DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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Office of the Secretary

[CMS–4201–F3 and CMS–4205–F]

RINs 0938–AV24 and 0938–AU96

Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024—Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)

AGENCY: Centers for Medicare & Medicaid Services (CMS), Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule will revise the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Care for the Elderly (PACE) regulations to implement changes related to Star Ratings, marketing and communications, agent/broker compensation, health equity, dual eligible special needs plans (D–SNPs), utilization management, network adequacy, and other programmatic areas. This final rule also codifies existing sub-regulatory guidance in the Part C and Part D programs.

DATES: *Effective date:* These regulations are effective June 3, 2024.

Applicability dates: The provisions in this rule are applicable to coverage beginning January 1, 2025, except as otherwise noted. The updates to marketing and communication provisions at §§ 422.2267(e)(34), 422.2274, and 423.2274 are applicable for all contract year 2025 marketing and communications beginning October 1, 2024. The updated provisions at §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) are applicable for all contract year 2026 marketing and communications beginning September 30, 2025, however, at plan option for contract year 2025 marketing and communications beginning September 30, 2024, the plan may use the model notice described in §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) to satisfy the MLI requirements set forth in §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i).

Sections 422.111(l) and 423.530 are applicable beginning January 1, 2026. This final rule also includes revisions to existing regulations in the Risk Adjustment Data Validation (RADV) audit appeals process, the appeals process for quality bonus payment determination at § 422.260, weighting of new Part C and D Star Ratings measures at §§ 422.166(e)(2) and 423.186(e)(2), and the rule for Part C and D Star Ratings non-substantive measure updates at §§ 422.164(d) and 423.184(d) applicable 60 days after the date of publication. The use and release of risk adjustment data provisions at §§ 422.310(f)(1)(vi), 422.310(f)(1)(vii), and 422.310(f)(3)(v) are applicable 60 days after the date of publication.

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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 amend the regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicare cost plan program, and Programs of All-Inclusive Care for the Elderly (PACE). This final rule includes a number of new policies that will improve these programs beginning with contract year 2025 and will codify existing Part C and Part D sub-regulatory guidance.

Additionally, this final rule will implement certain sections of the following Federal laws related to the Parts C and D programs:

- The Bipartisan Budget Act (BBA) of 2018.
- The Consolidated Appropriations Act (CAA), 2023.

2. Summary of the Major Provisions

a. Part D Medication Therapy Management (MTM) Program: Eligibility Criteria

Section 1860D–4(c)(2) of the Act requires all Part D sponsors to have an MTM program designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Section 1860D–4(c)(2)(A)(ii) of the Act requires Part D sponsors to target those Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary. CMS codified the MTM targeting criteria at § 423.153(d)(2).

Through this final rule, CMS establishes improved targeting criteria for the Part D MTM program that will help ensure more consistent, equitable, and expanded access to MTM services. After consideration of the comments received, we are finalizing proposed changes to the MTM eligibility criteria with modifications that are effective for January 1, 2025, as follows:

We are finalizing the provision at § 423.153(d)(2)(iii) that Part D sponsors must include all core chronic diseases in their targeting criteria for identifying beneficiaries who have multiple chronic diseases, as provided under § 423.153(d)(2)(i)(A). As part of this provision at § 423.153(d)(2)(iii), we are codifying the nine core chronic diseases currently identified in guidance and adding HIV/AIDS, for a total of 10 core chronic diseases. The 10 core chronic diseases are: (1) Alzheimer's disease; (2) Bone disease-arthritis (including osteoporosis, osteoarthritis, and rheumatoid arthritis); (3) Chronic congestive heart failure (CHF); (4) Diabetes; (5) Dyslipidemia; (6) End-stage renal disease (ESRD); (7) Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS); (8) Hypertension; (9) Mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions); and (10) Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders). Sponsors retain the flexibility to target

additional chronic diseases beyond those codified as core chronic diseases.

We are not finalizing the proposal at § 423.153(d)(2)(i)(B) to decrease the maximum number of Part D drugs a sponsor may require from eight to five for Contract Year 2025. At this time, we are retaining the maximum number of drugs a plan sponsor may require for targeting beneficiaries taking multiple Part D drugs as eight at § 423.153(d)(2)(i)(B). Part D sponsors will maintain the flexibility to set a lower threshold (a number between two and eight Part D drugs) for targeting beneficiaries taking multiple Part D drugs. We may consider revisiting this or similar policies in future rulemaking.

We are finalizing the provision at § 423.153(d)(2)(iv) to require sponsors to include all Part D maintenance drugs in their targeting criteria with minor modifications to the regulatory text to clarify that sponsors must include all Part D maintenance drugs and to provide flexibility for sponsors to include all Part D drugs in their targeting criteria. However, sponsors will not be permitted to limit the Part D maintenance drugs included in MTM targeting criteria to specific Part D maintenance drugs or drug classes. We are also finalizing the requirement at § 423.153(d)(2)(iv) that, for the purpose of identifying Part D maintenance drugs, plans must rely on information in a widely accepted, commercially or publicly available drug information database.

We are finalizing the provision at § 423.153(d)(2)(i)(C) with modification to set the MTM cost threshold at the average cost of eight generic drugs, as defined at § 423.4. CMS will calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug using the PDE data specified at § 423.104(d)(2)(iv)(C).

We are also codifying longstanding guidance at § 423.153(d)(1)(vii)(B)(2) to provide that a beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment. We are also finalizing other technical changes at § 423.153(d)(1)(vii)(B)(1)(i) to clarify that the CMR must include an interactive consultation that is conducted in person or via synchronous telehealth.

b. Improving Access to Behavioral Health Care Providers

We are finalizing regulatory changes that will improve access to behavioral health care by adding a new behavioral health provider specialty to our MA network adequacy standards. Specifically, we are finalizing requirements to add a new facility-specialty type to the existing list of facility-specialty types evaluated as part of network adequacy requirements and reviews. The new facility-specialty type, ''Outpatient Behavioral Health,'' will be included in network adequacy evaluations and can include providers of various types: Marriage and Family Therapists (MFTs), Mental Health Counselors (MHCs), Opioid Treatment Program (OTP) providers, Community Mental Health Centers or other behavioral health and addiction medicine specialists and facilities, including addiction medicine physicians, other providers. Other providers may include nurse practitioners (NPs), physician assistants (PAs) and Clinical Nurse Specialists (CNSs), who furnish addiction medicine and behavioral health counseling or therapy services and meet other specific criteria. Beginning January 1, 2024, MFTs and MHCs were eligible to enroll in Medicare and start billing for services due to the new statutory benefit category established by the Consolidated Appropriations Act (CAA) 2023. We aim to strengthen network adequacy requirements and improve beneficiary access to behavioral health services and providers by expanding our network adequacy evaluation requirements for MA organizations.

To address concerns that NPs, PAs, and CNSs might lack the necessary skills, training, or expertise to effectively address the behavioral health needs of enrollees and that the absence of criteria for incorporating these provider types could result in the creation of ''ghost networks'' (where providers may be listed in a provider directory without actively treating patients for behavioral health), we are also adopting specific criteria that MA organizations must use to determine when an NP, PA or CNS can be considered part of a network to meet the Outpatient Behavioral Health network adequacy standard. MA organizations must independently verify that the provider has furnished or will furnish such services to 20 patients within a recent 12-month period using reliable information about services furnished by the provider such as the MA organization's claims data, prescription drug claims data, electronic health records, or similar data.

c. Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (TPMOs)

Third-Party Marketing Organizations (TPMOs) are selling and reselling beneficiary contact information to skirt existing CMS rules that prohibit cold calling so they can aggressively market MA and Part D Plans. Beneficiaries are unaware that by placing a call or clicking on a generic-looking web-link they are unwittingly agreeing and providing consent for their personal contact information to be collected and sold to other entities for future marketing activities. As a result, we are finalizing requirements to prohibit personal beneficiary data collected by TPMOs for marketing or enrolling a beneficiary into an MA or Part D plan to be shared with other TPMOs, unless prior express written consent is given by the beneficiary. Furthermore, we are finalizing a one-to-one consent structure where TPMOs must obtain prior express written consent through a clear and conspicuous disclosure for each TPMO that will be receiving the beneficiary's data. This provision is designed to address complaints we have received from beneficiaries and their advocates and caregivers about receiving harassing and unwanted phone and email solicitations from individuals attempting to enroll them in MA and Part D plans. This final rule protects beneficiaries against unwanted calls, texts, email solicitations, and other contacts, while still ensuring that beneficiaries have control over their personal data and can connect with the TPMOs they would like to speak with, creating a more transparent and safer environment for beneficiaries to find the plan that best fits their health needs.

d. Establish Guardrails for Agent and Broker Compensation

Section 1851(j) of the Act requires that CMS develop guidelines to ensure that the use of agent and broker compensation creates incentives to enroll individuals in the MA plan that is intended to best meet their health care needs. To that end, for many years CMS has set upper limits on the amount of compensation agents and brokers can receive for enrolling Medicare beneficiaries into MA and PDP plans. We have learned, however, that many MA and PDP plans, as well as third-party entities with which they contract (such as Field Marketing Organizations (FMOs)) have structured payments to agents and brokers that allow for separate payments for these agents and brokers and have the effect of circumventing compensation caps. We also note that that these separate payments appear to be increasing. In this rule, we are finalizing requirements that will generally prohibit contract terms between MA organizations and agents, brokers or other TPMOs that may interfere with the agent's or broker's ability to objectively assess and

recommend the plan that best fits a beneficiary's health care needs; set a single, increased compensation rate for all plans to be updated annually; revise the scope of items and services included within agent and broker compensation; and eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services. We are also making conforming edits to the Part D agent broker compensation rules at § 423.2274. Collectively, we believe the impact of these changes will better align with statutory requirements to ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the plan that best fits a beneficiary's health care needs. Further, such changes align with the Biden-Harris Administration's commitment to promoting fair, open, and competitive markets and ensuring beneficiaries can make fully informed choices among a robust set of health insurance options.

e. Special Supplemental Benefits for the Chronically Ill (SSBCI)

We are finalizing regulatory changes that will help ensure that SSBCI items and services offered by MA plans are appropriate and meet applicable statutory and regulatory standards, including that the SSBCI items and services are reasonably expected to improve or maintain the health or overall function of chronically ill enrollees. First, we are finalizing requirements that, by the date on which it submits its bid to CMS, an MA organization must establish a bibliography of relevant acceptable evidence that an item or service offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. Second, we are clarifying in the regulation that an MA plan must follow its written policies based on objective criteria for determining an enrollee's eligibility for an SSBCI when making such eligibility determinations. Third, we are requiring that the MA plan document both denials and approvals of SSBCI eligibility. Additionally, we are codifying CMS's authority to review and deny approval of an MA organization's bid if the MA organization has not demonstrated, through relevant acceptable evidence, that its proposed SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. Finally, we are codifying CMS's authority to review SSBCI offerings annually for compliance, considering the evidence available at the time. We believe these revisions to § 422.102(f) will better ensure that the benefits offered as SSBCI are reasonably expected to improve or maintain the health or overall function of the chronically ill enrollee while also guarding against the use of MA rebate dollars for SSBCI that are not supported by acceptable evidence.

The new SSBCI requirements regarding creation of a bibliography and documentation of SSBCI eligibility for enrollees will apply to plans beginning with the CY2025 bid process. The codification of other SSBCI requirements regarding plans' obligation to follow written SSBCI eligibility policies, and our authority to decline to accept a bid if the MA organization has not demonstrated that its proposed SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee do not represent a change in policy and CMS will continue in practice during the CY2025 bid process and in subsequent years.

In addition, we are finalizing new policies to protect beneficiaries and improve transparency regarding SSBCI so that beneficiaries are aware that SSBCI are only available to enrollees who meet specific eligibility criteria. We are modifying and strengthening the current requirements for the SSBCI disclaimer that MA organizations offering SSBCI must use whenever SSBCI are mentioned. Specifically, we are requiring that the SSBCI disclaimer list the relevant chronic condition(s) the enrollee must have to be eligible for the SSBCI offered by the MA organization. The MA organization must convey in its SSBCI disclaimer that even if the enrollee has a listed chronic condition, the enrollee may not receive the benefit because other eligibility and coverage criteria also apply. We are also finalizing specific font and reading pace parameters for the SSBCI disclaimer in print, television, online, social media, radio, other voice-based ads, and outdoor advertising (including billboards). Finally, we are requiring that MA organizations include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI. We believe that imposing these new SSBCI disclaimer requirements will help to ensure that the marketing of and communication about these benefits is not misleading or potentially confusing to enrollees who rely on these materials to make enrollment decisions.

f. Mid-Year Enrollee Notification of Available Supplemental Benefits

In addition, over the past several years, the number of MA plans offering supplemental benefits has increased. The benefits offered are broader in scope and variety and we are seeing an increasing amount of MA rebate dollars directed towards these benefits. At the same time, plans have reported that enrollee utilization of many of these benefits is low. To help ensure MA enrollees are fully aware of all available supplemental benefits and to promote equitable access to care, we will now require MA plans to notify enrollees mid-year of the unused supplemental benefits available to them. The notice will list any supplemental benefits not utilized by the enrollee during the first 6 months of the year (January 1 to June 30). Currently, MA plans are not required to send any communication specific to an enrollee's usage of supplemental benefits and CMS believes such a notice could be an important part of a plan's overall care coordination efforts. As finalized, this policy will educate enrollees on their access to supplemental benefits to encourage greater utilization of these benefits and ensure MA plans are better stewards of the rebate dollars directed towards these benefits.

g. Annual Health Equity Analysis of Utilization Management Policies and Procedures

We are finalizing regulatory changes to the composition and responsibilities of the Utilization Management (UM) committee. These policies will require that at least one member of the UM committee have expertise in health equity. These policies will also require that the UM committee conduct an annual health equity analysis of the use of prior authorization at the plan-level. The analysis will examine the impact of prior authorization on enrollees with one or more of the following social risk factors (SRFs): (i) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or (ii) having a disability. To enable a more comprehensive understanding of the impact of prior authorization practices on enrollees with the specified SRFs at the plan level, the analysis must compare metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. Finally, the policies will require MA organizations to make the results of the analysis publicly available on their plan's website in a manner that is easily accessible and without barriers.

h. Amendments to Part C and Part D Reporting Requirements

In this final rule, we are affirming our authority to collect detailed information from MA organizations and Part D plan

sponsors under current regulations, in keeping with the Biden-Harris administration's focus on improving transparency and data in MA and Part D. We are revising §§ 422.516(a)(2) and 423.514(a)(2) as proposed (with a minor clarification in § 422.516(a)) to be consistent with the broad scope of the reporting requirements. This will lay the groundwork for new program-wide data collections to be established through the Paperwork Reduction Act (PRA) process, which will provide advance notice to interested parties and be subject to public comment. An example of increased data collection could be service level data for all initial coverage decisions and plan level appeals, such as decision rationales for items, services, or diagnosis codes to have better line of sight on utilization management and prior authorization practices, among many other issues.

i. Enhance Enrollees' Right To Appeal an MA Plan's Decision To Terminate Coverage for Non-Hospital Provider Services

Beneficiaries enrolled in Traditional Medicare and MA plans have the right to a fast-track appeal by an Independent Review Entity (IRE) when their covered skilled nursing facility (SNF), home health, or comprehensive outpatient rehabilitation facility (CORF) services are being terminated. Currently, Quality Improvement Organizations (QIO) act as the IRE and conduct these reviews. Under current regulations, MA enrollees do not have the same access to QIO review of a fast-track appeal as Traditional Medicare beneficiaries in connection with terminations of these types of services. In this final rule, we are finalizing proposals to: (1) require the QIO, instead of the MA plan, to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF; and (2) fully eliminate the current provision that requires the forfeiture of an enrollee's right to appeal a termination of services to the QIO when the enrollee leaves the CORF or SNF or ends HHA services. These will bring MA regulations in line with the parallel reviews available to beneficiaries in Traditional Medicare and expand the rights of MA beneficiaries to access the fast-track appeals process in connection with terminations of HHA, CORF, or SNF services.

j. Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products

Current regulations permit Part D sponsors to immediately remove from their formularies a brand name drug and substitute its newly released generic equivalent. Part D sponsors meeting the requirements can provide notice of specific changes, including direct notice to affected beneficiaries, after they take place; do not need to provide a transition supply of the substituted drug; and can make these changes at any time including in advance of the plan year. Consistent with these requirements, we proposed in the proposed rule titled ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications,'' which appeared in the December 27, 2022 **Federal Register** (hereinafter referred to as the December 2022 proposed rule), to permit Part D sponsors also to immediately substitute: (i) a new interchangeable biological product for its corresponding reference product; (ii) a new unbranded biological product for its corresponding brand name biological product; and (iii) a new authorized generic for its corresponding brand name equivalent.

Our proposed regulatory text in the December 2022 proposed rule did not specify how Part D sponsors could treat substitution of biosimilar biological products other than interchangeable biological products. Under current policy, Part D sponsors have to obtain explicit approval from CMS prior to making a midyear formulary change that removes a reference product and replaces it with a biosimilar biological product other than an interchangeable biological product. Further, if such a change is approved, the Part D sponsor may apply the change only to enrollees who begin therapy after the effective date of the change. In other words, enrollees currently taking the reference product are able to remain on the reference product until the end of the plan year without having to obtain an exception. In response to comments received on our initial proposal in the December 2022 proposed rule (discussed in section III.P. of this final rule), and to increase access to biosimilar biological products consistent with the Biden-Harris Administration's commitment to competition as outlined in Executive Order (E.O.) 14036: ''Promoting Competition in the American Economy,'' we proposed in the proposed rule titled ''Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications,'' which appeared in the November 16, 2023 **Federal Register** (hereinafter referred to as the November 2023 proposed rule) to add substitutions of biosimilar biological products other than interchangeable biological products to the type of formulary changes that apply to all enrollees (including those already taking the reference product prior to the effective date of the change) following a 30-day notice.

Having now considered comments (discussed in section III.P. of this final rule) received on the proposals in both the December 2022 and November 2023 proposed rules, we are finalizing regulations to permit Part D sponsors that meet all requirements: (1) to immediately substitute an interchangeable biological product for its reference product, a new unbranded biological product for its corresponding brand name biological product, and a new authorized generic for its brand name equivalent; and (2) to substitute upon 30 days' notice any biosimilar biological product for its reference product.

k. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization

We are finalizing, with some modifications, interconnected proposals to: (a) replace the current quarterly special enrollment period (SEP) with a one-time-per month SEP for dually eligible individuals and others enrolled in the Part D low-income subsidy program to elect a standalone PDP, (b) create a new integrated care SEP to allow dually eligible individuals to elect an integrated D–SNP on a monthly basis, (c) limit enrollment in certain D–SNPs to those individuals who are also enrolled in an affiliated Medicaid managed care organization (MCO), and (d) limit the number of D–SNP plan benefit packages an MA organization can offer for full-benefit dually eligible individuals in the same service area that it, its parent organization, or any entity that shares a parent organization with the MA organization offers an affiliated Medicaid MCO. This final rule will increase the percentage of full-benefit dually eligible MA enrollees who are in plans that—directly by the MA

organization or indirectly through the parent organization or a related entity—are also contracted to cover Medicaid benefits, thereby expanding access to integrated materials, unified appeal processes across Medicare and Medicaid, and continued Medicare services during an appeal. It will also reduce the number of MA plans overall that can enroll dually eligible individuals outside the annual coordinated election period, thereby reducing the number of plans deploying aggressive marketing tactics toward dually eligible individuals throughout the year.

l. For D–SNP PPOs, Limit Out-of-Network Cost Sharing

We are finalizing a limitation on out-of-network cost sharing for D–SNP preferred provider organizations (PPOs) for specific services. The final rule will reduce cost shifting to Medicaid, increase payments to safety net providers, expand dually eligible enrollees' access to providers, and protect dually eligible enrollees from unaffordable costs.

m. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes

Under existing regulations, CMS does not contract with and will not renew the contract of a D–SNP look-alike—that is, an MA plan that is not a SNP but in which dually eligible enrollees account for 80 percent or more of total enrollment. We are finalizing a reduction to the D–SNP look-alike threshold from 80 percent to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years. This provision will help address the continued proliferation of MA plans that are serving high percentages of dually eligible individuals without meeting the requirements to be a D–SNP.

n. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation Appeals Process

We are finalizing regulatory language to address gaps and operational constraints included in existing RADV appeal regulations. Currently, if MA organizations appeal both medical record review determinations and payment error calculations resulting from RADV audits, both issues must be appealed and move through the appeals process concurrently, which we foresee could result in inconsistent appeal adjudications at different levels of appeal that impact recalculations of the payment error. This has the potential to cause burden, confuse MA organizations, and negatively impact the operations and efficiency of CMS's appeals processes. This final rule will standardize and simplify the RADV appeals process for CMS and MA organizations, as well as address operational concerns at all three levels of appeal. We are finalizing requirements that MA organizations must exhaust all three levels of appeal for medical record review determinations before beginning the payment error calculation appeals process. This will ensure adjudication of medical record review determinations are final before a recalculation of the payment error is completed and subject to appeal. We are also finalizing several other revisions to our regulatory appeals process to conform these changes to our procedures.

Finally, we are clarifying and emphasizing our intent that if any provision of this final rule is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, it shall be severable from this final rule and not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances. Through this rule, we adopt provisions that are intended to and will operate independently of each other, even if each serves the same general purpose or policy goal. Where a provision is necessarily dependent on another, the context generally makes that clear (such as by a cross-reference to apply the same standards or requirements).

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3. Summary of Costs and Benefits

TABLE A1: SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision	Description	Financial Impact
1. Part D Medication Therapy Management (MTM) Program: Eligibility Criteria	We are finalizing changes to the MTM eligibility requirements to (1) codify the 9 core chronic diseases currently identified in sub-regulatory guidance and adding HIV/AIDS for a total of 10 core chronic diseases; (2) require Part D sponsors to include all core chronic diseases in their MTM targeting criteria, and to include all Part D maintenance drugs when determining the number of drugs an enrollee is taking; and (3) revise the methodology for the MTM cost threshold to calculate the dollar amount based on the average annual cost of 8 generic drugs.	The revisions to the MTM targeting criteria being finalized in this rule have an estimated annual administrative cost of $192.7 million. We are unable to score this provision largely due to challenges with estimating Part A/B savings.
2. Improving Access to Behavioral Health Care Providers	We are finalizing changes to add a new facility-specialty type called "Outpatient Behavioral Health" to the network adequacy standards under § 422.116(b)(2). For purposes of the network adequacy requirements, the new facility-specialty type will be evaluated using time and distance and minimum number standards adopted in this rule. The new facility type will include MFTs, MHCs, OTP or other behavioral health and addiction medicine specialists and facilities. Based on comments from stakeholders we are also finalizing how an organization will determine when certain providers (NP, PA, CNS) may be utilized to meet network adequacy.	The new provision adds requirements for a new facility specialty type, which include providers some of which we have data for and some which are new and for which we lack data. Therefore, we cannot quantify the effects of this provision though we expect it may increase access which may qualitatively increase utilization.
3. Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (TPMOs)	We are codifying that personal beneficiary data collected by a TPMO for marketing or enrolling the beneficiary into an MA or Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Further, we are codifying that prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained separately for each TPMO that receives the data through a clear and conspicuous disclosure.	We do not expect any cost impact to the Medicare Trust Fund.
4. Enhance Guardrails for Agent/Broker Compensation	We are modifying agent/broker compensation requirements to further ensure payment arrangements and structure are aligned with CMS's statutory obligation to set limits on compensation to ensure that the use of compensation creates incentives for agents and brokers to enroll prospective enrollees in plans that best fit their needs.	This provision has no costs because we are transferring funds the MA plans are already paying Marketing Agencies directly to the agents and brokers with some reductions due to some funds possibly being used inconsistent with the requirements of the regulation.

Provision	Description	Financial Impact
5. Special Supplemental Benefits for the Chronically Ill (SSBCI)	We are finalizing changes to require MA organizations to establish bibliographies for each SSBCI they include in their bid to demonstrate that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. This will shift the burden from CMS to the MA organizations to demonstrate compliance with this standard and help ensure that SSBCI items and services are offered based on current, reliable evidence. In addition, we are finalizing new policies to protect beneficiaries and improve transparency regarding SSBCI so that beneficiaries are aware that SSBCI are only available to enrollees who meet specific eligibility and coverage criteria. We are modifying and strengthening the current requirements for the SSBCI disclaimer that MA organizations offering SSBCI must use whenever SSBCI are mentioned.	The requirements for SSBCI are not expected to have any economic impact on the Medicare Trust Fund.
6. Mid-Year Enrollee Notification of Available Supplemental Benefits	We are finalizing requirements for MA plans to issue notices to enrollees who, by June 30th of a given year, have not utilized supplemental benefits, to ensure enrollees are aware of the availability of such benefits and ensure appropriate utilization.	Although these changes may result in increased utilization and ultimately create a savings to the Medicare Trust Fund, we cannot currently quantify this provision because it is new, and we lack data. See the Regulatory Impact Analysis for further discussion. The provision has an administrative cost of $23.7 million.
7. Annual Health Equity Analysis of Utilization Management Policies and Procedures	We are finalizing changes to the composition and responsibilities for the Utilization Management committee, to require: a member of the UM committee have expertise in health equity; the UM committee conduct an annual health equity analysis of prior authorization used by the MA organization using specified metrics; and require MA organizations to make the results of the analysis publicly available on its website.	We do not expect any cost impact to the Medicare Trust Fund.
8. Amendments to Part C and Part D Reporting Requirements	We are affirming our authority to collect detailed data from MA organizations and Part D plan sponsors under the Part C and D reporting requirements and finalizing the proposed regulatory revisions to be consistent with the broad scope of the reporting requirements.	We do not expect any cost impact to the Medicare Trust Fund.
9. Enhance Enrollees' Right to Appeal an MA Plan's Decision to Terminate Coverage for Non-Hospital Provider Services	We are finalizing regulations to (1) require QIOs to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF and (2) eliminate the provision requiring the forfeiture of an enrollee's right to appeal to the QIO a termination of services decision when they leave the facility.	The revisions to this provision have an estimated annual administrative cost of $683,910. This is a transfer from MA plans to QIOs; MA plans have a reduced cost while QIOs have a corresponding increased cost.

Provision	Description	Financial Impact
10. Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products	We are finalizing regulations to permit Part D sponsors to immediately substitute authorized generics for corresponding brand name drug products, interchangeable biological products for their reference products, and unbranded biological products marketed for the brand name biological product marketed under the same biologics license application. We also are finalizing regulations to permit substitutions of all biosimilar biological products with 30 days advance notice.	We do not expect any cost impact to the Medicare Trust Fund.
11. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services from the Same Organization	We are finalizing, with some modifications, policies to (a) replace the current dual/LIS quarterly SEP, (b) create a new integrated care SEP for full-benefit dually eligible individuals, (c) limit enrollment in certain D-SNPs to those full-benefit dually eligible individuals who are also enrolled in an affiliated Medicaid MCO, and (d) limit the number of D-SNPs an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, can offer in the same service area as an affiliated Medicaid MCO.	Over a 10-year horizon, we estimate a $1.3 billion savings to the Trust Fund for Part D plans and an additional $1 billion savings to the Trust Fund for Part C plans.
12. For D-SNP PPOs, Limit Out-of-Network Cost Sharing	We are finalizing a limitation on D-SNP PPOs' out-of-network cost sharing for certain Part A and Part B benefits, on an individual service level.	We do not expect any cost impact to the Medicare Trust Fund.
13. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes	We are lowering the D-SNP look-alike threshold from 80 percent to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years.	We estimate this provision will have an average annual impact of less than $1M for plan years 2025-2027 due to non-SNP MA plans meeting the lower D-SNP look-alike threshold transitioning enrollees into other plans. We also estimate this provision will have an average annual impact of less than $1M on MA plan enrollees for plan years 2025-2027 due to enrollees choosing a different plan. We expect cumulative annual costs to non-SNP MA plans and MA plan enrollees beyond plan year 2027 to also be less than $1M per year.

Provision	Description	Financial Impact
14. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) Appeals Process	We are revising when a medical record review determination and a payment error calculation appeal can be requested and adjudicated because RADV payment error calculations are based upon the outcomes of medical record review determinations. We are also finalizing other revisions to our appeals process to conform with these proposed changes. The changes could reduce burden on some MA organizations that, absent these revisions, will have otherwise potentially submitted payment error calculation appeals that could have been rendered moot by certain types of medical record appeals decisions. The potential reduction in burden to MA organizations cannot be quantified prior to the implementation of the new appeals process and until appeals have been fully adjudicated. While the MA RADV appeals regulations have been in place for a period of years, CMS did not issue RADV overpayment findings to MA organizations as we worked to finalize a regulation on our long-term RADV methodology. Therefore, any impact of these policies on MA organization behavior is further unquantifiable. The proposed changes do not impose any new information collection requirements.	The potential reduction in burden to MA organizations cannot be quantified prior to the implementation and execution of the appeals process pursuant to these changes.

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B. Background and Summary of the Final Rule

In this final rule, CMS addresses many of the remaining proposals from the December 2022 proposed rule in addition to the proposals from the November 2023 proposed rule. There are several proposals from the December 2022 proposed rule that were not finalized. CMS may address these proposals in a future final rule.

We received 3,463 timely pieces of correspondence containing one or more comments on the November 2023 proposed rule. 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.

C. General Comments on the December 2022 Proposed Rule and the November 2023 Proposed Rule Proposed Rule

We received some overarching comments related to the December 2022 and the November 2023 proposed rules, which we summarize in the following paragraphs:

Comment: A commenter expressed concern that CMS had not provided sufficient time for plan sponsors to understand the impact of recently finalized regulations, and the changes they have implemented, before proposing more policies that build on these areas. They recommended that in future years CMS allows time to measure and observe the impact of policy changes on plan sponsors and their members prior to layering new proposals.

Response: We appreciate the commenter's concern regarding the plans having enough time to understand the impact of finalized regulations. We will take their recommendation into consideration for future rulemaking.

Comment: A commenter requested that CMS extend the comment period by 60 days, through March 5, 2024, so they could effectively use the extended period in planning and preparing a response.

Response: Section 1871(b) of the Act requires that we provide for notice of the proposed regulation in the **Federal Register** and a period of not less than 60 days for public comment thereon. The proposed rule was available for public inspection on *federalregister.gov* (the website for the Office of **Federal Register**) on November 3, 2023. We did not extend the comment period because we believe the required 60 days provided the public with adequate time to prepare and submit responses.

Comment: In response to CMS–4201–P, a commenter suggested that CMS had not allowed for a 60-day comment period for the proposed rule because the beginning of the comment period was calculated from the date the proposed rule was made available for public inspection on the **Federal Register** website rather than the date that it appeared in an issue of the **Federal Register**. The commenter recommended that CMS provide an additional 60-day comment period on the proposed rule.

Response: Section 1871(b) of the Act requires that we provide for notice of the proposed regulation in the **Federal Register** and a period of not less than 60 days for public comment thereon. The proposed rule was available for public inspection on *federalregister.gov* (the website for the Office of **Federal Register**) on December 14, 2022. We believe that beginning the comment period for the proposed rule on the date it became available for public inspection at the Office of the Federal Register fully complied with the statute and provided the required notice to the public and a meaningful opportunity for interested

parties to provide input on the provisions of the proposed rule.

D. Status of the Overpayment Proposal in the December 27, 2022, Proposed Rule

Under the governing statute, any Medicare Advantage Organization (MA organization) that ''has received an overpayment,'' 42 U.S.C. 1320a–7k(d)(1), must ''report and return the overpayment,'' 42 U.S.C. 1320a–7k(d)(1)(A), no later than ''60 days after the date on which the overpayment was identified'' 42 U.S.C. 1320a–7k(d)(2)(A). CMS implemented this statutory overpayment provision through a May 23, 2014, final rule titled ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs''. See 79 FR 29844. A group of MA organizations challenged that rule's inclusion of instances where an MA organization ''should have determined through the exercise of reasonable diligence . . . that [it] has received an overpayment'' in the regulation's definition of ''identified,'' 42 CFR 422.326(c). The District Court for the District of Columbia held that this regulatory provision was impermissible under the statute. *See UnitedHealthcare Ins. Co.* v. *Azar,* 330 F. Supp. 3d 173, 191 (D.D.C. 2018), *rev'd in part on other grounds sub nom. UnitedHealthcare Ins. Co.* v. *Becerra,* 16 F.4th 867 (D.C. Cir. 2021), *cert. denied,* 142 S. Ct. 2851 (U.S. June 21, 2022) (No. 21–1140). CMS views the District Court's ruling as having invalidated the definition of ''identified'' set out in 42 CFR 422.326(c). However, MA organizations remain obligated to report and return all overpayments that they have identified within the meaning of the statute, 42 U.S.C. 1320a–7k(d)(2)(A). In the December 27, 2022 proposed rule titled ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications'' (the December 2022 proposed rule), CMS proposed revisions to regulations primarily governing Medicare Advantage (MA or Part C) and the Medicare Prescription Drug Benefit (Part D) (87 FR 79452). CMS proposed in the December 2022 proposed rule to remove the existing definition of ''identified'' in the Parts C and D overpayment regulations at 42 CFR 422.326 and 423.360 (as well as the corresponding Parts A and B regulation) (*see* 87 FR 79559). Under the Parts C and D overpayment proposal, an MA organization or Part D sponsor would have identified an overpayment when it had actual knowledge of the existence of the overpayment or acted in ''reckless disregard'' or ''deliberate ignorance'' of the overpayment. CMS has received inquiries regarding this proposal and want to be clear that it remains under consideration and that CMS intends to issue a final rule to revise the definition of ''identified'' in the overpayment rules as soon as is reasonably possible.

