)(4)(i)(B), that plans receiving passive enrollments under § 422.60(g)(1)(iii) send two notices to enrollees. We also clarify that for passive enrollments under § 422.60(g)(1)(i) and (ii), only one notice will continue to be required. Accordingly, we are modifying § 422.60(g)(4) to require, under new paragraph (g)(4)(i)(B), that plans receiving passive enrollments under § 422.60(g)(1)(iii) send two notices to enrollees. New § 422.60(g)(4)(i)(A) will retain the original requirement that one notice be provided to passive enrollee under § 422.60(g)(1)(iii). However, we note that we are making no changes to the criteria for determining plan eligibility for passive enrollment under § 422.60(g)(1)(iii).

In the proposed rule, we estimated that approximately 1 percent of the 373 active D–SNPs would meet the criteria 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. We therefore estimated that there would be only four instances (373 SNPs × 0.01) in which CMS would conduct passive enrollment each year. We did not receive any comments related to the overall number of respondents or our claim that the provision is exempt from the PRA.

Because we are not changing the eligibility criteria for integrated D–SNPs that may receive passive enrollments in this final rule, our estimated number of affected entities remains four. Since we estimate fewer than 10 respondents, the information collection requirements and burden related to the final provisions under § 422.60(g) are exempt (5 CFR 1320.3(c)) from the requirements of the PRA.

4. ICRs Regarding the Part D Tiering Exceptions (§ 423.578(a) and (c))

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). We did not receive any PRA-related public comments and are finalizing the proposed provisions without modification. Since this rule will not impose any new or revised requirements/burden, we are not making any changes under the 0938–0976 control number. As discussed in section II.A.9 of this rule, we are finalizing the proposed changes to § 423.578(a) and (c) without modification. The changes establish 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 changes also clarify the 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 current requirement to send written notice of an adverse coverage determination is not changed by this rule. We do not expect that any of the changes will significantly impact the overall volume or the approval rate of tiering exceptions requests, which represent a consistently low percentage of total request volume.

5. ICRs Regarding Establishing Limitations for the Part D Special Enrollment Period for Dual Eligible Beneficiaries (§ 423.38(c)(4))

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 enrollment processing and notification requirements and burden are currently approved by OMB under control number 0938–0964 (CMS–10141). Since this rule will not impose any new or revised requirements/burden, we are not making any changes under the 0938–0964 control number. We did not receive any comments pertaining to the burden discussion within our proposed rule.

As discussed in section II.A.10. of this rule, we are finalizing the proposed provision with modifications. The revisions do not affect any of our currently approved requirements and burden under OMB control number 0938–0964.

In section II.A.10. of this final rule, we are revising § 423.38(c) to limit the SEP for dual- and LIS-eligible individuals (other than potential at-risk or at-risk beneficiaries) so that it is only available onetime-per-calendar-quarter election during the first nine months of the year. In addition, we are establishing new SEPs at § 423.38(c)(9) and (c)(10) for beneficiaries who have a change in their dual or LIS-eligible status or have been assigned into a plan by CMS or a State, respectively.

In instances where an individual is not able to utilize the dual SEP because of this rule's 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 will send a notice to the beneficiary to acknowledge the voluntary disenrollment request. If the beneficiary is subject to the dual SEP limitation, the plan will send a notice to deny their voluntary disenrollment request. The requirement to acknowledge the beneficiary request and address the resolution will be the same in both scenarios, but the content of the notice will be different. As indicated earlier, the requirements and burden associated with the provision of both notices are currently approved by OMB under control number 0938–0964 (CMS–10141).

6. ICRs Regarding Medicare Advantage and Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.182, 422.184, and 422.186)

As discussed in section II.A.11. of this rule, we are finalizing our proposal to codify the existing measures and methodology for the Part C and D Star Ratings program. The provisions will not change any respondent requirements or burden pertaining to any of CMS' Star Ratings-related PRA packages including: OMB control number 0938–0732 for CAHPS (CMS–R–246), OMB control number 0938–0701 for HOS (CMS–10203), 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). We received no comments on our proposed burden discussion and therefore are finalizing this provision without modification. Since this rule will not impose any new or revised requirements/burden, we are not making changes under any of the aforementioned control numbers.

7. ICRs Related to Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

The general notice requirements and burden are currently approved by OMB under control number 0938–0964 (CMS–10141). We are finalizing the proposed provision with a modification that has no impact on our information collection requirements or associated burden estimates (see section II.A.14. of this rule for details). Since this rule would not impose any new or revised requirements/burden, we are not making any changes under the 0938–0964 control number.

In section II.A.14. of the proposed rule, we proposed to expedite certain generic substitutions and other midyear formulary changes by, for instance, permitting Part D sponsors to immediately substitute newly approved generic drugs as specified and, for other formulary changes, to provide 30 rather than 60 days notice and, as applicable, provide a month's supply rather than a 60-day supply. Also, we proposed to except applicable generic substitutions from the transition process. We are finalizing the provisions as proposed, with the following changes. We are specifying that Part D sponsors may substitute during the plan year generics that have are released after the date that they initially submit their formulary; that substituted generics must be offered on the same or lower cost-sharing tier rather than at the same or lower cost-sharing; and that Part D sponsors must provide, when required, an ''approved'' month's supply—that is, the month's supply approved in a plan's bid. 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 certain 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 burden.

While the proposed provisions would additionally require general notice that certain generic substitutions could take place immediately, this notice would appear in documents that Part D sponsors are already providing to their enrollees, such as formularies and EOCs. CMS will provide this language in the model documents it distributes as part of the yearly revisions to those documents. The marketing and beneficiary communications general notice requirements and burden are currently approved by OMB under control number 0938–0964 (CMS–10141). Similarly, § 423.128(d)(2)(ii) already requires websites to include information about drug removals and changes to cost-sharing. In other words, the general notice requirement would not require efforts in addition to routine updates to beneficiary communications materials and websites. 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 provision does require notice including direct notice to affected enrollees. However, our practice has been to approve all generic substitutions that would meet the requirements of this provision—which again means that the provisions will just permit those substitutions to take place sooner.

8. ICRs Regarding the Restoration of the MA Open Enrollment Period (§§ 422.60, 422.62, 422.68, 423.38, and 423.40)

The following requirements and burden will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). Since we did not receive any public comments pertaining to our burden estimates, we are finalizing them as proposed, with the exception of our wage and cost estimates for beneficiaries. (*Note:* While CMS–R–267 has expired, we are proposing to reinstate the collection through this final rule.)

As discussed in section II.B.1. of this rule, we are finalizing our proposal to codify the requirements for open enrollment and disenrollment opportunities at §§ 422.60, 422.62, 422.68, 423.38, and 423.40. This action will eliminate the existing MADP and establish an MA Open Enrollment Period (OEP). This new OEP revises a previous OEP which will 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 will be collected, the burden associated with this requirement will 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.[79] Using the 3 percent adjustment, we expect that 558,000 individuals (18.6 million MA beneficiaries × 0.03), will use the OEP to make an enrollment change.

We estimate it will take a beneficiary approximately 30 minutes (0.5 hours) at $23.86/hour to complete an enrollment request. The burden for all beneficiaries is estimated at 279,000 hours (558,000 beneficiaries × 0.5 hour) at a cost of $6,656,940 (279,000 hour × $23.86/hour) or $11.93 per beneficiary ($6,656,940/558,000 beneficiaries).

There are currently 468 MA organizations in 2017.[80] 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 will result in approximately 1,192 enrollments per organization (558,000 individuals/468 organizations) during the OEP each year.

We estimate it will 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).

[79] Medicare Beneficiary Database (MBD), December 29, 2016. *https://www.cms.gov/.*

[80] Medicare Beneficiary Database (MBD), December 29, 2016. *https://www.cms.gov/.*

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 the 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 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 $6,656,940 and a per beneficiary burden of 30 minutes at a cost of $11.93.

9. ICRs Regarding the Medicare Advantage Plan Minimum Enrollment Waiver (§ 422.514(b))

The requirements and burden associated with the submission of the minimum enrollment waiver in the application are currently approved by OMB under control number 0938–0935 (CMS–10237). We received no comments on our proposed provisions and are finalizing them without change. Consequently, we are not making any changes under the 0938–0935 control number.

Section 422.514(b) provides 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. Section 422.514(b) also requires 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, this rule removes 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). The revision to § 422.514(b)(2) now clarifies that CMS will only accept a waiver through the application process and that we will allow the minimum enrollment waiver, if approved by CMS, to remain effective for the first 3 years of the contract.

10. ICRs Regarding Disclosure Requirements (§§ 422.111 and 423.128)

CMS will submit the following requirements and burden to OMB for approval under control number 0938–1051 (CMS–10260). We did not receive any comments pertaining to our proposed requirements or burden estimates. With the exception of the added language in § 422.111(h)(2)(iii), we are finalizing them as proposed.

a. Timing of Disclosure (§§ 422.111(a)(3) and 423.128(a)(3))

As discussed in section II.B.4 of this rule, we are finalizing our proposal to revise the timing of disclosing the information required under § 422.111(a) and (b) and the timing of such disclosures under § 423.128(a) and (b) which provide for the disclosure of plan content information to beneficiaries. Sections 422.111(a)(3) and 423.128(a)(3) require that MA plans and Part D sponsors provide the information in §§ 422.111(b) and 423.128(b) by the first day of the annual enrollment period. This is a change from current practice, which requires that plans provide the information 15 days before that period. Importantly, plans must continue to distribute the ANOC 15 days prior to the AEP. In other words, the revised provision provides 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))

Sections 422.111(h)(2)(i) and 423.128(d)(2)(i) require that plans maintain a website 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 website ''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) requires the disclosures ''in the manner specified by CMS.''

In § 422.111(h)(2)(ii), we had proposed to modify the sentence stating that the posting of the EOC, Summary of Benefits, and provider network information on the plan's website does not relieve the plan of its responsibility to provide hard copies of these documents to beneficiaries ''upon request.'' In this final rule, we removed the ''Summary of Benefits'' from that sentence and added ''The summary of benefits. Posting does not relieve the MA organization of its responsibility under paragraph (a) of this section to provide hard copies to enrollees as CMS directs'' to § 422.111(h)(2)(iii) excepting the Summary of Benefits from electronic delivery of certain required documents. We also added the phrase ''in the manner specified by CMS'' in § 422.111(a).

The changes give 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 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, and EOC documents are those for which electronic posting and delivery of a hard copy upon request are permissible. Electronic delivery reduces plan burden by eliminating printing (paper and toner) and mailing costs, when applicable. Additionally, the IT systems of the plans are already set up to format and print these documents.

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,[81] and prescription drug contracts for contract year 2019. At this time, we have no mechanism for measuring the number of beneficiaries who have asked to receive this document electronically by opting into a plan's electronic delivery system. However, we expect this number to be not significant.

Based on reports from the internetSociety.org and Pew Research Center,[82] we estimate that 33 percent of these beneficiaries who are in MA and Prescription Drug contracts will prefer to opt in to receive hard copies instead of 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 32,026,000 beneficiaries (47,800,000 beneficiaries × 0.67).

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 pages per EOC/500 sheets per ream)]. Thus, we estimate that the total savings from paper is $24,019,500 (32,026,000 EOCs × $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 assume a cost of $50 for 10,000 pages. Each toner will print 66.67 EOCs (10,000 pages per toner/150 pages per EOC) at a cost of $0.005 per page ($50/10,000 pages) or $0.75 per EOC ($0.005 per page × 150 pages). Thus, we estimate that the total savings on toner is $24,019,500 (32,026,000 EOCs × $0.75 per EOC).

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 (0.016 ounces/page × 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/pounds × 1.5 pound × 32,026,000 EOCs).

In aggregate, we estimate an annual savings of $54,668,382 ($24,019,500 + $24,019,500 + $6,629,382).

11. ICRs Regarding Communication/Marketing Materials and Activities (Parts 422 and 423, Subpart V)

CMS will submit the following requirements and burden to OMB for approval under control number 0938–1051 (CMS–10260). As indicated, public comments were received and are summarized below along with our response. We are not making any changes to the proposed provisions, and we are finalizing them as proposed. However, we have made technical changes to correct errors identified in the proposed rule's burden analysis. To address a mathematical error, we have updated the total number of materials submitted from 80,110 to 79,584. We have also addressed an additional mathematical error for the material no longer submitted under the 6000 code from 1,407 to 1,667. As a result of these corrections, the total number of materials that will no longer be submitted has changed from 39,824 to 39,298, the total number of hours has changed from 19,912 to 19,649, and the cost saved has changed from $1,398,372 to $1,357,353. In addition, we removed the PACE and Medicare-Medicaid Plans from the chart as they will not be impacted by this regulation.

As discussed in section II.B.5. of this rule, we are finalizing our proposal 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 revised definition appropriately safeguards 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 narrowed definition reduces 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. Consistent with the figures in our currently approved information collection request, we continue to 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

[81] Per 42 CFR 417.427, cost plans must comply with § 422.111 and § 423.128.

[82] Global internet Report, 2017, internet Society, *http://www.internetsociety.org/globalinternetreport/2016/?gclid=EAIaIQobChMI-tz1nN_W1QIVgoKzCh1EVggBEAAYASAAEgLpj_D_BwE* and ''Tech Adoption Climbs Among Older Adults,'' Pew Research Center, *http://www.pewinternet.org/2017/05/17/tech-adoption-climbs-among-older-adults/.*

analysis, we also must estimate the number of marketing materials that would have been submitted to us under the current regulatory marketing definition.