E. Information on Cyber Resiliency

In light of recent cybersecurity events impacting health care operations nationally, we expect all payers to review and implement HHS's voluntary *HPH Cyber Performance Goals* (CPGs). These CPGs are part of *HHS' broader cybersecurity strategy* and designed to help health care organizations strengthen cyber preparedness, improve cyber resiliency, and ultimately protect patient health information and safety. We welcome input on our approach via email at *hhscyber@hhs.gov.*

II. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies

A. Definition of Network-Based Plan (§§ 422.2 and 422.114)

Private-fee-for-service (PFFS) plans were established by the Balanced Budget Act of 1997 (Pub. L. 105–33) and were originally not required to have networks. The Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) (MIPPA) revised the PFFS requirements to require that, beginning with contract year 2011, PFFS plans have a network when operating in the same service area as two or more network-based plans. For purposes of this requirement, section 1852(d)(5)(C) of the Act and § 422.114(a)(3)(ii) define network-based plans as a coordinated care plan (as described in section 1851(a)(2)(A) of the Act and § 422.4(a)(1)(iii)), a network-based MSA plan, and a section 1876 reasonable cost plan. The statutory and regulatory definitions both specifically exclude an MA regional plan that meets access requirements substantially through means other than written contracts, per § 422.112(a)(1)(ii).

When codifying this requirement in the final rule that appeared in the **Federal Register** September 18, 2008, titled ''Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs,'' (73 FR 54226), we included the definition of network-based plan in the section of the regulations for PFFS plans, as the definition was integral to the new requirement for PFFS plans (73 FR 54249). A network-based plan, however, has meaning in contexts other than PFFS. To ensure that the definition is readily and more broadly accessible for those seeking requirements related to network-based plans, we proposed in the December 2022 proposed rule (87 FR 79569) to move the definition of a network-based plan from § 422.114(a)(3)(ii) to the definitions section in § 422.2. Further, we proposed that the PFFS provision at § 422.114(a)(3)(ii) will continue to include language specifying the network requirement.

This proposed change has no policy implications for other provisions in part 422 in which the definition or description of network plans plays a role, for example, the network adequacy provisions at § 422.116 and the plan contract crosswalk provisions at § 422.530. However, in specifying the network adequacy requirements for the various plan types, § 422.116(a)(1)(i) references the current definition of a network-based plan at § 422.2 even though the definition for network-based plan currently remains at § 422.114(a)(3)(ii) because CMS inadvertently finalized what was intended to be a conforming change to § 422.116(a)(1)(i) [1] before we finalized our proposal to move the definition of network-based plan to § 422.2. In this final rule, we are moving the definition to § 422.2, making the current cross reference at § 422.116(a)(1)(i) correct. With respect to the regulation at § 422.530(a)(5), that provision specifically addresses the types of plans to which it applies and when CMS considers a crosswalk to be to a plan of a different type and refers to network-based PFFS plans without citing a specific definition. Therefore, we do not believe any amendment to § 422.530 is necessary in connection with moving the definition of network-based plan to § 422.2.

We did not receive any public comments on our proposal to move the definition and are finalizing the proposal for the reasons outlined in the December 2022 proposed rule with slight modifications to reorganize the regulation text for additional clarity.

[1] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Program of All-Inclusive Care for the Elderly (88 FR 22120).

B. Past Performance

We established at §§ 422.502(b) and 423.503(b) that we may deny an application submitted by MA organizations and Part D sponsors that failed to comply with the requirements of a previous MA or Part D contract, which we refer to as ''past performance.'' We proposed several technical changes to the regulation text related to past performance. These changes are intended to clarify the basis for application denials due to past performance and to ensure that the factors adequately account for financial difficulties that should prevent an organization from receiving a new or expanded MA or Part D contract.

One factor we consider regarding the past performance of MA organizations and Part D sponsors is their record of imposition of intermediate sanctions, because intermediate sanctions represent significant non-compliance with MA or Part D contract requirements. To clarify the basis for application denials due to intermediate sanctions, at §§ 422.502(b)(1)(i)(A) and 423.503(b)(1)(i)(A) we proposed to change ''Was subject to the imposition of an intermediate sanction'' to ''Was under an intermediate sanction.'' We proposed this revision because MA organizations and Part D sponsors may have a sanction imposed in one 12-month past performance review period and effective for all or part of the subsequent 12-month review period. For instance, CMS could impose a sanction in December 2022 that remains in effect until September 2023. The sanction would be in effect for the past performance review period that runs from March 2022 through February 2023 (for Contract Year 2024 MA and Part D applications filed in February 2023) and for the past performance review period that runs from March 2023 through February 2024 (for Contract Year MA and Part D applications filled in February 2024). Our proposal reflects our stated intent to deny applications from MA organizations and Part D sponsors when an active sanction existed during the relevant 12-month review period when we previously codified that intermediate sanctions are a basis for denial of an application from an MA organization or Part D sponsor in ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,'' which appeared in the **Federal Register** on January 19, 2021 (86 FR 5864) hereinafter referred to as the ''January 2021 final rule.'' When we codified this requirement, a commenter requested that sanctions lifted during the 12 months prior to the application denial be excluded from past performance. We responded that ''The applying organization will receive credit for resolving the non-compliance that warranted the sanction during the next past performance review period, when, presumably, the organization will not have an active sanction in place at any time during the applicable 12-month review period'' (86 FR 6000 through 6001). Since an intermediate sanction may be active during multiple consecutive review periods, our proposed language clarifies that an organization's application may be denied as long as the organization is under sanction, not just during the 12-month review period when the sanction was imposed.

An additional factor we consider regarding the past performance of MA organizations and Part D sponsors is involvement in bankruptcy proceedings. At §§422.502(b)(1)(i)(C) and 423.503(b)(1)(i)(C) we proposed to incorporate federal bankruptcy as a basis for application denials due to past performance and to conform the two paragraphs by changing the text to ''Filed for or is currently in federal or state bankruptcy proceedings'' from ''Filed for or is currently in State bankruptcy proceedings,'' at § 422.502(b)(1)(i)(C) and ''Filed for or is currently under state bankruptcy proceedings'' at § 423.503(b)(1)(i)(C). We codified state bankruptcy as a basis for an application denial for the past performance of an MA or Part D sponsor in ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which appeared in the **Federal Register** on May 9, 2022 (87 FR 27704). We codified that requirement because bankruptcy may result in the closure of an organization's operations and entering into a new or expanded contract with such an organization is not in the best interest of the MA or Prescription Drug programs or the beneficiaries they serve. This concern is equally applicable to both federal and state bankruptcy, so we proposed to revise the regulation so that applications from MA organizations or Part D sponsors that have filed for or are in state or federal bankruptcy proceedings may be denied on the basis of past performance. In addition, we also proposed to correct two technical issues identified since the final rule was published in May 2022. At § 422.502(b)(1)(i)(B), we proposed to change the reference to the requirement to maintain fiscally sound operations from § 422.504(b)(14) to the correct reference at § 422.504(a)(14). We also proposed to remove the duplication of § 422.502(b)(1)(i)(*A*) and (*B*).

We invited public comment on this proposal and received several comments in support of this proposal. We received no comments opposing this proposal. Therefore, we are finalizing this proposal without modification.

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Effect of Change of Ownership Without Novation Agreement (§§ 422.550 and 423.551)

In accordance with standards under sections 1857 and 1860 of the Act, each Medicare Advantage (MA) organization and Part D sponsor is required to have a contract with CMS to offer an MA or prescription drug plan. Further, section 1857(e)(1) and 1860D–12(b)(3)(D) of the Act authorizes additional contract terms consistent with the statute and which the Secretary finds are necessary and appropriate. Pursuant to this authority and at the outset of the Part C and Part D programs, we implemented regulations at §§ 422.550 and 423.551, respectively. These regulations require the novation of an MA or Part D contract in the event of a change of ownership involving an MA organization or Part D sponsor (63 FR 35106 and 70 FR 4561).

Our current regulations at §§ 422.550 and 423.551, as well as our MA guidance under ''Chapter 12 of the Medicare Managed Care Manual—Effect of Change of Ownership'' [2] require that when a change of ownership occurs, as defined in the regulation, advance notice must be provided to CMS and the parties to the transaction must enter into a written novation agreement that meets CMS's requirements. If a change of ownership occurs and a novation agreement is not completed and the entities fail to provide advance notification to CMS, the current regulations at §§ 422.550(d) and 423.551(e) indicate that the existing contract is invalid. Furthermore, §§ 422.550(d) and 423.551(e) provide that if the contract is not transferred to

[2] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c12.pdf.*

the new owner through the novation agreement process, the new owner must enter into a new contract with CMS after submission of an MA or Part D application, if needed.

The current regulations do not fully address what happens when the contract becomes ''invalid'' due to a change of ownership without a novation agreement and/or advance notice to CMS, or in other words, what happens to the existing CMS contract that was held by the purchased entity. In that circumstance, CMS would still recognize the original entity as the owner, even if the contract is now held by a different entity. Therefore, we proposed to revise §§ 422.550(d) and 423.551(e) to make it clear that in such a circumstance, CMS may unilaterally terminate the affected contract in accordance with §§ 422.510(a)(4)(ix) and 423.509(a)(4)(ix), which establish that failure to comply with the regulatory requirements contained in part 422 or part 423 (if applicable) is a basis for CMS to unilaterally terminate an MA or Part D contract.

In addition, we are strengthening CMS's enforcement authority regarding this process through the proposed amendments to §§ 422.550(d) and 423.551(e). Pursuant to CMS's authority under sections 1857 and 1860 of the Act, we proposed to amend the regulations at §§ 422.550(d) and 423.551(e) to outline the enforcement process CMS will follow, which includes imposing applicable sanctions before terminating a contract that has a change in ownership without a novation agreement in accordance with CMS requirements.

In the interest of protecting and effectively managing the MA and Part D programs, CMS, through either the novation agreement or the application process, must ensure that MA organizations and Part D Sponsors—through their respective legal entities—are eligible to contract with CMS. If CMS has no chance to assess the qualifications of the new entity and a change in ownership from one legal entity to another occurs without CMS approval of a novation agreement, CMS's ability to ensure the integrity of the MA and Part D programs and ability to monitor a contract's activity under the new legal entity would be compromised, thereby putting enrollees at risk. Thus, any change in ownership from one legal entity to another requires CMS to determine whether the new entity meets the statutory and regulatory requirements for operating a contract under the MA or Part D programs.

We proposed to impose enrollment and marketing sanctions, as outlined in §§ 422.750(a)(1) and (a)(3) and 423.750(a)(1) and (a)(3) on the affected contract. Such sanctions will remain in place until CMS approves the change of ownership, (including execution of an approved novation agreement) or the contract is terminated. We also proposed to provide an opportunity for organizations to demonstrate that the legal entity assuming ownership by way of a change of ownership without a novation agreement meets the requirements set forth by our regulations. This may be completed in the following ways:

- If the new owner does not participate in the same service area as the affected contract, at the next available opportunity, it must apply for and be conditionally approved for participation in the MA or Part D program and, within 30 days of the conditional approval (if not sooner), submit the documentation required under §§ 422.550(c) or 423.551(d) for review and approval by CMS (note that organizations may submit both the application and the documentation for the change of ownership concurrently); or
- If the new owner currently participates in the MA or Part D program and operates in the same service area as the affected contract, it must, within 30 days of imposition of intermediate sanctions, submit the documentation required under §§ 422.550(c) or 423.551(d) for review and approval by CMS.
- If the new owner is not operating an MA or Part D contract in the same service area and fails to apply for an MA or Part D contract in the same service area at the next opportunity to apply, the existing contract will be subject to termination in accordance with §§ 422.510(a)(4)(ix) or 423.509(a)(4)(x). Or, if the new owner is operating in the same service area and fails to submit the required documentation within 30 days of imposition of intermediate sanctions, the existing contract will be subject to termination in accordance with §§ 422.510(a)(4)(ix) or 423.509(a)(4)(x).

Imposition of intermediate sanctions under §§ 422.750(a)(1) and (a)(3) and 423.750(a)(1) and (a)(3) triggers the past performance rules applicable under §§ 422.502(b)(1) or 423.503(b)(1). Imposition of intermediate sanctions is a factor considered under CMS's evaluation and determination of an organization's information from a current or prior contract during the MA and Part D application process.

We solicited comments on these proposals. We appreciate stakeholders' input on the proposed changes. We received the following comments and have provided responses.

Comment: A commenter suggested that CMS not terminate a contract when a change of ownership has occurred without notification to CMS, but rather suggested CMS apply a substantial penalty or fine to the new legal entity.

Response: In the interest of managing the MA and Part D programs and protecting all enrollees, CMS must ensure, through the application process, that MA organizations and Part D sponsors are eligible to contract with CMS. This is existing policy that is also consistent with statutory requirements under sections 1855 and 1857 and 1860D–12 of the Act. The option to terminate the contract is a critical tool for CMS to ensure that only qualified entities can contract with CMS to serve enrollees. Imposing a substantial penalty or fine on the new owner would not protect enrollees who are already in MA or Part D plans that cannot adequately serve them. Moreover, under §§ 422.550(d)(2) and 423.551(e)(2), entities can cure any deficiencies within 30 days of the imposition of intermediate sanctions. If an entity wishes to avoid termination, it will have the opportunity to do so.

Comment: A commenter indicated that the proposed approach should not apply to those changes of ownership that occur under the same parent organization.

Response: In order to ensure the integrity of the MA and Part D programs, CMS must review any change in ownership from one legal entity to another, regardless of the relationship to the parent organization, to confirm whether the new legal entity meets the regulatory requirements for operating a contract in a given service area. As previously indicated, our current regulations at §§ 422.550 and 423.551, as well as our MA guidance under ''Chapter 12 of the Medicare Managed Care Manual—Effect of Change of Ownership,'' [3] require that when a change of ownership occurs, as defined in the regulation, advance notice must be provided to CMS and the parties to the transaction must enter into a written novation agreement that meets CMS's requirements.

Comment: A commenter expressed concern that CMS's application timelines would negatively impact potential changes of ownership and suggested instead that CMS not impose the proposed sanctions or that CMS implement the sanctions for a period of

[3] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c12.pdf.*

time that is less time than the application cycle.

Response: As previously noted, CMS must determine whether the new legal entity involved in the change in ownership meets all CMS requirements for operating a MA contract. CMS must also have the opportunity to review and evaluate the new entity. When a change in ownership from one legal entity to another occurs without CMS approval, it compromises CMS's ability to ensure the integrity of the MA and Part D programs and hampers CMS's ability to monitor a contract's activity under the new legal entity, thereby putting enrollees at risk. The ability of CMS to ensure that MA and Part D plans are adequate to cover enrollees' health care needs outweighs concerns about potential timeline issues.

We believe that our process provides a sufficient opportunity for organizations to demonstrate, and CMS to determine, that they meet all CMS's requirements as set forth in our regulations.

Comment: A commenter asked CMS to clarify the types of sanctions that would be applicable when a change of ownership without novation agreement occurs.

Response: CMS would impose enrollment and marketing sanctions, which are outlined in our regulations at § 422.750(a)(1) and (a)(3) and § 423.750(a)(1) and (a)(3). These sanctions will remain in place until CMS approves the change of ownership (including execution of an approved novation agreement) or the contract is terminated.

After considering the comments received and for the reasons discussed in the proposed rule and our responses to comments, we are finalizing our proposal to amend the regulations at §§ 422.550(d) and 423.551(e) with technical corrections to the cross-references proposed in § 423.551(e). The cross-references in paragraphs (e)(1) and (e)(2) have been corrected to reflect the appropriate Part D sections in the final regulatory text in this final rule. In addition, we are finalizing minor grammatical and organizational revisions to the regulations to improve the readability and clarity of the text.

B. Part D Global and Targeted Reopenings (§§ 423.308 and 423.346)

1. Executive Summary

2. Provisions of the Proposed Regulation (Preamble)

Pursuant to the authority under section 1860D–15(f)(1)(B) of the Act, the Secretary has the right to inspect and audit any books and records of a Part D sponsor or MA organization that pertain to the information regarding costs provided to the Secretary. We stated in the January 2005 Part D final rule (70 FR 4194, 4316) that this right to inspect and audit would not be meaningful, if upon finding mistakes pursuant to such audits, the Secretary was not able to reopen final payment determinations. Therefore, we established that CMS may rectify any final payment determination issues in a reopening provision at § 423.346. In the January 2005 Part D final rule, we established that a reopening was at CMS' discretion and could occur within the following timeframes after the final payment determination was issued: (1) 12 months for any reason, (2) 4 years for good cause, or (3) at any time when there is fraud or similar fault. We operationalized this provision by conducting program-wide reopenings (that is, global reopenings) and, when necessary, reopenings targeted to specific sponsors' contracts (that is, targeted reopenings).

In our December 2022 proposed rule, we proposed to codify the definitions of ''global reopening'' and ''targeted reopening.'' We also proposed to modify the timeframe CMS may perform a reopening for good cause from within 4 years to within 6 years to align with the 6-year overpayment look-back period described at § 423.360(f) and to help ensure that payment issues, including overpayments, can be rectified. In addition, we proposed to codify the circumstances under which CMS will notify the sponsor(s) of our intention to perform a final payment determination reopening and the requirement for CMS to announce when it has completed a reopening. We are finalizing our proposed changes without modifications.

a. Summary of the Current Process

Under the current process and under § 423.346, CMS performs a reopening of a Part D payment reconciliation (that is, the initial payment determination) as a result of revisions of prescription drug event (PDE) data and/or direct and indirect remuneration (DIR) data due to plan corrections, CMS system error corrections, post reconciliation claims activity, and audit and other post reconciliation oversight activity. Based on our experience in the Part D program and the PDE and DIR data changes, we understood that this process would require CMS to perform an initial payment determination reopening every contract year.

By calendar year 2013, CMS had reopened the 2006, 2007, and 2008 Part D payment reconciliations and, approximately 4 years after those reopenings were completed, began subsequent Part D payment reconciliation reopenings (consistent with the timing described at § 423.346(a)(2)). These reopenings included all Part D contracts that met the following criteria: (1) were in effect during the contract year being reopened, and (2) were either in effect at the time CMS completed the reopening or, if nonrenewed or terminated pursuant to § 423.507 through § 423.510 (collectively referred to as ''terminated'' for the purposes of these reopening provisions), had not completed the final settlement process by the time CMS completed the reopening. CMS has referred to this type of program-wide reopening as a ''global reopening.'' See, for example, HPMS memorandum, ''Reopening of the 2006, 2007, and 2008 Part D Payment Reconciliations,'' April 2, 2012 (available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/part%20dreopeningannoucement_199.pdf*).

In addition to ''global reopenings,'' CMS has performed reopenings as part of our process to correct certain issues. We would consider performing a reopening to correct issues such as those associated with CMS-identified problems with an internal CMS file that CMS used in a Part D payment reconciliation, a coverage gap discount program reconciliation, or a reopening; CMS corrections to a PDE edit that impacted a specific plan type (for example, EGWPs); fraud or similar fault of the Part D sponsor or any subcontractor of the Part D sponsor; or a Part D sponsor's successful appeal of a reconciliation result. See, for example, HPMS memorandum, ''Second reopening of the 2011 Final Part D Payment Reconciliation,'' July 7, 2017 (available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/second%20reopening%20of%20the%202011%20part%20d%20reconciliation_final_403.pdf*) and HPMS memorandum, ''Reopening of the 2014 Final Part D Reconciliation for Employer Group Waiver Plans (EGWPs),'' January 11, 2017 (available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/cy14%20egwp%20reopening%20announcement_01-11-17_404.pdf*). These reopenings are not program-wide, but rather are targeted to the Part D contracts that are impacted by the particular issue that needs to be addressed by CMS (that is, ''targeted reopenings''). The targeted reopenings

are not performed on a predictable schedule, and instead are utilized by CMS in the confines of the reopening timeframes described in the current regulation at § 423.346(a)(1) through (3).

Although CMS has in recent experience utilized targeted reopenings as part of our process to correct certain issues, under the current process, if a particular issue was program-wide, CMS would perform a global reopening to address that issue. This global reopening could be in addition to the scheduled global reopening that CMS has performed approximately 4 years after the Part D payment reconciliation for that year.

b. Aligning the Timing of Reopenings to the Overpayment Look-Back Period

Pursuant to the current § 423.346(a)(2), CMS may reopen and revise an initial or reconsidered final payment determination within 4 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon establishment of good cause for reopening. As already discussed, this paragraph (a)(2) has set up our current global reopening schedule. CMS performs the Part D payment reconciliation (that is, the initial payment determination) for a contract year, and then within 4 years of announcing the completion of that reconciliation, CMS performs a global reopening on that contract year.

This reopening process is used to recoup overpayments associated with PDE and DIR related overpayments. Pursuant to the current overpayment provision at § 423.360(f), there is a ''look-back period'' in which a Part D sponsor must report and return any overpayment identified within the 6 most recent completed payment years. As described at § 423.360, an overpayment occurs after the ''applicable reconciliation.'' The applicable reconciliation refers to the deadlines for submitting data for the Part D payment reconciliation.

The following example illustrates the timing of the look-back period. The deadlines for submitting data for the 2021 Part D payment reconciliation were in June 2022. Prior to the deadlines for submitting data for the 2021 Part D payment reconciliation, a PDE or DIR related overpayment could not exist for 2021, and the latest year for which an overpayment could occur was 2020. Therefore, prior to the deadlines for submitting data for the 2021 Part D payment reconciliation, the look-back period was 2015–2020.

This 6-year look-back period along with the 4-year reopening timeframe described at § 423.346(a)(2) results in overpayments being reported for a contract year after CMS has performed the global reopening for that contract year. Continuing the prior example, if a Part D sponsor identified a PDE or DIR related overpayment associated with contract year 2016 in May 2022 (that is, prior to the deadlines for submitting data for the 2021 Part D payment reconciliation), that overpayment falls within the 2015–2020 look-back period, and the sponsor would have reported the overpayment to CMS mid-2022. However, CMS completed the global reopening of the 2016 Part D payment reconciliation in January 2022. This discrepancy between the 4-year reopening timeframe and the 6-year overpayment look-back period results in operational challenges for CMS, as discussed subsequently in this section.

CMS had described a process for recouping PDE and DIR related overpayments after the global reopening for the contract year at issue had been completed. In the preamble to our final rule, ''Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,'' 79 FR 29843 (May 23, 2014) and in subsequent subregulatory guidance, we stated that overpayments reported after the global reopening would be reported by the sponsor with an auditable estimate and that CMS would recoup the overpayment by either requesting a check or offsetting monthly prospective payments for the amount provided in the auditable estimate. See HPMS memorandum, ''Reopening Process and Updates to the PDE/DIR-related Overpayment Reporting,'' April 6, 2018 (available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hpms%2520memo_reopen%2520and%2520overpay_04-06-2018_205.pdf*). For PDE and DIR related overpayments, that approach presents challenges primarily because sponsors have also reported PDE and DIR related underpayments after the global reopening, which we do not have a method to process other than the reopening process.

We have contemplated doing targeted reopenings to reconcile the changes in PDE and DIR data, but that also presents operational challenges. Targeted reopenings are conducted using the same payment reconciliation system that conducts the Part D payment reconciliation, the coverage gap discount program reconciliation, and the scheduled global reopening. Given the volume of reporting after the scheduled global reopening, it would be challenging to find the time and resources to run multiple targeted reopenings.

Therefore, we proposed to modify § 423.346(a)(2) such that CMS may reopen and revise an initial or reconsidered final payment determination after the 12-month period (described at § 423.346(a)(1)), but within 6 years after the date of the notice of the initial or reconsidered determination to the Part D sponsor, upon an establishment of good cause for reopening. This change will allow CMS to process all changes to PDE data and DIR data after the overpayment look-back period for a contract year. Once a contract year falls outside of the look-back period, we would perform the global reopening for that contract year within the new 6-year timeframe, to recoup the PDE and DIR related overpayments reported by sponsors for that contract year (and process underpayments).

Prior to the new reopening timeframe going into effect, CMS will provide operational guidance, as has been done for past regularly scheduled global reopenings. The following example describes the timing for performing the scheduled global reopening. The data for the 2020 Part D payment reconciliation was due in June 2021. That reconciliation was completed in November 2021. Assuming a 4-year schedule, the DIR data for the contract year 2020 global reopening would be due to CMS by the end of July 2025, PDE data would be due in September 2025, and the 2020 global reopening would be completed the end of 2025 or early 2026. However, the 2020 contract year remains in the overpayment look-back period through June 2027. Under the 6-year timeframe, data for the 2020 global reopening would be due middle to late 2027, and the global reopening would be completed late 2027 or early 2028, after the 6-year look-back period.

Comment: We received a comment that supported our proposal and our efforts to align the look-back period with the reopening timeframe.

Response: We thank the commenter for the support.

Comment: A commenter stated that while they do not have a conceptual problem with expanding the timeframe for overpayments associated with PDE record data and DIR data, they were concerned that looking back more than 4 years would result in administrative costs that exceed the value of the overpayment recoupment and recommended that CMS withdraw the proposal unless an analysis demonstrates that the expanded timeframe would result in overpayment

recoupments that exceed increased administrative costs.

Response: We are not, as the commenter states, expanding the timeframe for overpayments. Under the existing requirements, described at § 423.360(f), sponsors are required to report and return any overpayment identified within the 6 most recently completed payment years. To clarify, we proposed to modify the reopening timeframe, described at § 423.346(a)(2), which does not have any impact on the existing timeframe for reporting and returning overpayments.

We decline the commenter's recommendation to withdraw the proposal unless an analysis demonstrates that the expanded timeframe would result in overpayment recoupments that exceed increased administrative costs. We do not believe that expanding the reopening timeframe from within 4 years to within 6 years will result in any additional burden. Additionally, the intent of the proposed change is not strictly focused on overpayment recoupment, but rather, is a remedy to operational challenges associated with the misalignment of the overpayment look-back period and the reopening timeframe.

Comment: A commenter expressed concerns that DIR fees collected from pharmacies challenge patient access and pharmacies' viability. The commenter was concerned that extending the timeframe at § 423.346(a)(2) from within 4 years to within 6 years without any guardrails or protections in place for community pharmacies could lead to instances in which sponsors take advantage of the process to further claw back payments from pharmacies. To address this concern, the commenter requested that CMS consider establishing protections to prevent sponsors from recouping pharmacy overpayments.

Response: The intent of the proposed change is to remedy operational challenges associated with the misalignment of the reopening timeframe, described at § 423.346(a)(2), and 6-year overpayment look-back period, described at § 423.360(f). The change in the reopening timeframe from within 4 years to within 6 years does not, in any way, change a sponsor's responsibility to report and return overpayments within the 6-year look-back period. The impact of DIR fees collected from pharmacies, pharmacy claw backs, and the recoupment of overpayments from pharmacies are outside of the scope of the proposed change.

After consideration of comments, we are finalizing the proposed requirements related to aligning the timing of reopenings to the overpayment look-back period without modification.

c. Standards for Performing Global and Targeted Reopenings

Consistent with the existing regulation at § 423.346(a) and (d), reopenings are at CMS's discretion. Under the current process, CMS has used its discretion to perform a scheduled global reopening on a Part D payment reconciliation within the timeframe specified at § 423.346(a)(2). Given the significant time and costs associated with conducting a reopening, it is expected that CMS will use its discretion to conduct a targeted reopening (or an additional global reopening for a program-wide issue) only under limited circumstances. We would contemplate using our discretion to perform a targeted reopening (or an additional global reopening) to correct or rectify a CMS file or CMS-created PDE edit-type issue, revise a payment determination that was based on PDE and/or DIR data that was submitted due to fraudulent activity of the sponsor or the sponsor's contractor, or pursuant to a successful appeal under § 423.350. CMS will not use its discretion to conduct a reopening to reconcile data that will be, or should have been, reconciled in the scheduled global reopening, which would include data from plan corrections, claims activity, and audits completed after the deadline to submit data for the scheduled global reopening. In addition, we are unlikely to conduct a reopening solely pursuant to a sponsor's request.

We proposed that in order to be included in a reopening, a contract must have been in effect (that is, receiving monthly prospective payments and submitting PDE data for service dates in that year) for the contract year being reopened. Intuitively, if a contract was not in the reconciliation for a particular contract year, it cannot be included in the reopening of that contract year's reconciliation. We also proposed that if CMS has sent a nonrenewed or terminated contract the ''Notice of final settlement,'' as described at § 423.521(a), by the time CMS completes the reopening, described at proposed § 423.346(f), CMS will exclude that contract from that reopening. We established the proposed exclusion based on the timing of the issuance of the ''Notice of final settlement'' and completion of the reopening, as opposed to the announcement of the reopening, due to the potentially lengthy reopening process and the likelihood that the ''Notice of final settlement'' will be issued prior to CMS completing the reopening process. For example, under the current timeframe for the scheduled global reopening, CMS has typically announced in the Spring and completed the reopening in December of that year or January of the next. During that timeframe, nonrenewed or terminated contracts will likely go through the final settlement process, and as a result, will not be able to complete the reopening process. This is because, pursuant to § 423.521, after the final settlement amount is calculated and the ''Notice of final settlement'' is issued to the Part D sponsor, CMS will no longer apply retroactive payment adjustments, and there will be no adjustments applied to amounts used in the calculation of the final settlement amount. We proposed to codify these inclusion criteria at § 423.346(g).

We also proposed at § 423.346(g)(2) that, specifically for targeted reopenings, CMS will identify which contracts or contract types are to be included in the reopening. This is because targeted Part D contract reopenings are impacted by the particular issue that CMS needs to address. Therefore, in order to be included in a targeted reopening, the Part D contract must have been impacted by the issue that causes CMS to perform a reopening. To date, most targeted reopenings have been performed because of a CMS-identified issue that most sponsors were not aware of prior to CMS completing the targeted reopening. Accordingly, sponsors would not be aware of this specific inclusion criteria unless CMS informed the sponsors of the CMS-identified issue and the sponsors' contracts were impacted. Therefore, we proposed that CMS notify sponsors of this specific inclusion criteria via the proposed reopening notification and/or the proposed reopening completion announcement.

We did not receive comments on this section of the proposal and are finalizing the proposed requirements related to the standards for performing global and targeted reopenings without modification.

c. Reopening Notification and Reopening Completion Announcement

We proposed to add new paragraphs (e) and (f) at § 423.346 to codify our existing policy regarding reopening notifications and reopening completion announcements, respectively. We proposed to codify at § 423.346(e) that CMS will notify the sponsor(s) that will be included in the global or targeted reopening of its intention to perform a global or a targeted reopening—that is, the sponsor would receive prior notice

of the reopening—only when it is necessary for the sponsor(s) to submit PDE data and/or DIR data prior to the reopening. In contrast, if it is not necessary for the sponsor(s) to submit data prior to a reopening, we proposed to notify the sponsor(s) only after CMS completes the reopening. For example, if CMS identifies an error in an internal CMS file that CMS used in the reconciliation or reopening, CMS may correct that file and reopen (holding all other data originally used constant), without the need for the sponsor(s) to submit PDE data or DIR data. See, for example, HPMS memorandum, ''Second reopening of the 2011 Final Part D Payment Reconciliation,'' July 7, 2017 (available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/second%20reopening%20of%20the%202011%20part%20d%20reconciliation_final_403.pdf*).

We proposed at § 423.346(e)(1) that CMS will include in the notification the deadline for submitting PDE data and/or DIR data to be included in the reopening. We also proposed that the deadline to submit this data will be at least 90 calendar days after the date of the notice.

In addition, we proposed at § 423.346(e)(2) that the reopening notification will include inclusion criteria in the form of a description of the contract(s) (either specifically by contract number or generally by contract-type or contract status) that will be included in the reopening. This will put a sponsor on notice of whether its contracts are included in the reopening.

We proposed to codify at § 423.346(f) that CMS will announce when it has completed a reopening, including in cases where CMS issued a notice under proposed paragraph (e). This announcement is consistent with existing policy and past practice. At paragraph (f)(1), we proposed to specify that CMS will provide a description of the data used in the reopening. As in past reopenings, this data could include PDE data described by the processed date on the Prescription Drug Front-end System (PDFS) response report, DIR data described by the date received in the Health Plan Management System (HPMS), as well as any other relevant data used to perform the reopening.

At paragraph § 423.346(f)(2), we proposed to include in the announcement a statement of the contract(s) (either specifically by contract number or generally by contract-type or contract status) that were included in the reopening, consistent with proposed § 423.346(e)(2). We proposed to specify which contracts or contract types are included in the reopening in both the announcement of the completion of the reopening and the reopening notification because CMS' proposal would not require issuing a reopening notification when it is not necessary for the sponsor(s) to submit PDE data and/or DIR data prior to the reopening.

At paragraph § 423.346(f)(3), we proposed to include in the announcement of the completion of the reopening the date by which reports describing the reopening results will be available to the sponsor. In addition, at paragraph (f)(4), we proposed to include the date by which a sponsor must submit an appeal, pursuant to § 423.350, if the sponsor disagrees with the reopening results.

We did not receive comments on this section of the proposal and are finalizing the proposed requirements related to the reopening notification and the announcement of the completion of the reopening without modification.

d. Definitions of ''Global Reopening'' and ''Targeted Reopening''

We proposed to establish definitions of global reopening and targeted reopening at § 423.308. We proposed to define a global reopening as a reopening under § 423.346 in which CMS includes all Part D sponsor contracts that meet the inclusion criteria described at proposed § 423.346(g). We proposed to define a targeted reopening as a reopening under § 423.346 in which CMS includes one or more (but not all) Part D sponsor contracts that the meet the inclusion criteria described at proposed § 423.346(g). Finally, consistent with these proposed definitions, we proposed to include the terms ''global reopening'' and ''targeted reopening'' at the beginning of existing § 423.346(a) to clarify that the reopenings that CMS may perform under § 423.346(a) may be global or targeted, as defined in proposed § 423.308.

Comment: We received a comment supporting our proposal to codify the definitions of ''global reopening'' and ''targeted reopening.''

Response: We thank the commenter for the support.

We are finalizing the proposed definitions of ''global reopening'' and ''targeted reopening'' without modification.

The proposals described in this section of the final rule are consistent with our current guidance and requirements. None of the proposed changes would place additional requirements on Part D sponsors, nor do the proposed changes to §§ 423.308 and 423.346 place any additional burden on the Part D sponsors or their pharmacy benefit managers (PBMs). Our proposed rule does not change the extent to which Part D sponsors comply with the reopening process. Part D sponsors' compliance with this reopening process is evidenced by each Part D sponsor's signed attestation certifying the cost data (pursuant to § 423.505(k)(3) and (5)) that CMS uses in each of the reopenings. In addition, the burden associated with the submission of cost data is already approved under the OMB control numbers 0938–0982 (CMS–10174) and 0938–0964 (CMS–10141). Therefore, as our changes do not result in additional burden, we have not included a discussion a of this provision in the COI section of this rule. In addition, we are not scoring this provision in the Regulatory Impact Analysis section because industry is already complying with this process.

Based on the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed changes to the reopening provision at § 423.346 and the related changes to § 423.308 without modification.

C. Medicare Final Settlement Process and Final Settlement Appeals Process for Organizations and Sponsors That Are Consolidating, Nonrenewing, or Otherwise Terminating a Contract (§§ 422.500(b), 422.528, 422.529, 423.501, 423.521, and 423.522)

In our December 2022 proposed rule, we proposed to amend 42 CFR part 422, subpart K, and part 423, subpart K, to codify in regulation our final settlement process for Medicare Advantage (MA) organizations and Part D sponsors whose contracts with CMS have been consolidated with another contract, nonrenewed, or otherwise terminated. As described subsequently in this section, we are finalizing our proposed changes.

Sections 1857(a) and 1860D–12(b)(1) of the Act require contracts between CMS and the legal entity that offers, respectively, one or more MA plans or Part D plans to beneficiaries. Sections 1857(e)(1) and 1860D–12(b)(3)(D)(i) of the Act provide that these contracts shall contain terms and conditions that the Secretary may find necessary and appropriate in addition to the applicable requirements and standards set forth in the statute and the terms of payment set by the statute. At Part 422, subpart K, and Part 423, subpart K, we have codified provisions relating to the contracts between CMS and MA

organizations and Part D sponsors, including a description of minimum terms that must be included in the contract; the duration of contracts; minimum enrollment, reporting, and prompt payment requirements; and provisions regarding the consolidation, nonrenewal, or termination of a contract. In addition, these contracts require compliance with the regulations governing the program, which are adopted as standards implementing and interpreting the statutory requirement and as new terms and conditions that are not inconsistent with, and necessary and appropriate for administration of, the MA and Part D programs. This final rule will add to those requirements.

CMS makes monthly payments to MA organizations and Part D sponsors for each beneficiary enrolled in a plan for that month. If there is an update to the payment amount that was paid for a month, CMS will make an adjustment to a month's payment for a beneficiary in a later month. For example, if a beneficiary's Medicaid eligibility for a month is changed, CMS will recalculate the payment for that month after receipt of the updated Medicaid eligibility status for a beneficiary and make a retroactive payment update to that month's payment in a later month. In addition, CMS reconciles a number of different payment amounts after specified periods of time to permit plan data submission for a payment year as described subsequently in this section. These reconciliations typically take place the year after a payment year and result in retroactive payment adjustments for the prior payment year.

Generally, MA organizations and Part D sponsors continue to offer plans to beneficiaries from one year to the next. From time to time, a contract between CMS and an MA organization or Part D sponsor may consolidate, nonrenew, or otherwise terminate as a result of a plan-initiated termination, mutual termination, or CMS-initiated termination. Once a contract has consolidated, nonrenewed, or otherwise terminated, the retroactive payment adjustments for a year that would have been made had the contract remained in effect are not paid to the MA organization or Part D sponsor but are held until after the reconciliations for the final payment year are calculated as described subsequently in this section. After such time, all retroactive adjustments to payment for the consolidated, nonrenewed, or otherwise terminated contract are totaled and either a net payment amount is made to the MA organization or Part D sponsor, or an amount is charged to the MA organization or Part D sponsor.[4]

The process used to determine the final net payments for an MA organization or Part D sponsor, provide notice of these amounts to the MA organization or Part D sponsor, adjudicate disputes, and receive or remit payment constitutes the *final settlement process* and begins at least 18 months following the end of the last contract year in which the contract was in effect.

Before CMS determines the final settlement amount owed to or from an MA organization or Part D sponsor whose contract has consolidated, nonrenewed, or otherwise terminated, CMS first completes a series of reconciliation activities and calculates the related payment adjustments for both consolidated, nonrenewed, or otherwise terminated contracts as well as ongoing contracts: (1) MA risk adjustment reconciliation (described in § 422.310(g)), (2) Part D annual reconciliation (described in §§ 423.336 and 423.343), (3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320), and (4) medical loss ratio (MLR) report submission and remittance calculation (described in §§ 422.2460, 422.2470. 423.2460, and 423.2470). Each individual reconciliation process allows the MA organization or Part D sponsor to raise concerns about the calculation of that particular reconciliation amount. Once each reconciliation is complete and no errors have been identified, the MA organization or Part D sponsor is presumed to accept that reconciliation amount and it is not reconsidered during the final settlement process.

For a given consolidated, nonrenewed, or otherwise terminated contract, the *final settlement amount* is then calculated by summing the applicable reconciliation amounts from these 4 processes and any retroactive payment adjustments that accumulated after a contract has consolidated, nonrenewed, or otherwise terminated. Note that these reconciliation amounts represent all of the reconciliation amounts that could be included in the final settlement calculation. Whether each reconciliation amount will factor into the final settlement amount for a particular contract will depend on the specifics of that contract. For example, MA risk adjustment reconciliation would not be performed for a prescription drug plan contract.

The *final settlement adjustment period* is the period of time between when the contract consolidates, nonrenews, or otherwise terminates and the date the MA organization or Part D sponsor is issued a notice of the final settlement amount (also referred to herein as the *notice of final settlement*). The length of the final settlement period is determined by the time it takes for these reconciliations and related payment adjustments to be completed. During this time, CMS continues to calculate payment adjustments that reflect changes in beneficiary status.[5] CMS tracks all payment adjustments for a terminated contract for use in the final settlement for that contract.

The final settlement adjustment period ends on the date on the *notice of final settlement* that CMS issues to MA organizations and Part D sponsors. At the end of the final settlement adjustment period, CMS will no longer make adjustments to reconciliations for a contract that has consolidated, nonrenewed, or otherwise terminated, that would otherwise have been made for a continuing contract. Once the notice of final settlement has been issued, contracts that have been consolidated, nonrenewed, or otherwise terminated will also be excluded from reopenings, including program-wide reopenings, or reconciliations for prior payment years when the contract was in effect. For example, under § 423.346, CMS has the authority to reopen and revise an initial or reconsidered Part D final payment determination, including the Part D reconciliation amounts included in the final settlement amount, for a prior payment year. However, this reopening would not apply to consolidated, nonrenewed, or otherwise terminated contracts that have already received a notice of final settlement. This allows CMS to largely close out any outstanding financial responsibilities associated with consolidated, nonrenewed, or otherwise terminated contracts, either on the part of CMS or on the part of the MA organization or Part D sponsor.[6]

After determining the final settlement amount, CMS issues a notice of final settlement to the MA organization or Part D sponsor for each contract that has consolidated, nonrenewed, or otherwise

[4] In the case of a bankrupt or liquidated plan that owes CMS money, CMS still completes the reconciliations, final settlement process, and issues a notice of final settlement, but refers the plan to the Department of Justice to collect the money owed.

[5] A beneficiary profile status change reflects a change in a beneficiary's economic or health status, such as low-income status for Part D, Medicaid status, Hospice or ESRD status.

[6] Once a contract has completed final settlement, the MA organization or Part D sponsor may still have financial responsibilities under any other applicable statute or regulation.

terminated, even if the final settlement amount is $0. The notice of final settlement explains whether the MA organization or Part D sponsor will receive or owe a final settlement amount and provides the information needed to conduct the associated financial transaction. The notice of final settlement includes the information CMS used to calculate the final settlement amount, including the payment adjustments that are reported on all monthly membership reports created from the date the contract ended until the month the final settlement amount was calculated. It also includes information on the process and timeline for requesting a review concerning the accuracy of the final settlement amount calculation.

In our proposed rule, we proposed to codify longstanding and existing guidance pertaining to procedures for the final settlement process described in the previous paragraphs. In addition, we proposed to add a new appeals process for MA organizations or Part D sponsors that disagree with the final settlement amount. MA organizations or Part D sponsors may request an appeal of the final settlement amount within 15 calendar days of the date of issuance of the notice of final settlement. We believe that will provide organizations with sufficient time to request an appeal, as MA organizations and Part D sponsors will already be aware of the reconciliation amounts that factor into the final settlement amount at the time the notice of final settlement is issued, and requiring a request for appeal within this timeframe will help ensure accurate and timely payment of final settlement amounts. If an MA organization or Part D sponsor agrees with the final settlement amount, no response will be necessary or required. Failure to request appeal within 15 calendar days of the date of issuance of the notice of final settlement will indicate acceptance of the final settlement amount. We strongly encourage MA organizations and Part D sponsors to communicate their acceptance to CMS to facilitate prompt payment.

Finally, in addition to codifying our longstanding and existing review process under which MA organizations and Part D sponsors are able to request a reconsideration of CMS's final settlement amount calculation, we proposed to add two additional levels of appeal: (1) an informal hearing conducted by the CMS Office of Hearings to review CMS's initial determination, following a request for appeal of the reconsideration of CMS's initial determination, and (2) a review by the CMS Administrator of the hearing officer's determination if there is an appeal of the hearing officer's determination. We believe that these additional levels of appeal will afford MA organizations and Part D sponsors sufficient opportunities to present objections to the calculation of the final settlement amount. This additional process will only be available to appeal CMS's final settlement amount calculation and will not be used to review any prior payments or reconciliation amounts. MA organizations and Part D sponsors seeking review of prior payments or reconciliation amounts must do so during the appropriate reconciliation process. CMS believes that these additional levels of appeal will only be used in exceptional circumstances given the narrow, mathematical nature of the final settlement process. We anticipate that calculation errors will be rare, and, if they do occur, that they will be quickly corrected to the mutual satisfaction of both parties without a need for further review.

1. Process for MA Organizations and Part D Sponsors That Do Not Request an Appeal

If an MA organization or Part D sponsor that owes a final settlement amount to CMS does not request an appeal or provides an optional response acknowledging and confirming the amount owed to CMS within 15 calendar days of the date of the notice of final settlement, the MA organization or Part D sponsor will be required to remit full payment to CMS within 120 calendar days of receiving the notice of final settlement. If an MA organization or Part D sponsor is owed money and does not appeal the final settlement amount, CMS will remit payment to the MA organization or Part D sponsor within 60 calendar days of the date of issuance of the notice of final settlement. If an MA organization or Part D sponsor does not owe or is not owed a final settlement amount and does not request an appeal of the $0 final settlement amount within 15 calendar days of the date of issuance of the notice of final settlement, no further actions will occur. If an MA organization or Part D sponsor does not appeal the final settlement amount indicated in the notice of final settlement within 15 calendar days of the issuance of the notice of final settlement, no subsequent requests for appeal will be considered.

CMS did not receive comments on this section of the proposal.

2. Process for Appealing the Final Settlement Amount

In cases in which the MA organization or Part D sponsor submits a request for an appeal of the final settlement amount within 15 calendar days of the date of the notice of final settlement, the MA organization or Part D sponsor will have to specify the calculation with which they disagree and the reasons for their disagreement, as well as provide evidence supporting the assertion that CMS's calculation of the final settlement amount described in the notice of final settlement is incorrect. MA organizations and Part D sponsors will not be able to submit new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS will not consider information submitted for the purpose of retroactively adjusting a prior reconciliation.

CMS will not accept requests for appeal that are submitted more than 15 calendar days after the date of issuance of the notice of final settlement. As noted previously, if an MA organization or Part D sponsor does not reply within 15 calendar days, they will be deemed to accept the final settlement amount indicated in the notice of final settlement.

Once CMS has reconsidered the calculation of the final settlement amount in light of the evidence provided by the MA organization or Part D sponsor, CMS will provide written notice of the reconsideration decision to the MA organization or Part D sponsor.

If the MA organization or Part D sponsor does not agree with CMS's reconsideration decision, it will be able to request an informal hearing from a CMS hearing officer. The MA organization or Part D sponsor will have to submit a request for review within 15 calendar days of the date of CMS's reconsideration decision. The MA organization or Part D sponsor will be required to provide a copy of CMS's decision, the findings or issues with which it disagrees, and the reasons why it disagrees with CMS's decision. As the hearing officer's review will be limited to a review of the existing record, the MA organization or Part D sponsor will not be able to submit new evidence to support its assertion that CMS's calculation of the final settlement amount described in the notice of final settlement is incorrect in addition to the evidence submitted during CMS's reconsideration.

The CMS hearing officer will provide written notice of the time and place of the informal hearing at least 30 days before the scheduled date and the CMS

reconsideration official will provide a copy of the record that was before CMS when CMS made its reconsideration decision to the hearing officer. The CMS hearing officer will not receive new testimony or accept new evidence in addition to the evidence submitted by the MA organization or Part D sponsor during CMS's reconsideration to support its assertion that CMS's calculation of the final settlement amount is incorrect.

Once the hearing officer has reviewed the record, the hearing officer will send a written decision to the MA organization or Part D sponsor explaining the basis of the hearing officer's decision. The hearing officer's decision will be final and binding unless the decision is reversed or modified by the CMS Administrator.

If the MA organization or Part D sponsor does not agree with the hearing officer's decision, they will be able to request an additional, final review from the CMS Administrator. The MA organization or Part D sponsor will have to submit a request for review within 15 calendar days of the date of the issuance of CMS hearing officer's decision. The MA organization or Part D sponsor will be able to submit written arguments to the Administrator for review but will not be able to submit evidence in addition to the evidence submitted during CMS's reconsideration.

The CMS Administrator will have the discretion to elect to review the hearing officer's decision or decline to review the hearing officer's decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing officer's decision, the hearing officer's decision will be final and binding. If the Administrator elects to review the hearing officer's decision and any written argument submitted by the MA organization or Part D sponsor, the Administrator will review the information included in the record of the hearing officer's decision and any written argument submitted by the MA organization or Part D sponsor. Based on this review, the Administrator may uphold, reverse, or modify the hearing officer's decision. The Administrator's decision will be final and binding and no other requests for review will be considered.

If an MA organization or Part D sponsor requests an appeal of the final settlement amount, the financial transaction associated with the issuance or payment of the final settlement amount will be stayed until all appeals are exhausted. Once all levels of appeal are exhausted or the MA organization or Part D sponsor fails to request further review within the 15-day timeframe, CMS will communicate with the MA organization or Part D sponsor to complete the financial transaction associated with the issuance or payment of the final settlement amount, as appropriate.

At all levels of review, the MA organization or Part D sponsor's appeal will be limited to CMS's calculation of the final settlement amount. CMS will not consider information submitted for the purposes of retroactively adjusting a prior reconciliation. The MA organization or Part D sponsor will bear the burden of proof by providing evidence demonstrating that CMS's calculation of the final settlement amount is incorrect.

CMS did not receive comments on this section of the proposal.

3. Proposed Amendments to Regulations (§§ 422.500(b), 422.528, 422.529, 423.501, 423.521, and 423.522)

a. Definitions

We proposed to amend §§ 422.500(b) and 423.501 to add several definitions relevant for the codification of the final settlement process.

First, we proposed to add a definition for the term *final settlement amount,* which will be the final payment amount CMS calculates and ultimately pays to the MA organization or Part D sponsor or that an MA organization or Part D sponsor pays to CMS for a Medicare Advantage or Part D contract that has terminated through consolidation, nonrenewal, or other termination. The proposed definition provides that CMS will calculate the final settlement amount by summing retroactive payment adjustments for a contract that accumulate after that contract consolidates nonrenews, or otherwise terminates, but before the calculation of the final settlement amount, including the applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating the reconciliation amounts. These reconciliation amounts used in this process are: (1) MA risk adjustment reconciliation (described in § 422.310), (2) Part D annual reconciliation (described in §§ 423.336 and 423.343), (3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320), and (4) MLR report submission, including calculation of remittances (described in §§ 422.2470 and 423.2470).

We proposed to add a definition for the term *final settlement process* as the process by which CMS will calculate the final settlement amount for a Medicare Advantage or Part D contract that has been consolidated, nonrenewed, or otherwise terminated, issue the final settlement amount along with supporting documentation (described previously in section XXX) in the notice of final settlement to the MA organization or Part D sponsor, receive responses from MA organizations and Part D sponsors requesting an appeal of the final settlement amount, and take final actions to adjudicate an appeal (if requested) and make payments to or receive final payments from MA organizations or Part D sponsors. The proposed definition of *final settlement process* will specify that the final settlement process begins after all applicable reconciliations have been completed.

b. Final Settlement Process and Payment

We proposed to add §§ 422.528 (for MA) and 423.521 (for Part D) to our regulations to codify our process for notifying MA organizations and Part D sponsors of the final settlement amount and how payments to or from CMS will be made.

CMS will calculate and notify MA organizations and Part D sponsors of the final settlement amount. At paragraph (a) of proposed §§ 422.528 (for MA) and 423.521 (for Part D), we proposed to codify that CMS will send a notice of final settlement to MA organizations and Part D sponsors. Specifically, proposed paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) specify that the notice will contain at least the following information: a final settlement amount; relevant banking and financial mailing instructions for MA organizations and Part D sponsors that owe CMS a final settlement amount; relevant CMS contact information; and a description of the steps for the MA organizations or Part D sponsor to request an appeal of the final settlement amount calculation.

At paragraph (b) of proposed §§ 422.528 and 423.521, we proposed to establish that MA organizations and Part D sponsors will have 15 calendar days from the date of issuance of the notice to request an appeal. We proposed at paragraphs (b)(1) and (b)(2) of these new regulation sections that, if an MA organization or Part D sponsor agrees with the final settlement amount, no response will be required, and that, if an MA organization or Part D sponsor does not request an appeal within 15 calendar days, CMS will not consider any subsequent requests for appeal of the final settlement amount.

At paragraph (c) of proposed §§ 422.528 and 423.521, we proposed to codify the actions that will take place if an MA organization or Part D sponsor does not appeal the final settlement amount. Specifically, at paragraph (c)(1), we proposed to specify that, if an MA organization or Part D sponsor owed a final settlement amount from CMS does not appeal, CMS will remit payment within 60 calendar days of the date of the issuance of the notice of final settlement. At proposed paragraph (c)(2), we proposed that an MA organization or Part D sponsor that owes money to CMS and does not appeal will have to remit payment in full to CMS within 120 calendar days from issuance of the notice of final settlement. We further specify that an MA organization or Part D sponsor that does not appeal and does not remit payment within 120 calendar days of issuance of the notice will be subject to having any debts owed to CMS referred to the Department of the Treasury for collection.[7]

At paragraph (d) of proposed §§ 422.529 (for MA) and 423.522 (for Part D), we proposed to establish the actions following submission of a request for an appeal that will be taken.

At paragraph (e) of proposed §§ 422.529 (for MA) and 423.522 (for Part D), we proposed that after the final settlement amount is calculated and the notice of final settlement is issued to the MA organization or Part D sponsor, CMS will no longer apply retroactive payment adjustments for the terminated contract and there will be no adjustments applied to the final settlement amount.

c. Requesting an Appeal of the Final Settlement Amount

We proposed to add §§ 422.529 (for MA) and 423.522 (for Part D) to our regulations to codify that an MA organization or Part D sponsor will be able to request an appeal of the calculation of the final settlement amount, and the process and requirements for making such a request.

At paragraph (a) of proposed §§ 422.529 and 423.522, we proposed to establish requirements that will apply to MA organizations' and Part D sponsors' requests for appeal of the final settlement amount calculation.

Specifically, at proposed paragraph (a)(1), we proposed to establish the process under which an MA organization or Part D sponsor may request reconsideration of the final settlement amount. We proposed to specify that the 15-calendar-day period for filing the request will begin on the date the notice of final settlement from CMS is issued. We also proposed that MA organizations and Part D sponsors will have to include in their request: (1) the calculation with which they disagree and (2) evidence supporting the assertion that the CMS calculation of the final settlement amount is incorrect. We further specify that CMS will not consider (for purposes of retroactively adjusting a prior reconciliation), and MA organizations and Part D sponsors should not submit, new reconciliation data or data that was submitted to CMS after the final settlement notice was issued.

At proposed paragraph (a)(1)(iii), we proposed to establish that the CMS reconsideration official will review the final settlement calculation and evidence timely submitted by the MA organization or Part D sponsor supporting the assertion that the CMS calculation of the final settlement amount is incorrect. We further proposed to establish that the CMS reconsideration official will inform the MA organization or Part D sponsor of their decision on the reconsideration in writing and that their decision will be final and binding unless the MA organization or Part D sponsor requests a hearing officer review.

At proposed paragraph (a)(2), we proposed to establish that MA organizations and Part D sponsors that disagree with CMS's reconsideration decision under paragraph (a)(1) of this section will be able to request an informal hearing by a CMS hearing officer.

Specifically, at paragraph (a)(2)(i), we establish that MA organizations and Part D sponsors will have to submit their requests for an informal hearing within 15 calendar days of the date of the reconsideration decision. At paragraph (a)(2)(ii), we proposed that MA organizations and Part D sponsors will have to include in their request a copy of CMS's decision, the specific findings or issues with which they disagree, and the reasons for which they disagree. At paragraph (a)(2)(iii), we proposed to establish the informal hearing procedures. Specifically, we proposed that the CMS hearing officer will provide written notice of the time and place of the informal hearing at least 30 calendar days before the scheduled date and the CMS reconsideration official will provide a copy of the record that was before CMS when CMS made its reconsideration decision to the hearing officer. We further proposed that the hearing will be conducted by a hearing officer who will neither receive testimony nor accept new evidence. We finally proposed that the hearing officer will be limited to the review of the record that CMS had when making its decision. At paragraph (a)(2)(iv), we proposed that the CMS hearing officer will send a written decision to the MA organization or Part D sponsor explaining the basis for the decision. At proposed paragraph (a)(2)(v), we proposed to establish that the hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator.

We further proposed to establish at paragraph (a)(3) that MA organizations and Part D sponsors that disagree with the hearing officer's decision will be able to request a review by the CMS Administrator.

At paragraph (a)(3)(i), we establish that MA organizations and Part D sponsors will have to submit their requests for a review by the Administrator within 15 calendar days of the date of the decision and may submit written arguments to the Administrator for review. At paragraph (a)(3)(ii), we proposed that the CMS Administrator will have the discretion to elect or decline to review the hearing officer's decision within 30 calendar days of receiving the request for review. We further proposed that if the Administrator declines to review the hearing officer's decision, the hearing officer's decision will be final and binding. We proposed at paragraph (a)(3)(iii) that, if the Administrator elects to review the hearing officer's decision, the Administrator will review the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written arguments submitted by the MA organization or Part D sponsor, and determine whether to uphold, reverse, or modify the decision. At proposed paragraph (a)(3)(iv), we proposed that the Administrator's determination will be final and binding.

At proposed paragraph (b), we proposed to establish the matters subject to appeal and that an MA organization or Part D sponsor bears the burden of proof. At proposed paragraph (b)(1), we proposed to establish that the Part D sponsor's appeal will be limited to CMS's calculation of the final settlement amount. We further proposed that CMS will not consider information submitted for the purposes of retroactively adjusting a prior reconciliation. At proposed paragraph (b)(2), we proposed that the MA organization or Part D sponsor will bear the burden of proof by providing evidence demonstrating that

[7] In the case of a bankrupt or liquidated plan that owes CMS money, CMS still completes the reconciliations and the final settlement process and issues a notice of final settlement, but refers the plan to the Department of Justice to collect the money owed.

CMS's calculation of the final settlement amount is incorrect.

At proposed paragraph (c), we proposed that if an MA organization or Part D sponsor requests an appeal of the final settlement amount, the financial transaction associated with the issuance or payment of the final settlement amount will be stayed until all appeals are exhausted. Once all levels of appeal are exhausted or the MA organization or Part D sponsor fails to request further review within the 15-calendar-day timeframe, CMS will communicate with the MA organization or Part D sponsor to complete the financial transaction associated with the issuance or payment of the final settlement amount, as appropriate.

Proposed paragraph (d) clarifies that nothing in this section will limit an MA organization or Part D sponsor's responsibility to comply with any other applicable statute or regulation.

CMS did not receive comments on this section of the proposal.

Based on the lack of comments received, we are finalizing the additions to §§ 422.500(b), 422.528, 422.529, 423.501, 423.521, and 423.522 to codify the final settlement process as proposed.

D. Civil Money Penalty Methodology (§§ 422.760 and 423.760)

Sections 1857(g)(3)(A) and 1860D–12(b)(3)(E) of the Act provide CMS with the ability to impose Civil Money Penalties (CMPs) of up to $25,000 per determination (determinations are those which could otherwise support contract termination, pursuant to § 422.509 or § 423.510), as adjusted annually under 45 CFR part 102, when the deficiency on which the determination is based adversely affects or has the substantial likelihood of adversely affecting an individual covered under the organization's contract. Additionally, as specified in §§ 422.760(b)(2) and 423.760(b)(2), CMS is permitted to impose CMPs of up to $25,000, as adjusted annually under 45 CFR part 102, for each enrollee directly adversely affected or with a substantial likelihood of being adversely affected by a deficiency. CMS has the authority to issue a CMP up to the maximum amount permitted under regulation, as adjusted annually [8] for each affected enrollee or per determination, however CMS does not necessarily apply the maximum penalty amount authorized by the regulation in all instances because the penalty amounts under the current CMP calculation methodology are generally sufficient to encourage compliance with CMS rules.

On December 15, 2016, CMS released on its website, the first public CMP calculation methodology for calculating CMPs for MA organizations and Part D sponsors starting with referrals received in 2017. On March 15, 2019, CMS released for comment a proposed CMP calculation methodology on its website that revised some portions of the methodology released in December 2016. Subsequently, on June 21, 2019, CMS finalized the revised CMP calculation methodology document, made it available on its website, and applied it to CMPs issued starting with referrals received in contract year 2019 and beyond.[9]

On January 19, 2021, CMS published a final rule in the **Federal Register** titled ''Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.'' (86 FR 5864. *https://www.federalregister.gov/documents/2021/01/19/2021-00538/medicare-and-medicaid-programs-contract-year-2022-policy-and-technical-changes-to-the-medicare.* Hereinafter referred to as the January 2019 final rule). In January 2019 final rule, CMS finalized a policy, effective beginning in CY 2022, to update the minimum CMP penalty amounts no more often than every three years. Under this policy, CMS updates the CMP penalty amounts by including the increases that would have applied if CMS had multiplied the minimum penalty amounts by the cost-of-living multiplier released by the Office of Management and Budget (OMB) [10] each year during the preceding three-year period. CMS also tracks the yearly accrual of the penalty amounts and announces them on an annual basis.

The intent of the minimum penalty increase policy was to establish the CMP calculation methodology document in regulation to ensure consistency and transparency with CMP penalty amounts. Although parts of the regulations at §§ 422.760(b)(3) and 423.760(b)(3) have set standards for CMP penalties, in hindsight, CMS believes that other parts of the regulations unnecessarily complicated CMS's approach to calculating CMPs, which has the effect of limiting CMS's ability to protect beneficiaries when CMS determines that an organization's non-compliance warrants a CMP amount that is higher than would normally be applied under the CMP methodology. In addition, although CMS always has had the authority to impose up to the maximum authorized under sections 1857(g)(3)(A) and 1860D–12(b)(3)(E) of the Act, parts of the minimum penalty increase policy may have inadvertently given the impression that CMS was limiting its ability to take up to the maximum amount permitted in statute and regulation. This was not the intent of the rule. For example, there may be instances where an organization's non-compliance has so substantially adversely impacted one or more enrollees that CMS determines it is necessary to impose the maximum CMP amount permitted under statute, or an amount that is higher than the amount set forth in the CMP methodology guidance, to adequately address the non-compliance. In order to clarify its ability to adequately protect beneficiaries and encourage compliance, CMS proposed to modify its rules pertaining to minimum penalty amounts.

Specifically, we proposed to remove §§ 422.760(b)(3)(i)(E) and 423.760(b)(3)(i)(E), respectively, which is the cost-of-living multiplier. We also proposed to remove §§ 422.760(b)(3)(ii)(A)–(C) and 423.760(b)(3)(ii)(A)–(C), which describes how CMS calculates and applies the minimum penalty amount increase. Lastly, we proposed to revise and add new provisions §§ 422.760(b)(3) and 423.760(b)(3), which explain that CMS will set standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties in accordance with paragraphs (b)(1) and (b)(2) of paragraph (b) on an annual basis, and restates that CMS has the discretion to issue penalties up to the maximum amount under paragraphs (b)(1) and (2) when CMS determines that an organization's

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

[9] CMS Civil Money Penalty Calculation Methodology, Revised. June 21, 2019. *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2019CMPMethodology06212019.pdf.*

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

non-compliance warrants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

Once finalized, CMS would continue to follow our existing CMP methodology and would only impose up to the maximum CMP amount in instances where we determine non-compliance warrants a higher penalty. This update will also be incorporated in forthcoming revised CMP calculation methodology guidance.

Comment: A commenter suggested that removing the minimum penalty amount increase policy would lead to inconsistencies, and a lack of parity, in the CMP amounts we impose.

Response: We disagree with this comment. First, as discussed above and in the proposed rule, CMS has always had the statutory authority to impose up to the maximum CMP amount authorized under sections 1857(g)(3)(A) and 1860D–12(b)(3)(E) of the Act. Second, CMS would continue to follow our existing CMP methodology, which allows for parity, fairness, and consistency in calculating CMP amounts. We would only impose up to the maximum CMP amount in instances where we determine non-compliance warrants a higher penalty to adequately address the non-compliance.

After consideration of the comments received, we are finalizing our changes to §§ 422.760(b)(3) and 423.760(b)(3) as proposed.

E. Part D Medication Therapy Management (MTM) Program (§ 423.153(d))

1. MTM Eligibility Criteria (§ 423.153(d)(2))

a. Background

Section 1860D–4(c)(2) of the Act requires all Part D sponsors to have an MTM program designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. Section 1860D–4(c)(2)(A)(ii) of the Act requires Part D sponsors to target those Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary. Since January 1, 2022, Part D sponsors are also required by section 1860D–4(c)(2)(A)(ii)(II) of the Act to target all at-risk beneficiaries (ARBs) [11] in their Part D drug management program (DMP) for MTM. CMS has codified the MTM targeting criteria at § 423.153(d)(2).

As discussed in the December 2022 proposed rule (87 FR 79452), MTM eligibility rates have steadily declined over time to 8 percent in 2020. In conjunction with the decreasing eligibility rates, CMS has observed near-universal convergence among Part D sponsors to the most restrictive targeting criteria currently permitted under § 423.153(d)(2). When CMS finalized the current regulatory requirements for targeting criteria over 13 years ago, CMS elected to continue to give plan sponsors significant flexibility in establishing their MTM eligibility criteria. However, sponsors have used this flexibility to adopt increasingly restrictive criteria that we believe are limiting access to MTM for vulnerable, clinically high-risk beneficiaries.