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

BILLING CODE 4120–01–C

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 will no longer be Submitted	Hours per Response	Total Hours Saved	Wage Rate (Per Hour)	Cost Saved (in $)
1000	Enrollment and related documents	16,495	Enrollment forms	981	15,514	0.5	7,757	$69.08	535,853.56
1100	ANOC/EOC/LIS Rider	6,794	n/a	5,162	1,632	0.5	816	$69.08	56,369.28
2000	Disenrollment	5,942	n/a	0	5,942	0.5	2,971	$69.08	205,236.68
3000	Grievances	1,564	n/a	0	1,564	0.5	782	$69.08	54,020.56
4000	Advertisements	43,965	General advertising that includes benefits information	32,974	10,991	0.5	5,495.5	$69.08	379,629
5000	Formulary Drug	1,429	n/a		1,429	0.5	714.5	$69.08	49,397.66
6000	Presentations/Scripts/Surveys	2,836	Enrollment scripts	1,169	1,667	0.5	The	$69.08	57,578.18
8000	Creditable Coverage/LEP	559	n/a		559	0.5	279.5	$69.08	19307.86
	Total	79,584		40,286	39,298	0.5	19,649	$69.08	$1,357,353

By reducing the number of marketing materials submitted to CMS by 39,298 documents (79,584 current – 40,286 excluded) we estimate a savings of

19,649 hours (39,298 materials * 0.5 hours per material) at a cost savings of $1,357,353 (19,649 hours * 69.08 per hour). Some key points in the calculations are as follows:

- There were a total of 79,584 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 this final rule. The 79,584 figure also excludes codes 15000, 16000, and 17000 Medicare-Medicaid Plan (MMP) materials. The MMP materials are not being counted as the decision for review rests with the states and CMS.
- Section 1851(h) of the Act 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 79,584.
- 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 final rule.
- Marketing code 4000 covers all advertisements which constitute 55 percent (43,965) of the 79,584 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) will 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 79,584.
- 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 (currently approved under OMB control number 0938–0763 (CMS–R–262)). Formularies, however, will no longer fall under the new regulatory definition of marketing and hence will not be submitted separately for review as marketing materials.
- Marketing code 6000 includes sales scripts which are predominantly used to encourage enrollment, and will likely still fall under the scope of the new marketing definition. As such, we must subtract 1,169 documents (code 6013) from the 79,584 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.

We received the following comments. A summary of the comments and our response follow:

Comment: A commenter wanted CMS to include PACE marketing materials in the marketing chart.

Response: PACE marketing materials were intentionally omitted because PACE marketing is not impacted by changes to subpart V under both parts 422 and 423.

Comment: A commenter requested that Table 16 (currently Table F4) reflect the inclusion of materials that will fall under the purview of CMS review based on this final regulation.

Response: The intent of the chart is to provide an estimate of the aggregate savings that will result from the regulatory changes to Subpart V, rather than to provide a comprehensive list of the materials that will or will not require submission as a result of this final rule. As noted in response to comments in section II.B.5. of this rule, CMS intends on issuing subregulatory guidance to provide more detailed information on material status.

Comment: A commenter requested that the descriptions in the chart include all materials that fall under the general marketing code listed.

Response: In developing the chart, CMS used the marketing code descriptions reflected in HPMS. The description is meant to give the reader a sense of what materials fall under the code as opposed to an all-inclusive list. Listing all material types would not be practical. Readers can reference the marketing section of HPMS for a list of all codes and material types.

12. ICRs Related to Preclusion List Requirements for Individuals and Entities in MA, Cost Plans, and PACE (§ 422.222) and Prescribers in Part D (§ 423.120(c)(6))

a. Preclusion List Requirements for Part C (§ 422.222)

The following requirements and burden will be submitted to OMB for approval under control number 0938–0685 (CMS–855A, –855B, and –855I). We did not receive any comments pertaining to our proposed requirements, therefore we are finalizing them as proposed.

Consistent with the proposed rule (82 FR 56488), we estimate that 120,000 MA providers and suppliers have yet to enroll in Medicare via the CMS–855 application. Based on internal CMS statistics we estimate that 6,000 Part A providers and certain Part B certified suppliers would have completed the CMS–855A application, 24,000 Part B organizational suppliers would have completed the CMS–855B application, and 90,000 physicians and non-physician practitioners would have completed the CMS–855I application. We believe that savings will accrue for providers and suppliers from the elimination of our MA/Part C enrollment requirement under § 422.222. Table 17 summarizes the burden associated with the completion of each form.

TABLE 17—CMS–855 APPLICATION SAVINGS

[Time and costs]

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	Hours for completion *	Time savings (hours)	Cost savings ($)
CMS–855A	6,000	5	n/a	1	6	36,000	$1,641,960
CMS–855B	24,000	4	n/a	1	5	120,000	5,759,040
CMS–855I	90,000	2.5	0.5	n/a	3	270,000	16,676,100
Total	120,000	11.5	0.5	2	14	426,000	24,077,100

* The per response time estimate is consistent with what is currently approved by OMB.

In projecting the savings, we assume that a medical and health services manager will serve as the provider's or supplier's ''authorized official'' and will sign the CMS–855A or CMS–855B application on the provider's or supplier's behalf.

Therefore, we project the following total hour and savings:

- 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/hour × 5 hours) + ($105.16/hour × 1 hour)], we estimate a total savings of $1,641,960 (6,000 applications × $273.66).
- 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/hour × 4 hours) + ($105.16/hour × 1 hour)], we estimate a total savings of $5,759,040 (24,000 applications × $239.96).
- 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/hour × 2.5 hours) + ($202.08/hour × 0.5 hours)], we estimate a savings of $16,676,100 (90,000 applications × $185.29).

Given the foregoing, we estimate that providers and suppliers will experience a total reduction in hour burden of 426,000 hours (270,000 hours + 120,000 hours + 36,000 hours) and a total cost savings of $24,077,100 ($16,676,100 + $5,759,040 + $1,641,960). We expect these reductions and savings to accrue in 2019 and not in 2020 or 2021. Nonetheless, when distributed over the course of OMB's 3-year approval period (2019 to 2021), we expect an annual savings of 142,000 hours (426,000 hours/3 years) at $8,025,700 ($24,077,100/3 years) per year.

b. MA Encounter Data (§ 422.310(d)(5))

The requirements and burden associated with the collection and reporting of encounter data is currently approved by OMB under control number 0938–1152 (CMS–10340). Encounter data is a source to determine providers rendering MA services that should be on the preclusion list. Since this rule's provision is consistent with existing policy the change will not impose any new or revised requirements/burden. Consequently, we are not making any changes under the 0938–1152 control number.

This final rule revises § 422.310 by adding a new paragraph (d)(5) which requires that, for the data described in § 422.310(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 provision, since it is consistent with existing policy.

c. Preclusion List Requirements for Part D Sponsors

(1) Enrollment in Medicare Part D (§ 423.120(c)(6))

The following requirements and burden will be submitted to OMB for approval under control number 0938–1135 (CMS–855O). We did not receive any comments pertaining to our proposed requirements, therefore we are finalizing them as proposed.

As discussed in the proposed rule (82 FR 56474), we believe that savings will accrue for the prescriber community from this rule's elimination of the requirement under § 423.120(c)(6)) that prescribers enroll in Medicare in order to prescribe Part D drugs.

In the proposed rule (82 FR 56474), we estimated that approximately 420,000 prescribers have yet to enroll in Medicare via the CMS–855O application. Based on updated data we are revising this estimate to approximately 340,000 un-enrolled prescribers. However, our data shows that there are 25,000 providers who overlap leaving 315,000 unenrolled prescribers in Part D. We also estimate that it will take 0.5 hours for a prescriber to complete a CMS–855O application.

This is based on the following assumptions:

- A medical secretary will take 0.42 hours at $33.70/hour to prepare the application.
- A physician will take 0.08 hours at $202.08/hour to review and sign the application.

This will result in a per application cost of $30.32 [(0.42 hours × $33.70/hour) + (0.08 hours × $202.08/hour)] and a total savings of $10,308,800 (315,000 applications × $30.32) and 170,000 hours (315,000 applications × 0.5 hours). We believe that these savings will accrue in 2019.

(2) Part D Sponsor Requirements

The following notice preparation and distribution requirements and burden will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). We did not receive any comments pertaining to our proposed requirements, therefore we are finalizing them as proposed.

As discussed in sections II.D.10. and 11. of this rule, we are finalizing our proposal under § 423.120(c)(6) to 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 will be the time and effort necessary for Part D adjudication systems to be programmed and for model notices to be created, generated, and disseminated. However, we are not finalizing the provision that required 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.

For 2019, we estimate that it will take all 30 sponsors and PBMs with Part D adjudication systems a total of approximately 93,600 hours 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 since all changes were implemented in 2019. The sponsors and PBMs will need approximately 6 to 12 months to perform system changes and testing. The total time 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 results in the aforementioned 93,600 hour figure (3 workers × 1,040 hours × 30 sponsors/PBMs) at a cost of $9,006,192 (93,600 hours × $96.22/hour).

Consistent with the May 6, 2015 IFC, we continue to estimate that 212 parent organizations will need to create two template notices to notify beneficiaries and prescribers that prescriptions will be rejected due to the prescriber's inclusion on the Preclusion List. We project that it will take each organization 3 hours at $69.08/hour for a business operations specialist to create the two template notices. For 2019, we estimate a one-time total burden of 636 hours (212 organizations × 3 hours) at a cost of $43,935 (636 hours × $69.08/hour) or $207.24 per organization ($43,935/212 organizations). As mentioned, there will be no burden associated with 2020 and 2021 since all changes were implemented in 2019.

We also estimate that it will 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 800 prescribers will be on the preclusion list in early 2019 with roughly 80,000 Part D beneficiaries affected; that is, 80,000 beneficiaries will have been receiving prescriptions written by these prescribers and will therefore receive the notice referenced in § 423.120(c)(6). In 2019 we estimate a total burden of 6,640 hours (80,000 responses × 0.083 hours) at a cost of $260,421 (6,640 hours × $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 will be added to the preclusion list, though this will 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).

TABLE 18—ESTIMATED TIME FOR PART D NOTICE PREPARATION AND DISTRIBUTION

[Hours]

	2019	2020	2021	3-year average
Part D Sponsor—System Programming	93,600	0	0	31,200
Part D Sponsor—Template Creation	636	0	0	212
Part D Sponsor—Letter Preparation and Distribution	6,640	1,245	1,245	3,043
Total	100,876	1,245	1,245	34.455

TABLE 19—ESTIMATED COST FOR PART D NOTICE PREPARATION AND DISTRIBUTION

[Dollars]

	2019	2020	2021	3-year average
Part D Sponsor—System Programming	$9,006,192	$0	$0	$3,002,064
Part D Sponsor—Template Creation	43,935	0	0	14,645
Part D Sponsor—Notice Preparation and Distribution	260,421	48,829	48,829	119,360
Total	9,310,548	48,829	48,829	3,136,069

13. ICRs Regarding the Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152)

CMS will submit the following requirements and burden to OMB for approval under control number 0938–1023 (CMS–10209). We did not receive any comments pertaining to our proposed requirements or burden estimates. Consequently, we are finalizing them as proposed. (*Note:* While CMS–10209 has inadvertently expired, we are proposing to reinstate the collection through this final rule.)

As discussed in section II.B.11. of this rule, we are finalizing our proposal to remove the Quality Improvement Project (QIP) requirements (and CMS-direction of QIPs) from the Quality Improvement (QI) Program requirements. The driver of the anticipated savings is the removal of requirement to attest having a QIP annually.

To derive our savings, we estimate that it takes 1 MA organization 15 minutes (0.25 hour) at $67.54/hour for a compliance officer 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 are 750 QIP attestations annually.

Using these assumptions, we estimate that the removal of the QIP provision will result in a total annual savings of 187.5 hours (750 contracts × 0.25 hour) at $12,663.75 (187.5 hours × $67.54/hour) or $16.89 per contact ($12,663.75/750 contracts).

14. ICRs Regarding Medical Loss Ratio Reporting Requirements (§§ 422.2460 and 423.2460)

The following requirements and burden will be submitted to OMB for approval under control number 0938–1232 (CMS–10476). We received a comment pertaining to our proposed requirements or burden estimates. As discussed later, we are finalizing them as proposed. A summary of the public comment and our response are set out below.

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. As discussed in section II.C.1. of this final rule, our amendments to §§ 422.2460 and 423.2460 will 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 will 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. In the information collection request currently approved by OMB under control number 0938–1232 (CMS–10476), we estimate that 616 MA and Part D contracts will be subject to the MLR data submission requirements for each contract year. Our previous estimate of 616 was based on the number of MA and Part D contracts that we expected would be subject to the

MLR requirements at the time that we published the May 23, 2013 final rule (78 FR 31284). We are revising this estimate to reflect the average number of MA and Part D contracts subject to the MLR data submission requirements for contract years 2014 to 2018. Based on this more recent data, we estimate that 587 MA and Part D contracts will be subject to the MLR data submission requirements for each contract year. The total number of MA and Part D contracts is relatively stable from year to year.

Our estimate for the amount of time that MA organizations and Part D sponsors will spend on administrative tasks related to the amended MLR reporting requirements is based on the burden estimates that are currently approved by OMB under control number 0938–1232 (CMS–10476), but updated to reflect the revised number of contracts discussed earlier and also updated for more current wage and cost information. This is consistent with the approach used in the proposed rule regarding burden estimates. In the approved information collection request, we estimate that, on average, MA organizations and Part D sponsors will spend 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. 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. In our proposed rule, we corrected 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 will 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 this rule's provision to scale back the MLR reporting requirements will reduce the amount of time spent on administrative work by 11 hours, from 47 hours to 36 hours. We also 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 will incur annual MLR reporting costs of approximately $5,045 per contract on average under this final rule as opposed to $6,587 per contract under the current regulations. Consequently, the changes will, on average, reduce the annual administrative costs by $1,542 per contract. Across all MA and Part D contracts, we estimate that this rule's amendment will reduce the annual administrative burden related to MLR reporting by 6,457 hours along with a savings of $904,884. Table 20 compares the estimated administrative burden related to current MLR reporting requirements, burden with updated contract and cost information, and the burden under this final rule.

TABLE 20—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
Annual burden under currently approved collection (OMB control number 0938–1232) (CMS–10476).	616	47	28,952	$135.58/hr	$3,925,312	$6,372
Annual burden (with updated number of contracts and cost) under current regulation.	587	47	27,589	$140.14/hr	$3,866,322	$6,587
Annual burden under this final rule	587	36	21,132	$140.14/hr	2,961,438	5,045
Change in burden under this final rule	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.

We received the following comment, and our response follows:

Comment: A commenter expressed support for the reduction in the MLR reporting burden, and requested that we continue to produce and make available form CMS–10476 as it is useful to assist submitters with their MLR calculations.

Response: We appreciate the support. We intend to continue to make available the prior years' MLR Report on our website (*CMS.gov*) as well as in the Health Plan Management System (HPMS). Therefore, the commenter can continue to utilize the prior years' more detailed MLR Reports to assist with their MLR calculations.