We performed an extensive analysis to identify potential disparities in MTM program eligibility and access, as discussed in the December 2022 proposed rule, and we identified the high cost threshold and increasingly restrictive plan criteria (*e.g.,* targeting select core chronic diseases or specific drugs) as the main drivers of the eligibility gaps. The targeting criteria used by most plans now require three or more chronic diseases, require eight or more Part D drugs, and target a narrow and variable list of chronic diseases. And because of variation in plans' criteria for MTM enrollment, enrollees with equivalent patient profiles (for example, same chronic diseases, same number of chronic diseases, same number of Part D drugs, and similar estimated drug costs) may or may not be eligible for MTM depending on the criteria their plan requires. Under the current MTM cost threshold methodology at § 423.153(d)(2)(i)(C), the annual cost threshold for 2024 is $5,330, which also significantly limits the number of beneficiaries who are eligible to be targeted for MTM enrollment. In the December 2022 proposed rule, CMS proposed changes to the MTM program eligibility criteria to address these concerns and help ensure beneficiaries with more complex drug regimens who would benefit most from MTM services are eligible.

The proposed changes included:

- Requiring plan sponsors to target all core chronic diseases identified by CMS, codifying the current nine core chronic diseases in regulation,[12] and adding HIV/AIDS for a total of 10 core chronic diseases;
- Lowering the maximum number of covered Part D drugs a sponsor may require from eight to five drugs and requiring sponsors to include all Part D maintenance drugs in their targeting criteria; and
- Revising the methodology for calculating the cost threshold ($5,330 in 2024) to be commensurate with the average annual cost of five generic drugs ($1,004 in 2020).

CMS received many comments on these proposed changes, including the following general comments, and our responses follow.

Comment: Many commenters cited studies that demonstrated the value of MTM services and supported changes to the targeting criteria to optimize therapeutic outcomes, decrease adverse medication events, and avoid unnecessary costs. Commenters also acknowledged that studies show medication-related problems such as poor medication adherence and polypharmacy are widespread among individuals taking multiple prescription medications. These studies emphasized the value of MTM, including maintaining the wellbeing of Part D enrollees, resolving medication-related problems, improving health outcomes, empowering patients, and coordinating care. Some commenters cited a study that showed net cost savings (*i.e.,* a reduction in total annual health expenditures minus patient copayments, coinsurance, and deductible amounts) divided by the incremental cost of providing MTM services resulted in a return on investment of more than $12 in cost savings for each $1 spent on MTM. Commenters added that when patients better understand the goals of their medication therapy, medication adherence may increase, and hospital readmissions can be reduced. One commenter cited an analysis by a regional Medicare Advantage plan that found enrollees who received a comprehensive medication review (CMR) had an average savings of up to $4,000 in medical claims compared to members who did not receive a CMR. The commenter stated that the analysis also found that all enrollees who received a CMR had a 5 percent reduction in total cost of care compared to those who were eligible for but did not receive a CMR. Another commenter emphasized that access to pharmacists'

[11] Defined at § 423.100.

[12] The current core chronic diseases are: diabetes*, hypertension*, dyslipidemia*, chronic congestive heart failure*, Alzheimer's disease, end stage renal disease (ESRD), respiratory disease (including asthma*, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders), bone disease-arthritis (osteoporosis, osteoarthritis, and rheumatoid arthritis), and mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions). Enumerated in statute (*).

clinical skills and increased opportunities for patient-centric care through MTM could help offset shortages of physicians and nurses. Lastly, commenters pointed out that MTM fosters collaboration between clinicians, pharmacists, and patients who take multiple medications and/or have multiple chronic diseases.

Several commenters agreed that the proposed changes to the MTM eligibility criteria have the potential to significantly improve the effectiveness of the MTM program and achieve equity for underserved Medicare patients. One commenter noted studies highlighting that individuals with multiple comorbid chronic conditions tend to have the greatest disparities in accessing the care and treatments they need. The commenter also cited studies that noted that the current MTM eligibility criteria do not optimally target beneficiaries most at risk of underuse or poor adherence and that eligibility is limited to beneficiaries with high drug use and high spending, which systematically excludes beneficiaries who could benefit from these services. Another commenter suggested that rather than using MTM to improve outcomes and reduce health care costs for Part D enrollees with multiple chronic diseases, plan sponsors have instead used it as a cost control tool by focusing on enrollees who take high-cost drugs.

Response: We thank the commenters for their support of the proposed changes to the MTM eligibility criteria to better focus on beneficiaries with more complex drug regimens who would benefit most from MTM. We appreciate the citation of many studies reinforcing the value of MTM and the need for more equitable access. Almost all of the chronic diseases targeted for MTM identified at section 1860D–4(c)(2)(A)(ii)(I)(aa) of the Act and in the current CMS MTM guidance (See HPMS Memorandum Contract Year 2024 Part D Medication Therapy Management Program Guidance and Submission Instructions dated April 21, 2023) are more prevalent among minorities and lower income populations. As a result, we anticipate that these changes will increase eligibility rates among those populations by promoting more equitable access to MTM services and closing eligibility gaps.

Comment: Many commenters opposed the proposed eligibility criteria changes partially or in whole, and several expressed significant concerns about the costs and resource burden associated with implementing such a large-scale expansion of the MTM program. Some of these commenters opined that the proposed changes would increase Part D premiums and cost sharing for all enrollees. One commenter estimated that the proposed changes would more than double MTM administrative costs. Some commenters stated that the proposed MTM expansion would be cost-prohibitive without any documented benefit to enrollees. Another commenter suggested finalizing the proposed changes would result in a loss of rebate dollars that would otherwise be used to improve affordability or provide supplemental benefits that support enrollee well-being. Several commenters referenced competing priorities between the proposed MTM expansion and implementation of the Inflation Reduction Act of 2022 (IRA). A few commenters emphasized that many of the same resources needed to support IRA implementation for 2024 and beyond would also be needed to implement changes to the MTM program, and finalizing the MTM changes as proposed would put successful implementation of both the IRA and the MTM expansion at risk.

Response: We acknowledge the concerns raised regarding the cost and burden of the proposed expansion of MTM. In light of these comments, we are finalizing the proposed changes with modifications that will result in a more moderate program size increase and less burden and lower costs than initially estimated in our December 2022 proposed rule. We provide more details about the specific modifications in the responses to comments later in this section of the preamble.

Comment: Several commenters who were opposed to the proposed changes raised concerns about a decline in MTM program quality that could result from a significant increase in program size, which would dilute plans' ability to target MTM interventions to those beneficiaries who would most benefit from them. Other commenters were concerned that MTM providers may ''water down'' their approach due to the increased volume resulting in lower-value programs that satisfy the MTM requirements but are much less likely to improve health outcomes due to shorter consultations or fewer interventions. Another commenter stated that the pool of MTM vendors has decreased while costs have increased due to the loss of competition, hindering the ability of plan sponsors to administer quality MTM programs.

Response: We understand the commenters' concerns about the impact on the quality of the MTM programs and services delivered due to a large increase in program size as proposed. CMS is finalizing the proposed changes with modifications that will ensure a smaller increase in program size and promote the administration of high-value MTM programs. Currently, due to the increasing cost threshold and variations in the targeting criteria adopted by sponsors, Part D enrollees with more complex drug regimens who would benefit most from MTM services are often not eligible. In addition, enrollees with equivalent patient profiles (for example, with the same chronic diseases and taking the same Part D drugs) may or may not be eligible for MTM depending on the criteria their plan requires. The eligibility criteria changes we are finalizing in this rule aim to address the key drivers of the eligibility gaps, discussed in detail in the December 2022 proposed rule, while maintaining a reasonable program size and the ability of plans to administer effective MTM services.

MTM is a patient-centric and comprehensive approach to improve medication use, reduce the risk of adverse events, and improve medication adherence. To continue to provide quality MTM services to an expanded population and better manage resources, we remind sponsors that the delivery of MTM may be tailored to meet each enrollee's needs. For example, the length of the CMR consultation or number of follow-up interventions needed following targeted medication reviews (TMRs) may vary between MTM enrollees with more complex drug regimens and those who are stable on their medication regimens as long as the minimum level of MTM services is met as specified in § 423.153(d)(1)(vii). Sponsors may also leverage effective MTM programs to improve several measures in the Medicare Part D Star Ratings and display page such as medication adherence, polypharmacy, and gaps in therapy. Lastly, while we acknowledge commenters' concerns regarding the availability of MTM vendors, we note that Part D plan sponsors may use in-house resources, one or more external vendors, or a combination of both, to administer their MTM programs.

Comment: Some commenters stated that a large increase in the MTM enrollee population would require significant resources and that there would be limited time to hire and train additional staff, implement the necessary processes, and upgrade clinical and administrative infrastructures. Commenters estimated needing to double or triple their staffing to accommodate MTM enrollment increases of up to 60 percent in one year. A commenter stated that many plan sponsors that utilize local

community pharmacists to furnish MTM services would not be able to meet the higher demand in time, or that there would be pressure to use call centers, possibly employing customer service representatives without clinical training, which may lead to lower quality of care or member experience. Other commenters were concerned that rapid expansion of the MTM program size would exacerbate the existing pharmacist workforce shortage or would not be feasible given the expanded scope of pharmacy practice. One commenter also suggested that MTM vendors would drop smaller clients to service larger ones as a result of not being able to hire enough pharmacists to accommodate the increase in MTM enrollees.

Response: We are optimistic that the increase in demand for MTM services will incentivize plan sponsors to strengthen their hiring efforts. It is not clear what methodology the commenters used to estimate staffing needed to accommodate certain MTM program size increases. However, CMS plans to finalize our proposed changes to the MTM eligibility criteria with the modifications described later in this section of the preamble. CMS believes that this scaled back MTM expansion may alleviate a portion of the staffing concerns raised by commenters.

Comment: A few commenters, particularly commenters representing dual eligible special needs plans (D–SNPs), were concerned that due to the higher prevalence of chronic diseases in their enrollees, they will be disproportionately impacted by the changes in the MTM eligibility criteria and estimated that the majority of their plan enrollment would be eligible for the MTM program. They asserted that it would not be feasible to perform outreach or offer the MTM services to all their enrollees.

A few other commenters stated that when combined the proposed changes would result in MTM enrollment increases that exceeded the estimated program-wide size (23 percent of Part D enrollees) in the proposed rule (for example, increasing enrollment to 60 percent of their Medicare population, by five times, etc.), depending on the population or type of plan. Commenters asserted that such an increase in MTM enrollment would increase administrative costs, resulting in increased premiums, and could limit the offering of Part D plans.

Response: We acknowledge that some Part D contracts may have actual MTM enrollment rates above or below the average rate for the program as a whole because they have higher or lower enrollments of beneficiaries with the chronic diseases targeted for MTM under the changes to the MTM requirements we are finalizing in this rule. This is also true under the current MTM requirements, and there is no evidence that higher than average MTM enrollment has increased administrative costs and thus premiums to the point of limiting Part D plans' offerings, including MA–PDs that are D–SNPs. However, based in part on considerations about how the estimated program size under the proposals in the December 2022 proposed rule would impact MTM enrollment differently across contracts and increase the MTM enrollment volume to greater levels than some sponsors could feasibly handle, we are finalizing the proposed changes to the MTM eligibility criteria with modifications that we expect to decrease estimated program size relative to the proposed rule.

Comment: Some commenters expressed concerns that Part D MTM programs overlap with other programs such as disease management or care management (including post-discharge medication reconciliation; hypertension, diabetes, and dyslipidemia case management; and annual wellness visits) and may cause enrollee confusion, frustration, or complaints due to multiple outreach attempts, beneficiaries not answering calls from the plan sponsor, or beneficiaries requesting to be placed on the plan's do-not-call list. A commenter discussed that MTM-like interventions occur outside of the Part D MTM program and achieve improvements to health outcomes, and many MTM services, such as drug-drug interaction (DDI) analyses, could be automated (outside of CMRs) without beneficiary participation.

Response: We believe that Part D MTM programs complement efforts under other programs rather than overlap with them. MTM programs—which use a comprehensive approach to improve medication use, reduce the risk of adverse events, and improve medication adherence for beneficiaries at increased risk of medication-related problems due to having multiple chronic diseases and taking multiple Part D drugs—are distinct from disease-specific disease management programs. We acknowledge that recommendations arising from MTM services may result in referrals to other specialized, disease-specific programs that may not be a part of the Part D MTM program. To reduce the risk of beneficiary confusion and frustration, plan sponsors should be mindful of the timing and frequency of enrollee outreach for MTM relative to complementary disease management programs.

In addition, we remind Part D sponsors that while a CMR must be an interactive consultation with the beneficiary and the pharmacist or other qualified provider, other aspects of MTM may be automated as described in CMS MTM guidance (See HPMS Memorandum Correction to Contract Year 2024 Part D Medication Therapy Management Program Guidance and Submission Instructions dated April 21, 2023).[13] As described in this guidance, sponsors are required to perform TMRs for all beneficiaries enrolled in their MTM program with follow-up interventions when necessary. Part D sponsors must assess the findings of these reviews to determine if a follow-up intervention is necessary for the beneficiary and/or their prescriber. These assessments could be person-to-person or system generated.

Comment: Many commenters stated that the proposed eligibility criteria changes would result in a substantive update to the Part D Star Rating MTM Program CMR Completion Rate measure (MTM Star Rating Measure) due to the program size expansion and impacts to resources. Therefore, the commenters urged CMS to move the MTM Star Rating Measure to a display measure for at least 2 years to adjust to the new levels. A few commenters suggested specification changes to the MTM Star Rating Measure. Other commenters suggested that expanding the program size in such a short timeframe would incentivize plans to prioritize quantity over quality of care.

Response: Per §§ 422.164(d)(2) and 423.184(d)(2), substantively updated Star Ratings measures are moved to the display page for at least 2 years after the substantive update is adopted.[14] Refer to sections VII.B.2 and VII.D of this final rule, where we address the proposal to modify the Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) measure and discuss the weight of newly modified measures, respectively. The MTM Program Completion Rate for CMR measure is being updated in this rule to align with the revised targeting criteria finalized at § 423.153(d); the updated

[13] *https://www.cms.gov/files/document/memo-contract-year-2022-medication-therapy-management-mtm-program-submission-v-083121.pdf.*

[14] Information for measures on the display page are available online at: *https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data*. Please download the zipped file ''2024 Display Measures'' for display measure scores, data and explanatory technical notes.

measure will move to the display page entirely for the 2025 and 2026 measurement years and will return as a new measure to the Star Ratings program no earlier than the 2027 measurement year for the 2029 Star Ratings. We will share the additional suggestions for specification changes with the Pharmacy Quality Alliance (PQA), the measure steward.

Comment: A few commenters suggested that MTM program expansion could be limited to those beneficiaries who are newly eligible for the Part D MTM program or have recently added, removed, or changed drugs. One commenter also asserted that the newly eligible would see the greatest benefit from MTM services, resulting in improved health outcomes and reduced overall costs. This commenter also stated that the value of the CMR declines for enrollees with no changes in health status and that broadening the targeted disease states would increase burden and administrative costs with diminishing benefits for both plan sponsors and enrollees. Another commenter suggested that enrollees who have had a CMR in the last 12 months should requalify for MTM only with the addition of a new drug to their drug regimen and/or a new disease state.

Response: Section 1860D–4(c)(2)(A)(ii) of the Act requires Part D sponsors to target those Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary. Since January 1, 2022, Part D sponsors are also required by section 1860D–4(c)(2)(A)(ii)(II) of the Act to target all at-risk beneficiaries (ARBs) in their Part D drug management program (DMP) for MTM. Furthermore, for 2013 and subsequent plan years, the Affordable Care Act (ACA) amended the Act by adding section 1860D–4(c)(2)(C)(i), which requires all Part D sponsors to offer all enrollees targeted for MTM an annual CMR. These requirements are codified in the regulations at § 423.153(d)(1) and (2).

We acknowledge that the needs and goals of newly eligible MTM enrollees may be different from those who have already received MTM services and continue to be eligible for MTM. However, for both populations of beneficiaries, annual CMRs may be an opportunity to understand new information about the beneficiary, including but not limited to if the beneficiary's goals have changed, if they have new or unresolved medication therapy problems, or if they have any social risk factors that may be affecting their medication use that can only be assessed through an interactive consultation.

Comment: A few commenters suggested that CMS should engage the industry to determine alternative options for better targeting or increased CMR participation rather than finalize the proposed modifications to the eligibility criteria. A commenter stated that many MTM enrollees choose not to participate, and to be more consistent with the Administration's health equity goals, CMS should engage those already eligible, who have the greatest need. Another commenter suggested changes to the Medicare Plan Finder (MPF) that would highlight the value added by specific plans' MTM programs and provide guidance to beneficiaries on why selecting plans based on MTM program specifics may be beneficial. The commenter cited recent precedent in 2019 to 2020 when CMS engaged plans, PBMs, developers, and patient groups on how to improve the MPF, resulting in major improvements supported by a wide range of interested parties. A few commenters also suggested that CMS could engage plans and PBMs to assess MTM and alternative programs to determine whether MTM eligibility criteria expansion is warranted, whether to include cancer as a core chronic condition, the effect of including any additional core chronic diseases on specialized MTM provider training and program size, and whether MTM services are an effective mechanism for management of certain diseases (for example, those with high use of Part B drugs or frequently changing medication regimens).

Response: Through this rulemaking, we have engaged numerous interested parties to solicit feedback on implementing MTM eligibility criteria changes. We have also engaged in our own analysis. As discussed in the December 2022 proposed rule, we conducted an extensive data analysis that identified several issues with the current MTM targeting criteria, and we proposed specific regulatory changes in an effort to increase MTM eligibility rates, reduce variability of MTM eligibility criteria across plans, and address disparities to ensure that those who would benefit the most from MTM services have access. Taken together, we believed that the proposed changes to the MTM program targeting criteria would balance eligibility and program size while allowing us to address specific problems identified in the Part D MTM program, including marked variability and inequitable beneficiary access to MTM services.

As discussed later in this preamble, we are finalizing the proposals with modifications in response to public comments we received. However, we are committed to addressing the main drivers of the inequities in MTM program eligibility discussed in the December 2022 proposed rule. Accordingly, we will continue to request input from interested parties on improving aspects of the MTM program in the future, including enhanced targeting and better engagement with MTM enrollees. We will also look for opportunities to improve the information available for beneficiaries on CMS' websites about Part D MTM programs.

Comment: A few commenters suggested that additional analyses are needed to assess the effectiveness of MTM programs, optimize current MTM programs, and review alternative medication management methods already being used by plan sponsors and their contracted providers. One commenter asserted that CMS would be unable to determine which part of the eligibility criteria expansion worked or failed as they believed the metrics for MTM success to be ill-defined. The commenter also asked if CMS has conducted any evaluation of the requirement to target DMP enrollees for MTM enrollment. Another commenter encouraged CMS to find a new approach to measuring MTM success in the future through metrics that assess the quality of MTM services provided and not just the overall volume of services provided. Another commenter noted the documented successes of MTM in a number of situations but recognized room for improvement in the program. The commenter stated that in many cases, MTM benefits patients directly and can decrease the burden of healthcare costs, but that results are not consistent across the board, suggesting a need to increase the overall quality of MTM evaluations. The commenter concurred with researchers in recommending that future studies should consider increasing study size and incorporating multiple sites to bolster the reliability of the results and suggested that CMS could use its authority to influence changes to MTM studies. Another commenter suggested that further study can help improve the MTM program due to limited evidence that MTM improves medication adherence and patient outcomes. The commenter recommended that CMS initiate a study including a large set of geographically diverse, Part D plans to better understand the overall effectiveness of the MTM program and

potential areas for improvement. The commenter also suggested that it would be particularly useful to understand the experience and impact of pharmacists' involvement in MTM programs.

Response: We routinely analyze CMS and plan-reported data to oversee the Part D MTM programs, including implementation of the new requirement to target DMP ARBs for MTM enrollment. However, we agree that additional analysis would be beneficial to assess MTM program effectiveness, and we will continue to explore ways of conducting such analysis. We appreciate the comments on potential research and analysis topics and agree that the high degree of variability between MTM program targeting criteria has made it difficult to evaluate MTM programs. We are hopeful that standardizing the criteria as finalized in this rule will allow more research to be done on MTM outcomes. We will also engage with industry to develop additional consensus-based measures to evaluate the quality of MTM programs which may be considered for the Star Ratings program in the future, and we are encouraged by recent efforts by the PQA to convene MTM leaders on evidence-based priorities for measurement.[15]

Comment: Another commenter urged CMS to increase transparency regarding the costs of the MTM program (that is, how much plans are saving versus how much they are allocating to pay pharmacists for the services) and whether Part D plans are incentivized to offer robust MTM services.

Response: We remind commenters that per § 423.153(d)(5)(ii), even though a Part D sponsor must disclose to CMS the amount of the management and dispensing fees and the portion paid for MTM services to pharmacists and others, reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

Comment: A commenter stated that CMS's proposals in the December 2022 proposed rule to add Part D measures to the Star Ratings, such as the focus on polypharmacy measures, may present an opportunity to improve MTM. The commenter felt that the proposed changes to the MTM program eligibility criteria would expand eligibility but do not address the issue of providing MTM to Medicare beneficiaries who could truly benefit from it.

Response: We thank the commenter for the feedback. We agree that MTM programs may present an opportunity to improve plan performance in Star Ratings measures such as polypharmacy and help with overall improvement of medication use among Part D beneficiaries. Refer to Section VII.B.3 for discussion about the Part D Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS), Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and Concurrent Use of Opioids and Benzodiazepines (COB) Measures.

Comment: Some commenters encouraged CMS to continue to examine policy options that expand access to MTM and improve patient outcomes and, in particular, to release the findings from the fifth and final year of the Part D Enhanced MTM model (Enhanced MTM model). Another commenter suggested that the Enhanced MTM model can address alarming trends of medication underuse and overuse. The commenters also encouraged CMS to collaborate with interested parties to leverage the findings from the Enhanced MTM model and identify best practices in MTM to scale nationally, as well as to guide future reforms before taking action to change MTM.

Response: CMS will continue to examine policy options within our authority that expand access to MTM and improve patient outcomes. In February 2023, CMS released the fifth and final evaluation report for the Enhanced MTM model available at: *https://www.cms.gov/priorities/innovation/innovation-models/enhancedmtm.* We will continue to review the results of the Enhanced MTM model and collaborate with interested parties to identify best practices and lessons learned that may help improve the traditional Part D MTM programs. We disagree that CMS should leverage model findings or run additional analyses before making changes to the Part D MTM programs, as our disparities analysis discussed in the December 2022 proposed rule identified specific eligibility gaps that need to be addressed. As such, we are moving forward with finalizing modifications to the MTM targeting criteria in this final rule.

Comment: A commenter urged CMS to require plan sponsors to report MTM enrollee data and analyze the data using demographic information to measure and address disparities among the enrollees.

Response: Plan sponsors are currently required to report MTM program beneficiary-level data to CMS through the Part D Reporting Requirements (OMB 0938–0992). We used these data and other program data, including demographic information, to perform the MTM disparities analysis. Furthermore, researchers may request access to a Part D MTM data file through ResDAC[16] which could be linked to encrypted beneficiary and demographic variables in the CCW.

Comment: Many commenters suggested that if CMS finalizes the combination of changes as proposed, the updated eligibility criteria should be implemented on a delayed or phased-in basis. Commenters stated that such an approach would provide plan sponsors with the additional time necessary to build up staffing, processes, and infrastructure over several years; to coordinate with other internal programs to manage medications for the core chronic diseases; and to ensure local networks can accommodate the increased volume. Commenters who suggested delays were concerned about implications for costs and the timing for bid submissions as well as the need for operational enhancements. Commenters who advocated for a phased-in approach suggested ways to finalize one or more of the proposed MTM criteria changes over time on an annual basis. Another commenter suggested that CMS take a stepwise approach by first finalizing the proposal to require plan sponsors to target all 10 core chronic diseases to evaluate how MTM engagement improves, and then allow some flexibility in how plans target within broad therapeutic categories.

Response: We appreciate the suggestions to implement the proposed changes using a delayed or phased-in approach. However, we do not agree that such an approach is necessary because CMS is finalizing the proposed changes with modification, and—as discussed later in this preamble—the resulting program size will be about 35 percent smaller than originally estimated in the December 2022 proposed rule. The reduced program size mitigates the need for a phased-in approach to accommodate the new MTM enrollees. Additionally, the changes will be effective in 2025 rather than 2024 as initially proposed, which will provide additional time for Part D plan sponsors to build up the necessary infrastructure to support the anticipated increase in MTM enrollment.

We now address comments on specific aspects of the proposed eligibility criteria changes and describe our rationale for finalizing the proposed changes with modifications.

[15] *https://www.pqaalliance.org/mtm-convenes.*

[16] Information on the Part D MTM Data File available through ResDAC at: *https://resdac.org/cms-data/files/part-d-mtm.*

b. Multiple Chronic Diseases

The regulation at § 423.153(d)(2)(i)(A) specifies that to be targeted for MTM, beneficiaries must have multiple chronic diseases, with three chronic diseases being the maximum number a Part D sponsor may require for targeted enrollment. In the current CMS MTM guidance (See HPMS Memorandum Correction to Contract Year 2024 Part D Medication Therapy Management Program Guidance and Submission Instructions dated April 21, 2023), CMS identifies nine core chronic diseases.

In the December 2022 proposed rule, we proposed to amend the regulations at § 423.153(d)(2) by adding a new paragraph (iii) to require all Part D sponsors to include all core chronic diseases when identifying enrollees who have multiple chronic diseases, as provided under § 423.153(d)(2)(i)(A). As part of the proposed new provision at § 423.153(d)(2)(iii), we also proposed to codify the nine core chronic diseases currently identified in guidance and to add HIV/AIDS, for a total of 10 core chronic diseases. We explained that the current flexibility afforded to plans to identify enrollees with multiple chronic diseases had led to variability across plans and was a main driver of eligibility gaps and inequitable beneficiary access to MTM services. Under our proposal to codify the 10 core chronic diseases, plan sponsors would maintain the flexibility to target beneficiaries with additional chronic diseases that are not identified as core chronic diseases, or to include all chronic diseases in their targeting criteria.

In the December 2022 proposed rule, CMS also solicited comment on whether we should consider including additional diseases in the core chronic diseases proposed at § 423.153(d)(2)(iii), including cancer to support the goals of the Cancer Moonshot.[17] We sought comments on broadly including cancer as a core chronic condition or alternatively including specific cancers that are likely to be treated with covered Part D drugs such as oral chemotherapies where MTM could be leveraged to improve medication adherence and support careful monitoring. We were interested in comments on the impact of including any additional core chronic diseases on specialized MTM provider training and on MTM program size. We also solicited comments on whether MTM services furnished under a Part D MTM program are an effective mechanism for management of certain diseases (for example, those with high use of Part B drugs or frequently changing medication regimens) given the statutory goals of the MTM program—specifically, reducing the risk of adverse events, including adverse drug interactions, and ensuring that covered Part D drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use.

The comments we received on our proposed policies with respect to targeting of core chronic diseases are summarized below along with our responses.

Comment: Many commenters supported the proposal to add HIV/AIDS to the list of core chronic diseases. Several commenters applauded CMS for recognizing and attempting to address disparities within the HIV/AIDS community. Other commenters pointed out that antiretroviral medications are not only high cost but part of complex regimens that require frequent monitoring and re-evaluation. Supporters of this proposal also emphasized the importance of MTM services for HIV/AIDS patients with many comorbidities.

Response: CMS thanks the commenters for their support for the proposal to add HIV/AIDS as a core chronic disease. We agree that Part D enrollees with HIV/AIDS often have complex Part D drug regimens where medication adherence is critical, very high Part D drug costs, and multiple comorbidities. In addition, these individuals are more likely to be members of populations affected by health disparities. For these reasons and for the reasons discussed in the December 2022 proposed rule, we are finalizing the proposal to include HIV/AIDS in the core chronic diseases at § 423.153(d)(2)(iii).

Comment: Many commenters were opposed to including HIV/AIDS as a core chronic disease and expressed concerns regarding the potential of MTM programs disrupting therapy that is already being closely monitored by a specialized team. Other commenters were concerned that the pharmacists reviewing the drug regimen for individuals with HIV/AIDS may not have the specialized training needed. One commenter suggested additional qualifications to identify high-risk medication use among this population. Lastly, some commenters stated that the data needed for a successful CMR for this population, including lab values, are not always available.

Response: We acknowledge that Part D sponsors, especially PDPs, may not always have complete and up to date information at the time of a CMR, but the CMR may provide the opportunity to obtain additional information regarding an individual's current therapy. As discussed in CMS MTM guidance (See HPMS Memorandum Contract Year 2024 Part D Medication Therapy Management Program Guidance and Submission Instructions dated April 21, 2023), a CMR is a systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them with the patient, caregiver, and/or prescriber. The CMR is designed to improve patients' knowledge of their prescriptions, over-the-counter (OTC) medications, herbal therapies and dietary supplements, identify and address problems or concerns that patients may have, and empower patients to self-manage their medications and their health conditions. MTM services should be complementary, not disruptive, to services furnished by the beneficiary's care team, and an MTM provider may make referrals or recommendations to the beneficiary's prescribers to resolve potential medication-related problems or optimize the beneficiary's medication use.

The CMS analysis presented in the December 2022 proposed rule found that, on average, Part D enrollees with HIV/AIDS have 4 core chronic diseases (including HIV/AIDS), take 12 Part D covered drugs (including eight maintenance drugs), and incur $40,490 in Part D annual drug spend. Because beneficiaries with HIV/AIDS are likely to have complex drug regimens and are at increased risk of medication-related problems, they could benefit from MTM to improve medication use. Despite having multiple chronic diseases, taking multiple Part D drugs, and incurring high Part D drug costs, many of these individuals were not eligible for MTM because their plan did not target HIV/AIDS or did not target enough of their other chronic diseases. However, we also found that HIV/AIDS was more likely to be targeted by plans (about 10 percent of plans in 2021) than any other non-core chronic disease, suggesting that these plans have already recognized the value of offering MTM services to this population.

Comment: Some commenters questioned whether data privacy policies and state laws would allow Part D sponsors to engage in data sharing with MTM vendors. Others voiced concern over the sensitive nature of an

[17] *https://www.whitehouse.gov/cancermoonshot/CE.*

HIV/AIDS diagnosis and that giving MTM providers access to enrollees' health information would increase the risk of a data breach or cause member concerns over privacy.

Response: CMS requires Part D sponsors to comply with all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information per § 423.136. Those laws may require additional steps for Part D sponsors to share information with MTM providers, such as obtaining beneficiary consent. In establishing the requirement to include HIV/AIDS as a core chronic disease, we do not intend to change or modify any legal obligations that entities may have under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule or any other law. Regarding the potential for data breaches, we expect plan sponsors and their MTM providers to have appropriate safeguards in place to protect personal health information for beneficiaries with HIV/AIDS just as they do for enrollees with other diseases or medication regimens.

Comment: Many commenters supported the proposal to require Part D sponsors to include all core chronic diseases when identifying enrollees who have multiple chronic diseases. Some of these commenters emphasized the importance of MTM services for beneficiaries with diseases such as ESRD and mental health conditions. We received suggestions to expand the inclusion of Alzheimer's disease on the list of core chronic diseases to include neurodegenerative diseases (including multiple sclerosis) and/or other dementias such as Lewy Body disease or frontotemporal lobar degeneration and pain as core chronic diseases.

Other commenters who supported the proposal suggested that requiring the 10 core chronic diseases should provide more consistency in MTM eligibility between plans and broaden beneficiaries' eligibility for MTM in each plan.

Response: We thank the commenters for their supportive comments regarding our proposal to require sponsors to include all core chronic diseases when identifying enrollees who have multiple chronic diseases. We are finalizing that proposal at § 423.153(d)(2)(iii). Plan sponsors will be required to target all 10 core chronic diseases beginning January 1, 2025. This change will address the concerns we discussed in the December 2022 proposed rule regarding increasingly restrictive criteria implemented by plan sponsors (for example, by targeting select core chronic diseases), which have been one of the main drivers of reduced eligibility rates for MTM. By reducing the variability in targeting criteria across plans, we will eliminate situations where enrollees meet the requirement in § 423.153(d)(2)(i)(A) of having three chronic diseases but are not targeted for MTM enrollment because their plan does not target their chronic diseases. This change will also ensure that plan sponsors are targeting all of the chronic diseases specified in the statute at section 1860D–4(c)(2)(A)(ii)(I)(aa) of the Act, along with certain other chronic diseases that we have identified as prevalent in the Part D population and commonly treated with Part D drugs. This reduced variability should also allow CMS to more accurately estimate program size when calculating burden and assessing impact.

We will continue to analyze chronic diseases that are highly prevalent in the Part D population, align with common targeting practices across sponsors, and are commonly treated with Part D drugs, where MTM services could most impact therapeutic clinical outcomes, including those suggested by the commenters, and may consider proposing additional core chronic diseases such as neurodegenerative diseases and/or other dementias in future rulemaking. Although we are not adding pain as a core chronic disease in this final rule, we remind sponsors that as of January 1, 2022, they are now required to target ARBs as defined at § 423.100 for MTM enrollment. We also note that plan sponsors retain the flexibility to target additional chronic diseases beyond those codified as core chronic diseases.