We are finalizing this provision without modification.

C. Summary of Information Collection Requirements and Burden

TABLE 21—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	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/hr	$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/hr	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/hr	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/hr	1,606,110
422.152 QIP	0938–1023	468	(750)	(15 min)	(188)	$67.54/hr	(12,664)
422.222 enrollment**	0938–0685	120,000	(120,000)	varies	(426,000)	varies	(24,077,100)
422.2260 and 423.2260 marketing materials.	0938–1051	527	(39,298)	(30 min)	(19,649)	$69.08/hr	(1,357,353)
422.2460 and 423.2460 MLR reporting.	0938–1232	587	(587)	(11 hr)	(6,457)	$140.14/hr	(904,884)
423.120(c)(6 enrollment)**	0938–1135	340,000	(340,000)	varies	(170,000)	varies	(10,308,800)
423.120(c)(6) create model notices	0938–0964	212	212	3 hr	636	$69.08/hr	43,935
423.120(c)(6) Prepare and test system changes.	0938–0964	90	90	1040	93,600	$96.22	9,006,192
423.120(c)(6) 2019 prepare and distribute the notices.	0938–0964	212	80,000	0.083 hr	6,640	$39.22/hr	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/hr	48,829
423.153(f) notice preparation	0938–0964	219	3,693	0.083 hr	307	$39.22/hr	12,041
423.153(f) notice upload	0938–0964	219	3,693	5 hr	1,095	$81.90/hr	89,681
Subtotal: Private Sector Burden		*varies*	*varies*	*varies*	*(407,171)*	*varies*	*(21,096,484)*
422.62, 423.38, and 423.40 complete enrollment.	0938–0753	18,600,000	558,000	30 min	279,000	*$23.86*	*6,656,940*
Subtotal: Burden on Beneficaries		*18,600,000*	*558,000*	*30 min*	*279,000*	*$23.86*	*6,656,940*
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)
Subtotal: Non-Labor Burden		*n/a*	*(32,026,000)*	*n/a*	*n/a*	*n/a*	*(54,668,382)*
Total		varies	varies	varies	(128,171)	varies	(69,107,926)

*OMB control numbers and corresponding CMS ID numbers: 0938–0753 (CMS–R–267), 0938–1023 (CMS–10209), 0938–0685 (CMS–855A, –855B, and –855I), 0938–1051 (CMS–10260), 0938–1232 (CMS–10476), 0938–1135 (CMS–855O, and 0938–0964 (CMS–10141).

**The requirements and burden were set out in the NPRM text, but the figures were inadvertently excluded from the burden summary table.

This table reflects the following changes from the proposed rule:

- The marketing provision (section II.B.5. of this rule) has changes due to numerical errors and more accurate estimates as documented in the marketing provision.
- The minimum wage was changed from $7.25 an hour to $23.86 an hour. This is explained earlier in the opening section.
- Two rows were deleted from the Table 21 for the CARA provision (section II.B.14. of this rule) since they are properly addressed in the section IV. of this rule (Regulatory Impact Analysis) and do not belong in the this section (Collection of Information).
- One row was added to the preclusion provision (section III.B.12. of this rule) to reflect an omitted row on the burden to programmers to implement changes. The totals and subtotals were updated accordingly.
- Added enrollment figures under §§ 422.222 and 423.120(c)(6).

IV. Regulatory Impact Analysis

A. Statement of Need

This final 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.

This final rule affects Medicare Advantage plans and Part D sponsors (NAICS category 524114 with a minimum threshold for small business size of $38.5 million (*http://www.sba.gov/content/small-business-size-standards*). This final rule additionally effects hospitals (NAICS subsector 622), and a variety of provider categories including physicians, specialists, and laboratories (subsector 621).

To clarify the flow of payments between these entities and the Federal government, note that Medicare Advantage Organizations (MAO) submit proposed plan designs, called bids, in June 2018 for operation in contract year 2019. These bids project payments to hospitals, providers and staff as well as the cost of administration and profits. These bids in turn determine the payments of the Medicare Trust Fund to the MAOs who reimburse providers and other stakeholders for their services. Consequently, our analysis will focus on MAOs.

There are various types of health plans including, HMOs (Part D sponsors and MA plans), Demonstrations, Cost Plans, Prescription Drug Plans (PDP) and PACE plans. 42% of all Medicare health plan organizations are not-for-profit and 32% of all Part D sponsors and MA plans are not for profit (These figures were determined by examining records from the most recent year for which we have complete data, 2016).

There are a variety of ways to assess whether MAOs meet the $38.5 million threshold for small businesses. The assessment can be done by examining net worth, net income, cash flow from operations and projected claims as indicated in their bids. Using projected monetary requirements and projected enrollment for 2018 from submitted bids, 32 percent of the MAOs fell below the $38.5 million threshold for small businesses. Additionally, an analysis of 2016 data, the most recent year for which we have actual data on MAO net worth, also shows that 32 percent of all MAO falls below the minimum threshold for small businesses.

If a final rule has a substantial impact on a substantial number of small entities, the final rule must discuss steps taken, including alternatives, to minimize burden on small entities. While a significant number (more than 5 percent) of not-for-profit organizations and small businesses are affected by this final rule, the impact is not significant. To assess impact we use the data in Table G10 of this section which shows that the raw (not discounted) net effect of this final rule over five years is 1.5 billion dollars. Comparing this number to the total monetary amounts projected to be needed just for 2019, based on plan submitted bids, we find that the impact of this rule is significantly below the 3 percent–5 percent threshold for significant impact. Had we compared the 2019 impact of the final rule to projected 2019 monetary need, the impact would be still less.

In considering the requirements of the RFA certain other aspects of this rule have bearing. The impact of this rule is positive, that is, the rule has a net savings and in fact almost all provisions reduce burden.

We also note that economic burden, when it exists, is not a significant problem for MAOs (whether small or big) since the MAOs pass all burden on to the Trust Fund through the bid and therefore a further alternative to relieve burden is not needed.

Consequently, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities and the requirements of the RFA have been met.

In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any final rule 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 final 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 final 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 final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this final 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 final 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 will take approximately 15.6 hours for each person to review this final 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. Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions

Section 423.153(f) will 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. In the NPRM for this rule, we provided 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 included in the NPRM was 2015. We note that the measurement year for the revised estimates included in Table G22 is 2017.

TABLE 22—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	Estimated number of potentially at-risk Part D beneficiaries
				Original estimates (2015)	Revised estimates (2017) *
1	>=90	4+	4+	33,053	11,753.
	>=90	6+	1+	Minimum Criteria	
2	>=90	4+	4+	52,998	22,569.
	>=90	5+	1+		
3	>=90	3+	3+	103,832	44,332 Minimum Criteria.
	>=90	5+	1+		
4	>=90	3+	3+	152,652	72,246.
	>=90	4+	1+		
5	>=90	3+	3+	319,133	152,438.
	>=90	3+	1+		
	Average MME	Number of opioid prescribers *OR* opioid dispensing pharmacies		Estimated number of potentially at-risk Part D beneficiaries	Estimated number of potentially at-risk Part D beneficiaries
6	Any MME level	7+	7+	47,427 (add'l above Option 1) Supplemental Criteria.	22,841 (add'l above Option 3) Supplemental Criteria.

* Revised estimates use more recent 2017 PDE data (as of January 6, 2018), updated cancer exclusion specifications, and latest opioid drug list and CDC MME conversion factors. Also, buprenorphine products included in prescriber and pharmacy counts.

Under Option 1, CMS proposed to integrate the CARA lock-in provisions with our current Part D Opioid Overutilization Policy/Overutilization Monitoring System (OMS). We proposed to initially define frequently abused drugs as all and only opioids for the treatment of pain. The guidelines to identify at-risk beneficiaries will be the current Part D OMS criteria finalized for 2018 after stakeholder input. Plans that adopt a drug management program will have to engage in case management of the opioid use of all enrollees who meet these criteria, which will be reported through OMS and plans must provide a response for each case. The integration of CARA lock-in provisions with our current policy will allow plans to use pharmacy/prescriber lock in as an additional tool to address the opioid overutilization of identified at-risk beneficiaries.

In the proposed rule, we estimated that the CARA provisions would result in a net savings of $10 million (the estimated savings of $13 million [rounded up from $12.6 million] less the total estimated costs of $2,836,651 = $10,163,349) in 2019. However, as noted in the preamble, we are finalizing modifications to our proposed policy on implementation of drug management. These modifications will have implications on the projected savings for the CARA provisions. First, we are expanding the definition of frequently abused drugs to include opioids and benzodiazepines for purposes of Part D drug management programs beginning 2019. Second, with respect to clinical guidelines, we are finalizing the criteria we proposed in Option 3 above as a ''floor'' that Part D plan sponsors must adopt, consistent with the current policy as well as allowing sponsors to continue to report additional beneficiaries to OMS—and will adopt the following supplemental criteria, which will serve as a ''ceiling'': Use of opioids (regardless of average daily MME) during the most recent 6 months with 7 or more opioid prescribers OR 7 or more opioid dispensing pharmacies. These ceiling criteria were included in the additional criteria options that we set forth in the chart above in the proposed rule; specifically, in Row 2 of option 6. We are finalizing as the clinical guidelines floor and ceiling criteria that include a program size of approximately 67,000 beneficiaries—44,000 of whom Part D sponsors with drug management programs must review and 23,000 of whom such sponsors may review.

Therefore, we estimate that the finalized CARA provisions, in 2019, will result in a net cost of $2,836,652 to industry (plan sponsors) with a benefit of reduction in opioid prescriptions which will reduce Trust Fund spending by $19 million dollars. The following are details on each of these estimates.

There are an additional ~23,000 at-risk beneficiaries that we estimate would be added to the drug management programs as a result of the ceiling criteria. 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 will impact the remaining 39 percent of at-risk beneficiaries. CMS anticipates between 10 and 30 percent reduction in prescriptions for frequently abused drugs will be possible through drug management programs and picked the average, 20 percent. Therefore, in the proposed rule, we stated that we believe there could be a 20 percent reduction in the prescriptions for frequently abused drugs for at-risk beneficiaries. Similar to the ~44,000 at-risk beneficiaries identified by the floor criteria, we assumed that 39 percent of the additional 23,000 will reduce their opioid usage by 20 percent under the program.

We used a proxy to identify costs for these additional 23,000 at-risk beneficiaries, which is to pull the beneficiaries with opioid scripts with 7 or more pharmacies in the most recent 6 months who weren't part of the 44,000 under the floor criteria. However, we got only about 20,000 count. Since we couldn't pull those with 7 or more prescribers easily, we assumed the remaining 3,000 were those with 7 or more prescribers. For those 20,000, their opioid cost was only $31 million and their benzodiazepines cost was $1 million. Similar to the other 44,000, we assumed that 39 percent of the 20,000 will reduce their opioid usage by 20 percent under the program. For those 39 percent, the opioid cost for the additional at-risk beneficiaries that would be identified by the ceiling criteria was only $10 million and their benzodiazepine cost was less than $0.4 million. In fact, the 39 percent of those

44,000 at-risk beneficiaries identified by the floor criteria only incurred $1 million of benzodiazepine costs. As a result, because the benzodiazepine spending among at-risk beneficiaries was so small and the potential savings from this program should be much smaller than that for opioids, CMS did not include the potential savings for benzodiazepines to this savings estimate.

Because we used a proxy to identify costs for the additional 23,000 at-risk beneficiaries and the opioid spend was not that significant, we assumed the cost distribution is similar to those 20,000. Since CMS scored the opioid savings for $2 million on the 20,000, we scaled it up by 23,000/20,000 to get $2.3 million savings in opioid for the ceiling criteria.

Therefore, the combined projected dollar savings to the Medicare Trust Fund for opioids for at-risk beneficiaries identified by both the ceiling criteria ($2.3 million) and floor criteria ($16.3 million) is about $19 million (rounded up from $18.6 million) in 2019. Since the $19 million is an effect of the rule, it is classified as a benefit.

TABLE 23—ESTIMATED BENEFITS TO THE TRUST FUND OF THE CARA 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							
Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions.	Various	19	19	19	20	20	$97

Part D plan sponsors will 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 decides 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 will 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 × 0.083 hour) at a cost of $12,040.54 (307 hour × $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 will 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/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 $101,722 ($12,041 + $89,681) in 2019 in section III of this final 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 will 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 × $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 × 20 hours per sponsor) at a cost of $505,720 (3,760 hour × $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 will 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 will 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 will 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 × $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 will 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 × 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 appeals × 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 hours × $197.66.

In aggregate, this provision will result, in 2019, in a net cost of $2,836,652 ($101,722 + $547,415 + $2,152,332 + $35,183). Additionally, an effect of the regulatory lock-in is a benefit of reduced opioid scripts resulting in a reduction of $19 million in payments by the Trust Fund.

We received the following comments and our response follows:

Comment: A commenter agreed with CMS's estimate that the proposed Medicare lock-in program could prevent or reduce the human toll of opioid abuse and overuse and generate a savings in 2019 of $13 million to the Trust Fund because of reduced scripts, and that our estimate of savings are consistent with recent research that found that lock-in programs have reduced spending on opioid prescriptions and decreased the number of prescriptions and pharmacies used by at-risk individuals in state Medicaid programs.

Response: We thank the commenter for their agreement. We do note that modifications to the CARA provisions have been finalized, which has changed the regulatory impact. We now anticipate a projected savings of $17 million in 2019.

2. Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503 and 423.504)

The final provision will 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 will 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 will 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® website 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 website 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 × 1,103 × 1 hour) that is 5,294,400 hours of burden that will be eliminated by this proposal. If we add pharmacists, pharmacy technicians, billing offices, physician practice groups, we will 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 will be expected to take the training under the current regulation, but we hope this example demonstrates the reduction in burden this proposal will mean for the industry.

We requested comment in order to develop a more complete monetization of cost savings. However, we received no comments on this burden estimate in the proposed rule.

We did receive numerous comments on the corresponding regulatory proposal, with overwhelming support for finalizing the provision as proposed. Most commenters who expressed their support for the proposal commented on the tremendous burden the current CMS compliance training requirements imposed, and agreed with CMS that the proposal would greatly reduce burden on FDRs and sponsoring organizations.

Therefore we are finalizing this provision as proposed without a quantitative estimate of impact.

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 × 2 = $109.74. Therefore, we estimate a savings of 2 hours per plan × 2,743 plans = 5,486 hours reduction in hourly burden with a savings in cost of 5,486 hours × $109.74 = $602,033.64, rounded down to $0.6 million to be

saved annually under this proposal. The $0.6 million reflects a savings to industry from reduced use of actuarial resources.

The number of plan bids received by CMS may increase because of a variety of factors that are not related to the elimination of the meaningful difference requirement, such as payments, bidding and service area strategies, serving unique populations, and in response to other program constraints or flexibilities. Business decisions made by MA organizations or potential MA program new entrants that are not related to the elimination of the meaningful difference requirement are not included in this impact analysis. As noted in the preamble discussion, several commenters expressed concerns about the ability of Medicare beneficiaries to make the nuanced comparisons among various plan types and benefit packages, limited resources to assist beneficiaries with complicated decisions, and older people and people with disabilities not using technology to the same extent as non-Medicare beneficiary populations in making plan comparisons (for example, MPF). CMS expects that eliminating the meaningful difference requirement will improve plan choice for beneficiaries by driving provider network and benefit package innovation and affordable health care coverage. Several commenters, as discussed in the preamble, noted that eliminating the current meaningful difference requirement that established arbitrary differences between plans will allow MA organizations to put the beneficiary at the center of benefit design as MA organizations will not be pressured to make benefit changes to comply with an arbitrary requirement that may ultimately result in higher premiums and/or cost sharing for beneficiaries. This will result in MA organizations being able to offer a portfolio of plan options with clear differences between benefits, providers, and premiums that are more easily understood by beneficiaries. CMS expects that eliminating the meaningful difference requirement will improve the plan options available for beneficiaries, but does 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. As it is unknown how many organizations will choose to add plan options as a result of this provision, we are unable to estimate the impact to beneficiaries should this lead to more competition. CMS expects increased competition will lead to potentially lower premiums and/or cost-sharing for Medicare beneficiaries. CMS does not anticipate beneficiaries will need additional time to compare differences between plans related to the elimination of the meaningful difference requirement. This particular change is expected to help MA organizations differentiate plan offerings more effectively so that beneficiaries can make decisions more efficiently. We believe that the tools and information CMS provides for beneficiaries to make decisions (for example. Medicare Plan Finder, Medicare and You Handbook, 1–800–MEDICARE), in addition to our enforcement of communication and marketing requirements, aim to mitigate any potential choice overload.

CMS does not believe this 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. In addition, CMS does not expect a significant increase in time spent on bid review as a result of eliminating meaningful difference requirement nor does CMS expect this change will increase provider burden.

We received the following comments, and our response follows:

Comment: A few commenters supported this proposal and referenced the potential savings in a positive manner.

Response: We thank the commenters for their support.

Comment: Some commenters had concern that eliminating the meaningful difference requirement would result in a large number of plan options and believe this potential outcome may challenge or complicate beneficiary decision-making; these commenters questioned if elimination of the requirement provides enough benefits to outweigh the risks. A commenter did not support this proposal but noted that the estimated savings from eliminating the meaningful difference requirement was significant. This commenter stated concern that this proposal would result in beneficiary choice anxiety from the potential increase in plan options. Another commenter did not find the estimated savings significant enough to warrant finalizing this proposal.

Response: The intention of this proposal is 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. The primary motivation for our proposal is the improvement of plan innovation for a growing MA beneficiary population; reduction of resources and plan expenses was not a major factor in this particular proposal. The number of plan bids may increase because of a variety of factors that are not related the elimination of the meaningful difference requirement, such as new MA entrants, payments, bidding and service area strategies, serving unique populations, and in response to other program constraints or flexibilities. MA organizations are expected to continue designing PBPs that, within a service area, are different from one another with respect to key benefit design characteristics. MA organizations also consider beneficiary choice anxiety when developing their own portfolio of plan offerings, so that sales and broker personnel and marketing materials can highlight key differences between their plan offerings and support informed choice. CMS will continue to provide beneficiaries with tools, such as MPF, to evaluate plan options and assist in choosing the best option. Beneficiaries may continue to limit their choices based on characteristics, such as plan type, Part D coverage, differences in provider network, Part B and plan premiums, and unique populations served (for example, special needs plans). As stated in Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review (§§ 422.254 and 422.256), we are going to use our existing authority at § 422.2268, and CMS will monitor to ensure organizations are not engaging in activities that are discriminatory or potentially misleading or confusing to Medicare beneficiaries. CMS will communicate and work with organizations that appear to offer a large number of similar plans in the same county and discuss any concerns. For example, from a beneficiary's perspective, CMS would expect plans within the same contract, plan type and county be distinguishable by beneficiaries using such factors as the inclusion or exclusion of Part D coverage, provider network, plan premium, Part B premium buy-down, estimated out-of-pocket costs, and benefit design. CMS intends to issue guidance through the annual Call Letter process and HPMS memoranda to help organizations avoid potential beneficiary confusion; we expect a minimal number of contacts with MA organizations regarding these concerns.

We received less than 10 comments on this proposal that specifically

referenced the estimated savings of eliminating the meaningful difference requirement and the only concern noted about the estimated savings was that it was not significant. Therefore, we are finalizing this provision without modification.

4. Physician Incentive Plans—Update Stop-Loss Protection Requirements (§ 422.208)

As we discussed in the proposed rule, 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. With this final rule we are replacing the current insurance schedule in the regulation with updated stop-loss insurance requirements that will allow insurance with higher deductibles. This updated schedule will 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 described below.

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.

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TABLE 24: COMBINED ATTACHMENT POINTS

Combined Institutional And Professional	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	1400	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	Above 25,000
Net Benefit Premiumm 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

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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 24, 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.

Next, we compute the premium under the finalized rule. We still assume an average of 6,000 capitated members. However, the finalized rule allows higher deductibles corresponding to medical inflation. The new deductibles may be found in Table 26. 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 difference in premium between using (i) § 422.208(f)(iii) to calculate deductibles (combined attachment point) and (ii) using Table 26 to calculate deductibles results in a savings of $2,000 − $1,500 = $500 PMPY. We assume that the average loading for profit and administrative costs is roughly 20 percent. So our PMPY savings is 20 percent × 500 = $100 PMPY.

The $500 PMPY savings is not true savings since the plans and physicians are simply trading claims for premiums to the insurance company. Since the net impact is $0, the $500 is not listed as either a savings or transfer. However, the reduced $100 PMPY for profit and admin reflects a reduction in reinsurance service resources and hence is classified as a savings. However, not all of the $100 PMPY results in reductions in dollars spent by the Trust Fund. The details are as follows.

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 million × 11 percent = 2,046,000 MA members are paid under some degree of global capitation. Accordingly, using our revised stop loss insurance requirement in this final rule, we estimate the total aggregate projected annual savings, reflecting a reduction in reinsurance services will be roughly $100 PMPY × 2,046,000 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 ⅔. We therefore assumed that of the $204.6 million in annual savings, the Medicare Trust fund will reduce payments by 35 percent × $204.6 million = $71,610,000; the remaining 65 percent × $204.6 million = $132,990,000 will be returned to the plans as rebates. These rebates will 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.*

We received no comments on our impact analysis. However, we did receive comments on the methodology CMS is using to calculate stop loss insurance requirements. We respond to those comments in the preamble and the section for the Physician Incentive Plan regulation update to 42 CFR 422.208.

We are finalizing the update to the physician incentive regulation stop-loss table as proposed.

5. Changes to the Agent/Broker Requirements (§§ 422.2272(e) and 423.2272(e))

We proposed 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 proposed 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 will 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.

We received no comments on this proposal and therefore are finalizing this provision without modification.

6. Coordination of Enrollment and Disenrollment Through MA Organizations and Effective Dates of Coverage and Change of Coverage

We proposed 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 and issue written notification of the enrollment a minimum of 60 days in advance of their Medicare eligibility.

Our proposal represented the partial codification of existing policy on seamless conversion enrollment that has been specified in subregulatory guidance since 2006, but with additional parameters and limits. Under the new requirements, seamless conversion default enrollments can only occur from the organization's Medicaid managed care plan into an integrated D–SNP with facilitation from the state (in the form of a contract term and provision of data). This will result in the discontinuation of the use of the current 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 changes will have any impact to the Medicare Trust Funds.

We did not receive comments on the burden estimates associated with this proposal. We did receive comments on the substantive proposal, which we address in this final rule. As indicated in the preamble to this final rule, we are finalizing the proposed changes with the following modifications, none of which we believe will result in any impact to the Medicare Trust Funds.

• Section 422.66(c)(2)(i) is revised to clarify that we will allow default enrollment into a FIDE–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.

• Section 422.66(c)(2)(i) is revised to clarify that, for an organization to be approved for default enrollment, it must have an overall quality rating, from the most recently issued ratings, under the rating system described in §§ 422.160 through 422.166, of at least 3 stars or is a low enrollment contract or new MA plan as defined in § 422.252. In addition, the MA organization must not be under an enrollment suspension.

• Section 422.66(c)(2)(ii) is revised to include an approval period not to exceed 5 years, subject to CMS authority to rescind or suspend approval if the plan is non-compliant.

• Section 422.66(c)(2)(iv) is revised to state that the notice issued by the MA organization will include information on the differences in premium, benefits and cost sharing between the individual's current Medicaid managed care plan and the dual eligible MA special needs plan and the process for accessing care under the MA plan; an explanation of 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 MA plan; and a general description of alternative Medicare health and drug coverage options available to an individual in his or her Initial Coverage Election Period.

• Section 422.66(c)(2)(iv) is revised to clarify that the mandatory notice is in addition to the information and documents required to be provided to new enrollees under § 422.111.

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 estimating the additional costs for the projection window 2019–2023, we assumed that approximately 24,600 MA-enrolled individuals would 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 research [1] 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 will take advantage of the new open enrollment period.

We applied 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 figured that 24,600 (20,512,000 × 10 percent × 15 percent × 40 percent × 20 percent) people are expected to enroll in the 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 costs 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 25 that demonstrates the calculations and displays the cost estimates for each year 2019–2023. These costs are classified as transfers since there is no increase in resources. The costs reflect switching from health plans without bonuses to health plans with bonuses. Thus the healthcare services to the enrollees that switch remain the same (no increase in resources) albeit at a higher cost.

TABLE 25—CALCULATION OF INCREASED DOLLAR SPENDING BY 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

To the impact on the Trust Fund, must be added the impact on Part C plans and Part D sponsors from enrollment. This impact was estimated in the Collection of Information section as $6.1 million ($3.2 million for determining eligibility + $0.64 million for notification of enrollees + $0.64 million for submission of enrollment information to CMS + $1.6 million for storage of enrollment forms). Determination of eligibility, notification of enrollees, and submission to CMS use added resources and therefore are classified as a cost to the plan. However, the cost of storage is classified as a transfer since the costs of storage of enrollment by the plan elected during

the open enrollment period are offset by the savings of cost of storage of enrollment by the former plan from which enrollment is taking place. Thus, $1.6 million of the $6.1 million is a transfer between plans and sponsors while the remaining $6.1 − $1.6 = $4.5 million is an actual cost.

Hence, the total cost of this open enrollment provision for 2019 is $4.5 million with a transfer of $10.6 million ($9 million to the Trust fund + $1.6 million in enrollment actions).

We received no comments on the reduction in burden estimates associated with this proposal. We received comments on the substantive proposal, which we address in this final rule. As indicated in the preamble to this final rule, we are finalizing this provision as proposed.

8. Lengthening Adjudication Timeframes for Part D Payment Redeterminations and IRE Reconsiderations

We believe the 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. 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 website 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 changes involve requests for payment where the enrollee has already received the drug, we do not believe the changes will impose undue burden on enrollees.

We did not receive comments on the reduction in burden estimates associated with this proposal. We did receive comments on the substantive proposal, which we address in this final rule. As indicated in the preamble to this final rule, we are finalizing this provision as proposed.

9. Elimination of Medicare Advantage Plan Notice for Cases Sent to the IRE

The changes at § 422.590(f) will 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 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 website 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, result in $34.66 an hour. Thus, the reduction in administrative time spent will be 0.083 hours × 47,108 cases = 3,910 hours with a consequent savings of 3,910 hours × $34.66 per hour = $135,520. This is a savings to industry since it reduces the computer and staff resources needed to produce and send out notices.

We do not believe the change will adversely impact health plan enrollees. The notice requirement we are eliminating is duplicative and enrollees will be notified by the IRE that their case was received by the IRE for review.

We did not receive comments on the burden estimates outlined in the proposed rule, therefore we are finalizing this provision as proposed.

10. Revisions to Parts 422 and 423, Subpart V, Communication/Marketing Materials and Activities

CMS proposed 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 will 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 will more specifically outline the materials that are and are not considered marketing materials.

We believe the net effects of the proposed changes will 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 final rule, we estimated the reduced burden to industry at $1.4 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 × $1.4 million = $0.14 million.

We received no comments on our proposal and therefore we are finalizing this provision without modification.

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

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 modify the methodology of the Star Ratings assigned to consolidating contracts and to codify that methodology. The methodology and measures 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 will 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 will dissuade many plans from consolidating contracts since it will be possible for some plans to lose QBPs under certain scenarios. If less contracts consolidate to higher Star Ratings, less QBPs will be paid to plans and this will result in Trust Fund transfers. Plans receiving smaller or no bonuses may reduce benefits, thus transferring the costs of benefits to the beneficiary, but we do not believe this will be widespread since plans would lose enrollees if they excessively curtailed benefits.

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 will 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 Star Rating methodology changes, there will still be 50 percent of the projected impacted enrollees that will 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 26. These savings are classified as transfers because there is no reduction of resources. The savings result from enrollee transfers between health plans with and without QBP. Thus the healthcare services remain the same (no reduction), albeit at a cheaper price.

TABLE 26—CALCULATIONS OF NET SAVINGS PER YEAR TO THE MEDICARE TRUST FUND 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	$200,000 \times 1.03$	44.73×1.05^{2}	12	50	66	86	35
2021	$200,000 \times 1.03^{2}$	44.73×1.05^{3}	12	50	66	86	37
2022	$200,000 \times 1.03^{3}$	44.73×1.05^{4}	12	50	66	86	40
2023	$200,000 \times 1.03^{4}$	44.73×1.05^{5}	12	50	66	86	44

We received the following comments and our response follows:

Comment: A commenter urged CMS to provide additional detail underlying its estimate in the regulatory impact analysis of the proposed rule.