Comment: Many commenters opposed the proposal to require Part D sponsors to include all core chronic diseases to identify beneficiaries who meet the targeting criterion of having multiple chronic diseases. Some commenters suggested that CMS limit core diseases to those that do not require specialized training or requested extra time to hire specialized staff. Another commenter urged CMS to continue to allow plan sponsors to have flexibility to establish a targeted population within the 10 core chronic diseases. Other commenters wanted to limit the core chronic diseases to those that are easily identified using Part D claims only or to those associated with the Star Ratings medication adherence measures. A commenter noted that even though the core chronic diseases are not entirely new, the requirement for sponsors to include all of them will necessitate IT development for file transfer of medical claims data, adding complexity, as most plans utilize only prescription drug claims data to identify members. For example, the commenter mentioned that to target beneficiaries with many of the core chronic diseases, plans will need to submit diagnosis codes from medical claims to MTM vendors in order to identify such members. Another commenter was concerned that lab work or other relevant data points may not be easily accessible by the plan's MTM pharmacist. One commenter felt that MTM pharmacists are not in the best position to positively impact (and may detract from) a beneficiary's care with a CMR and routine TMR assessments for ESRD.

Response: Plan sponsors' flexibility to target select core chronic diseases was a main driver of inequitable access to MTM in the Part D program that we addressed in our proposed changes to the Part D MTM requirements in the December 2022 proposed rule. CMS strongly believes pharmacists or other qualified MTM providers with extensive knowledge and training of prescribed medications are in an excellent position to impact a beneficiary's medication use, regardless of the chronic diseases they have or the Part D drugs they take. For instance, beneficiaries with ESRD typically have multiple co-morbidities being treated with multiple Part D drugs which may benefit from a CMR and assessment for dose adjustments due to kidney function. If a beneficiary requires more specialized services or coordinated care, MTM may be a means to identify and refer the beneficiary to such services. We also remind commenters that the eligibility criteria, including core chronic diseases, help identify beneficiaries who may be at increased risk of medication-related problems. However, MTM services should not focus only on the core chronic diseases or drugs within classes used to treat those diseases. For example, the CMR should include a review of all of the MTM enrollee's prescription medications, OTC medications, herbal therapies, and dietary supplements. As they do today, plan sponsors should optimize their targeting algorithms and methods using data available to them to identify enrollees who are eligible for MTM. Some plan sponsors may need to update their IT systems or workflows to expand the use of data sources available to them to better optimize their targeting methods.

Comment: Some commenters requested clarification on whether all diseases included under the 10 core chronic disease categories must be targeted, or whether plans will have the flexibility to choose specific diseases within the core chronic diseases. A few

commenters were concerned that requiring targeting for all core chronic diseases removes sponsors' ability to customize their MTM program to target members they deem well-suited for MTM services.

Response: Plan sponsors must target all 10 core chronic diseases, including all conditions within each core chronic disease. As discussed in the proposed rule, our analysis found that a significant proportion of the Part D population that we identified as having three or more core chronic diseases and using eight or more drugs were not eligible to be targeted for MTM, and variation in plan-specific targeting criteria (for example, plans targeting fewer than all of the core chronic diseases) was a key driver of gaps in eligibility for MTM. By reducing the variability in targeting criteria across plans, we can significantly reduce situations where enrollees meet the requirement in § 423.153(d)(2)(i) of having three chronic diseases but are not targeted for MTM enrollment because their plan does not target their chronic diseases. The proposal to require plan sponsors to target all 10 core chronic diseases, which we are finalizing in this rule, aims to close this gap in access and better ensure that the beneficiaries who are most in need of MTM services are targeted for enrollment. Plan sponsors will still have the flexibility of targeting additional chronic diseases beyond the core diseases codified in this rule.

Comment: A commenter wanted CMS to provide greater specificity when codifying core diseases. For example, they asked that CMS clarify how ''other chronic lung disorders'' are defined under respiratory disease and how ''chronic/disabling mental health conditions'' are defined under mental health.

Response: CMS does not have guidance for plan sponsors to define or code core chronic diseases such as ''other chronic lung disorders'' or ''chronic/disabling mental health conditions.'' Sponsors should retain documentation supporting their eligibility criteria determinations.

Comment: In response to our request for information and feedback on including additional diseases, such as cancer, in the list of core chronic diseases, a couple of commenters supported including cancer as a core chronic disease. One commenter felt it would align well with some pharmacies' specialty pharmacy offerings and clinical services. We also received some comments opposed to adding cancer as a core chronic disease for MTM program eligibility. Some commenters indicated that complex cancer treatment needs timely, on-going monitoring by specialists with expertise across Part B and Part D medications (for which data sets may or may not be available) and may not be best managed by Part D MTM programs through annual CMRs or by pharmacists without specialized training. Other commenters noted that specialty pharmacies, which dispense the majority of oral cancer medications (including specialty pharmacies within oncology clinics), already provide monitoring or counseling for their oncology patients. A commenter was concerned that beneficiaries with cancer may find MTM outreach to be intrusive and unwanted, and another was concerned with patient sensitivity when in remission. Another commenter that opposed including cancer as a core chronic disease noted that beneficiaries who meet the current MTM eligibility criteria who are also taking oncology drug(s) would still benefit from the MTM review for side effects, safety, and potential drug-drug interactions.

Response: Equitable access to cancer screening and targeting the right treatments for cancer patients is a top priority under the goals of the Cancer Moonshot. However, while section 1860D–4(c)(2)(A)(ii)(I)(aa) of the Act provides us the authority to specify and include other chronic diseases, after consideration of the comments received in response to the RFI, we do not believe it would be appropriate to add cancer to the core chronic diseases specified in § 423.153(d)(2)(iii) in this final rule. We agree that including cancer may be potentially disruptive to the medication management that is already a part of standard clinical practice in oncology and specialty centers. Moreover, it is unclear that cancer patients' needs can be met through Part D MTM program annual CMRs centered on Part D medication use delivered by MTM pharmacists who typically lack the specialized training in oncology. Cancer treatment goals are often different than the goals for treatment of the other chronic diseases included in Part D MTM program (such as diabetes), where MTM may be used to review and stabilize drug regimens that are likely to be long term. In contrast, many cancers involve a high utilization of physician-administered Part B drugs and frequently changing medication regimens. Also, cancer is not currently commonly targeted by Part D plans as a chronic disease for their MTM program eligibility.

While we are not adding cancer as a core chronic disease at this time, we emphasize that some cancer patients may still be eligible for MTM based on meeting the eligibility criteria. We encourage Part D plans and MTM providers to seek opportunities to promote cancer screening where possible for MTM enrollees and to coordinate with specialty cancer programs to develop medication safety recommendations for cancer patients. In support of the Cancer Moonshot, CMS has initiated other activities, such as the Enhancing Oncology Model (EOM),[18] which is designed to test how best to place cancer patients at the center of high-value, equitable, evidence-based care. CMS has also adopted rules providing payment for principal illness navigation services to help patients and their families navigate cancer treatment and treatment for other serious illnesses.[19]

c. Multiple Part D Drugs

Section 1860D–4(c)(2)(A)(ii) of the Act requires that targeted beneficiaries be taking multiple covered Part D drugs. The current regulation at § 423.153(d)(2)(i)(B) specifies that eight is the maximum number of Part D drugs a Part D plan sponsor may require for targeted MTM enrollment. In accordance with the technical HPMS User Guide for the MTM Program submission module, sponsors are permitted to include all Part D drugs, all Part D maintenance drugs, or specific drug classes.

We proposed to revise § 423.153(d)(2)(i)(B) to decrease the maximum number of Part D drugs a sponsor may require for targeted enrollment from eight to five for plan years beginning on or after January 1, 2024. As discussed in the preamble to the December 2022 proposed rule, while there is no consensus definition of polypharmacy in terms of the use of a certain number of medications or medication classes concurrently, the proposed change would ensure the MTM program continues to focus on more individuals with complex drug regimens and increased risk of medication therapy problems. In addition, although we proposed changes to the targeting criteria with respect to the number of Part D drugs, we noted that the CMR described in § 423.153(d)(1)(vii)(B) should continue to include review of all prescription medications, OTC medications, herbal therapies, and dietary supplements.

We also proposed to add a new provision at § 423.153(d)(2)(iv) to

[18] *https://www.cms.gov/newsroom/press-releases/biden-administration-announces-new-model-improve-cancer-care-medicare-patients.*

[19] *https://www.cms.gov/newsroom/press-releases/cms-finalizes-physician-payment-rule-advances-health-equity?ref=upstract.com.*

require all sponsors to include all Part D maintenance drugs in their targeting criteria. Plans are currently able to include all maintenance drugs in their targeting criteria as an option in the MTM Submission Module in HPMS; however, CMS does not have guidance related to how maintenance drugs are identified for this purpose. To ensure consistency across the MTM program, we also proposed that, for the purpose of identifying maintenance drugs, plans would be required to rely on information contained within a widely accepted, commercially or publicly available drug information database commonly used for this purpose, such as Medi-Span or First Databank, but would have the discretion to determine which one they use. Under this proposal, sponsors would no longer be allowed to target only specific Part D drug classes but would be required to target all Part D maintenance drugs. However, plans would retain the option to expand their criteria by targeting all Part D drugs. CMS solicited public comment on our proposed parameters for defining maintenance drugs, including potential additional sources for making such determinations.

Below, we address comments on the proposed revisions to the maximum number of covered Part D drugs a plan sponsor may require and our proposal to require sponsors to include all Part D maintenance drugs in their targeting criteria. We also describe our rationale for finalizing the proposed changes with modifications.

Comment: Many commenters supported the proposal to lower the maximum number of covered Part D drugs a sponsor may require from eight to five drugs. These commenters supported overall expansion of the MTM program, which they believed would increase medication safety. A commenter who supported the proposal suggested additional targeting criteria, such as targeting individuals taking high-risk medications.

Response: We appreciate the support for this proposal. However, we remind commenters that section 1860D–4(c)(2)(A)(ii) of the Act requires plans to target beneficiaries taking multiple covered Part D drugs. We note, however, that plans retain the flexibility to enroll beneficiaries taking high-risk medications in their MTM programs through expanded eligibility, even if they do not meet the statutory criteria for targeted enrollment. In addition, high-risk medication use may be addressed through MTM interventions.

Comment: Many commenters opposed the proposal to lower the maximum number of covered Part D drugs a sponsor may require from eight to five drugs. Commenters were concerned that MTM would not be as useful for beneficiaries with less complex drug regimens and suggested that beneficiaries should qualify for MTM enrollment based on higher pill burdens and more complicated medication regimens. One commenter stated that a typical enrollee with three or more chronic diseases takes between seven and 10 medications and recommended retaining the current maximum number of drugs at eight. Another commenter suggested initially only decreasing this threshold from eight to five drugs for sponsors that use specific classes of drugs in their criteria, and then fully implementing the proposed change for all plan sponsors the following year.

Response: After consideration of these comments, and the general comments expressing concerns about increased burden and costs, current pharmacy and vendor shortages, and other resource challenges due to the combination of MA and Part D program policy changes plan sponsors must implement over the next several years, we are not finalizing our proposal to lower the maximum number of covered Part D drugs a sponsor may require from eight to five drugs at this time. We are retaining the maximum number of drugs a plan sponsor may require for targeting beneficiaries taking multiple Part D drugs at eight (see § 423.153(d)(2)(i)(B)). Plan sponsors will maintain the flexibility to set a lower threshold (between two and eight Part D drugs) for targeting. This will maintain the MTM program focus on beneficiaries with the most complex drug regimens and will result in a more moderate expansion of the MTM program size. Additionally, our decision not to finalize this aspect of our proposed modifications to the MTM eligibility criteria is supported by CMS' data analysis included in the December 2022 proposed rule (87 FR 79542–79546). We found that the beneficiaries identified as having 3 or more core chronic conditions and using 8 or more drugs who were not eligible for MTM took on average eight to nine Part D drugs, which suggests that the number of Part D drugs criterion is not a main driver of MTM eligibility disparities under our current policies. This change to our proposal allows us to respond to commenters' concerns regarding the potential impact of reducing the maximum number of Part D drugs from eight to five, while still addressing the barriers to eligibility posed by the increasingly restrictive plan criteria (for example, by targeting select core chronic diseases or drugs) and the high cost threshold, which were identified in our analysis as the main drivers of reduced eligibility rates for MTM. CMS will continue to monitor the impact of the number of Part D drugs criterion on MTM eligibility rates and consider whether to propose any changes in future rulemaking.

Comment: No commenters specifically supported or opposed the proposal to include all Part D maintenance drugs in the targeting criteria. One commenter requested clarification on whether specific Part D drug classes could still be targeted. A few commenters recommended either Medispan or First DataBank as sources for identifying maintenance drugs but wanted discretion to determine which one they use.

Response: We appreciate the comments. As we stated in the December 2022 proposed rule, under the proposed modifications to the MTM eligibility criteria, Part D sponsors would no longer be allowed to target only specific Part D drug classes but would be required to target all Part D maintenance drugs at a minimum. However, plans would retain the option to expand their criteria by targeting additional Part D drugs or all Part D drugs. While we proposed that plan sponsors would be required to identify Part D maintenance drugs using information contained within a widely accepted drug database, such as Medi-Span or First Databank, we expressly stated that Part D plans would retain discretion to determine which database to use.

We are finalizing the proposed provision at § 423.153(d)(2)(iv) with modification. Specifically, we are revising the regulation text to clarify that sponsors must include all Part D maintenance drugs and to expressly state that Part D sponsors retain the flexibility to include all Part D drugs in their targeting criteria. Additionally, we are finalizing the requirement that sponsors rely on information contained within a widely accepted, commercially or publicly available drug information database to identify Part D maintenance drugs. We are also updating the text of this provision to reflect that these requirements will apply beginning on January 1, 2025. We are not finalizing the proposal to lower the maximum number of covered Part D drugs a sponsor may require from eight to five drugs at this time.

d. Annual Cost Threshold

Section 1860D–4(c)(2)(A)(ii) of the Act specifies that beneficiaries targeted for MTM must be likely to incur annual costs for covered Part D drugs that

exceed a threshold determined by CMS. The regulation at § 423.153(d)(2)(i)(C) codifies the current cost threshold methodology, which was set at costs for covered Part D drugs greater than or equal to $3,000 for 2011, increased by the annual percentage specified in § 423.104(d)(5)(iv) for each subsequent year beginning in 2012. The annual cost threshold for 2024 is $5,330. The cost threshold has increased substantially since it was established in regulation, while the availability of lower cost generics and the generic utilization rates have also increased significantly since the Part D program began. Together, these factors have resulted in a cost threshold that is grossly misaligned with CMS' intent and inappropriately reduces MTM eligibility among Part D enrollees who have multiple chronic diseases and are taking multiple Part D drugs. The cost threshold has been identified as a significant barrier to MTM access, and, in the past, interested parties have recommended that it be lowered.

In the December 2022 proposed rule, we proposed to amend the regulation at § 423.153(d)(2)(i)(C) to set the MTM cost threshold at the average cost of five generic drugs, as defined at § 423.4, for plan years beginning on or after January 1, 2024. Under this proposal, CMS would calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug using the PDE data specified at § 423.104(d)(2)(iv)(C). As noted in the December 2022 proposed rule, based on 2020 data, the average annual cost of five generic drugs was $1,004. In the proposed rule, CMS indicated that for 2024, the calculation would use PDE data from 2022 to identify the average daily cost of a generic fill, multiplied by 365 days for an annual amount. The average daily cost for a drug would be based on the ingredient cost, dispensing fees, sales tax, and vaccine administration fees, if applicable, and would include both plan paid amounts and enrollee cost sharing. Based on 2022 PDE data analyzed after publication of the December 2022 proposed rule, the average annual cost of five generic drugs was $994. In the December 2022 proposed rule, we noted that in subsequent years, the MTM cost threshold would be published in the annual Part D Bidding Instructions memo.

Below, we address comments on the proposed revisions to the annual cost threshold and describe our rationale for finalizing a modified MTM cost threshold methodology at § 423.153(d)(2)(i)(C) based on the average annual cost of eight generic drugs, which will be applicable beginning January 1, 2025.

Comment: Many commenters opposed the proposal to set the MTM cost threshold at the average cost of five generic drugs. While many of these commenters agreed that the current MTM cost threshold is too high, they opposed our proposal to base the cost threshold on the average cost of five generic drugs due to the estimated impact on MTM program size. Instead, some commenters supported a less significant cost threshold reduction. A few commenters suggested that the cost threshold is irrelevant as the number of drugs, not their cost, is a key metric. A health plan commented that over 40 percent of its enrollees would have annual drug costs that meet the proposed MTM cost threshold and suggested that the overarching aim should instead be to continue targeting enrollees who are at risk for polypharmacy. This commenter cited a study suggesting the range of rates of ambulatory elderly patients who experience adverse drug reactions is 20 to 25 percent and that targeting a much larger percentage of Medicare Advantage membership to enroll in an MTM program may divert the focus from the population that would most benefit from program inclusion. Other commenters did not recommend decreasing the cost threshold to align with annual average generic drug costs because that would target beneficiaries who would not benefit from a CMR consultation regarding cost savings opportunities. Another commenter suggested that CMS consider increasing the annual cost threshold, instead of decreasing it, to better account for inflation in the prescription drug market and allow plans to have greater capacity to target MTM services to high need members.

Some commenters suggested alternative proposals for lowering the MTM cost threshold. One commenter suggested CMS seek insight from the industry, such as the PQA, on how best to adjust the cost threshold. A few commenters recommended alternative approaches to establish the cost threshold, such as commensurate with the average cost of eight generic drugs, a specific dollar amount, the cost of a mix of brand and generic drugs as many beneficiaries take at least one brand drug, or an incremental approach to decreasing the cost threshold, starting with the annual cost of six or seven drugs.

Response: After considering the comments and suggestions we received, we are persuaded to finalize a modified MTM cost threshold methodology at § 423.153(d)(2)(i)(C) based on the average annual cost of eight generic drugs beginning January 1, 2025. This revised cost threshold methodology aligns with our decision not to finalize our proposal to reduce the maximum number of covered Part D drugs a sponsor may require from eight to five drugs. Lowering the cost threshold removes a significant barrier to MTM enrollment, but setting the threshold at the cost of eight (instead of five) generic drugs yields a more moderate program size expansion, which will address commenters' concerns about cost and burden. Encouraging the use of generic or lower cost drugs when medically appropriate remains a pillar of the Part D program. Under our final policy, beneficiaries meeting the criteria of having multiple chronic diseases and taking multiple Part D drugs, but who are taking lower cost generic alternatives, may now be targeted for MTM enrollment. MTM enrollees, especially those with high drug costs, may continue to benefit from cost saving opportunities from CMRs. However, even if a CMR consultation does not result in cost savings, there are other benefits of CMRs beyond cost savings.

Comment: Many commenters requested clarification regarding the MTM cost threshold calculation, including which five generic drugs will be used to determine this new cost threshold; what methodology CMS will use to select the drugs; how authorized generics, biosimilars, or un-branded biologics factor into the determination; whether the proposed methodology would utilize the top five utilized generic drugs by prescription volume or the top five generic drugs by plan paid amount; whether the calculation includes or excludes generic specialty medications; whether there is a process to detect outlier national drug codes (NDCs) to ensure they are not included in the calculation; and whether the cost of five generic drugs is per 30-day supply of medication. A few commenters asked if the proposed cost threshold would be expected to increase or decrease annually. Another commenter suggested that CMS reevaluate cost data for generic drugs, as costs of many generic drugs have increased since 2020 due to global supply chain issues after the COVID–19 pandemic. One commenter asked if enrollees would be required to receive the generic drugs only.

Response: The average daily cost of one generic drug was calculated as total gross drug cost divided by total days supply for all Part D covered generic drugs utilized by all Part D enrollees during the plan year. The average daily

cost of one generic drug was then multiplied by eight drugs and 365 days to compute an average annual cost of eight generic drugs. The total gross drug cost used in this calculation is the sum of the ingredient cost, dispensing fees, sales tax, and vaccine administration fees, if applicable, during the relevant plan year and includes both plan paid amounts and enrollee cost sharing. This calculation does not include the cost of biologic products or authorized generics. Compound drug claims are also excluded.

Beginning January 1, 2025, CMS will calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug as determined using PDE data from the plan year that ended 12 months prior to the applicable plan year, which is the PDE data currently used to determine the specialty-tier cost threshold as specified in the provision at § 423.104(d)(2)(iv)(C). CMS will analyze the PDE data for all Part D covered generic drugs utilized by all Part D enrollees during the plan year to calculate the average daily cost of one generic fill and multiply the average daily cost of one generic fill by 365 days to determine an annual amount. Therefore, the cost threshold may change annually. Although average costs for all Part D covered generic drug fills will be used to calculate the MTM cost threshold, a beneficiary would not be required to only take generic drugs to meet the eligibility criteria for MTM, and beneficiary-specific drug costs may vary from the averages.

For example, based on 2022 PDE data, the average annual cost of eight generic drugs was $1,591. If the MTM threshold were set at this amount, plans would be required to target beneficiaries who are likely to incur annual covered Part D drug costs greater than or equal to $1,591 (across all Part D drugs they take, not just generic drugs) and meet the other MTM targeting criteria for having multiple chronic diseases and taking multiple Part D drugs for enrollment in their MTM program.

Based on analysis of 2023 PDE data, the MTM cost threshold will be $1,623 for 2025. The MTM cost threshold will be published in the annual Part D Bidding Instructions memo for future years.

Following consideration of the comments received on the cost threshold, as well as on the maximum number of Part D drugs plans may target, we are finalizing a modified MTM cost threshold methodology at § 423.153(d)(2)(i)(C) based on the average annual cost of eight generic drugs as defined at § 423.4. This new cost threshold methodology will be applicable beginning January 1, 2025.

e. Summary

After consideration of the comments received, we are finalizing proposed changes to the Part D MTM program eligibility requirements with the modifications discussed. The changes are effective January 1, 2025 and are summarized below.

- We are finalizing the provision at § 423.153(d)(2)(iii) that Part D sponsors must include all core chronic diseases in their targeting criteria for identifying beneficiaries who have multiple chronic diseases, as provided under § 423.153(d)(2)(i)(A). As part of this provision at § 423.153(d)(2)(iii), we are codifying the nine core chronic diseases currently identified in guidance and adding HIV/AIDS, for a total of 10 core chronic diseases. The 10 core chronic diseases are: (A) Alzheimer's disease; (B) Bone disease-arthritis (including osteoporosis, osteoarthritis, and rheumatoid arthritis); (C) Chronic congestive heart failure (CHF); (D) Diabetes; (E) Dyslipidemia; (F) End-stage renal disease (ESRD); (G) Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS); (H) Hypertension; (I) Mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions); and (J) Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders). Sponsors retain the flexibility to target additional chronic diseases beyond those codified as core chronic diseases.
- We are not finalizing the proposal at § 423.153(d)(2)(i)(B) to decrease the maximum number of Part D drugs a sponsor may require from eight to five at this time. We are retaining the maximum number of drugs a plan sponsor may require for targeting beneficiaries taking multiple Part D drugs as eight at § 423.153(d)(2)(i)(B). Part D sponsors will maintain the flexibility to set a lower threshold (a number between two and eight Part D drugs) for targeting beneficiaries taking multiple Part D drugs. We may revisit the maximum number of Part D drugs (eight) a sponsor may require in future rulemaking.
- We are finalizing the provision at § 423.153(d)(2)(iv) to require sponsors to include all Part D maintenance drugs in their targeting criteria with minor modifications to the regulatory text to clarify that sponsors must include all Part D maintenance drugs and to provide flexibility for sponsors to include all Part D drugs in their targeting criteria. However, sponsors will not be permitted to limit the Part D maintenance drugs included in MTM targeting criteria to specific Part D maintenance drugs or drug classes. We are also finalizing the requirement at § 423.153(d)(2)(iv) that, for the purpose of identifying Part D maintenance drugs, plans must rely on information in a widely accepted, commercially or publicly available drug information database.
- We are finalizing the provision at § 423.153(d)(2)(i)(C) with modification to set the MTM cost threshold at the average cost of eight generic drugs, as defined at § 423.4. CMS will calculate the dollar amount of the MTM cost threshold based on the average daily cost of a generic drug using the PDE data specified at § 423.104(d)(2)(iv)(C).

We believe these final policies will allow us to address specific gaps identified in MTM program eligibility by reducing marked variability across plans and ensuring more equitable access to MTM services; better align with Congressional intent while focusing on beneficiaries with complex drug regimens; and keep the program size manageable. The changes also take into consideration the burden a change in the MTM program size would have on sponsors, MTM vendors, and the health care workforce as a whole. With these changes, we estimate that the number and percent of Part D enrollees eligible for MTM will increase from 3.6 million (7 percent of Part D enrollees based on actual 2022 MTM enrollment data) to a total of 7.1 million (13 percent of Part D enrollees estimated using 2022 data), which is smaller than the estimated program size of 11 million beneficiaries in the December 2022 proposed rule. Burden estimates and impacts are discussed in sections X. and XI. of this proposed rule, respectively.

2. Define ''Unable To Accept an Offer To Participate'' in a Comprehensive Medication Review (CMR)

In guidance issued annually, CMS has consistently stated that we consider a beneficiary to be unable to accept an offer to participate in a CMR only when the beneficiary is cognitively impaired and cannot make decisions regarding their medical needs. In the December 2022 proposed rule, we proposed to codify this definition by amending the current regulation text at § 423.153(d)(1)(vii)(B)(2) to specify that in order for the CMR to be performed with an individual other than the beneficiary, the beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment.

We received the following comments on this proposal, and our responses follow:

Comment: A commenter voiced their support for our proposal.

Response: CMS appreciates the commenter's support.

Comment: A few commenters opposed or voiced concerns about the proposal, stating that many beneficiaries who are not cognitively impaired request that their caregiver or a trusted family member participate in the CMR on their behalf. For example, one commenter mentioned hearing impairment as a barrier for the beneficiary receiving the CMR directly from the provider. Another commenter pointed out that many beneficiaries receive MTM services in long-term care facilities where nurses who manage their medications should be allowed to participate in the reviews on the beneficiary's behalf. They argued that caregivers should be allowed to participate in the CMR as long as HIPAA Privacy Rule policies are not violated, and proper documentation is maintained.

Response: Our proposal to codify the definition of ''unable to participate'' does not preclude beneficiaries from inviting other individuals to join them for the CMR. MTM enrollees may continue to include caregiver or family member participation during the MTM process, though we emphasize that MTM is a beneficiary-centric program. Instead, this rule codifies the definition of ''unable to participate,'' which is different from a beneficiary requesting a CMR to be completed with another individual. Generally, we expect the beneficiary being ''unable to participate'' due to cognitive impairment to be an uncommon designation that should be reported through the Part D Reporting Requirements (OMB 0938–0992). We will continue to monitor the percentages of beneficiaries who are unable to accept a CMR offer for outlier rates, and sponsors should retain documentation supporting any instance in which a beneficiary is designated as ''unable to participate'' in their reported data.

CMS would also like to remind plan sponsors that they are expected to put in place safeguards against discrimination based on the nature of their MTM interventions. Hearing impairment should not prevent a beneficiary from receiving MTM services. Relevant federal regulations for MTM programs may include Federal Communications Commission requirements for accessibility, as defined in 47 CFR part 64 Subpart F; Americans with Disabilities Act (ADA): Nondiscrimination on the Basis of Disability by Public Accommodations and in Commercial Facilities, 28 CFR part 36; Nondiscrimination on the Basis of Race, Color, National Origin, Sex, Age, or Disability in Health Programs or Activities Receiving Federal Financial Assistance and Programs or Activities Administered by the Department of Health and Human Services Under Title I of the Patient Protection and Affordable Care Act or by Entities Established Under Such Title, 45 CFR Part 92; Section 504 of the Rehabilitation Act, Nondiscrimination on the Basis of Handicap in Programs or Activities Receiving Federal Financial Assistance, 45 CFR part 84; and 21st Century Communications and Video Accessibility Act (CVAA). Part D sponsors should also refer to the standards for communications and marketing found at 42 CFR 423.2267(a).

After consideration of the comments received, we are finalizing the definition of a ''unable to accept an offer to participate'' in a CMR as proposed at § 423.153(d)(1)(vii)(B)(2) to provide that a beneficiary must be unable to accept the offer to participate in the CMR due to cognitive impairment.

3. Requirement for In Person or Synchronous Telehealth Consultation

As discussed in the December 2022 proposed rule, we proposed to amend the existing regulation text at § 423.153(d)(1)(vii)(B)(1)(i) to require that the CMR be performed either in person or via synchronous telehealth to clarify that the CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth. As discussed in the December 2022 proposed rule, while the consultation must be conducted in real-time, under this proposal, plans would continue to have the discretion to determine whether the CMR can be performed in person or using the telephone, video conferencing, or another real-time method.

We received the following comments on this proposal, and our responses follow:

Comment: Several commenters supported clarifying the regulatory language on the use of telehealth. A few commenters expressly stated that their support for the proposal was conditioned on ''telehealth'' including a telephone option. Another commenter expressed concern regarding lower levels of engagement due to fewer people wanting in-person interactions in a pharmacy setting and fewer people answering their phone, even when it is their local pharmacy calling.

Response: We thank these commenters for their feedback and confirm that telephonic communication meets the definition of synchronous telehealth. We believe updating the regulation to clarify that a CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via telehealth, will ensure that beneficiaries receiving a CMR via telehealth have the same opportunities to engage with their providers in real time as beneficiaries who receive a CMR in-person. Sponsors are encouraged to offer multiple methods of engagement since beneficiaries may prefer in-person or telehealth interactions.

After consideration of the comments received, we are finalizing the proposed revisions to § 423.153(d)(1)(vii)(B)(1)(i) without modification.

4. MTM Program Technical Changes

In the December 2022 proposed rule, we proposed several technical changes to the regulation text related to the Part D MTM program. At § 423.4, we proposed to add a definition for ''MTM program'' to clarify the meaning of this term as used in Part 423. In the heading for § 423.153(d), we proposed to remove the dash and replace it with a period to be consistent with other paragraph headings in Subpart D. We proposed to amend § 423.153(d) by striking ''or'' from the end of existing paragraph (d)(2)(i)(C)(2) to clarify that, consistent with section 1860D–4(c)(2)(A)(ii) of the Act, plan sponsors must target enrollees described in paragraph (d)(2)(i) and enrollees described in paragraph (d)(2)(ii). Throughout Part 423, Subpart D, we proposed to replace ''MTMP'' with ''MTM program'' to ensure that the terminology is used consistently.

We did not receive any comments regarding these changes and are finalizing these MTM program technical changes as proposed.

F. Part D Subcontractors May Terminate Only at the End of a Month (§ 423.505)

At § 423.505(i), we proposed to require Part D sponsors to include a provision in certain contracts with first tier, downstream, and related entities (FDRs) (as defined at § 423.501) that the FDR may terminate its contract only at the end of a calendar month after providing at least 60 days' prior notice. Specifically, we proposed that this prior notice be required in contracts with FDRs that perform critical functions on the sponsor's behalf, as described in the December 2022 proposed rule. We believe this change is necessary to protect beneficiaries from disruptions in receiving Part D benefits and to protect

the Part D program from incurring additional financial liability. We are finalizing this provision as proposed.

As discussed in the December 2022 proposed rule preamble, Part D sponsors contract with FDRs to perform many of the services critical to the operation of the Part D program. For example, FDRs administer formularies, process beneficiary enrollments into plans, contract with pharmacies, process Part D claims at the point of sale, and administer enrollee appeals and grievance processes. Many Part D sponsors do not have the internal capability to take over administration of these functions from their FDRs on short notice. If an FDR ceases operations under a contract, enrollees in an affected plan may therefore be left without access to their Part D benefits until the sponsor is able to make alternative arrangements. For these reasons, CMS has a critical interest in ensuring Part D sponsors' contracts with these FDRs protect beneficiaries and the program.

Occasionally, Part D sponsors face financial difficulties so severe that they may stop paying FDRs for services provided under their Part D contracts. Such difficulties may also cause sponsors to be placed into receivership or bankruptcy. In response to such developments, an FDR may terminate its contract with the Part D sponsor or, in the case of FDRs that administer claims at the point of sale, stop paying claims to prevent or minimize operating losses. Such actions may be prompted by overdue reimbursement from the sponsor or anticipated payment stoppages and can occur in the middle of a month, depending on the termination notice terms in the sponsor's contract with the FDR. Fortunately, such mid-month terminations are rare. However, when they occur, they can result in significant disruptions for enrollees, including a lack of access to needed prescriptions through their Part D plan. For instance, a PDP contract was terminated in the middle of March 2021 due, in part, to the PDP's PBM terminating its contract mid-month for nonpayment. This disrupted care for almost 40,000 beneficiaries and forced CMS to incur additional expense to ensure that all beneficiaries had continuous coverage for the month of March.