Response: CMS compared the Star Ratings for those plans that were cross-walked from one contract to a different contract. The enrollment estimate of 160,000 in 2018 was calculated by estimating the number of enrollees that were cross-walked from a non-Quality Bonus Payment plan in 2017 to a Quality Bonus Payment plan in 2018. An updated estimate would be significantly higher if CMS were to have compared the enrollment from the non-Quality Bonus Payment plans in the 2018 star ratings before cross-walks to the enrollment from Quality Bonus Payment plans in the 2018 star ratings after cross-walks. Since the preliminary Star Ratings are published in the fall of the prior year, the plans are given time to complete the cross-walk procedures before the Medicare Advantage bids are submitted in the spring of the following year.

Summary of Regulatory Changes

For the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the provisions as proposed at §§ 422.162(b)(3) and 423.182(b)(3) without modification.

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, as discussed in the following sentences. 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 CMS estimates, we do not anticipate additional government or beneficiary cost impacts from this provision.

TABLE 27—ESTIMATED AGGREGATE COSTS AND SAVINGS TO THE HEALTH CARE SECTOR FOR THE ANY WILLING PHARMACY 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

Final clarification of Any Willing Pharmacy rules, and clarification of the definition of retail pharmacy will 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.'' [83] [84] 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.

We received the following comments and our response follows:

Comment: A commenter suggested that by eliminating preferred pharmacy networks, the proposed any willing pharmacy policy would cost the government in excess of $175 million for even a moderate decrease in the number of preferred pharmacies. This same commenter, along with others, urged us to clarify that we are not rolling back Part D plan sponsors' ability to create and maintain preferred pharmacy networks.

Response: We thank the commenters, however, their concern was predicated on the idea that we proposed to eliminate Part D plan sponsors' ability to create and maintain preferred pharmacy networks. As we explicitly stated and elaborated elsewhere in this final rule, this policy in no way changes existing policy regarding Part D plan sponsors' ability to create and maintain preferred pharmacy networks.

We are finalizing as proposed our timing of contracting requirements at § 423.505. We are finalizing, as modified, our definition of retail pharmacy at § 423.100, having removed the mention of retail cost sharing. We are not finalizing our proposed definition of mail order pharmacy.

13. Eliminating the Requirement To Provide PDP Enhanced Alternative (EA) to EA Plan Offerings With Meaningful Differences (§ 423.265)

The 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''. When 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 will be approximately 275 EA to EA plan pairings that will be required actuary time spent in evaluation of the meaningful difference requirement. We further estimate that it will 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 = $60,357. 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). As it is unknown how many organizations will choose to add a second EA plan as a result of this provision, we are unable to estimate the impact to beneficiaries should this lead to more competition. Presumably, increased competition could lead to potentially lower premiums and/or cost-sharing for Medicare beneficiaries.

We did not receive comments, specific to the regulatory impact analysis, on this proposal.

14. 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 provisions will be those identified in the collection of information section of this final 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 will accrue from individuals and entities no longer required to enroll in or opt-out of Medicare to prescribe Part D drugs or furnish Part C services and items. The savings and cost by year are summarized in Table 28. As explained in the Collection of Information section of this final rule, the savings and cost of this analysis reflect increased and reduced use of resources respectively: Providers and suppliers save $10.3 and $24.1 million from the removal of the requirement to enroll in Medicare as a prerequisite to furnishing health care items and services to Medicare Advantage enrollees; this reduces

[83] 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.*

[84] 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.*

resources needed for such enrollment. Part D sponsors or their PBMs spend $9.3 million in additional resources to program edits into plan systems as well as produce and send required notifications to enrollees. The net savings, is $25.1 million as shown.

TABLE 28—SAVINGS AND COST TO INDUSTRY AND PROVIDERS ARISING FROM THE PRECLUSION PROVISION

Item/year	2019	2020	2021	2022	2023
Part D Cost	−$9,310,548	−48,829	−48,829	−48,829	−48,829
Part D Savings	10,308,800	.....	.....	.....	.....
Part C Savings	24,077,100	.....	.....	.....	.....
Net Savings	25,075,352	−48,829	−48,829	−48,829	−48,829

Costs associated with an alternative approach are found in the Alternatives Considered portion of this section.

We will be responsible for the development and monitoring of the preclusion list using our own resources. We do not anticipate a change in the number of individuals or entities billing for service, for we will 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 welcomed public comment on these estimates, for we believed that stakeholder feedback could assist us in developing more concrete projections. We received no comments on this proposal and therefore are finalizing this provision without modification.

15. Removal of Quality Improvement Project for Medicare Advantage Organizations (§ 422.152)

This provision will 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 government reviews these attestation submissions. To estimate amounts, we considered how many QIP attestations are performed annually.

We estimated that—

- This review requires one person reviewing for 0.25 hours for a single QIP attestation. We assumed 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 website at *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2017/general-schedule/.*
- We calculated 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) ($750 \times 1 \times \$102.96 \times 0.25$ 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 final rule, and $19,305 are savings to the federal government.

We received no comments on the RIA for this proposal, and therefore, we are finalizing the RIA without modification.

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 to perform initial analyses or desk reviews of the detailed MLR reports submitted by MA organizations and Part D sponsors. These initial analyses or desk reviews are done by our contractors 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 will be receiving only the minimum amount of data from MAOs and Part D sponsors, we expect that we will 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 will continue to use the HPMS or a similar system to submit and attest to their simplified MLR submissions, we will 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 that, by eliminating these services, we will reduce our payments to contractors by approximately $100,000 a year.

In total, we estimate that the changes to the MLR reporting requirements will save the government $490,000 a year. As noted in the Collection of Information section of this final rule, the 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 final 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) will 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.

We received no comments on our regulatory impact analysis and are finalizing this provision.

17. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes (§§ 423.100, 423.120, and 423.128)

The provisions will 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) generics released after their initial formulary submission date 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 two 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 proposed 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 website, *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 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 will 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 will overlap across plan years a minimal amount of times. We received no comments on our regulatory impact analysis and are finalizing this provision with modifications discussed in II.A.14.

18. Similar Treatment of Biosimilar and Interchangeable Biological Products and Generic Drugs for Purposes of LIS Cost Sharing

a. Savings

Codification of lower cost sharing for biosimilar and interchangeable biological products for LIS enrollees will reduce marketplace confusion about what level of cost-sharing Part D enrollees should be charged for biosimilar and interchangeable biological products. By establishing cost sharing at the lower level for LIS enrollees, this provision will also improve LIS enrollee incentives to use biosimilar and interchangeable biological products instead of reference biological products. As discussed in the proposed rule, this will reduce costs for 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 enrollee protections while also improving enrollee incentives to choose biosimilar and interchangeable biological products over reference biological products. Improved incentives to choose lower-cost alternatives will reduce costs to Part D enrollees and the Part D program. CMS estimates this proposal will provide a modest savings of $10 million in 2019, with savings increasing by approximately $1 million each year through 2028. These savings are classified as transfers since there is no reduction in services; drugs are still being sold, albeit at a cheaper price because of the use of biosimilar biological products.

CMS anticipates some natural shift from reference biological products to biosimilar and interchangeable biological products, but biosimilar 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 nine approved (as of March 7, 2018) biosimilar biological products. The market dynamic between Neupogen® and Zarxio® has behaved consistent with CMS' anticipation and CMS expects other biosimilar biological products to follow the similar pattern. Based on 2017 year-to-date data on the per script price difference between Neupogen® and Zarxio®, CMS estimated biosimilar biological products to be 16 percent less expensive than their reference biological product. CMS estimates this proposal will result in a minor shift of an additional 5 percent of prescriptions to biosimilar biological products by LIS enrollees under this proposal. Consequently, savings are not estimated to be significant at this time.

TABLE 29—ESTIMATED SAVINGS TO THE MEDICARE TRUST FUND FOR CALENDAR YEARS 2019 THROUGH 2023 FOR SIMILAR TREATMENT OF BIOSIMILAR AND INTERCHANGEABLE BIOLOGICAL PRODUCTS AND GENERIC DRUGS FOR PURPOSES OF LIS COST SHARING

Provision	Regulation section(s)	Calendar year ($ in millions)					Total CYs 2019–2023 ($ in millions)
		2019	2020	2021	2022	2023	
Federal Government (Medicare) Impacts							
Similar Treatment of Biosimilar and Interchangeable Biological Products and Generic Drugs for Purposes of LIS Cost Sharing.	§ 423.4	10	11	12	13	14	60

b. Benefits of Similar Treatment of Biosimilar and Interchangeable Biological Products and Generic Drugs for Purposes of LIS Cost Sharing

Final codification of lower cost sharing for biosimilar and interchangeable biological products for LIS enrollees will reduce marketplace confusion about what level of cost-sharing LIS enrollees should be charged for biosimilar and interchangeable biological products. By establishing cost sharing at the lower level, this provision will also improve Part D enrollee incentives to use biosimilar and interchangeable biological products instead of reference biological products. As discussed previously, this will reduce costs to Part D enrollees and generate savings for the Part D program.

We received the following comments, and our response follows:

Comment: A couple of commenters noted that our proposed change generates administrative burden for Part D plan sponsors due to programming changes.

Response: We appreciate the commenters' perspective, however we believe that the benefit to LIS Part D enrollees outweigh the concerns regarding Part D plan sponsor's administrative burden. Given the low number of biosimilar biological products on the market, it is not apparent to us that this would require significant administrative burden on

Part D plans to identify such products and implement this change.

We are finalizing our proposal as modified, amending § 423.782(a)(2)(iii)(A) and § 423.782(b)(3) instead of § 423.4.

19. Changes to the Days' Supply Required by the Part D Transition Process (§ 423.120)

We do not believe that finalizing 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 supplies to plan enrollees in the LTC and outpatient settings, they will only have to make a technical change to these systems that consists of changing the required number of days' supply to the approved month's supply in their plan benefit package. 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 provision would impose any new burden on LTC facilities and the pharmacies that serve them. We believe this regulation will eliminate the additional time that LTC facilities and pharmacies have to transition Part D patients—time we now believe they do not need to effectuate the transition.

In the context of requesting that we not reduce the transition supply from 90 days to a month, commenters generally indicated that preparing for transitions created an administrative burden. We acknowledge and appreciate the efforts undertaken to smooth transitions, but do not believe our provision in and of itself would create any new burden. While they would have a smaller time frame in which to take actions, LTC facilities and pharmacies would need to make the same outreach calls to health care providers as has previously been the case—albeit within a shorter period of time. And while we are recommending that LTC pharmacies try to anticipate and plan for somewhat predicable events such yearly changes to benchmark status necessitating beneficiary moves, it is not inconceivable that to the extent required, these entities might undertake contingency planning that could ultimately lessen the administrative burdens over the long run.

We believe this provision would 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.

D. Alternatives Considered

1. 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.

2. Similar Treatment of Biosimilar and Interchangeable Biological Products and Generic Drugs for Purposes of LIS Cost Sharing

The critical policy question was how to provide lower cost sharing for biosimilar and interchangeable biological products for LIS enrollees. Classifying biosimilar and interchangeable biological products as generic drugs only for cost-sharing purposes for LIS enrollees risked confusion in the marketplace which could lead to inappropriate utilization of biosimilar and interchangeable biological products and in turn, increased costs to the Part D program. Adding biosimilar and interchangeable biological products to regulatory cost-sharing provisions for LIS enrollees can appropriately resolve marketplace confusion while also improving Part D enrollee incentives to choose lower cost alternatives.

3. Preclusion List

We considered a preclusion list that will include providers and suppliers who are prescribing Part D drugs and 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: Encounter data and Prescription drug event (PDE) which 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 will occur after the service, item or drug was provided to the Medicare beneficiary. We estimate that it will cost the Trust Fund approximately $42.8 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 will 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 460,000 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 1,840 new revocations. Based on the approximate 1-month delay in the availability of the PDE and encounter data, 3 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 1,840 new revocations, a delay in screening will cost the Trust Fund approximately $42.8 million ($3,324 × 7 × 1,840). 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.

E. Accounting Statement

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Table 30 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 30 is based on Table 31 which lists savings, costs, and transfers by provision.

TABLE 30—ACCOUNTING STATEMENT: CLASSIFICATIONS OF ESTIMATED SAVINGS, COSTS, AND TRANSFERS FROM CALENDAR YEARS 2019 TO 2023

[$in millions]

	Savings			Whom to whom
	Discount rate		Period covered	
	7%	3%		
Net Annualized Monetized Savings	295.23	296.29	CYs 2019–2023	MA Organizations and Part D Sponsors, Industry, Govt.
Annualized Monetized Savings	302.53	303.59	CYs 2019–2023	MA Organizations and Part D Sponsors, Industry, Govt.
Annualized Monetized Cost	(7.30)	(7.30)	CYs 2019–2023	MA Organizations and Part D Sponsors, Industry, Govt.
Transfers	37.17	37.41	CYs 2019–2023	Federal Government, MA plans and Part D Sponsors, Providers and Re-insurers.

Note: Monetized figures in 2018 dollars. Positive numbers indicate aggregate level annualized savings at the giving percentage. Transfers are a separate line item. Table 30 is based on Table 31. Minor (cent) errors are due to rounding.

The following Table 31 summarizes savings, costs, and transfers by provision and formed a basis for the accounting table.

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TABLE 31: SAVINGS, COSTS, AND TRANSFERS BY PROVISION

	2019 Savings	2019 Transfers	2020 Savings	2020 Transfers	2021 Savings	2021 Transfers	2022 Savings	2022 Transfers	2023 Savings	2023 Transfers
Totals	280.8		271.7		290.0		310.3		332.9	
Tot savings	288.1		279.0		297.3		317.6		340.2	
Tot costs	-7.3		-7.3		-7.3		-7.3		-7.3	
Total Transfers		31.4		34.4		37.4		40.4		44.4
CARA	-2.8		-2.8		-2.8		-2.8		-2.8	
OEP	-4.5	-10.6	-4.5	-11.6	-4.5	-11.6	-4.5	-12.6	-4.5	-13.6
MLR	1.4		1.4		1.4		1.4		1.4	
Disclosure	54.7		54.7		54.7		54.7		54.7	
Marketing	1.5		1.5		1.5		1.5		1.5	
Meaningful Difference (Part C)	0.6		0.6		0.6		0.6		0.6	
Meaningful Difference (Part D)	0.1		0.1		0.1		0.1		0.1	
Stop Loss (PIP)	204.6		220.6		238.9		259.2		281.8	
Part C/D Preclusion	25.1									
Elimination of notices for cases sent to IRE	0.1		0.1		0.1		0.1		0.1	
Treatment of Biosimilar and Interchangeable Biological Products as Generic Drugs		10.0		11.0		12.0		13.0		14.0
Star Ratings		32.0		35.0		37.0		40.0		44.0

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. All numbers are rounded to the nearest $100,000.

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F. Conclusion

This final rule has a net savings of between $280 to $335 million for each of the next 5 years. The savings are equivalent to a level annualized amount of about $295 million per year for both 7 percent and 3 percent interest rates. These net savings are to Part D sponsors, Part C plans, pharma, providers, industry, as well as the federal government. Transfers between the federal government, Part C plans, Part D sponsors, re-insurers, and providers are between $30 and $45 million and are equivalent to a monetized level amount of about $37 million per year at the 3-percent and 7-percent levels. Both industry and the federal government save from program efficiencies and reduced work.

As a result of benefits, savings, and transfers of this final rule, the Medicare Trust Fund, in 2019, will reduce in aggregate its cost for paying for plan benefits by $123.6 million dollars ($19 million from the CARA provision + $71.6 million from the physician incentive plans provision + $10 million from the provision to treat biosimilar and interchangeable biological products as generic drugs for purposes of LIS cost sharing + $32 million from the star ratings provision −9 million from the open enrollment provision). This reduction in Medicare Trust Fund costs will gradually increase; in 2028, the Trust Fund is expected to reduce costs by $241.7 million dollars. These savings to the Medicare Trust Fund are actuarially equivalent to a level amount of about $170 million per year in 2018 dollars ($171.69 million discounted at the 3% level, and $167.75 million per

year discounted at the 7% level). These savings do not include the MLR provision savings of $490,000 savings a year due to not paying a contractor nor the marketing material provision savings of $140,000 a year due to reduced time spent by Federal employees reviewing marketing materials.

Additionally, this final rule is beneficial to beneficiaries. The impact of this final rule on beneficiaries is complicated with some provisions beneficial, one provision burdensome, and the rest neutral. Although quantitative formulations of the impacts can sometimes be provided, because of the variability of many factors, in many cases, impact can only be measured qualitatively.

The following provisions are beneficial for beneficiaries for the reasons indicated:

- *CARA:* Enrollees will—(1) have fewer enrollment forms to fill out (because they are locked in); (2) there will be fewer enrollee opioid addictions; (3) the illnesses arising from opioid addiction will be reduced; we estimate that the Trust Fund, in 2019, will spend $19 million less because of reduced opioid prescriptions; enrollees are therefore saving coinsurance on these payments;
- *Passive enrollment flexibilities:* Enrollees are relieved of the burden of filling out enrollment forms; plans are relieved of the burden of verifying eligibility and storage of these forms. There is a cost to enrollees of the ability to actively choose a new plan; this cost is minimized by the special election period afforded to enrollees and described in the two passive enrollment notifications. Additionally, if enrollees remain in the plan they are passively enrolled into, they will continue receiving services from an integrated D–SNP similar to the plan they previously chose.
- *Disclosure:* Plans have the option to deliver required documents using alternate methods including electronic delivery. Enrollees of these plans may receive disclosure documents electronically and have enhanced electronic search capabilities available; furthermore, enrollees have greater access to their documents at any location with a browser. Plans that opt to use alternative methods of delivery (including electronic delivery) must provide the documents in hard copy upon request.
- *Expedited generic substitutions and midyear formulary changes:* Part D sponsors have the option to provide enrollees with access to generics sooner than currently permitted. While we will require Part D sponsors to provide all enrollees with general advance notice that immediate generic substitutions can take place, under this revision Part D sponsors no longer have to provide advance notice of the generic substitution to enrollees who are currently taking the brand name drug. This means that enrollees who would might have so chosen may not have the chance to consult with their prescribers before they receive the generic drug. We believe these consequences are mitigated by the fact that beneficiaries have general familiarity with generic drug substitutions as part of the larger pharmacy market and that additionally they may still avail themselves of the strong Medicare beneficiary protections, including the exceptions process.
- *Preclusion:* The removal of the Part D and Medicare Advantage enrollment requirements for prescribers and providers as a prerequisite for prescribing drugs and furnishing health care items and services will result in greater ease for enrollees in obtaining needed drugs and health care items and services;
- *PDP EA to EA meaningful difference:* Enrollees may experience lower Part D supplemental premiums if enrolled in an EA plan, as sponsors will not be pressured to make benefit changes to comply with a requirement that ultimately results in higher supplemental premiums for beneficiaries. We believe that the tools CMS provides for beneficiaries to make decisions (for example. Medicare Plan Finder, Medicare and You Handbook, 1–800–MEDICARE), in addition to our enforcement of communication and marketing requirements, aim to mitigate any potential choice overload should this provision result in additional PDP plan offerings;
- *Similar Treatment of Biosimilar and Interchangeable Biological Products as Generic Drugs:* This provision will reduce confusion in the marketplace surrounding this issue, will improve enrollee protections while also improving enrollee incentives to choose biosimilar and interchangeable biological products over reference biological products. Improved incentives to choose lower-cost alternatives will reduce costs to Part D enrollees. Note, the co-insurance portion of the estimated reductions in dollars spent by the Trust Fund, $10 million in 2019, reflects quantitative estimates of savings to Part D plan sponsors and reduced costs of enrollees;
- *Part C Meaningful Difference:* As discussed earlier in this section, CMS expects the elimination of the Part C meaningful difference evaluation, in conjunction with the expansion of benefit flexibilities, will allow organizations to provide benefit offerings that satisfy the unique needs of beneficiaries, increase enrollee satisfaction, reduce overall plan expenditures, and result in more affordable plans. Beneficiaries will continue to compare plans as they have in the past, that is, limit their choices based on characteristics, such as plan type, Part D coverage, differences in provider network, Part B and plan premiums, unique populations served, and benefits. CMS and MA organizations will continue to provide beneficiaries with tools, such as MPF and communication materials, to evaluate plan options and assist in choosing the best plan option. In addition, the elimination of the meaningful difference provision is not necessarily encouraging ''new'' plans, but rather allowing plans to use existing capabilities and expanded flexibilities discussed in the proposed rule to improve innovation within existing and new plans. It is unknown how many organizations will choose to add plan options, decrease premiums and/or cost sharing and by what degree. CMS expects that increased competition will provide value to beneficiaries through more innovative health plans that meet their needs, and affordability through benefits and premiums. These factors are difficult to accurately measure quantitatively and as such, we consider the benefits qualitative. CMS also believes that the tools and information CMS provides for beneficiaries to make decisions (for example, Medicare Plan Finder, Medicare and You Handbook, 1–800–MEDICARE), in addition to our enforcement of communication and marketing requirements, aim to mitigate any potential choice overload.

Only one provision, OEP, is burdensome to beneficiaries. Enrollees will have the burden of filling out enrollment forms and plans will have the burden of verifying eligibility, sending notifications to enrollees and CMS, and storing enrollment forms. This burden has been assessed quantitatively in the Collection of Information section as costing $6.1 million to plans and $6.7 million to beneficiaries.

The remaining provisions are neutral because either the provision codified or clarified existing practice (coordination of enrollment/disenrollment, any willing pharmacy), the provision had no new or revised information requirements (limitations on SEP for Part D duals, Part D tiering, changes to transition supply), the provision did not change practice and therefore had no

impact (minimum enrollment waiver), the provision removed duplicative efforts (removal of quality improvement projects, lengthening adjudication timeframes), or the provisions reduced burden on other stakeholders without impacting enrollees (removal of quality improvement projects reduced the burden on CMS review staff, marketing materials reduced the burden on CMS review staff, elimination of notices for IRE reduced plan burden, Medical Loss Ratio reduced plan burden, compliance training reduction affected staff training, physician incentive plans reduced costs of insurance for MA organizations, agent-broker gives plans more flexibility in dealing with unlicensed brokers).

G. Reducing Regulation and Controlling Regulatory Costs

This rule, as finalized, will be an Executive Order (E.O.) 13771 regulatory action. Details on the estimated costs and cost savings can be found in the preceding analysis. Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that this final rule is a significant regulatory action as defined by Executive Order 12866. This final rule is considered an E.O. 13771 deregulatory action. We estimate that this rule generates annualized cost savings of $365.55 discounted relative to year 2016 at 7 percent over a perpetual time horizon.

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, Incorporation by reference, Medicare, Penalties, 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 amends 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 contacts 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 (1)(iii), 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 (2)(ii), 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 that is described in paragraph (g)(2)(i) of this section and 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) of this section 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 from the most recently issued ratings, under the rating system described in §§ 422.160 through 422.166, of at least 3 stars 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:

(i) In the case of a passive enrollment described in paragraphs (g)(1)(i) and (ii) of this section, 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. This notice must be provided to all potential passively-enrolled enrollees, in a form and manner determined by CMS, prior to the enrollment effective date (or as soon as possible after the effective date if prior notice is not practical).

(ii) In the case of a passive enrollment described in paragraph (g)(1)(iii) of this section, two notices that describe the costs and benefits of the plan and the process for accessing care under the plan and clearly explain the beneficiary's ability to decline the enrollment or choose another plan.

(A) The first notice described in paragraph (g)(4)(ii) of this section must be provided, in a form and manner determined by CMS, no fewer than 60 calendar days prior to the enrollment effective date.

(B) The second notice described in paragraph (g)(4)(ii) of this section must be provided, in a form and manner determined by CMS, no fewer than 30 days prior to the enrollment effective date.

(5) *Special election period.* In the case of a passive enrollment described in this paragraph, individuals will be provided with a special enrollment period described in at § 423.38(c)(10) of this chapter.

■ 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) of this chapter.

(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) of this chapter.

(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 communications 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 dual eligible 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 (including a fully integrated dual eligible special needs plan as defined in § 422.2) 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 dual eligible MA special needs plan 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;

(E) CMS has approved the MA organization to use default enrollment under paragraph (c)(2)(ii) of this section;

(F) The MA organization has a minimum overall quality rating from the most recently issued ratings, under the rating system described in §§ 422.160 through 422.166, of at least 3 stars or is a low enrollment contract or new MA plan as defined in § 422.252; and

(G) The MA organization does not have any prohibition on new enrollment imposed by CMS.

(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 approval will be for a period not to exceed five years, although CMS may suspend or rescind approval prior to the expiration of this period if 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 dual eligible MA special needs plan is effective the month in which the individual is first entitled to both Part A and Part B.

(iv) *Notice requirement for default enrollments.* In addition to the information described in § 422.111 and no fewer than 60 calendar days prior to the enrollment effective date described in paragraph (c)(2)(iii) of this section, the MA organization must provide to each individual who qualifies for deemed enrollment under paragraph (c)(2) of this section a notice that includes the following:

(A) Information on the differences in premium, benefits and cost sharing between the individual's current Medicaid managed care plan and the dual eligible MA special needs plan and the process for accessing care under the MA plan;

(B) 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 MA plan; and

(C) A general description of alternative Medicare health and drug coverage options available to an individual in his or her Initial Coverage Election Period.

(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 while 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. Beginning no earlier than January 1, 2020, 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.

(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 on 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. Beginning no earlier than January 1, 2020, 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; beginning no earlier than January 1, 2020, CMS may 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. Beginning no earlier than January 1, 2020, 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.

(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) and adding paragraph (h)(2)(iii) 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 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.

(iii) Posting does not relieve the MA organization of its responsibility under paragraph (a) of this section to provide hard copies of the Summary of Benefits to enrollees when CMS determines hard copy delivery of the Summary of Benefits is in the best interest of the beneficiary.

* * * * *

§ 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.

(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.* Except for § 422.162(b)(3), 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 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 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 website 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 measures 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), with both the reward factor and CAI applied as applicable, as described in § 422.166(f). 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 for such measures 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.

(v) This provision governing the Star Ratings of surviving contracts is applicable to contract consolidations that are approved on or after January 1, 2019.

(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, data submitted by plans, and CMS administrative data.

(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 nationally endorsed and in alignment with the private sector, such as measures developed by National Committee for Quality Assurance (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 (e) 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 (f); 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 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 scores will be converted to measure-level Star Ratings by determining the cut points using hierarchical clustering algorithms in accordance with § 422.166(a)(2)(i) through (iii).

(vi) The Part D improvement measure cut points for MA–PDs and PDPs will be determined using separate clustering algorithms in accordance with §§ 422.166(a)(2)(iii) and 423.186(a)(2)(iii) of this chapter.

(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/substandards 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. CMS will 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 is 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 is 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 are 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, 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 criteria in paragraphs (a)(3)(i)(A) and (B) of this section are met plus at least one of the criteria in paragraphs (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 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.

(iii) A contract is assigned 3 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, 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, the reliability is low, and 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 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.

(v) A contract is assigned 5 stars if both of the following criteria in paragraphs (a)(3)(v)(A) and (B) of this section are met plus at least one of the criteria in paragraphs (a)(3)(v)(C) or (D) of this section is met:

(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 standard error above the 80th percentile.

(4) *5-Star Scale.* 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 2.

(iv) Access measures receive a weight of 2.

(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 (f).

(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; 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 (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 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 (f)(2) 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 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) 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 from 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) The Star Ratings measures that remain after the exclusion criteria, paragraph (f)(2)(ii) of this section, have been applied will be adjusted for the determination of the CAI. CMS will announce the measures identified for adjustment in the calculations of the CAI under this paragraph (f)(2) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(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 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 (overall, Part C, Part D for MA–PD, and Part D for PDPs) 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 the 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) 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.

(ii) If the highest rating is less than 4 stars without the use of the improvement measure(s) and 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)(1):

(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) to read 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:

■ a. In paragraph (a) by adding the definitions of ''Combined Stop-Loss Insurance Deductible Table (Table PIP–11)'', ''Global capitation'', ''Net benefit premium'', ''Non-Risk Patient Equivalents (NPE)'', and ''Separate Stop-Loss Insurance Deductible Table (Table PIP–2)'' in alphabetical order;

■ b. By revising paragraph (f)(2)(iii); and

■ c. By adding paragraphs (f)(2)(iv) through (vi) and (f)(3).