Mid-month terminations can also result in CMS incurring additional costs. CMS makes prospective monthly capitation payments to Part D sponsors, as provided in section 1860D–15(a)(1) of the Act and codified in § 423.315(b). When an FDR performing critical functions on a sponsor's behalf terminates a contract mid-month, CMS has already paid the sponsor for the services that the FDR was supposed to render for the remainder of that month. To protect beneficiaries from suffering further harm, CMS may find it necessary to terminate a sponsor's contract pursuant to § 423.509 or come to terms for a mutual termination pursuant to § 423.508. CMS reassigns affected beneficiaries to other Part D plans in the same service area when such terminations occur at any time other than the end of a contract year. When these reassignments occur mid-month, CMS makes a full prospective payment for that month to the plan into which enrollees are reassigned, so that CMS pays twice for the same month. For example, if contract 1 terminates effective May 15 and CMS reassigns enrollees to contract 2, CMS would pay contract 2 for the full month of May even though it already paid contract 1 for the month of May. CMS has authority under § 423.509(b)(2)(ii) to recover the prorated share of the capitation payments made to the Part D sponsors covering the period of the month following the contract termination, but as a practical matter, a contract terminated due to financial difficulties usually does not have the funds available to repay CMS. Nor is CMS able to make a prorated monthly payment to the contract into which enrollees are reassigned.

To protect beneficiaries and the Part D program from the consequences of mid-month terminations of certain FDR contracts, we proposed to establish at § 423.505(i)(6) a requirement that all Part D sponsors' contracts with FDRs that perform certain key Part D functions require a minimum of 60-days' prior notice of termination with an effective date that coincides with the end of a calendar month. We are adopting this change pursuant to our authority at section 1857(e) of the Act, made applicable to Part D through section 1860D–12(b)(3)(D), which authorizes the Secretary to adopt contract terms and conditions as necessary and appropriate and not inconsistent with the Part D statute. This policy is consistent with the existing requirement that FDRs must comply with Part D requirements and support the sponsor's performance of its Part D functions, including ensuring access to covered Part D drugs under § 423.120(a), as required at § 423.505(i)(3)(iii) and (iv). Because Part D sponsors are paid prospectively and in units of no less than one calendar month, they and their subcontractors should be able to negotiate arrangements for access to covered Part D drugs in no less than 1-month increments by, for example, requiring Part D sponsors to provide a surety bond to compensate the FDR in the event of the sponsors' fiscal insolvency. We do not believe that this will result in significant additional expense for Part D sponsors because mid-month terminations have been very rare to date.

The proposed provision at new paragraph (6) requires the contract between a Part D sponsor and an FDR providing certain functions to state that a contract termination could only occur after a 60-day notice period and have an effective date that coincides with the end of a calendar month. The functions for which this requirement would apply would be—

- Authorization, adjudication, and processing of prescription drug claims at the point of sale;
- Administration and tracking of enrollees' drug benefits in real time;
- Operation of an enrollee appeals and grievance process; and
- Contracting with or selection of prescription drug providers (including pharmacies and non-pharmacy providers) for inclusion in the Part D sponsor's network.

All of these functions are critical to beneficiaries maintaining access to Part D drugs and ensuring that they pay appropriate out of pocket costs. The disruption of any one of these functions could result in beneficiaries failing to receive necessary drugs or incurring unnecessary costs.

We received comments on this proposal, which are summarized below, and respond to them as follows.

Comment: One commenter requested clarification on whether the proposed rule was applicable to terminations initiated by Part D sponsors or limited to terminations initiated by FDRs.

Response: The proposed rule would only apply to terminations initiated by FDRs. Part D sponsors would remain free to terminate their FDRs mid-month or on less than 60 days' notice if their contracts with FDRs permit such terminations. CMS notes that any sponsor seeking to terminate an FDR mid-month or on short notice would remain accountable for ensuring that its enrollees continue to receive uninterrupted Part D benefits in compliance with the statute, regulation, and its contract with CMS.

Comment: A few commenters expressed support for the proposal but requested that CMS include an exemption for terminations initiated by Part D sponsors based on fraud or member harm.

Response: CMS appreciates commenters' support. We note that the proposed rule would not limit Part D sponsors' ability to terminate their FDRs for any reason. Therefore, sponsors' ability to terminate FDR contracts based on fraud or member harm would be unaffected by the proposed rule.

After considerations of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the provision as proposed with one grammatical edit regarding capitalization.

G. Application of 2-Year Ban on Reentering the Part D Program Following Non-Renewal (§§ 423.507 and 423.508)

In the December 2022 proposed rule, we proposed to amend §§ 423.507(a)(3) and 423.508(e) to clarify that the prohibition on PDP sponsors that non-renew or mutually terminate a contract entering into a new PDP contract for 2 years applies at the PDP region level. That is, if a sponsor non-renews or mutually terminates a PDP contract, the two-year exclusion would only prohibit them from entering into a new or expanded PDP contract in the PDP region(s) they exited and would not prevent them from entering into a new or expanded contract in another region(s). We also proposed to clarify that the 2-year exclusion applies whenever a PDP sponsor terminates all of its plan benefit packages (PBPs) in a PDP region, commonly known as a ''service area reduction,'' even if they continue to serve other PDP regions under the contract.

Under current regulations at §§ 423.507(a)(3) and 423.508(e), Part D sponsors that non-renew or mutually terminate their contracts with CMS are ineligible to enter into a new Part D contract for two years following the non-renewal or mutual termination, absent circumstances that warrant special consideration. CMS adopted the two-year exclusion at the beginning of the Part D program in 2006 in order to implement the requirements of section 1857(c)(4) of the Act, made applicable to the Part D program by section 1860D–12(b)(3)(B) of the Act. The 2-year exclusion following contract non-renewal or mutual termination promotes stability in the Part D program, as the additional period of contracting ineligibility causes organizations to consider more than just the year-to-year fluctuations in the Part D market in deciding whether to discontinue their participation in the program.

As described in the proposed rule, the 2-year exclusion at the PDP region level would sufficiently promote the market-stabilizing purpose of the exclusion by prohibiting PDP sponsors from non-renewing all their plans in a region and returning to the same market after only one year of absence from the program. We believe the 2-year exclusion as applied at the regional level would prevent sponsors from undermining the nondiscrimination requirements at section 1860D–11(e)(2)(D)(i) of the Act by, for example, terminating PBPs in a region so they would no longer receive LIS auto-enrollment. If the two-year exclusion were not applied at the regional level, the effective penalty for the Part D sponsors choosing to stop serving LIS beneficiaries would be only one year's absence from offering plans in that region, rather than two. However, these same concerns do not apply across regions. A sponsor that non-renews a plan receiving LIS auto-enrollments in one region that wishes to enter a different region the next year would not simply be seeking to enroll more desirable beneficiaries who had declined to enroll in their previous plan; instead, they would be competing in a completely different market. Therefore, we see no reason to prohibit sponsors that non-renew their plans in one region from offering plans in a new region before the 2-year exclusion period elapses.

We proposed to modify §§ 423.507(a) as follows:

- Revising paragraph (3) to add regulatory text clarifying that the requirements in this paragraph pertain to PDP sponsors' ineligibility to enter into a contract for 2 years;
- Redesignating paragraph (a)(3) regarding the current regulatory requirement regarding a 2-year contracting ban following non-renewal of a PDP contract as new paragraph (a)(3)(i);
- Adding language to new paragraph (a)(3)(i) stating that CMS cannot enter into a new contract in the PDP region or regions served by the non-renewing contract;
- Adding new paragraph (a)(3)(ii) to authorize CMS to make organizations that non-renew all of their PBPs in a PDP region ineligible to have plan bids approved again in that region for 2 years; and
- Adding new paragraph (a)(3)(iii) exempting new EGWP PBPs from the 2-year ban.

Similarly, we proposed to apply our policy limiting the offering of plans at the PDP region level for 2 years to mutual terminations under § 423.508. We proposed to add a sentence to the existing regulatory text at paragraph (e) stating that a mutual termination of participation in a PDP region makes a PDP sponsor ineligible to apply for qualification to offer new plans in that region for 2 years. While we already require sponsors seeking a mutual termination to agree not to apply for a new contract for two years, we believe that the same concerns that support applying the 2-year exclusion for non-renewals at the regional level pertain to mutual terminations. Allowing a sponsor that mutually terminates a contract in one PDP region to apply for a new contract in another PDP region does not incentivize the market-destabilizing practice of entering and exiting the PDP market in rapid succession. Therefore, we believe our application of the 2-year exclusion should be consistent between non-renewals and mutual terminations.

We note that this proposed provision would not apply to a PDP sponsor's non-renewal of its EGWP plans since those plans do not affect the availability of plan choices to beneficiaries or the number of plans that qualify for automatic LIS enrollments. We are also not concerned that non-renewal of EGWP plans would be driven by a sponsor's attempt to engage in adverse selection because EGWP plans are subject to contract negotiation between employers and sponsors and are not open to enrollment to all beneficiaries in the service area.

We received a comment on this proposed provision.

Comment: The commenter was generally supportive of the proposal and of exempting EGWP plans from the 2-year ban following nonrenewal or mutual termination. The commenter requested that we also exempt PDP PBPs and contracts terminated as part of a consolidation of plans and contracts after an acquisition.

Response: We appreciate the commenter's support for our proposal. We understand the commenter's concern regarding the application of the 2-year ban following a PDP consolidation, but do not believe any modification of the proposal is necessary because the termination of a PDP contract as part of a consolidation would not trigger the 2-year ban so long as the surviving contract continued to offer PDP PBPs in the affected regions. A consolidation occurs when two or more PDP contracts operated by the same sponsor or by sponsors that are subsidiaries of the same parent organization combine into a single contract. Consolidations often occur after the acquisition of a sponsor by a parent organization that has subsidiaries that offer PDP PBPs in the same region as the acquired sponsor. CMS limits the

number of PDP PBPs that a sponsor (or subsidiaries of the same sponsor) can offer to three plans per region under § 423.265(b)(3) and consolidations are often required to comply with this requirement following an acquisition. So long as the contract into which the plans are consolidated continues to offer PDP PBPs in the affected region(s), the sponsor (or the sponsor's parent organization) is not exiting the region and therefore would not be subject to the 2-year ban on reentering the region.

After consideration of the comments received and for the reasons outlined in the proposed rule and our response to those comments, we are finalizing the provision as proposed with minor grammatical and formatting changes.

H. Crosswalk Requirements for Prescription Drug Plans (§ 423.530)

1. Overview and Summary

In the December 2022 proposed rule, we proposed to codify, with modifications, the current process and conditions under which PDP sponsors can transfer their enrollees into a different PDP's plan benefit packages (PBPs) from year to year when such enrollees have made no other election. This process is known as a ''plan crosswalk'' and does not apply to enrollees in employer group health or waiver plans. Our proposal defined plan crosswalks and crosswalk exceptions; codified the circumstances under which enrollees can be transferred into different PDP PBPs from year to year; established the circumstances under which enrollees can be transferred into PDP PBPs offering different types of prescription drug coverage (''basic'' or ''enhanced alternative'' coverage); established the circumstances under which enrollees can be transferred due to contract consolidations of PDPs held by subsidiaries of the same parent organization; and provided protections against excessive premium increases resulting from crosswalks. We also proposed to limit the ability of PDP sponsors to create new PDP PBPs to replace non-renewing PBPs under certain circumstances.

We requested comment on whether and under what circumstances we should permit crosswalks from PBPs offering basic prescription drug coverage to PBPs offering enhanced alternative prescription drug coverage, whether we should require sponsors that non-renew an enhanced alternative PBP while continuing to offer individual market coverage in the same PDP region to crosswalk affected beneficiaries into another PBP, and limitations we should place on premium and cost increases for enrollees who are crosswalked between different PBPs. We were particularly interested in how best to balance avoiding gaps in prescription drug coverage, preserving beneficiary choice and market stability, and preventing substantial increases in costs to beneficiaries resulting from crosswalks.

Finally, we proposed to codify the current procedures that a Part D sponsor must follow when submitting a crosswalk or crosswalk exception request.

2. Proposed General Rules for Plan Crosswalks (§ 423.530(a))

Section 1860D–1(b)(1)(B) of the Act requires the Secretary to use rules similar to and coordinated with the rules for enrollment, disenrollment, termination, and change of enrollment in MA–PD plans under certain provisions of section 1851 of the Act. Therefore, in codifying general rules for plan crosswalks, we seek both to maintain current policy and, to the extent possible, be consistent with the requirements for MA plan crosswalks codified at § 422.530 in the final rule published in the January 19, 2021 **Federal Register** (CMS–4192–F2) (86 FR 5864).

At § 423.530(a)(1), we proposed to define a plan crosswalk as the movement of enrollees from one PDP PBP to another PDP PBP. We noted that this definition is consistent with current policy and with the definition of crosswalks for MA plans, codified at § 422.530(a)(1).

We proposed at § 423.530(a)(2)(i) through (iii) to adopt the crosswalk prohibitions in current CMS subregulatory guidance, described in the ''Guidance for Prescription Drug Plan (PDP) Renewals and Nonrenewals'' (hereinafter referred to as the PDP Renewal and Nonrenewal Guidance), issued in April 2018 and posted to the CMS website at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionbDrugCovbContra/Downloads/Guidance-for-Prescription-Drug-Plan-PDP-Renewals-and-Non-Renewals-.pdf*. First, we proposed to prohibit crosswalks between PBPs in different PDP contracts unless the PDP contracts are held by the same Part D sponsor or by sponsors that are subsidiaries of the same parent organization. Second, we proposed to prohibit crosswalks that split enrollment of one PBP into multiple PBPs. Third, we proposed to prohibit crosswalks from PBPs offering basic coverage to PBPs offering enhanced alternative coverage.

In the preamble to the December 2022 proposed rule, we noted that, in the past, organizations have sought exceptions to the prohibition of basic-to-enhanced alternative crosswalks on the grounds that one of the available enhanced alternative PBPs is lower cost or otherwise a better alternative for enrollees in a non-renewing basic PBP than the available basic PBP. These requests come in the context of proposed contract consolidations crosswalks and, because CMS prohibits PDP contracts from offering more than one PBP offering basic coverage in a region under § 423.265(b)(2), there would only be one option for the enrollees in non-renewing basic PBP to be transferred into. PBPs offering basic prescription drug coverage can vary widely in premium and estimated out-of-pocket costs. Enhanced alternative PBPs sometimes offer lower premiums than basic PBPs under the same contract. However, as discussed previously in section IV.AD.2. of the December 2022 proposed rule, a portion of the premium for an enhanced alternative PBP is the ''supplemental'' premium and any LIS-eligible individuals transferred from a basic to an enhanced alternative PBP might therefore have to pay more than they would in the available basic PBP, even if the enhanced alternative PBP has a lower overall premium. 87 FR 79602. Therefore, we proposed to continue our current policy in order to protect LIS-eligible beneficiaries from unanticipated premium increases.

We solicited comments on whether and under what circumstances to allow crosswalks from PBPs offering basic prescription drug coverage to enhanced alternative coverage. CMS was particularly interested in how such crosswalks could be administered in a way that protects LIS-eligible beneficiaries from premium and other cost increases.

Plan crosswalks often occur in the context of contract renewals and non-renewals. We proposed at § 423.530(a)(3) to require sponsors seeking crosswalks to comply with rules in §§ 423.506 and 423.507 governing renewals and non-renewals, respectively. This requirement is consistent with the requirement for MA plan crosswalks codified at § 422.530(a)(3). We also proposed at § 423.530(a)(4) to make clear that only enrollees eligible for enrollment under § 423.30 can be crosswalked from one PBP to another. Finally, we proposed at § 423.530(a)(5) to continue to allow enrollees in employer group health or waiver PBPs to be transferred between PBPs in accordance with the usual

process for enrollment in employer group health or waiver plans, rather than in accordance with the proposed provisions of § 423.530. This proposal would ensure that the process for enrollment in employer group health or waiver plans is not disrupted by this proposed rule.

3. Mandatory Crosswalks (§ 423.530(b))

We proposed at § 423.530(b)(1) and (2) to require enrollees in PDP PBPs that are renewing to be transferred into the same PBP for the following contract year. This is consistent with the current process summarized for renewal plans in the PDP Renewal and Nonrenewal Guidance. As discussed in the December 2022 proposed rule preamble, this requirement would continue to apply to PBPs offering both enhanced alternative and basic coverage and would continue to facilitate evergreen enrollment as required by section 1851(c)(3)(B) of the Act. We also noted that the proposal was consistent with the requirements for MA renewal crosswalks codified at § 422.530(b)(1)(i).

4. Plan Crosswalk Exceptions (§ 423.530(c))

We proposed at § 423.530(c) to classify consolidated renewal and contract consolidation crosswalks as ''crosswalk exceptions.'' We proposed to define ''consolidated renewals'' and ''contract consolidations'' consistent with the current policy described previously in section IV.AD.2. of the December 2022 proposed rule. We proposed to codify our current policy for the two types of plan crosswalk exceptions with some modifications.

For consolidated renewals, we proposed to codify current policy at § 423.530(c)(1)(i) through (iv) with modifications that balance concerns for beneficiaries in non-renewing plans losing coverage with concerns about market stability and limiting unexpected premium increases. Specifically, we proposed that:

- The plan ID for the upcoming contract year PBP must be the same plan ID as one of the PBPs for the current contract year;
- The PBPs being consolidated must be under the same PDP contract;
- A PBP offering basic prescription drug coverage may not be discontinued if the PDP contract continues to offer plans (other than employer group waiver plans) in the service area of the PBP; and
- Enrollment from a PBP offering enhanced alternative coverage may be crosswalked either into a PBP offering either enhanced alternative or basic prescription drug coverage.

We also proposed four major modifications to current policy with respect to consolidated renewals:

- At § 423.530(c)(1) to allow, but not require, plan crosswalks in consolidated renewal scenarios. PDP sponsors could request a crosswalk of enrollment from a non-renewing PBP to another PBP under the same contract, provided it meets the other requirements of § 423.530;
- At § 423.530(c)(1)(v), to require enrollees from non-renewing PBPs offering enhanced alternative coverage to be crosswalked into the PBP that will result in the lowest premium increase;
- At § 423.530(c)(1)(vi), to prohibit plan crosswalks if the crosswalk would result in a premium increase greater than 100 percent, unless the dollar amount of the premium increase would be less than the base beneficiary premium, as described in § 423.286(c), compared to the current year premium for the non-renewing PBP; and
- At § 423.530(c)(1)(vii), to prohibit sponsors that fail to request and receive a plan crosswalk exception from offering a new enhanced alternative PBP in the same service area for the contract year after they non-renew an enhanced alternative PBP.

As discussed in the preamble to the December 2022 proposed rule, we recognize that premiums are not the only aspect of a PBP's structure that affect costs to beneficiaries or the beneficiary experience. The PBP's formulary and cost-sharing structure are also important elements affecting beneficiary costs. However, premiums for a PBP are the same for every enrollee and are therefore the most straightforward factor to use to protect enrollees from unexpected cost increases. We solicited comments on whether we should use other factors, such as differences in estimated out of pocket costs (OOPC) between the non-renewing and surviving PBPs, rather than simply the difference in plan premiums, to determine whether approving a plan crosswalk exception is the best option for enrollees in a non-renewing PBP. We also requested comments on whether to allow plan crosswalks to a higher premium plan if the difference between the higher premium plan and the lower premium plan is less than a certain dollar amount—for example, should CMS permit a crosswalk to a higher premium surviving PBP despite the availability of a lower premium surviving PBP if the difference between the premiums is less than a fixed dollar amount. Finally, we sought comment on alternatives to using the base beneficiary premium. Potential alternatives included a fixed dollar amount, the low-income premium subsidy amount, described in § 423.780(b), for the non-renewing PBP's region, or the national average monthly bid amount, described in § 423.279.

These four proposed changes represented a significant shift from current policy. As such, we solicited comments on alternative approaches. Possible alternatives included, but were not limited to: (1) requiring plan crosswalks when a sponsor non-renews an enhanced alternative PBP while continuing to offer individual market coverage under the same PDP contract, but prohibiting sponsors from creating a new PBP to replace the non-renewing PBP; (2) adopting the requirements as proposed, but prohibiting sponsors from creating new PBPs to replace non-renewing PBPs even if a plan crosswalk exception is requested and received; (3) using an alternative measure, such as OOPC, instead of or in addition to plan premiums to assess whether a plan crosswalk exception should be granted; or (4) adopting the current subregulatory policy without modification.

We also proposed requirements for contract consolidations that would reflect our current subregulatory policy, but with two significant differences that parallel the proposals with respect to consolidated renewals. We proposed at § 423.530(c)(2)(i)–(iv) to adopt the following requirements of current subregulatory policy:

- The non-renewing PDP contract and the surviving contract must be held by the same legal entity or by legal entities with the same parent organization;
- The approved service area of the surviving contract must include the service area of the non-renewing PBPs whose enrollment will be crosswalked into the surviving contract;
- Enrollment may be crosswalked between PBPs offering the same type of prescription drug coverage (basic or enhanced alternative); and
- Enrollment from a PBP offering enhanced alternative coverage may be crosswalked into a PBP offering basic prescription drug coverage.

We proposed the following significant changes to current policy with respect to contract consolidations:

- At § 423.530(c)(2)(v), require plan crosswalks from non-renewing PBPs offering enhanced alternative coverage into the PBP that would result in the lowest premium increase; and
- At § 423.530(c)(2)(vi), prohibit plan crosswalks that would result in a premium

increase greater than 100 percent, unless the dollar amount of the premium increase would be less than the base beneficiary premium, as

described in § 423.286(c), compared to the current year premium for the non-renewing PBP.

5. Procedures for Requesting Plan Crosswalks (§ 423.530(d))

We proposed to codify current procedures for submitting plan crosswalks and/or making plan crosswalk exception requests at § 423.530(d), as described in ''Bid Pricing Tool for Medicare Advantage Plans and Prescription Drug Plans'' CMS–10142, posted for final comment pursuant to the Paperwork Reduction Act of 1995 at 87 FR 2441 (February 14, 2022). We proposed that a Part D sponsor must submit all mandatory plan crosswalks in writing through the bid submission process in HPMS by the bid submission deadline. We further proposed that a Part D sponsor must submit all plan crosswalk exceptions by the plan crosswalk exception request deadline announced annually by CMS. Through the bid submission process, the Part D sponsor may indicate if a plan crosswalk exception is needed at that time; however, the Part D sponsor must also ultimately request a crosswalk exception through the crosswalk exception functionality in HPMS in accordance with the deadline announced annually. CMS would verify the exception request and notify the requesting Part D sponsor of the approval or denial of the request after the plan crosswalk exception request deadline. CMS would approve any plan crosswalk exception that met the requirements of the regulation. Because plan crosswalks are requested when a PBP is non-renewing, a denied crosswalk request would result in the PBP being non-renewed without enrollment being crosswalked. Part D sponsors would be required to submit these exception requests to ensure that PBP enrollment is allocated properly.

6. Response to Comments

We are finalizing crosswalk requirements for PDPs at § 423.530 without modification, as discussed in the responses to comments that follow.

Comment: Several commenters asked that we consider plan characteristics other than total premiums when determining which plan or plans beneficiaries could be crosswalked into. They noted that crosswalks can result in more changes than just a change in premium, including changes to cost sharing and formulary drugs. They suggested that CMS consider factors such as the beneficiary OOPC estimate in the plan bid and the formulary composition and structure, in addition to the plan premium, when assessing which PBP beneficiaries can be crosswalked into in consolidated renewal and contract consolidation scenarios.

Response: CMS acknowledges and shares the concerns that commenters expressed regarding the impact that changing PBPs can have on individual beneficiaries' costs and access to drugs. However, it is very difficult to predict which formulary will be best for the greatest number of beneficiaries. CMS reviews all formularies to ensure that they contain the required number of Part D drugs from each therapeutic category and class and an appropriate range of strengths and dosages of those drugs, that utilization management requirements (including prior authorization and step therapy requirements) are appropriate, and that the formularies otherwise meet all Part D requirements. While this ensures that all plans offer appropriate coverage of and access to Part D drugs, individual beneficiaries may find that certain formularies offer better coverage of, or pricing for, the drugs they utilize. CMS does not currently have a methodology to determine whether a particular approved formulary will be ''better'' for a group of beneficiaries than another approved formulary, given the variety of ways that an individual beneficiary may deem a certain formulary ''better'' and the diversity of needs from one beneficiary to the next. For instance, one beneficiary may find inclusion of utilization management to be off-putting whereas another values a low tier placement. Despite these hypotheticals, premiums have been shown to be a key factor in plan choice for beneficiaries.

Each plan does have an estimated OOPC value, which estimates the average monthly out-of-pocket costs for enrollees in a PBP. But while that is a useful bid review and actuarial tool, the actual costs incurred by beneficiaries are highly variable because they are based on characteristics—including but not limited to LIS status, health status, medications used, pharmacies chosen—that vary widely among beneficiaries. Premiums, on the other hand, are uniform for all beneficiaries. We believe that attempting to use other information, including OOPC and formulary composition and structure, to determine which plans beneficiaries may be crosswalked into is too complicated to be practical at this time.

CMS will continue to encourage beneficiaries to investigate the cost and benefits of available Part D plans during each Annual Election Period (AEP). Beneficiaries can use Medicare Plan Finder and other tools to assess which plans offer the combination of premiums, cost sharing, pharmacy networks, and formulary coverage that best meets their individual needs. Part D sponsors will continue to be required to send Annual Notices of Change (ANOCs), Evidences of Coverage (EOCs) and other materials as described in § 423.2267(e) to all beneficiaries enrolled in their plans before the AEP so that beneficiaries will have information such as formulary coverage, cost sharing, and prior authorization requirements to use when comparing plans.

Comment: A few commenters requested that CMS provide a special election period (SEP) to beneficiaries subject to consolidated renewal and contract consolidation crosswalks. These commenters believe that beneficiaries do not always realize how their Part D benefits are changing for the new year and that they may benefit from an SEP so they may select new plans after the new plan year begins.

Response: CMS acknowledges commenters' concerns. However, plan premiums, cost sharing, and formularies can significantly change year-to-year even when beneficiaries are not being crosswalked into a new PBP. CMS does not believe that beneficiaries subject to crosswalks, particularly with the safeguards we are finalizing in this rule, are any more vulnerable to not understanding the resulting changes to their Part D benefits than beneficiaries who are continuing in the same PBP without being crosswalked. Therefore, we do not believe an SEP is appropriate for crosswalked beneficiaries. Crosswalked beneficiaries will receive the same notice of changes—the ANOC—that all other beneficiaries in continuing Part D coverage will receive before the AEP. They will also receive all other required material, including the EOC and Summary of Benefits, which provide details about premiums, deductibles, and cost sharing for the new plan. CMS continues to encourage all beneficiaries to compare available coverage offerings during every AEP.

Comment: One commenter representing a Part D plan requested that CMS delay the effective date of the crosswalk provisions until after the premium stabilization protections in the Inflation Reduction Act of 2022 (''IRA'') go into effect.

Response: CMS notes that the premium stabilization provisions of the IRA, which provide a mechanism to limit the growth in the base beneficiary premium (used to calculate the plan-specific base premium) to a 6 percent increase compared to the previous year, went into effect for plan year 2024. There is therefore no need to further

delay implementation of the crosswalk provisions based on the concerns expressed by this commenter.

Comment: Some commenters opposed limiting consolidated renewal and contract consolidation crosswalks to those that would result in the lowest premium increase and barring such crosswalks when they would result in premium increases greater than 100 percent. These commenters believed plans needed greater flexibility in determining the appropriate plan into which to crosswalk members. Specifically, they wanted CMS to take formulary structure, cost sharing, and network composition into account. They also expressed concern over the effect that the implementation of various provisions of the IRA would have on plan premiums. They were concerned that the cost sharing limits for insulin and certain adult vaccines (which went into effect in 2023), ending beneficiary cost sharing for covered Part D drugs during the catastrophic phase of the benefit (effective in 2024), and the new beneficiary Part D out-of-pocket spending limit (effective in 2025), among other provisions, will create unanticipated volatility in Part D premiums. They requested that if CMS finalizes these requirements as proposed, we delay implementation of the provisions of the proposed crosswalk regulation that limit premium increases until at least 2026 to give the market time to adjust to the changes.

Response: As we noted in the preamble to the proposed rule, crosswalks have rarely resulted in premium increases greater than 100 percent. We therefore do not think it is necessary to preserve ''flexibility'' for plans to implement such crosswalks in the future. We also note that the proposed crosswalk requirements would grant plans more flexibility in some respects by allowing them to choose to non-renew an enhanced alternative plan without crosswalking enrollees into another plan. Earlier in this preamble, we also pointed out in response to a comment requesting that CMS consider factors other than premiums in assessing the appropriateness of a proposed crosswalk that taking formulary comparisons or anticipated out-of-pocket costs into account would not be practical at this time.

CMS understands the commenters' concerns about the unanticipated consequences of changes to the Part D program required by the IRA. As discussed earlier in this preamble in response to another comment, the IRA includes a mechanism to limit the growth in the base beneficiary premium (used to calculate the plan-specific base premium) for Part D plans starting on January 1, 2024. The 2024 Part D premiums reflect both the IRA's premium stabilization provisions and its provisions limiting cost sharing for covered insulin products and recommended adult vaccines and ending beneficiary cost sharing for covered Part D drugs during the catastrophic phase of the benefit. Rather than increasing, the average total monthly premium for Medicare Part D coverage was projected to decrease 1.8 percent from $56.49 in 2023 to $55.50 in 2024 for 2024.[20] We anticipate that premiums will continue to remain stable as the IRA is fully implemented.

While we do not believe it is necessary to suspend or delay these elements of the proposed rule, we will delay implementation of this proposal until January 1, 2026 to allow time for necessary system updates to be made to the CMS systems for the 2026 bid cycle that commences in June 2025. To the extent that commenters are concerned about the burden of implementing the new crosswalk requirements while adjusting to major changes under the IRA, this delay should allay their concerns.

Comment: A commenter recommended allowing LIS beneficiaries to be crosswalked from basic to enhanced alternative plans when the premium for the enhanced alternative plan is lower than for the available basic plan. The commenter believed that this would save the government money by reducing LIS payments. The commenter alternatively recommended allowing the creation of LIS-only plans to be offered by all sponsors to address the unique needs of LIS beneficiaries.

Response: We thank the commenter for their input. While we acknowledge that a lower premium enhanced alternative plan may indeed lower the LIS subsidy the government would pay for an LIS beneficiary enrolled in the plan, the commenter's recommendation does not address the primary reason we prohibit such crosswalks. As we discussed in the proposed rule, CMS can only provide the LIS for the portion of the monthly beneficiary premium attributable to basic coverage, pursuant to § 423.780(b)(1)(i). This does not include the amount attributed to supplemental coverage for enhanced alternative plans. Any LIS-eligible individuals enrolled in a non-renewing PBP offering basic prescription drug coverage that were transferred into a PBP offering enhanced alternative coverage, and who did not change their election, might therefore have to pay more than they would for a PBP offering basic prescription drug coverage, even if the enhanced alternative PBP had a lower overall premium. The commenter's recommendation for an LIS-only offering is beyond the scope of our proposal.

Comment: One commenter requested clarification on how CMS would compare a premium increase to the base beneficiary premium when considering whether to allow a crosswalk that would result in a premium increase of over 100 percent compared to the non-renewing plan's total plan premium. The commenter interpreted the requirement proposed for § 423.530(c)(1)(vi) and (2)(vi) to compare the base beneficiary premium to the premium increase amount, not to the total premium after the increase. The commenter interpreted our proposal to allow a consolidated renewal or contract consolidation crosswalk if the premium increase were the same or lower than the base beneficiary premium and asked for confirmation of that interpretation.

Response: The commenter's interpretation of the proposed language is accurate. CMS will evaluate compliance with this requirement by comparing the anticipated premium increase for crosswalked beneficiaries to the base beneficiary premium.

Comment: One commenter expressed concern that ''forcing'' plans to crosswalk members into certain plans would negatively impact current members in those plans by increasing premiums based on the claims history of the crosswalked members.

Response: This commenter appears to confuse our current crosswalk policy, which does mandate crosswalks when sponsors non-renew an enhanced alternative plan while continuing to offer PDP PBPs in a service area, with the proposal, which would no longer require such crosswalks. Under the proposed policy, sponsors could choose not to perform a consolidated renewal crosswalk for members from a non-renewing enhanced alternative PDP PBP into another PBP under the same contract. CMS would bar the sponsor from creating a new enhanced alternative plan to replace the non-renewing one if the sponsor opted not to crosswalk membership from the non-renewed plan, but CMS would no longer require plans to perform such crosswalks.

Comment: A commenter expressed general support for codifying the

[20] CMS Press Release, ''Medicare Advantage and Medicare Prescription Drug Programs to Remain Stable in 2024,'' September 26, 2023, available at *https://www.cms.gov/newsroom/press-releases/medicare-advantage-and-medicare-prescription-drug-programs-remain-stable-2024*.

crosswalk requirements as proposed because it would create clear requirements for PDP crosswalks. They asked that CMS consider other factors in the PDP market that create incentives for plan sponsors to consolidate PDP offerings and that may result in unnecessary premium increases. Specifically, the commenter asked that CMS make modifications to the Prescription Drug Hierarchical Condition Category (Rx-HCC) Risk Adjustment Model to enhance the predictive power of the tool and ensure more appropriate reimbursement to plan sponsors. They believe that the current model may no longer adequately mitigate against plan sponsors' incentives to engage in risk selection. They specifically asked that CMS take steps to reduce the lag time for including updated claims data in the model to not more than three years.