The additions and revisions read as follows:

§ 422.208 Physician incentive plans: requirements and limitations.

(a) * * *

Combined Stop-Loss Insurance Deductible Table (Table PIP–11) means the table described and developed using the methodology in paragraph (f)(2)(iv) of this section.

Global capitation means a specific type of ''capitation'' that includes both professional and institutional services. Services covered by global capitation may also include prescription drug benefits and supplemental benefits as well as basic benefits (as those terms are defined in § 422.100(c)). For purposes of Tables PIP–11 and PIP–12 global capitation includes all Parts A and B services except hospice.

Net benefit premium means the total amount of stop-loss claims (90 percent of claims above the deductible) for that panel size divided by the panel size. It is determined for each panel size and shown in Table PIP–11, described in paragraph (f)(2)(iv) of this section. It is then used in Table PIP–12, described in paragraph (f)(2)(vi) of this section, to identify all separate institutional and separate professional deductible combinations that meet the stop-loss requirements for multi-specialty physician groups participating in PIPs.

Non-Risk Patient Equivalents (NPE) means the estimate of annual claims for physician rendered services for non-risk patients served by the physician or physician group divided by what the PMPY capitation for physician rendered services would be if the beneficiary were part of the risk arrangement. Both Medicare and non-Medicare patients are included in this calculation.

* * * * *

Separate Stop-Loss Insurance Deductible Table (Table PIP–2) means the table described and developed using the methodology in paragraph (f)(2)(vi) of this section.

* * * * *

(f) * * *

(2) * * *

(iii)(A) Stop-loss protection must cover at least 90 percent of costs of referral services 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 the required stop-loss protection for the various panel sizes for contract years beginning on or after January 1, 2019 is determined using the Combined Stop-Loss Insurance Deductible Table (Table PIP–11). For panel sizes not shown on Table PIP–11 and for values not shown on Table PIP–12, linear interpolation (between the table values) may be used to identify the maximum deductible(s) for the required stop-loss coverage. Tables PIP–11 and PIP–12 apply to only multi-specialty physician groups in global capitation arrangements with per-patient stop-loss insurance. For all other physician incentive plan arrangements, the MA organization must assure that the physician or physician group entering into the physician incentive plan arrangement is covered by actuarially equivalent stop-loss protection that meets the requirements of this regulation.

(B) Using Table PIP–11, the deductible is identified for the panel size that is the number of risk patients plus non-risk patient equivalents. Non-risk patient equivalents may add a maximum of $100,000 to the deductible. The deductible for the stop-loss insurance required to be provided for the physician or physician group is then based on the lesser of:

(*1*) The deductible for the risk patient panel size plus $100,000; and

(*2*) The deductible for the panel size that is the total of the number of risk patients plus non-risk patient equivalents.

(iv) Table 1 is developed and updated by CMS using the methodology in this paragraph. CMS publishes Table PIP–11 in guidance (such as an attachment to the Rate Announcement issued under section 1853(b) of the Act) in advance of the bid due date for the upcoming year if CMS determines that an update would be prudent for that year.

(A) The stop-loss tables are calculated using claims data for a statistically valid sample of beneficiaries enrolled in Fee-for-Service Medicare Parts A and B from the most available recent year. The sample includes only claims for beneficiaries eligible for both Part A and Part B for whom Medicare is the primary insurer and excludes hospice claims. The estimate of medical group income is derived from payments for all Part A and Part B services (excluding hospice) in the sampled claims data (to emulate a multi-specialty practice). The central limit theorem is used to obtain the distribution of claim means for a multi-specialty group of any given panel size. The distribution of claim means is 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 no more than 25 percent of potential payments. This point is the deductible in Table PIP–11 for the given panel size.

(B) The 'net benefit premium' (NBP) column in Table PIP–11 is not used for computation of combined insurance but is used to determine the separate deductibles for professional services and institutional services in the *Separate Stop-Loss Insurance Deductible Table* (Table PIP–12).

(C) 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 so long as the separate deductibles for institutional services and professional services are determined using Table 2 as described in paragraph (f)(2)(vi)(B) of this section. Table PIP–2 is developed and updated by CMS using the methodology in paragraph (f)(2)(vi). CMS publishes Table PIP–2 in guidance (such as an attachment to the Rate Announcement issued under section 1853(b) of the Act) in advance of the bid due date for the upcoming year if CMS determines that an update would be prudent for that year.

(B) The maximum deductibles for each category of services (institutional and professional claims) are identified by using the net benefit premium (NBP) determined in Table PIP–11 as the starting point in Table PIP–12. Any combination of institutional and professional attachment points for which the NBP in Table PIP–12 is greater than the NBP determined in Table PIP–11 is permissible. Interpolation may be used to find the NBP values in Table PIP–12 that are closest to the NBP identified in Table PIP–11.

(vi) Table PIP–12 is developed using a methodology similar to that for Table PIP–11.

(A) Claims data are obtained as described in paragraph (f)(2)(iv)(A).

(B) Professional and institutional claims are defined and categorized based on industry standards and based on payments for 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.

(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 Tables PIP–11 and PIP–12. 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) Meets 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 42 CFR part 498.

(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 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 D 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 D 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 is amended by adding paragraph (d)(5) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(d) * * *

(5) 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.

* * * * *

(c) * * *

(1) * * *

(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.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(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.

■ 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 (a) 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 subpart D of this part. A Part C summary plan rating is calculated as provided in § 422.166.

* * * * *

(i) * * *

(2) * * *

(v) 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—

■ a. By removing paragraph (a)(3);

■ b. By redesignating paragraphs (a)(4) and (5) as paragraphs (a)(3) and (4);

■ c. In newly redesignated paragraph (a)(4) introductory text by removing the reference ''paragraph (a)(4)'' and adding in its place the reference ''paragraph (a)(3)''.

■ d. By 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)(1)(iv) 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) * * *

(1) * * *

(iv) 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 prior 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) 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

(2) 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 paragraph (b)(1) of this section and stop-loss insurance that is adequate and acceptable to CMS; and

(3) 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.

As used in this subpart—

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 activities and use of materials that meet the following:

(1) Conducted by the MA organization or downstream entities.

(2) Intended to draw a beneficiary's attention to a MA plan or plans.

(3) Intended to influence a beneficiary's decision-making process when selecting an MA plan for enrollment or deciding 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) Materials used by marketing representatives such as scripts or outlines for telemarketing or other presentations.

(3) Presentation materials such as slides and charts.

Materials that do not include the following are not considered marketing materials:—

(1) Information about the plan's benefit structure or cost sharing;

(2) 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;

(4) Unless otherwise specified by CMS based on their use or purpose, materials that are required under § 422.111; or

(5) Any materials specifically designated by CMS as not meeting the definition of the proposed marketing definition based on their use or purpose.

■ 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 and CMS may determine, upon review of such materials, that the 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. Revising the section heading;

■ b. Removing the introductory text; and

■ c. 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 does 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 vital materials 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 unsolicited 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);
■ d. Redesignating paragraph (b)(3) as paragraph (b)(2); and
■ e. In newly redesignated paragraph (b)(2)(ii)(A) by removing the reference ''paragraph (b)(3)(iii)'' and adding in its place the reference ''paragraph (b)(2)(iii)''.

§ 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—
■ a. By redesignating paragraph (a) introductory text and paragraphs (a)(1) and (2) as paragraphs (a)(1), (2), and (3), respectively;
■ b. By adding a new paragraph (a) subject heading and revising newly redesignated paragraph (a)(1);
■ c. By adding paragraph (a)(4);
■ d. In paragraph (b)(1), by removing the word ''costs'' and adding in its place the phrase ''costs other than those that are related to fraud reduction'';
■ e. In paragraph (b)(5), by adding the phrase ''(and that are not related to fraud reduction activities under paragraph (a)(4)(ii) of this section)'' after ''capabilities''; and
■ f. By 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) of this section.

* * * * *

(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''; and
■ 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—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 56. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 58. Section 423.32 is amended by:
■ a. Revising paragraph (b) introductory text; and
■ b. 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 paragraphs (c) introductory text, (c)(4), and (c)(8)(i)(C);
■ b. Adding paragraphs (c)(9) and (10);
■ 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)(i) Except as provided in paragraph (ii), the individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in § 423.772, who is making an allowable onetime-per-calendar-quarter election between January through September.

(ii) An individual described in paragraph (i) is not eligible for this special enrollment period if he or she has been notified that he or she has been identified as a ''potential at-risk beneficiary'' or ''at-risk beneficiary'' as defined in § 423.100 and such identification has not been terminated in accordance with § 423.153(f)).

* * * * *

(8) * * *

(i) * * *

(C) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communications as outlined in subpart V of this part.

* * * * *

(9) The individual is making an election within 3 months after a gain, loss, or change to Medicaid or LIS eligibility, or notification of such a change, whichever is later.

(10) The individual is making an election within 3 months after notification of a CMS or State-initiated enrollment action or that enrollment action's effective date, whichever is later.

(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) of this chapter, 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) of this chapter, 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) of this chapter 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 open enrollment 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) of this chapter, 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'', and ''Frequently abused drug'';
■ 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 this section);

(ii) Not an exempted beneficiary; and

(iii) Determined to be at-risk for misuse or abuse of such frequently abused drugs by a Part D plan sponsor under its 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 and such identification had not been terminated upon disenrollment.

* * * * *

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 the standards in § 423.153(f)(16) and, beginning with contract year 2020, will be published in guidance annually.

* * * * *

Exempted beneficiary means with respect to a drug management program, an enrollee who—

(1) Has elected to receive hospice care or is receiving palliative or end-of-life 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) Is being treated for active cancer-related pain.

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.

* * * * *

Potential at-risk beneficiary means a Part D eligible individual—

(1) Who is identified using clinical guidelines (as defined in this section); 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 and such identification had not been terminated upon disenrollment.

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 of this chapter.

(ii) The prescriber is currently under a reenrollment bar under § 424.535(c) of this chapter.

(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 (1)(iii), 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 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 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 ''30 days'';

■ f. In paragraph (b)(5)(i)(B), by removing the phrase ''60 day supply'' and adding in its place the phrase ''an approved month's supply'';

■ 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 paragraph (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) * * *

(i) * * *

(B) Not apply in cases in which a Part D sponsor substitutes a generic drug for a brand name drug as permitted under paragraph (b)(5)(iv) 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 an approved month's supply of medication, unless the prescription is written by a prescriber for less than an approved month's supply and requires the Part D sponsor to allow multiple fills to provide up to a total of an approved 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 on the same or lower cost-sharing tier and with 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 submitted its initial formulary for CMS approval consistent with paragraph (b)(2) of this section 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 (c)(5)(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 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*) Subject to all other Part D rules and plan coverage requirements, provide an advance written notice to any beneficiary who has received a prescription from a prescriber on the preclusion list as soon as possible but to ensure that the beneficiary receives the notice no later than 30 days after publication of the most recent preclusion list.

(*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*) 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 paragraphs (a)(3) and (d)(2)(iii) to read as follows:

§ 423.128 Dissemination of Part D plan information.

(a) * * *

(3) At the time of enrollment and at least annually thereafter, by the first day of the annual coordinated election period.

* * * * *

(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 clinical staff conducting case management required under paragraph (f)(2) of this section, including that the staff must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United Stated (that is, Puerto Rico), or the District of Columbia.

(ii) The necessary and appropriate contents of files for case management required under paragraph (f)(2) of this section, which must include documentation of the substance of prescriber and beneficiary contacts.

(iii) Monitoring reports and notifications about incoming enrollees who meet the definition of an at-risk

beneficiary or 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 met 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 prescribers have not responded to the inquiry described in paragraph (f)(2)(i)(B) of this section, make reasonable attempts to communicate with the prescribers telephonically and/or by another effective communication method designed to elicit a response from 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 still 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 any or 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) Both.

(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) Except in the case of a pharmacy limitation imposed pursuant to paragraph (f)(3)(ii)(B) of this section, obtained the agreement of at least one prescriber 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)(A) Except as provided in paragraph (f)(2)(ii)(B) of this section regarding a prescriber limitation, if the sponsor has complied with the requirement of paragraph (f)(2)(i)(C) of this section about attempts to reach prescribers, and the prescribers were not responsive after 3 attempts by the sponsor to contact them within 10 business days, then the sponsor has met the requirement of paragraph (f)(4)(i)(B) of this section for eliciting information from the prescribers.

(B) The sponsor may not implement a prescriber limitation pursuant to paragraph (f)(3)(ii)(A) of this section if no prescriber was responsive.

(5) *Initial notice to a beneficiary.* (i) After conducting the case management required by paragraph (f)(2) of this section, a Part D sponsor that intends to limit the access of a potential at-risk beneficiary, or subject to the exception in paragraph (f)(8)(ii) of this section, of an at-risk beneficiary (as defined in subparagraph (2) of the definition in § 423.100), 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 § 423.582 and § 423.584.

(*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.

(iv) If the Part D plan sponsor subsequently intends to make a change to the terms of an ongoing limitation(s) established under paragraph (f)(3) of this section, including the intention to impose an additional limitation on the at-risk beneficiary, the sponsor must comply with the requirements of paragraph (f)(3) of this section, as well as all applicable requirements for beneficiary notices described in paragraphs (f)(5) through (8) 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, 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.

(iii) 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) *Notices: Timing and exceptions.* (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 60 days after the date of the initial notice described in paragraph (f)(5) of this section.

(ii) A gaining plan sponsor may forgo providing the initial notice and may immediately provide a second notice described in paragraph (f)(6) of this section to an at-risk beneficiary as defined in subparagraph (2) of the definition in § 423.100), 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, if the edit is the same as the one that was implemented in the immediately prior plan.

(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 or change 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 that the beneficiary continues to have reasonable access to frequently abused drugs, taking into account all relevant factors, including but not limited to—

(i) Geographic location;

(ii) Beneficiary preference;

(iii) The beneficiary's predominant usage of a prescriber or pharmacy or both;

(iv) The impact on cost-sharing;

(v) Reasonable travel time;

(vi) Whether the beneficiary has multiple residences;

(vii) Natural disasters and similar situations; and

(viii) 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, or the selection of an out-of-network provider is necessary; 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, unless the selection of an out-of-network pharmacy is necessary.