Response: CMS appreciates the commenter's support for this proposed rule. CMS does not believe there are additional factors related to premium increases that could be addressed through our proposed crosswalk requirements. The comments regarding the Rx-HCC Risk Adjustment Model are beyond the scope of this proposal.

After considerations of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the plan crosswalk provisions as proposed but with minor grammatical and formatting changes and a delayed effective date from January 1, 2025 to January 1, 2026.

I. Call Center Text Telephone (TTY) Services (§§ 422.111 and 423.128)

We proposed to make a technical change by modifying §§ 422.111(h)(1)(iv)(B) and 423.128(d)(1)(v)(B) to require a plan's call center to establish contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services, rather than establishing contact with a TTY operator within 7 minutes on no fewer than 80 percent of incoming calls. Our proposed change was intended to remove any ambiguity that might result from our use of the term ''TTY operator,'' because our intent was to ensure a beneficiary could establish contact with a customer service representative within 7 minutes. When an MA organization or Part D sponsor operates their own TTY device and thereby creates a direct TTY to TTY communication, the plan customer representative is also the TTY operator. However, when MA organizations and Part D sponsors use telecommunications relay systems, a TTY operator serves as an intermediary between the caller and the plan's customer service representative and is not able to answer the caller's questions about plan benefits.

We received several comments supporting and no comments opposing this proposal. CMS thanks those in support of our proposal. For the reasons outlined in the proposed rule, we are finalizing the revision as proposed.

J. Clarify Language Related to Submission of a Valid Application (§§ 422.502 and 423.503)

1. Overview and Summary

In the December 2022 proposed rule, we summarized the history of our treatment of substantially incomplete applications and proposed to amend the language in §§ 422.502 and 423.503 to codify CMS's authority to decline to consider a substantially incomplete application for a new or expanded Part C or D contract. We also proposed to codify longstanding criteria for determining that an application is substantially incomplete. We are finalizing these provisions as proposed.

We proposed to modify §§ 422.502 and 423.503 by adding new paragraphs (a)(3) and (a)(4), respectively, regarding substantially incomplete applications. At §§ 422.502(a)(3)(i) and 423.503(a)(4)(i), we proposed to codify that we do not evaluate or issue a notice of determination as described in §§ 422.502(c) and 423.503(c), respectively, when an entity submits a substantially incomplete application. This proposed modification to the regulatory text is consistent with our longstanding policy to treat substantially incomplete applications as if they were not submitted by the application deadline and therefore the submitting entity is not entitled to review of its submitted material or an opportunity to cure deficiencies.

We also proposed at §§ 422.502(a)(3)(ii) and 423.503(a)(4)(ii) to codify our definition of a substantially incomplete application as one that does not include responsive materials to one or more sections of the MA or Part D application. Pursuant to §§ 422.501(c) and 423.502(c), entities seeking to qualify as an MA organization (or to qualify to offer a specialized MA plan for special needs individuals (a SNP)) and/or Part D sponsor to must fully complete all parts of a certified application, in the form and manner required by CMS. Applications for service area expansions are subject to the same rules and review processes because we treat the expansion of a plan service area as a new application for a new area. We prescribe the form and manner in an application published annually. This application is subject to the Paperwork Reduction Act review process. The form and manner vary somewhat from year to year, but generally include several sections that require an entity to demonstrate compliance with specific categories of program requirements. For instance, Part D applications for new Part D contracts include: (1) a series of attestations whereby the applicant agrees that it understands and complies with various program requirements; (2) a contracting section that requires entities to demonstrate compliance with Part D requirements by submitting certain first tier, downstream, and related entity contracts and network pharmacy templates; (3) a network section that requires entities to submit lists of contracted pharmacies that meet geographic and other access requirements; (4) a program integrity section that requires entities to submit documentation that they have documented and implemented an effective compliance program as required by § 423.504(b)(vi); and (5) a licensure and solvency section that requires entities to meet applicable licensure and fiscal solvency requirements. MA applications require substantially similar information related to the operation of an MA plan, and SNP applications include additional sections related specifically to SNP requirements for the type of SNP the applicant seeks to offer. Consistent with past practice, CMS proposed to treat an application that does not include required content or responsive materials for one or more of these sections as substantially incomplete. In our assessment, applications that fail to include significant amounts of responsive information and/or materials, including failing to include required content or responsive material for any section of the application, in their submission by the application deadline are merely submitting placeholder applications that do not merit additional opportunities to meet CMS requirements.

An example of a Part D application that would be incomplete and therefore excluded from further consideration under the proposed rule is one that failed to include (by uploading to the application system) a retail pharmacy list that would allow CMS to determine whether it met pharmacy access requirements. This would include failure to submit a list at all, submitting a list containing fictitious pharmacies, or submitting a list that contained so

few pharmacies that CMS could reasonably conclude that no good faith effort had been made to create a complete network. CMS would also deem as substantially incomplete any application that failed to submit any executed contracts with first tier, downstream, or related entities that the applicant had identified as providing Part D services on its behalf.

An example of an MA application that would be incomplete and therefore excluded from further consideration is one that failed to upload either a state license or documentation that the state received a licensure application from the applicant before the CMS application due date. Another example of an incomplete MA application might be one that failed to upload network adequacy materials, including failing to submit network lists for designated provider types, submitting fictitious providers, or submitting a list that contained so few providers that CMS could only conclude that no good faith effort had been made to create a complete network.

An example of a SNP application that would be incomplete and therefore excluded from further consideration is one that failed to upload a model of care (MOC) that would allow CMS to determine whether or not it met MOC element requirements. This would include failure to submit MOC documents at all or submitting incomplete documents that did not contain all of the required MOC elements.

Finally, we proposed at §§ 422.502(a)(3)(iii) and 423.503(a)(4)(iii) to explicitly state that determinations that an application is substantially incomplete are not contract determinations as defined at §§ 422.641 and 423.641, respectively. Because they are not contract determinations, determinations that an application is substantially incomplete are not entitled to receipt of specific notices or to file an appeal under Parts 422 and 423, subpart N. CMS has consistently taken this position when determining an application is substantially incomplete because a submission that is so incomplete as to not be deemed a valid application did not meet the application deadline and cannot be meaningfully reviewed. Nevertheless, a few entities have used the contract determination hearing process to appeal CMS's determination that they did not submit a substantially complete application by the application deadline. In such cases, the Hearing Officer has ruled that such determinations were not contract determinations entitled to hearings under §§ 422.660 and 423.650.

We do not believe that our proposed regulatory provisions at §§ 422.502(a)(3)(i) and 423.503(a)(4)(i) will have a significant impact on the Part C or D programs. Only a handful of entities have attempted to submit substantially incomplete applications in recent years. We believe that codifying our treatment of substantially incomplete applications will further discourage entities from submitting placeholder applications and ensure that materials submitted by the application deadline represent entities' good faith efforts to meet application requirements.

We received comments on this proposal, which are summarized below:

Comment: A commenter expressed support for the proposal and appreciated the clarifications regarding what constitutes a substantially incomplete application.

Response: CMS appreciates the commenter's support.

Comment: Several commenters generally supported the proposal but requested clarification on what documentation would be sufficient to indicate that an application was not substantially incomplete. A few commenters specifically requested further clarification on what constitutes evidence that a state licensure application was filed. One commenter wanted additional clarity on what evidence would indicate that a plan made ''best efforts'' to complete an application.

Response: CMS appreciates the commenters' support. As summarized from the proposed rule earlier in this section, an example of a substantially incomplete application is one where the organization failed to provide evidence of state licensure or documentation that the state received a licensure application from the applicant before the CMS application due date. When an entity submits, with the MA application, documentation that the entity has filed a complete state licensure application with the appropriate state before the CMS MA and Part D application due date, CMS will not determine that the application is substantially incomplete based on a failure to provide responsive materials in the state licensure section of the MA application. (However, all other portions of the MA application must also be complete for CMS to review and evaluate the application.) Documentation to demonstrate that the entity has applied for the appropriate state licensure for its MA application could consist of a copy of the application and a receipt or other documentation that the application was sent to and received by the state before the CMS MA and Part D application due date. MA organizations must be licensed in the state(s) of the service area(s) covered by the application in order to ultimately have their application approved by CMS.

CMS did not propose and does not currently use a ''best efforts'' standard for determining whether an application is substantially incomplete. In the proposed rule (87 FR 79520), we described an example of an MA applicant submitting a list of providers that was so few that CMS could only conclude that that applicant had not even made a good faith effort to create a complete network by the application deadline, which is key to demonstrating the ability to provide adequate access to covered services. For example, an application would be substantially incomplete if it only included a single pharmacy in the retail pharmacy network submission, regardless of how much effort the organization submitting the application put into enrolling pharmacies in the network. An organization that was acting in good faith would not have filed an application wherein they certified they met application requirements if they had not been able to enroll more than a single pharmacy by the application deadline. While CMS recognizes that it can be challenging for an organization to prepare to offer MA and Part D plans, CMS expects any organization filing an application to have already made sufficient progress in its preparations to provide responsive materials to all parts of the application.

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the revisions to §§ 422.502(a)(3) and 423.503(a)(4) as proposed without substantive modification. The final regulation text includes minor stylistic changes.

K. Expanding Network Adequacy Requirements for Behavioral Health

Section 1852(d)(1) of the Act allows an MA organization to select the providers from which an enrollee may receive covered benefits, provided that the MA organization, in addition to meeting other requirements, makes such benefits available and accessible in the service area with promptness and assures continuity in the provision of benefits. Further, our regulation at § 422.112(a), requires that a coordinated care plan maintain a network of appropriate providers that is sufficient

to provide adequate access to covered services to meet the needs of the population served. To establish standards for these requirements, CMS codified network adequacy criteria and access standards in the ''Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program'' final rule, which appeared in the **Federal Register** on June 2, 2020 (85 FR 33796), hereinafter referred to as the ''June 2020 final rule.'' In that final rule, we codified, at § 422.116(b), the list of 27 provider specialty types and 13 facility specialty types subject to CMS network adequacy standards. Further, as part of the ''Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs'' published in the **Federal Register** January 12, 2022 (87 FR 1842) proposed rule, hereinafter referred to as the ''January 2022 proposed rule,'' we solicited comments through a Request for Information (RFI), regarding challenges in building MA behavioral health networks and opportunities for improving access to services. In response to the RFI, stakeholders commented on the importance of ensuring adequate access to behavioral health services for enrollees and suggested expanding network adequacy requirements to include additional behavioral health specialty types. As a result, in the ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' final rule, which appeared in the **Federal Register** on April 12, 2023, (88 FR 22120) hereinafter referred to as the ''April 2023 final rule,'' CMS finalized the addition of two new specialty types to the provider-specialty types list at § 422.116(b)(1), Clinical Psychology and Clinical Social Work, to be subject to the specific time and distance and minimum provider number requirements used in CMS's network adequacy evaluation.

While our regulation at § 422.116(b)(3) authorizes the removal of a specialty or facility type from the network evaluation criteria for a specific year without rulemaking, CMS did not implement a process in § 422.116 to add new provider types without rulemaking. In a continued effort to address access to behavioral health services within MA networks, we proposed to add to the list of provider specialties at § 422.116(b) and add corresponding time and distance standards at § 422.116(d)(2).

In addition to meeting the network adequacy evaluation requirements, MA organizations are required at § 422.112(a) to maintain and consistently monitor their provider networks to ensure they are sufficient to provide adequate access to covered services that meet the needs of enrollees. This also helps MA organizations maintain a complete and accurate health plan provider directory as required under §§ 422.111(b)(3) and 422.120(b). The Health Plan Management System (HPMS) provides MA organizations with access to the ''Evaluate my Network'' functionality, which allows MA organizations the opportunity to test their provider networks against the evaluation standards in § 422.116 outside of a formal network review. The ''Evaluate my Network'' functionality provides MA organizations the ability to test their networks using the standards in § 422.116(a)(2) in different scenarios, including at the Plan Benefit Package (PBP) level, to consistently monitor whether their provider networks are meeting the current network adequacy standards. We encourage MA organizations to utilize the HPMS ''Evaluate my Network'' tool to monitor their PBP-level active provider networks and keep abreast of any network issues that could hinder access to care for enrollees. We also remind MA organizations to report any compliance issues or significant changes in their provider network to their CMS Account Manager.

With the revisions applicable to coverage beginning January 1, 2024, MA organizations are required to demonstrate that they meet network adequacy for four behavioral health specialty types: psychiatry, clinical psychology, clinical social work, and inpatient psychiatric facility services. The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328) amended the Act to authorize payment under Medicare Part B for services furnished by a Marriage and Family Therapist (MFT) and by a Mental Health Counselor (MHC), effective January 1, 2024. Specifically, section 4121 of the CAA amends section 1861(s)(2) of the Act by adding a new subparagraph (II) that establishes a new benefit category under Part B for MFT services (as defined in section 1861(lll) of the Act) and MHC services (as defined in section 1861(lll) of the Act). MA organizations are required to cover virtually all Part B covered services. As such, these new services must be covered as defined and furnished, respectively, by MFTs, as defined in section 1861(lll)(2) of the Act, and MHCs, as defined in section 1861(lll)(4) of the Act. As a practical matter, MA organizations need to ensure access to these new Medicare-covered services that can only be provided by these types of individual providers and therefore must contract with these types of providers in order to furnish basic benefits as required by section 1852 of the Act (when furnished by different providers, the services will be supplemental benefits covered by the MA plan).

In addition, we discussed in the April 2023 final rule that the responses CMS received to the January 2022 proposed rule RFI emphasized the importance of expanding network adequacy standards to include other outpatient behavioral health physicians and health professionals that treat substance use disorders (SUDs) to better meet behavioral health care needs of enrollees. Medicare fee-for-service claims data for 2020 shows that Opioid Treatment Program (OTP) providers had the largest number of claims for SUD services during that timeframe. At the time of publishing our April 2023 final rule, we indicated that while we were not able to finalize adding a combined specialty type called ''Prescribers of Medication for Opioid Use Disorder,'' which included OTPs and Medication for Opioid Use Disorder (MOUD) waivered providers to the facility-specialty type list in § 422.116(b)(2) as proposed, we would consider the appropriateness of setting network adequacy standards for OTPs in future rulemaking.

Considering the statutory changes to section 1861 of the Act as mentioned, and our interest in establishing network adequacy standards for SUD providers, CMS proposed to amend the MA network adequacy requirements to address the new provider types and SUD provider types through a combined behavioral health specialty type to include MFTs, MHCs, OTPs, Community Mental Health Centers and other behavioral health and addiction medicine specialty providers that will help us enhance behavioral health access for enrollees. This is consistent with the explanation in our April 2023 final rule that setting a meaningful access standard for the OTP specialty type will be possible under a combined behavioral health specialty type.

CMS is committed to improving access to behavioral health care services for enrollees in the MA program. The

CMS Behavioral Health Strategy,[21] aims to improve access and quality of mental health care and services, including access to substance use disorder prevention and treatment services. We proposed to extend network adequacy requirements to additional behavioral health and substance use disorder providers and facilities by adding time and distance and minimum provider number requirements for a combined provider category. Specifically, we proposed to add Outpatient Behavioral Health as a new type of facility-specialty in § 422.116(b)(2) and to add Outpatient Behavioral Health to the time and distance requirements in § 422.116(d)(2). For purposes of network adequacy evaluations under § 422.116, Outpatient Behavioral Health can include, MFTs (as defined in section 1861(lll) of the Act), MHCs (as defined in section 1861(lll) of the Act), OTPs (as defined in section 1861(jjj) of the Act), Community Mental Health Centers (as defined in section 1861(ff)(3)(B) of the Act), or those of the following who regularly furnish or will regularly furnish behavioral health counseling or therapy services, including, but not limited to, psychotherapy or prescription of medication for substance use disorders: physician assistants, nurse practitioners, and clinical nurse specialists (as defined in section 1861(aa)(5) of the Act); addiction medicine physicians; or outpatient mental health and substance use treatment facilities. Per § 422.2, the term ''provider'' means (1) any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and (2) any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation. Although we are not using the term ''provider'' specifically here in listing the type of healthcare professionals that we expect to be available to furnish services in order to count for purposes of the proposed new network evaluation standard, all applicable laws about the practice of medicine and delivery of health care services must be met and specific healthcare professionals must be appropriately licensed or certified to furnish the applicable services.

We proposed to add this combined facility-specialty type instead of adding individual provider-specialty types for a few reasons. First, data from the U.S. Department of Labor, Bureau of Labor Statistics show that currently MFTs and MHCs are generally providing services in outpatient behavioral health settings, such as community mental health centers, substance abuse treatment centers, hospitals, and some private practices. [22] [23] These types of clinical settings offer a fuller range of services and usually provide access to additional providers, such as advanced practice nurses and physician assistants who provide counseling and other therapeutic services to individuals with behavioral health conditions; our review of the Place of Service codes recorded on professional claims for behavioral health services in the Medicare FFS program illustrates this. In addition, currently, there are a limited number of (if any) claims in the Medicare FFS program from MFTs and MHCs; combining the MFT and MHC provider types into the ''Outpatient Behavioral Health'' facility type provides time for CMS to develop additional data as FFS claims are submitted by MFTs and MHCs to show patterns of access to these provider types across the country. CMS needs such claims and utilization data to support the development of time and distance standards for these particular provider-specialty types. Finally, categorizing these provider specialties as a facility type is consistent with our practice under § 422.116, wherein physical therapy (PT), occupational therapy (OT), and speech therapy (ST) providers have traditionally been categorized as facility types, even though care is typically furnished by individual health care providers. These provider types (that is, PT, OT, ST) are reported for network adequacy purposes under facility specialty types on Health Service Delivery (HSD) tables.

As mentioned previously, the statutory change under the CAA will allow MFTs and MHCs to bill Medicare directly for services provided beginning January 1, 2024. We acknowledge that these provider types may not always be located in facilities and provide facility-based services. As such, we will continue to monitor the appropriateness of maintaining this proposed new behavioral health specialty type as a facility-specialty type (that is, under § 422.116(b)(2)) for network adequacy review purposes. Similarly, as the list [24] of OTPs enrolled in Medicare continues to expand, we will continue to monitor whether network adequacy for OTPs is best measured under a combined facility type for the purpose of network adequacy reviews. Thus, we may engage in future rulemaking to revise this requirement if the landscape of providers changes such that access will be best evaluated separately for MFTs, MHCs, or OTPs instead of under the one facility-specialty type we proposed in this rule. Any related changes will be proposed in future rulemaking. We proposed that MA organizations are allowed to include on their facility HSD tables for the proposed new facility type (Outpatient Behavioral Health) the following: contracted individual practitioners, group practices, or facilities that are applicable under this specialty type. We proposed that MA organizations may not submit a single provider for purposes of meeting the Outpatient Behavioral Health requirement if they have already submitted that provider under another specialty. For example, MA organizations would not be permitted to submit a single provider as a psychiatry, clinical social work, or clinical psychologist provider specialty and as an Outpatient Behavioral Health facility.

Our current regulations, at § 422.116(a)(2), specify that an MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility-specialty type. Therefore, as part of the proposed changes to our list of facility specialty types under § 422.116(b)(2), we proposed base time and distance standards in each county type for the new specialty type as follows:

[21] *https://www.cms.gov/cms-behavioral-health-strategy.*

[22] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook,* Marriage and Family Therapists, at *https://www.bls.gov/ooh/community-and-social-service/marriage-and-family-therapists.htm* (visited *July 03, 2023*).

[23] Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook,* Substance Abuse, Behavioral Disorder, and Mental Health Counselors, at *https://www.bls.gov/ooh/community-and-social-service/substance-abuse-behavioral-disorder-and-mental-health-counselors.htm* (visited *July 06, 2023*).

[24] *https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opioid-treatment-program-providers.*

TABLE CK-1: MAXIMUM TIME AND DISTANCE STANDARDS:

Provider/ Facility type	Large Metro		Metro		Micro		Rural		Counties with Extreme Access Considerations (CEAC)	
	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance
Outpatient Behavioral Health	20	10	40	25	55	40	60	50	110	100

In the proposed rule titled ''Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' which appeared in the **Federal Register** on February 18, 2020 (85 FR 9002) (hereinafter referred to as the ''February 2020 proposed rule''), we explained how CMS developed the base time and distance standards and the minimum provider requirements used in § 422.116 (85 FR 9094 through 9103). Further, we explained in the February 2020 proposed rule how CMS determines the minimum number requirement for all provider and facility specialty types, which is now codified in § 422.116(e). We codified at § 422.116(e)(2)(iii) that all facilities, except for acute inpatient hospitals facilities, have a minimum number requirement of one. Because we had previously established paragraph (e)(2)(iii) to refer to all facility types listed in paragraph (b)(2)(ii) through (xiv) and proposed to add Outpatient Behavioral Health as a facility type at paragraph (b)(2)(xiv), we did not propose any revisions to paragraph (e)(2)(iii). We followed the analysis and methodology described in the February 2020 proposed rule to develop the time and distance standards that we proposed to apply to the new behavioral health facility-specialty type described here. However, we utilized updated data, including outpatient facility and professional Part B claims data from August 1, 2021, through July 31, 2022, to inform our proposed standard.

Finally, as we indicated in the April 2023 final rule, Medicare FFS claims data shows that telehealth was the second most common place of service for claims with a primary behavioral health diagnosis in 2020 (88 FR 22170). Per § 422.116(d)(5), MA plans may receive a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards for certain providers when the plan includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, in its contracted network. Currently, § 422.116(d)(5) specifies 14 specialty types for which the 10-percentage point credit is available. Because we understand from stakeholders who commented on our April 2023 final rule that they were supportive of usage of the 10-percentage point credit for behavioral health specialty types, we also proposed to add the new Outpatient Behavioral Health facility-specialty type to the list at § 422.116(d)(5) of the specialty types that will receive the credit if the MA organization's contracted network of providers includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, for covered services.

We solicited comments on this proposal. Our responses to the comments received are outlined below.

Comment: Numerous commenters supportive of our proposal to improve behavioral health network adequacy standards in MA plans. Commenters commended CMS for continuing to work towards increasing access to behavioral health and improving health equity for MA enrollees through these efforts. However, several commenters expressed concerns regarding the proposal to consolidate several specialty and facility types into a new single category for purposes of evaluating network adequacy in MA. Specifically, commenters expressed concern that combining mental health (MH) and substance use disorder (SUD) specialties into one category may diminish the distinct access needs for these individual specialty types and that the combined standard as proposed was too broad.

Recognizing the specialized nature of these services, commenters advocated for differentiating MH and SUD network adequacy requirements. Many commenters recommended establishing separate specialty categories for ''Outpatient Mental Health'' and ''Outpatient Substance Use Disorder,'' while other commenters suggested separate categories for Opioid Treatment Programs (OTPs), and separate standards for MFTs and MHCs. Commenters stated that the creation of separate standards for these specialties would allow for more visibility for enrollees of the availability of these services and better meet enrollees' behavioral health and SUD needs.

Response: We thank commenters for their support and careful consideration of our proposal. We agree with stakeholders that establishing policies that improve network adequacy is critical to improving access to behavioral health care, including access to substance use disorder prevention and treatment services in MA.

We indicated in the November 2023 proposed rule that setting meaningful network adequacy standards that include MFTs, MHCs, and OTPs at this time is possible under a combined behavioral health specialty type. We determined this through our review of U.S. Department of Labor data and the Place of Service codes recorded on certain professional claims data from 2017–2020 for behavioral health services in the Traditional Medicare program, which indicate that MFTs and MHCs are generally providing services in outpatient behavioral health settings.[25] [26] As we have also stated in our April 2023 final rule, setting a meaningful access standard for the OTP specialty type would be possible under a combined behavioral health specialty type. We are taking this approach to provide additional time for CMS to collect the specific claims and utilization data for MFTs and MHCs. We may engage in future rulemaking to establish specific time and distance

[25] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Marriage and Family Therapists, at *https://www.bls.gov/ooh/community-and-social-service/marriage-and-family-therapists.htm* (visited July 03, 2023).

[26] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Substance Abuse, Behavioral Disorder, and Mental Health Counselors, at *https://www.bls.gov/ooh/community-and-social-service/substance-abuse-behavioral-disorder-and-mental-health-counselors.htm* (visited July 06, 2023).

standards for these specialties separately. More robust claims and utilization data will help us to evaluate how enrollees are accessing these benefits in Medicare Advantage and Traditional Medicare. Additionally, we noted our intent to continue monitoring the availability of OTPs across the country and determine whether network adequacy for OTPs is best measured separately from the broader Outpatient Behavioral Health facility-specialty type.

The Outpatient Behavioral Health facility-specialty type will include individual practitioner and facility providers that furnish psychotherapy and/or counseling services to individuals with mental health or substance use disorders. Our review of certain Traditional Medicare claims data from 2017–2020 (Place of Service codes, Type of Bill codes, CCN codes, and Revenue Center codes) indicates that facility types treat individuals with both mental health disorders and substance use disorders. While the individual providers may specialize in either mental health or substance use disorder treatment, many of the facility providers will offer a variety of services and provider types to meet the range of enrollees' behavioral health needs. In the absence of more robust utilization and claims data, the Outpatient Behavioral Health specialty type should be effective for use in our MA plan network adequacy standards at this time.

Finally, § 422.116(a) requires that each network-based MA plan demonstrate that it has an adequate contracted provider network that is sufficient to provide access to medically necessary covered services consistent with standards in section 1851(d) of the Act, the regulations at §§ 422.112(a) and 422.114(a), and when required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year (see section II.A. of this final rule regarding the definition of ''network-based plan''). In addition, § 422.112 requires MA coordinated care plans (which are network-based plans) to ensure covered services are accessible and available to enrollees. Therefore, MA organizations must always provide access to all covered services whether or not access to a particular provider specialty is specifically evaluated by CMS through our network adequacy standards.

Comment: Many commenters requested that CMS revise the proposed Outpatient Behavioral Health time and distance standards to align with those already established for Qualified Health Plans (QHPs). Commenters emphasized that shortening the standards to reflect the benchmarks set for QHPs would potentially benefit enrollees as behavioral health services may be needed more frequently. Commenters emphasized that aligning these standards would provide consistent and adequate access across Federal programs and support operational needs of health plans.

Response: We are interested in aligning policies across Medicare, Marketplace, and Medicaid wherever practicable. However, for MA plans, CMS utilizes data on the unique health care utilization patterns and geographic locations of Medicare beneficiaries and providers and facilities to set the MA network adequacy time and distance as well as the minimum provider and facility number requirements under 42 CFR 422.116. Therefore, at this time, we believe the requirements we proposed, and are finalizing in this rule, are appropriate for providing access and meeting the health care needs of the specific beneficiary population served by this program.

Comment: Multiple commenters expressed concerns that MA provider network adequacy standards could be met utilizing Nurse Practitioners (NPs), Physician Assistants (PAs), and Clinical Nurse Specialists (CNSs) within the new Outpatient Behavioral Health facility-specialty type. Commenters suggested that the absence of clear and transparent criteria for incorporating these provider types could result in the creation of ''ghost networks,'' and one commenter referred to ghost networks as networks where providers may be listed in a provider directory without actively treating patients for behavioral health. Further, commenters indicated that these provider types (NPs, PAs, CNSs) might lack the necessary skills, training, or expertise to effectively address the mental health and substance use disorder needs of enrollees.

Response: We appreciate the feedback regarding the inclusion of NPs, PAs, and CNSs within the new Outpatient Behavioral Health facility-specialty type. We reiterate that the revisions to § 422.116(b) and (d), as proposed and finalized, mandate that for purposes of network adequacy evaluation, providers, including NPs, PAs, and CNSs, must regularly furnish or will regularly furnish behavioral health counseling or therapy services, including psychotherapy or the prescription of medication for substance use disorders, in order for those providers to be included in the new facility specialty Outpatient Behavioral Health. Further, by defining the new facility specialty Outpatient Behavioral Health so broadly, we expect that these facilities will generally deliver a comprehensive array of services. This includes services from MFTs, MHCs, OTPs, community mental health centers, addiction medicine physicians, and outpatient mental health and substance use treatment facilities.

Recognizing the diverse capabilities of NPs, PAs, and CNSs in providing services to beneficiaries, CMS acknowledges the concerns raised by stakeholders regarding the use of NPs, PAs, and CNSs to satisfy the Outpatient Behavioral Health network adequacy standards without verifying their qualifications to address and actual practice of addressing behavioral health or SUD needs. To address this, we are finalizing a clarification in § 422.116(b)(2)(xiv) to limit when MA organizations may list an NP, PA, or CNS, for purposes of network evaluation under the Outpatient Behavioral Health facility-specialty type. Specifically, the final rule establishes a standard to identify when an NP, PA, or CNS regularly furnishes, or will furnish, behavioral health counseling or therapy services, including psychotherapy or medication prescription for SUDs.

For an NP, PA, or CNS to satisfy the Outpatient Behavioral Health network adequacy standards, the NP, PA, and/or CNS must have furnished certain psychotherapy or SUD prescribing services to at least 20 patients within the previous 12-months. The 20-patient threshold is consistent with the minimum denominator requirement of several quality measures, including many that are measured at the clinician-level in the Merit-based incentive payment system (MIPS) in Traditional Medicare. If the threshold is an important minimum for individual practitioners being held accountable for the quality of care delivered in Traditional Medicare, then having a similar threshold here for when the practitioner ''regularly furnishes'' behavioral health care will ensure that the NP, PA, or CNS is providing a meaningful amount of behavioral health counseling or therapy services, including psychotherapy or medication prescription for SUDs. In addition, we believe the 12-month period timing will provide the best reflection of current practice and is a sufficient time predicter of the next year's practice by the provider.

Further, this standard supports the intent that a provider who is an NP, PA or CNS, must ''regularly furnish or will regularly furnish'' behavioral health

services. This will help ensure that organizations only include providers who have expertise in delivering services to be counted for network adequacy purposes. The 12-month and 20 patient threshold demonstrates that an NP, PA, or CNS has provided the applicable services on an ongoing basis, and it will also provide a standard for organizations that wish to utilize these provider types for network adequacy evaluation.

As part of this minimum threshold for identifying that a specific PA, NP and CNS regularly furnishes behavioral health services, we are adopting specific requirements in new paragraphs (b)(2)(xiv)(A) and (B) for how this threshold will be used. The list of psychotherapy or SUD prescribing services to be used for this purpose will be identified by CMS in the Health Service Delivery (HSD) Reference File (described in § 422.116(a)(4)(i)). CMS will identify the applicable services in the HSD Reference File, using HCPCS code(s), narrative descriptions, or something sufficiently similar to specify the necessary type of services on an annual basis.

The MA organization must annually verify that this standard is met by each individual NP, PA and/or CNS it intends to submit for purposes of the Outpatient Behavioral Health facility type by analyzing reliable information about services furnished by the provider such as the MA organization's claims data, prescription drug claims data, electronic health records, or similar data. This analysis must be performed at least annually using a recent 12-month period and must be completed before the MA organization includes the NP, PA and/or CNS to CMS for purposes evaluation of the MA organization's network for the Outpatient Behavioral Health facility type. If there is insufficient evidence of these provider types having previous practice experience sufficient to meet the threshold of 20 patients within a recent 12-month period, MA organizations must have a reasonable and supportable basis for concluding that the provider will meet the threshold in the next 12 months. If an NP, PA, or CNS is new to independent practice (and therefore doesn't have the appropriate claims record in previous years), has received psychiatry or addiction medicine specialized training, and is listed as a psychiatry or addiction medicine NP, PA, or CNS on public-facing websites, this would be a reasonable and supportable basis for concluding that the practitioner would meet the requirement in the next 12 months, and therefore able to be utilized towards meeting network adequacy standards for Outpatient Behavioral Health. We are establishing these requirements in § 422.116(b)(2)(xiv)(B)(1) and (2).

This requirement is designed to prevent MA organizations from including providers in their networks submitted to CMS for review that are lacking a history of delivering or intent to deliver behavioral health services, thereby improving the reliability of MA organization's network's once operational. Further, this requirement will help MA organizations identify the requisite services that NPs, PAs, and CNSs must provide. MA organizations may be required to demonstrate, in the specified form and manner requested by CMS, that the MA organization has verified the service provision threshold. These criteria aim to enhance transparency and accountability while preventing the formation of ''ghost networks.'' This ensures that beneficiaries receive care from providers with proven expertise in treating mental health and substance use disorders.

Finally, we are also adopting a requirement, at § 422.116(b)(2)(xiv)(B)(3) that an MA organization must submit evidence and documentation to CMS, upon request and in the form and manner specified by CMS, of the MA organization's determination that the PA, NP, and/or CNS has furnished or is reasonably expected to furnish one or more of the specified psychotherapy or medication prescription to at least 20 patients within a 12 month period.