(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. For prescribers, this notification occurs during case management as described in paragraph (f)(2) or when the prescriber provides agreement pursuant to paragraph (f)(4)(i)(B) of this section.

(ii) The sponsor must receive confirmation from the prescriber(s) or pharmacy(ies) or both, as applicable, that the selection is accepted before conveying this information to the at-risk beneficiary, unless the pharmacy has agreed in advance in a network agreement with the sponsor to accept all such selections and the agreement specifies how the 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 limitation under this paragraph, to be an at-risk beneficiary; or

(ii)(A) The end of a one year period calculated from the effective date of the limitation, as specified in the notice provided under paragraph (f)(6) of this section, unless the limitation was extended pursuant to paragraph (f)(14)(ii)(B) of this section.

(B) The end of a two year period calculated from the effective date of the limitation, as specified in a notice provided under paragraph (f)(6) of this section, subject to the following requirements:

(*1*) The plan sponsor determines at the end of the one year period that there is a clinical basis to extend the limitation;

(*2*) Except in the case of a pharmacy limitation imposed pursuant to paragraph (f)(3)(ii)(B) of this section, the plan sponsor has obtained the agreement of a prescriber of frequently abused drugs for the beneficiary that the limitation should be extended.

(*3*) The plan sponsor has provided another notice to the beneficiary in compliance with paragraph (f)(6) of this section.

(*4*) If the prescribers were not responsive after 3 attempts by the sponsor to contact them within 10 business days, then the sponsor has met the requirement of paragraph (f)(14)((ii)(B)(2) of this section.

(*5*) The sponsor may not extend a prescriber limitation implemented pursuant to paragraph (f)(3)(ii)(A) of this section if no prescriber was responsive.

(15) *Data disclosure.* (i) CMS identifies potential at-risk beneficiaries 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) Provide information 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 meets paragraph (1) of the definition in § 423.100 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 about any potential at-risk beneficiary that meets paragraph (2) of the definition in § 423.100 that a sponsor identifies within 30 days from the date of the most recent CMS report identifying potential at-risk beneficiaries.

(D) Provide information to CMS as soon as possible but no later than 7 days of the date of the initial notice or second notice that the sponsor provided to a beneficiary, or as soon as possible but no later than 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.

(E) 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 a 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. Adding paragraph (b)(2)(iv);
■ d. Revising paragraph (b)(4); and
■ e. 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 October 31, 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, 2020, the standards specified in paragraphs (b)(2)(iv) and (b)(3), (b)(4)(ii), (b)(5)(iii), and (b)(6) of this section.

(2) * * *

(iv) 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), to provide for the communication of a prescription or related prescription-related information between prescribers and dispensers for the following:

(A) GetMessage.
(B) Status.
(C) Error.
(D) NewRxRequest.
(E) NewRx.
(F) RxChangeRequest.
(G) RxChangeResponse.
(H) RxRenewal Request.
(I) Resupply.
(J) RxRenewalResponse.
(K) Verify.
(L) CancelRx.
(M) CancelRxResponse.
(N) RxFill.
(O) DrugAdministration.
(P) NewRxRequest.
(Q) NewRxResponseDenied.
(R) RxTransferRequest.
(S) RxTransferResponse.
(T) RxTransferConfirm.
(U) RxFillIndicatorChange.
(V) Recertification.
(W) REMSIinitiationRequest.
(X) REMSIinitiationResponse.
(Y) REMSRequest.
(Z) REMSResponse.

* * * * *

(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, 2020, Either the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide Version 8, Release 1 (Version 8.1), October 2005 (incorporated by reference in paragraph (c)(1)(i) 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)(v) of this section.

(ii) On or after January 1, 2020, 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.

* * * * *

■ 66. Sections 423.180, 423.182, 423.184 and 423.186 are added to subpart D to read as follows:

Subpart D—Cost Control and Quality Improvement Requirements

* * * * *

Sec

§ 423.180 Basis and scope of the Part D Prescription Drug Plan 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.* Except for § 423.182(b)(3), 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 Prescription Drug Plan 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 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 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 website 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 measures 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 unweighted mean of the individual measure ratings under the topic area in accordance with § 423.186(b). Summary ratings are the weighted mean of the individual measure ratings for Part C or Part D in accordance with § 423.186(c), with both the reward factor and CAI applied as applicable, as described in § 423.186(f). Overall Star Ratings are calculated by using the weighted mean 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.

(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.

(iii) This provision governing the Star Ratings of surviving contracts is applicable to contract consolidations that are approved on or after January 1, 2019.

(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 measurements of health outcomes and other indices of quality. Part D sponsors 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.

§ 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 (NCQA) and the Pharmacy Quality Alliance (PQA) 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) 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 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 (e) 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 (f); 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 scores will be converted to measure-level Star Ratings by determining the cut points using hierarchical clustering algorithms in accordance with § 423.186(a)(2)(i) through (iii).

(vi) The Part D improvement measure cut points for MA–PDs and PDPs will be determined using separate clustering algorithms in accordance with §§ 422.166(a)(2)(iii) and 423.186(a)(2)(iii).

(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 measures based on data that a Part D organization must submit to CMS under § 423.514 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. CMS will 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 is 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 is 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 D IRE data, the reduction is applied to both of the contract's Part D appeals measures.

(F) 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.

(G) 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.

(H) 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.

(I) Contracts are 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.

(J) 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.

(K) A contract's lower bound is compared to the thresholds of the scaled reductions to determine the IRE data completeness reduction.

(L) 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, 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, 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 criteria in paragraphs (a)(3)(i)(A) and (B) of this section are met plus at least one of the criteria in paragraphs (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 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.

(iii) A contract is assigned 3 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, 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, the reliability is low, and 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 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.

(v) A contract is assigned 5 stars if both of the following criteria in paragraphs (a)(3)(v)(A) and (B) of this section are met plus at least one of the criteria in paragraphs (a)(3)(v)(C) or (D) of this section is met:

(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 standard error above the 80th percentile.

(4) *5-Star Scale.* 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) 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.

(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 2.

(iv) Access measures receive a weight of 2.

(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 (f).

(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(f)(2) 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 from 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) The Star Ratings measures that remain after the exclusion criteria, paragraph (f)(2)(ii) of this section, have been applied will be adjusted for the determination of the CAI. CMS will announce the measures identified for adjustment in the calculations of the CAI under this paragraph (f)(2) through the process described for changes in and adoption of payment and risk adjustment policies in section 1853(b) of the Act.

(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 (overall, Part D for MA–PD, and Part D for PDPs) 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 the 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) 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.

(ii) If the highest rating is less than 4 stars without the use of the improvement measure(s) and 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''.

(1) *Medicare Plan Finder performance icons.* Icons are displayed on Medicare Plan Finder to note performance as provided in this paragraph (h)(1):

(i) *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.

(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 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.

* * * * *

■ 68. Section 423.272 is amended by revising paragraph (b)(3)(ii) to read as follows:

§ 423.272 Review and negotiation of bid and approval of plans submitted by potential Part D sponsors.

* * * * *

(b) * * *

(3) * * *

(ii) *Transition period for PDP sponsors with new acquisitions.* After a 2-year transition period, as determined by CMS, CMS approves a bid offered by a PDP sponsor (or by a parent organization to that PDP sponsor) that recently purchased (or otherwise acquired or merged with) another Part D sponsor if it finds that the benefit package or plan costs represented by that bid are substantially different from benefit packages or plan costs represented by another bid submitted by the same Part D sponsor (or parent organization to that Part D sponsor), as provided under § 423.265(b)(2).

* * * * *

§ 423.503 [Amended]

■ 69. 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.

■ 70. 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.

* * * * *

■ 71. 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 7 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]

■ 72. Section 423.507 is amended by removing and reserving paragraph (b).

■ 73. 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.

* * * * *

■ 74. Section 423.509 is amended by revising paragraph (a)(4)(v)(A) and adding paragraphs (a)(4)(xiii) and (xiv) and (b)(1)(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) * * *

(1) * * *

(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.

* * * * *

■ 75. 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).

* * * * *

■ 76. Section 423.560 is amended by—

■ a. Revising the definition of ''Appeal'';

■ b. Adding the definition of ''At-risk determination'' in alphabetical order;

■ c. Revising the definitions of ''Grievance'', ''Reconsideration'', and ''Redetermination''; and

■ d. Adding the definition of ''Specialty tier'' in alphabetical order.

The revisions and additions 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.

At-risk determination means a decision made under a plan sponsor's drug management program in accordance with § 423.153(f) that involves the identification of an individual as an at-risk beneficiary for prescription drug abuse; a limitation, or the continuation of a limitation, on an at-risk beneficiary's access to coverage for frequently abused drugs (that is, a beneficiary specific point-of-sale edit or the selection of a prescriber and/or pharmacy and implementation of lock-in, or); and information sharing for subsequent plan enrollments.

* * * * *

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.

■ 77. 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.). Determinations made in accordance with the processes at § 423.153(f) are collectively referred to as an at-risk determination, defined at § 423.560, made under a drug management program.

* * * * *

(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.

* * * * *

■ 78. 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.

* * * * *

■ 79. Section 423.578 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(1), (2), (4) introductory text, (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.

* * * * *

■ 80. 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.

■ 81. 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).

* * * * *

■ 82. 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.)

* * * * *

■ 83. 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;

* * * * *

■ 84. 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;

* * * * *

■ 85. 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.

■ 86. 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]

■ 87. Section 423.652 is amended in paragraph (b)(1) by removing the phrase ''July 15'' and adding in its place ''September 1''.

■ 88. 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.

* * * * *

■ 89. 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 of this part 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).

* * * * *

■ 90. 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.

* * * * *

■ 91. Section 423.782 is amended by revising paragraphs (a)(2)(iii)(A) and (b)(3) to read as follows:

§ 423.782 Cost-sharing subsidy.

(a) * * *

(2) * * *

(iii) * * *

(A) A copayment amount of not more than $1 for a generic drug, biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved, or preferred drugs that are multiple source (as defined under section 1927(k)(7)(A)(i) of the Act) or $3 for any other drug in 2006, or for years after 2006 the amounts specified in this paragraph (a)(2)(iii)(A) for the percentage increase in the Consumer Price Index, rounded to the nearest multiple of 5 cents or 10 cents, respectively; or

* * * * *

(b) * * *

(3) For covered Part D drugs above the out-of-pocket limit (under § 423.104(d)(5)(iii)) in 2006, copayments not to exceed $2 for a generic drug, biological product for which an application under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is approved, or preferred drugs that are multiple source drugs (as defined under section 1927(k)(7)(A)(i) of the Act) and $5 for any other drug. For years beginning in 2007, the amounts specified in this paragraph (b)(3) for the previous years increased by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs, rounded to the nearest multiple of 5 cents.

* * * * *

■ 92. 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]

■ 93. 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]

■ 94. 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]

■ 95. Section 423.2022 is amended by—

■ a. Removing the first appearance of the 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]

■ 96. 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]

■ 97. 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]

■ 98. 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]

■ 99. 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]

■ 100. 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]

■ 101. 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]

■ 102. 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]

■ 103. 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

■ 104. The subpart V heading is revised to read as set forth above.

■ 105. Section 423.2260 is revised to read as follows:

§ 423.2260 Definitions.

As used in this subpart—

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 activities and use of materials that meet the following:

(1) Conducted by the Part D sponsor or downstream entities.

(2) Intended to draw a beneficiary's attention to a Part D plan or plans.

(3) Intended to influence a beneficiary's decision-making process when selecting a Part D plan for enrollment or deciding 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) Materials used by marketing representatives such as scripts or outlines for telemarketing or other presentations.

(iii) Presentation materials such as slides and charts.

(2) *Materials that do not include the following are not considered marketing 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

(iv) Unless otherwise specified by CMS based on their use or purpose, materials that are required under § 423.128; or

(v) Any materials specifically designated by CMS as not meeting the definition of the proposed marketing definition based on their use or purpose.

■ 106. Section 423.2262 is amended by revising paragraph (d) to read as follows:

§ 423.2262 Review and distribution of marketing materials.

(d) *Enrollee communication materials.* Enrollee communication materials may be reviewed by CMS and CMS may determine, upon review of such materials, that the materials must be modified, or may no longer be used.

■ 107. 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, 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.

■ 108. 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 vital materials, unless in the language of these individuals. Specifically, Part D sponsors 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 unsolicited 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]

■ 109. Section 423.2272 is amended by removing paragraph (e).

§ 423.2274 [Amended]

■ 110. 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 paragraphs (b)(3) and (4) as paragraphs (b)(2) and (3);

■ e. In newly redesignated paragraph (b)(2)(ii)(A) by removing the reference ''paragraph (b)(3)(iii)'' and adding in its place the reference :paragraph (b)(2)(iii)''; and

■ f. 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]

■ 111. 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]

■ 112. Section 423.2420 is amended—
■ a. By removing and reserving paragraph (b)(2)(viii);
■ b. By revising paragraph (d)(2)(i); and
■ c. By 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.

* * * * *

■ 113. Section 423.2430 is amended—
■ a. By redesignating paragraphs (a) introductory text and paragraphs (a)(1) and (2) as paragraphs (a)(1), (2), and (3), respectively;
■ b. By republishing the paragraph (a) subject heading and revising newly redesignated paragraph (a)(1);
■ c. By adding paragraph (a)(4);
■ d. In paragraph (b)(1), by removing the word ''costs'' and adding in its place the phrase ''costs other than those that are related to fraud reduction'';
■ e. In paragraph (b)(5), by adding the phrase ''(and that are not related to fraud reduction activities under paragraph (a)(4)(ii) of this section)'' after ''capabilities''; and
■ f. By 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.

* * * * *

■ 114. 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]

■ 115. 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]

■ 116. 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)

■ 117. 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)).

■ 118. 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.

■ 119. 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]

■ 120. Section 460.68 is amended by removing paragraph (a)(4).

§ 460.70 [Amended]

■ 121. Section 460.70 is amended by removing paragraph (b)(1)(iv).

§ 460.71 [Amended]

■ 122. Section 460.71 is amended by removing paragraph (b)(7).

■ 123. 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

■ 124. The authority citation 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).

■ 125. 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.

* * * * *

■ 126. 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: March 29, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 2, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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