This provision will help to ensure compliance.

Comment: Some commenters stressed that network adequacy requirements should accurately reflect the actual availability of health care providers. These commenters emphasized that CMS should tailor its approach to address the unique barriers that underserved rural areas face in accessing behavioral health services. Some commenters suggested that including NPs, PAs, and CNSs is particularly important in rural areas where there is often a shortage of health care providers. Commenters noted that NPs are increasingly providing behavioral health services, with a significant percentage treating conditions like depression in their practice. Commenters supported the proposed changes to expand the definition of behavioral health providers through the Outpatient Behavioral Health network adequacy requirement since it will not only address the provider shortage, but also align with the goal of ensuring that MA enrollees have access to comprehensive and high-quality behavioral health care.

Response: We thank commenters for their support of our proposal to include certain provider types such as NPs, PAs, and CNSs as part of the Outpatient Behavioral Health network adequacy standard. Our network adequacy standards take into account the unique access challenges in rural areas. Network adequacy is assessed at the county level, and counties are classified into five county type designations: Large Metro, Metro, Micro, Rural, or CEAC (Counties with Extreme Access Considerations), this allows us to set our criteria to represent the geographic variations across the United States based on population size and density of each county.

Comment: We received numerous comments supporting our proposal to add Outpatient Behavioral Health specialty type to the list at § 422.116(d)(5), which would provide a 10 percent credit towards the percentage of beneficiaries residing within published time and distance standards when the plan includes one or more telehealth providers that offer additional telehealth benefits as defined in § 422.135 in its contracted network. Commenters agreed that network access through telehealth benefits is critical, especially for enrollees in rural areas where traditional services may be less accessible.

A few commenters suggested that CMS should increase the telehealth credit from the proposed 10 percent up to 30 percent or that we increase the credit and make it applicable to all behavioral health network adequacy standards under § 422.116(d)(5). Other commenters expressed concerns regarding CMS's proposal to add Outpatient Behavioral Health to the list at § 422.116(d)(5). Commenters cautioned against an over-reliance on telehealth that may not provide the same level of care as in-person visits. These commenters emphasized the need for telehealth services to adhere to the same capacity and accessibility standards as in-person services, including the ability to accept new patients and deliver specified services promptly.

Response: Our decision to extend the telehealth credit for the new Outpatient Behavioral Health facility-specialty type is consistent with our established practice for MA organizations receiving the credit as part of a network adequacy evaluation. As we previously mentioned, Medicare Fee-For-Service (FFS) claims data indicated that telehealth was the second most common place of service for claims with a

primary behavioral health diagnosis in 2020.

The telehealth credit is designed to encourage the use of telehealth services but is not a replacement for in-person care. Per § 422.116(d)(5), the telehealth credit is available when the MA plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in the listed specialties. Consistent with § 422.135, MA plans that cover additional telehealth benefits must offer enrollees the option to choose their preferred mode of care delivery and to access the services in person. This requirement underlines our commitment to encouraging use of and access to telehealth without compromising the availability of in-person care. Providers who receive the telehealth credit are listed under § 422.116(d)(5) and currently include all outpatient behavioral health providers that are evaluated for network adequacy purposes.

We understand and appreciate the concerns raised about the potential over-reliance on telehealth services. We agree it is necessary for these services to meet the same standards of capacity and accessibility as in-person visits, including the acceptance of new patients and the timely delivery of specified services. We recognize the careful balance between expanding access through telehealth and maintaining the quality and immediacy of care. As we move forward, CMS will continue to monitor the effectiveness and impact of the telehealth credit on network adequacy, especially in the context of Outpatient Behavioral Health services. We remain open to considering adjustments to the telehealth credit percentage in future rulemaking based on evidence, stakeholder feedback, and the evolving landscape of telehealth services. Our goal is to ensure that our policies support the effective use of telehealth in enhancing access to care while maintaining high standards of care delivery for MA enrollees.

Comment: Commenters requested clarification from CMS on whether primary care practices that integrate behavioral health services, including those staffed by MFTs, MHCs, and addiction medicine physicians, fall under the ''Outpatient Behavioral Health'' category. Commenters expressed that this clarification is critical to accurately reflect network adequacy, especially since many MFTs work in medical offices that provide behavioral health services.

Response: We confirm that primary care practices that integrate behavioral health services are within the scope of the ''Outpatient Behavioral Health'' category provided that the practice includes providers of the type listed in § 422.116(b)(2)(xiv), such as MFTs and MHCs, and PAs, NPs, CNSs, and addiction medicine physicians who regularly furnish or will regularly furnish behavioral health counseling or therapy services. These services can be represented at the level of individual providers or as a facility, depending on their billing practices.

We are committed to conducting an in-depth evaluation of network adequacy, acknowledging the changing landscape of healthcare delivery where behavioral health services are becoming an integral part of primary care. To that end, CMS annually publishes a Provider Supply file (42 CFR 422.116(a)(4)(ii)) that lists available providers and facilities and their corresponding office locations and specialty types. MA organizations may use this as a resource to identify providers and facilities. However, given the dynamic nature of the market, MA organizations remain responsible for conducting validation of data used for network adequacy review purposes.

Comment: Some commenters raised concerns regarding the possibility of delays in the enrollment of MFTs and MHCs as Medicare providers, as these providers will be registering for the first time. Commenters suggested that CMS should closely monitor any potential backlogs of providers or delay implementation of this rule if such issues arise.

Response: We are monitoring any potential issues or backlogs with MFTs and MHCs enrolling as Medicare providers. We do not foresee any such barriers to new provider enrollments at this time, and therefore would not need to delay implementation of this rule.

Comment: Several commenters suggested that CMS should create a complete list of qualifications for MFTs and MHCs so that MA plans can properly determine and incorporate eligible providers.

Response: The qualifications for MFTs and MHCs are specified in section 1861(lll) of the Act. Specifically, MFT services are defined in section 1861(lll)(1) and the term MFT is defined in section 1861(lll)(2); MHC services are defined in section 1861(lll)(3) and the term MHC is defined in section 1861(lll)(4) of the Act. These definitions provide the necessary information for MA organizations to understand and comply with the requirement to cover Part B covered services, which now includes the services furnished by MFTs and MHCs as newly defined eligible providers. MA organizations are required to cover these services as defined in the Act and ensure that they are furnished by providers who meet the qualifications specified in section 1861(lll)(2) of the Act for MFTs and in section 1861(lll)(4) of the Act for MHCs. We also direct readers to the regulations at 42 CFR 410.53 and 410.54 for CMS regulations on Medicare-covered MFT and MHC services.

Comment: Commenters suggested policy adjustments to allow for more realistic and flexible standards for network adequacy in underserved rural areas. For example, a few commenters recommended that CMS introduce waivers or exceptions to address difficulties faced by plans in contracting with a diverse range of providers due to workforce shortages.

Response: We acknowledge the unique circumstances in rural areas. CMS already addresses these circumstances when setting network time and distance standards according to county type to account for the different level of access in existing patterns of care for populations in these areas. To further account for the specific landscape in a particular area, CMS's time and distance standards measure the relationship between the approximate locations of beneficiaries and the locations of the network providers and facilities (42 CFR 422.116(d)(1)(i)). In addition, we have established guidelines under 42 CFR 422.116(f), which were finalized in our June 2020 final rule, that outline the circumstances under which an MA plan may request an exception to the network adequacy criteria. These provisions are designed to provide flexibility while ensuring that beneficiaries have access to necessary healthcare services.

Comment: Commenters expressed that many behavioral health providers possess multiple professional credentials, enabling them to qualify for more than one behavioral health specialty category. Commenters recommended that CMS permit providers holding multiple credentials to be included in the new behavioral health specialty category and be counted within each applicable specialty.

Response: In our proposal, we indicated that MA organizations may not submit a single provider as a psychiatry, clinical social work, or clinical psychologist provider specialty to meet that network specialty requirement and then submit that same provider as an ''Outpatient Behavioral Health facility'' to meet this separate standard. 88 FR 78485. We explained that because Outpatient Behavioral Health is not a specialty on its own,

such as other specialty types like Primary Care Physicians or Cardiologists, but rather is an umbrella term for which several specialties can be used to meet the requirement, it is important to make this distinction. We acknowledge that there are other circumstances when providers may hold multiple credentials that enable them to be counted under more than one network adequacy standard. We clarify here that MA organizations are still allowed to submit these types of providers, for purposes of network adequacy evaluation, under each applicable category that meets the specialty type requirements as defined under statute and meet the requirements of the standard in § 422.116. Organizations are responsible for ensuring that the contracted providers meet state and federal licensing requirements as well as the organization's credentialing requirements for each specialty type.

Comment: A few commenters requested that CMS consider postponing the new Outpatient Behavioral Health network adequacy standard until 2026 in order to provide flexibility for provider certification and contracting discussions with the relevant provider types.

Response: Behavioral health services, including the OTP benefit, MFT and MHC services are covered under Traditional Medicare today, so MA plans should have a network in place that assures adequate access to those services when medically necessary for enrollees under section 1852(d) of the Act and § 422.112. Therefore, we expect that MA organizations are already conducting ongoing work related to provider contracting and evaluating prevailing patterns of health care delivery in their service areas. We anticipate issuing guidance on the specified behavioral health services that need to be regularly furnished by PAs, NPs, and CNSs, for them to be submitted under the Outpatient Behavioral Health facility-specialty type after release of this final rule so that MA organizations can determine how to include those providers in their HSD tables for CMS to evaluate the provider network. The applicability date of January 1, 2025, of this final rule, provides sufficient time for organizations to prepare to include these provider types for the formal network adequacy evaluations conducted by CMS under § 422.116 beginning in 2025.

Based on our review and consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing these provisions as proposed with modifications to outline the criteria MA organizations must use to determine when an NP, PA or CNS can be considered as part of a network to meet the Outpatient Behavioral Health network adequacy standard. To address concerns that NPs, PAs, and CNSs might lack the necessary skills, training, or expertise to effectively address the behavioral health needs of enrollees and that the absence of criteria for incorporating these provider types could result in networks where these providers may be listed in a provider directory without actively treating patients, '' we are finalizing provisions in § 422.116(b)(2)(xiv) to establish specific criteria that MA organizations must use to determine when an NP, PA or CNS can be considered part of a network to meet the Outpatient Behavioral Health network adequacy standard. MA organizations must independently verify that the provider has furnished or will furnish certain services to 20 patients within a recent 12-month period, using reliable information about services furnished by the provider such as the MA organization's claims data, prescription drug claims data, electronic health records, or similar data. For NPs, PAs, or CNSs new to independent practice, MA organizations must have a reasonable and supportable basis for concluding that the practitioner would meet the requirement in the next 12 months, including information related to psychiatry or addiction medicine specialized training, and that the provider listed as a psychiatry or addiction medicine NP, PA, or CNS on public-facing websites.

L. Improvements to Drug Management Programs (§§ 423.100 and 423.153)

Section 1860D–4(c)(5)(A) of the Act requires that Part D sponsors have a drug management program (DMP) for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs), currently defined by CMS as opioids and benzodiazepines. CMS codified the framework for DMPs at § 423.153(f) in the April 16, 2018 final rule ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Programs, and the PACE Program'' (83 FR 16440), hereafter referred to as the April 2018 final rule.

Under current DMP policy, CMS identifies potential at-risk beneficiaries (PARBs) who meet the clinical guidelines described at § 423.153(f)(16), which CMS refers to as the minimum Overutilization Monitoring System (OMS) criteria. CMS, through the OMS, reports such beneficiaries to their Part D plans for case management under their DMP. There are also supplemental clinical guidelines, or supplemental OMS criteria, which Part D sponsors can apply themselves to identify additional PARBs. Under § 423.153(f)(2), sponsors are required to conduct case management for PARBs, which must include informing the beneficiary's prescribers of their potential risk for misuse or abuse of FADs and requesting information from the prescribers relevant to evaluating the beneficiary's risk, including whether they meet the regulatory definition of exempted beneficiary.

If the sponsor determines through case management that the enrollee is an at-risk beneficiary (ARB), after notifying the beneficiary in writing, the sponsor may limit their access to opioids and/or benzodiazepines to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale claim edit, in accordance with the requirements at § 423.153(f)(3). CMS regulations at § 423.100 define exempted beneficiary, at-risk beneficiary, potential at-risk beneficiary, and frequently abused drug.

1. Definition of Exempted Beneficiary § 423.100

Section 1860D–4(c)(5)(C)(ii) of the Act defines an exempted individual as one who receives hospice care, who is a resident of a long-term care facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, or who the Secretary elects to treat as an exempted individual. At § 423.100 CMS defines an exempted beneficiary as an enrollee being treated for active cancer-related pain, or who has sickle-cell disease, resides in a long-term care facility, has elected to receive hospice care, or is receiving palliative or end-of-life care.

The OMS criteria finalized in the April 2018 final rule were developed to align with available information and guidelines, such as the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain (2016 CDC Guideline) issued in March 2016.[27] The current policy to exempt beneficiaries with cancer from DMPs was developed through feedback from interested parties and alignment with the 2016 CDC Guideline's active cancer treatment exclusion. Patients within the scope of

[27] *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.*

the 2016 CDC Guideline included cancer survivors with chronic pain who have completed cancer treatment, were in clinical remission, and were under cancer surveillance only. The 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain (2022 CDC Guideline) [28] expands and updates the 2016 CDC Guideline to provide evidence-based recommendations for prescribing opioid pain medication for acute, subacute, and chronic pain for outpatients aged ≥18 years, excluding pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care.

In the interest of alignment with the 2022 CDC Guideline regarding applicability in individuals with cancer, we proposed to amend the regulatory definition of ''exempted beneficiary'' at § 423.100 by replacing the reference to ''active cancer-related pain'' with ''cancer-related pain.'' With this proposal, we would expand the definition of exempted beneficiary to more broadly refer to enrollees being treated for cancer-related pain to include beneficiaries undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only.

We solicited comments on this proposal.

Comment: Most commenters supported the proposal to expand the definition of exempted beneficiary to more broadly refer to enrollees being treated for cancer-related pain to include beneficiaries undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only. One commenter suggested that expanding the definition to cancer-related pain beyond beneficiaries undergoing active cancer treatment better encompasses the range of patients with cancer related circumstances who are in need of extended pain relief. Other commenters agreed that the proposed definition was aligned with the 2022 CDC Guideline regarding individuals with cancer or cancer-related pain treatment. Other commenters agreed that enrollees being treated for cancer-related pain require long-term pain management, commonly including opioid pain medications, and thus, should be exempted from DMPs that are intended to address potential opioid misuse. Another commenter wanted to ensure that patients experiencing pain while not in the active cancer phase can still reliably access treatment options. Another commenter agreed that many patients in cancer survivorship experiencing pain-related lasting effects of treatment or disease should be excluded from these exemptions.

Response: We thank the commenters for their support.

Comment: A commenter appreciated CMS's efforts to improve the definition of an ''exempted beneficiary'' but was concerned that the proposal was too broad and would inadvertently include individuals who are not experiencing cancer- or cancer treatment-related pain, but instead are experiencing pain and have a prior, unrelated cancer diagnosis. The commenter wanted to ensure clinicians involved in case management will be able to exercise their professional judgement in determining whether an opioid used for ''cancer-related pain'' is reasonable, particularly when the cancer has been resolved for several years and/or required minimal treatment. The commenter wanted to ensure that CMS does not change the OMS criteria based on this change in definition. The commenter also suggested that a member who meets the criteria for identification in the OMS should not be omitted based solely on a diagnosis code indicating a history of cancer or cancer-related pain.

Response: CMS disagrees that the proposal is too broad. Our analysis of beneficiary data estimates only a small increase in exempted beneficiaries as a result of the proposed updated definition, which we used to estimate burden in the proposed rule. Refer to section X. Collection of Information Requirements, ICRs Regarding to Improvements to Drug Management Programs in this final rule for additional details. Beneficiaries who meet the regulatory definition for exempted beneficiary must be exempted from the DMP despite meeting all other OMS criteria. CMS attempts to remove exempted beneficiaries from OMS reporting; however, we acknowledge that the data we have at the time of quarterly OMS reporting may not be complete. Part D sponsors must use data available to them or obtained through case management to identify exempted beneficiaries, including those who are reported by OMS or when the sponsor is reviewing cases and making its own determinations based on OMS criteria. Therefore, a Part D sponsor's DMP may identify a beneficiary who meets the OMS criteria and allow clinicians to perform case management until it is determined that the beneficiary is exempt and must be removed from the program. This proposal changes the definition of ''exempted beneficiary'' at § 423.100 and does not change the OMS criteria or clinical guidelines described at § 423.153(f)(16).

Comment: One commenter was concerned with identification of patients whose opioid use is appropriately linked to cancer-related pain but who are not otherwise receiving active treatment for some form of cancer. The commenter pointed out that while plans have access to clinical data on members, there is a need to conduct additional administrative and clinical reviews of patient records to properly exempt individuals meeting this new standard from participation in DMPs. The commenter also anticipated a slight increase in the number of individuals who will be exempted from DMPs due to cancer-related pain under the proposed definition and a transition period in which existing processes designed to identify ARBs evolve to match the broader exemption for cancer-related pain.

Response: We acknowledge that there will be a transition period for DMPs to adapt their processes for the proposed exemption. Part D sponsors may identify exempted beneficiaries before or during case management. We expect sponsors to diligently engage in case management, but there is no deadline for sponsors to complete it. We also recognize that every case is unique and that the time needed for case management will vary depending on many factors, such as the complexity of the case, and the promptness with which, and whether, prescribers respond to sponsors' outreach. While the approach to case management may vary based on the facts and circumstances of the case, the general goal of case management is to understand why the beneficiary meets the OMS criteria and whether a limitation on access to coverage for FADs is warranted for the safety of the beneficiary. Thus, Part D sponsors are expected to address all cases without unreasonable delay and to triage their review of the most concerning cases to the extent possible.

Comment: A commenter agreed with the proposed updates but recommended that CMS establish a clinical documentation code that reflects the new definition, as is the case today with ''active cancer-related pain.'' The commenter suggested that for accurate identification of exempted beneficiaries, Part D plans would need specific exclusion identifiers for the term ''cancer-related pain.'' The commenter also asked that CMS provide guidance allowing case management

[28] *https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm.*

documentation to be sufficient for ''cancer-related pain'' in situations when there is no code submitted by a provider. Another commenter suggested that it would be extremely helpful if CMS could indicate in the detailed OMS report the reason why a member was identified for DMP review and, when this is based on a diagnosis, when the diagnosis was made. The commenter also stated that stand-alone Prescription Drug Plans (PDPs) have no access to medical encounter data or to the member's medical history and even Medicare Advantage Prescription Drug Plans (MA–PDs) lack visibility into events that pre-date a member's enrollment with the MA–PD.

Response: We will share all exemption codes used in the OMS reporting in the technical user guide, including any codes for cancer-related pain. Should there be no code for cancer-related pain available from a provider, plans should ensure that case management documentation is sufficiently clear to justify OMS case responses to CMS.

We will also consider how best to update future OMS reporting, including the level of detail reported for PARBs. As detailed in the OMS technical user guide available on the CMS Part D Overutilization website,[29] the quarterly OMS report to Part D sponsors currently provides a list of beneficiaries meeting the minimum OMS criteria during the measurement period and information including the criteria met (*i.e.,* based on level of opioid use from multiple prescribers/pharmacies (referred to as MIN1) or history of opioid-related overdose (referred to as MIN2)).

Comment: Another commenter agreed with the proposed updates to the definition of exempted beneficiary but requested further guidance on when and how to intervene earlier when it is unclear that a beneficiary is using drugs aberrantly, which may increase DMP case volume without achieving the program's goal. The commenter also requested that CMS publish any criteria under consideration for use.

Response: While Part D sponsors may not vary the OMS criteria to include more or fewer beneficiaries in their DMPs, they may apply the criteria more frequently than CMS currently does, which is quarterly. A sponsor must remove an exempted beneficiary from a DMP as soon as it reliably learns that the beneficiary is exempt (including in their internal claims systems), whether that be via the beneficiary, the facility, a pharmacy, a prescriber, or an internal or external data source. As part of ongoing case management, CMS expects plan sponsors to have a process in place to regularly monitor such information for enrollees in their DMP, and to take appropriate action expeditiously, when they obtain new information. In the November 2023 proposed rule, CMS provided information on data analysis and solicited feedback on potentially using a machine-learning model to enhance the minimum or supplemental OMS criteria in the future. This Request for Information is addressed in section III.N. Improvements to Drug Management Programs, OMS Criteria Request for Feedback of this final rule.

Comment: Another commenter agreed with the proposed update but added that the CDC Guideline also refers to specialty guidelines as an evidence-based resource for pain management in certain populations. A commenter noted that the guidelines may be an additional useful resource for plans as this policy is updated and implemented. The commenter referred to the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Adult Cancer Pain, NCCN Clinical Practice Guidelines in Oncology: Survivorship, and Management of Chronic Pain in Survivors of Adult Cancers: American Society of Clinical Oncology Clinical Practice Guideline for recommendations on pain management for patients with cancer and patients who have survived cancer and American Society of Hematology 2020 Guidelines for Sickle Cell Disease: Management of Acute and Chronic Pain.

Response: We thank the commenter for the feedback and agree that CMS should refer Part D sponsors to the guidelines for both cancer-related pain and sickle-cell disease. We remind Part D sponsors that while both cancer-related pain and sickle-cell disease diagnoses exempt Part D enrollees from DMPs and coverage limitations on FADs, Part D sponsors must still comply with other utilization management requirements in § 423.153 to continue to monitor the safe use of opioids.

After reviewing the comments received, we are finalizing the proposal to amend the regulatory definition of ''exempted beneficiary'' at § 423.100 by replacing the reference to ''active cancer-related pain'' with ''cancer-related pain'' without modification.

2. Drug Management Program Notices: Timing and Exceptions § 423.153(f)(8)

As discussed above under section III.N. Improvements to Drug Management Programs of this final rule, sponsors must provide case management for any PARB that meets the OMS criteria to determine whether the individual is an ARB and whether to implement a limitation on their access to FADs. Under section 1860D–4(c)(5)(B)(i)(I) of the Act, a sponsor must send an initial and second notice to such beneficiary prior to imposing such limitation. In the April 2018 final rule (83 FR 16440), CMS adopted requirements for the initial and second notices at §§ 423.153(f)(5) and 423.153(f)(6). The initial notice must inform the beneficiary that they have been identified as a PARB and must include information outlined in § 423.153(f)(5)(ii). The second notice must inform the beneficiary that they have been identified as an ARB and of the limitations on the beneficiary's coverage of FADs, as specified in § 423.153(f)(6)(ii). In the event that, after sending an initial notice, a sponsor determines that a PARB is not an ARB, a second notice is not sent; instead, an alternate second notice is sent. Though not required by the Act, CMS codified a requirement at § 423.153(f)(7) to provide an alternate second notice for the purpose of informing the beneficiary that they are not an ARB and that no limitation on their coverage of FADs will be implemented under the DMP.

Section 1860D–4(c)(5)(B)(iv) of the Act establishes that sponsors must send a second notice on a date that is not less than 30 days after the initial notice. The 30 days allow sufficient time for the beneficiary to provide information relevant to the sponsor's determination, including their preferred prescribers and pharmacies. CMS codified at § 423.153(f)(8) the timing for providing both the second notice and alternate second notice. Currently, CMS requires sponsors to send either the second or alternate second notice on a date not less than 30 days from the date of the initial notice and not more than the earlier of the date the sponsor makes the determination or 60 days after the date of the initial notice.

We proposed to change the timeframe within which a sponsor must provide an alternate second notice to a beneficiary who is determined to be exempt from the DMP subsequent to receiving an initial notice. Specifically, we proposed to redesignate existing § 423.153(f)(8)(ii) as § 423.153(f)(8)(iii), and to revise the text at § 423.153(f)(8)(ii) to specify that, for such exempted beneficiaries, the sponsor must provide the alternate second notice within 3 days of determining the beneficiary is exempt, even if that occurs less than 30 days from the date of the initial notice. In other words, we proposed to remove the

[29] *https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/improving-drug-utilization-review-controls-part-d.*

requirement that sponsors wait at least 30 days from the date of the initial notice to send the alternate second notice to exempted beneficiaries.

Through program oversight, including audits of Part D sponsors, CMS has observed that initial notices are sometimes sent to Part D enrollees who meet the definition of an exempted beneficiary at § 423.100, often because the sponsor does not have the necessary information—for example, that the enrollee has a cancer diagnosis or is receiving palliative care or end-of-life care—at the time the sponsor sends the initial notice. However, this information may be provided later by the enrollee or their prescriber in response to the initial notice. In some cases, sponsors identify exemptions very quickly after issuing the initial notice, prior to 30 days elapsing. Under current CMS regulations, if a beneficiary meets the definition of an exempted beneficiary, the beneficiary does not meet the definition of a PARB. For this reason, exempted beneficiaries cannot be placed in a Part D sponsor's DMP. Therefore, as stated in the preamble to the April 2018 final rule (83 FR 16455), a sponsor must remove an exempted beneficiary from a DMP as soon as it reliably learns that the beneficiary is exempt (whether that be via the beneficiary, their representative, the facility, a pharmacy, a prescriber, or an internal or external data source, including an internal claims system). CMS understands that sponsors may have already been sending alternate second notices after determining that a beneficiary is exempt, without waiting for 30 days to elapse. This proposed change would specify that sponsors must send such notices to exempted beneficiaries sooner than 30 days after the provision of the initial notice.

CMS reminds Part D sponsors that, during their review and during case management, they are expected to use all available information to identify whether a PARB is exempt in advance of sending an initial notice to protect these vulnerable beneficiaries from unnecessary burden, anxiety, and disruptions in medically necessary drug therapy. Thorough review of plan records and robust outreach efforts to prescribers during case management help to minimize the risk that an exempted beneficiary would receive an initial notice.

Sections 8.1 and 8.2.2 of the DMP guidance [30] state that if a sponsor learns that a beneficiary is exempt after sending an initial notice, the sponsor should inform the beneficiary that the initial notice is rescinded. If less than 30 days have passed since the initial notice, a sponsor should send a Part D Drug Management Program Retraction Notice for Exempted Beneficiaries. The model retraction notice addresses the required 30-day timing issue in the current regulation. As proposed, the Part D Drug Management Program Retraction Notice for Exempted Beneficiaries would no longer be used because sponsors would instead send the alternate second notice. We did not estimate any reduction of burden for sponsors no longer using the Retraction Notice. The Retraction Notice was implemented as a temporary solution for Part D sponsors to use for exempted beneficiaries in place of the alternate second notice, which had been accounted for in the latest version of CMS–10141 (OMB control number 0938–0964).

We note that sponsors may determine that a PARB is not an ARB prior to 30 days elapsing for reasons other than the beneficiary being exempt. However, we believe the existing 30-day requirement before a sponsor may send an alternate second notice in such situations is important to maintain because it allows the beneficiary and other prescribers enough time to provide the sponsor with information that may influence the sponsor's determination.

We received the following comments on this proposal and our responses follow.

Comment: We received several comments supporting our proposal to eliminate the requirement that sponsors wait 30 days to send an alternate second notice to a beneficiary determined to be exempt after receiving an initial notice. Commenters described the proposal as efficacious, reasonable, and aimed at protecting exempted beneficiaries from unnecessary burden, including interrupted treatments. No commenters opposed this proposal. One commenter expressed support for discontinuing use of the Part D DMP Retraction Notice for Exempted Beneficiaries, noting that the Retraction Notice would no longer be needed under this proposal.

Response: We thank the commenters for their support and are finalizing this provision as proposed.

We proposed an additional technical change related to the timeframe for providing second notices and alternate second notices. The current regulation at § 423.153(f)(8)(i) requires that a sponsor provide a second notice or alternate second notice not more than the earlier of the date the sponsor makes the relevant determination or 60 days after the date of the initial notice. It is critical that beneficiaries receive timely written notice about changes to their access to Part D drugs, as well as information about appeal rights, and the second notice and alternate second notices are tied to the date of the plan's determination. However, CMS understands that sponsors may not always be able to issue printed notices on the exact day they make a determination for a variety of reasons, such as they made the determination on a day when there is no United States Postal Service mail service, or later in the day after files have been sent to a print vendor. Specifically, we proposed to add at § 423.153(f)(8)(i)(A) a window of up to 3 days to allow for printing and mailing the second notice or alternate second notice. We noted in the proposed rule that this change would provide sponsors sufficient time to print and mail the notices while ensuring that beneficiaries receive timely information about DMP limitations. Sponsors must continue to issue these notices as soon as possible when a determination is made, and CMS does not expect that sponsors will routinely take the maximum amount of time.

We did not propose to change the requirement in § 423.153(f)(8)(i)(B) that the second notice or alternate second notice must be provided no later than 60 days from the date of the initial notice. This is because sponsors have ample time to account in advance for the days needed to print and mail these notices.

We received the following comments on this proposal and our responses follow.

Comment: We received several comments on this proposal. Commenters were supportive of adding a window of time between making a determination and providing the second notice or alternate second notice; no commenters were opposed. Most of these commenters noted the importance of notifying beneficiaries as soon as practicable about DMP determinations.

Response: CMS thanks the commenters for their support.

Comment: Several of the commenters that generally supported this proposal opined that CMS should allow more than 3 days for sponsors to provide the second notice or alternate second notice following a determination, and offered specific recommendations, including allowing up to 4 days, 5 business days, or 7 calendar days. One commenter stated that weekends and holidays would make the proposed 3-day window almost impossible to meet. Another commenter opined that sponsors should not be held to the same timeframe that applies to written notice of a Part D coverage determination

[30] *https://www.cms.gov/files/zip/cy-2023-part-d-dmp-guidance-april-20-2023.zip.*

because of the impracticality of verbally conveying the information in a DMP notice prior to mailing the written notice. The commenter instead recommended that the timing align with the 7-day window that applies to other current requirements, including certain DMP data disclosure requirements. One commenter appeared to have misunderstood the existing timeframes for providing the second notice and alternate second notice.

Response: We thank the commenters for their feedback but disagree with their recommendations to allow more than 3 days between making the determination and providing the notice. These notices contain important information concerning a beneficiary's prescription drug access and must not be unnecessarily delayed. As described above and in the November 2023 proposed rule, there is precedent for establishing a 3-day window for sponsors to provide a written notice for coverage determinations under §§ 423.568(d) and (f) and 423.572(b). CMS recognizes that the DMP notices do not follow initial verbal notification, but that makes timely written notification even more important for these cases. Additionally, sponsors already have established processes for providing written notices within a 3-day timeframe, and these processes can be leveraged for sending DMP notices.

Regarding the data disclosure provision at § 423.153(f)(15)(ii)(D) that requires sponsors to update DMP information in MARx as soon as possible but no later than 7 days from the date the sponsor provides an initial notice or second notice to a PARB or ARB or terminates a DMP limitation, it is important to note that this requirement is unrelated to beneficiary notification and thus not as urgent. The purpose of the data disclosure is not comparable to the purpose of sending beneficiary notices regarding a restriction on their access to Part D drugs; therefore, it is not an appropriate benchmark to use to establish this timeframe. CMS does not expect plans to routinely take the maximum amount of time possible and reminds sponsors that the maximum 60-day timeframe from the date of the initial notice is unchanged under our proposal. For example, if a determination is made on day 60, the second notice or alternate second notice must be provided on the same day.

Currently, under § 423.153(f)(8)(i), Part D sponsors must provide the second notice or the alternate second notice on the date of the determination, with no additional window of time for providing (*i.e.,* printing and mailing) the written notice. As such, this change extends from 0 days to up to 3 days the time sponsors have to provide a notice after making a determination. After consideration of the comments received and existing Part D beneficiary notice requirements, CMS believes this change allows sponsors sufficient time to print and mail the notices while ensuring that beneficiaries receive timely information about their DMP limitations.

Comment: Some commenters requested clarification on how CMS will calculate the 3-day window for providing the alternate second notice and second notice and whether the provision refers to calendar or business days. One commenter asked whether CMS intends for plans to ensure the DMP notices are mailed within 3 days of the determination, or whether CMS intends for the beneficiary to receive the notice within 3 days of the determination.

Response: CMS intends that a sponsor will have issued (*i.e.,* printed and mailed, or sent electronically if the beneficiary has indicated such a preference) the second notice or alternate second notice within 3 days of making the relevant determination. We do not require sponsors to send these notices in a manner that tracks receipt by the beneficiary and consequently would be unable to enforce such a timeframe. We further clarify that this proposal refers to calendar days, consistent with the other DMP notice requirements specified at § 423.153(f)(8) and various beneficiary notice requirements throughout Part 423, Subpart M. CMS will update the 2025 DMP guidance to provide these clarifications as they relate broadly to the DMP beneficiary notice requirements.

After consideration of the comments received, we are finalizing the regulation text at §§ 423.153(f)(8)(i)(A) and 423.153(f)(8)(ii) as proposed.

3. OMS Criteria Request for Feedback

CMS regulations at § 423.153(f)(16) specify that CMS and Part D sponsors identify PARBs and ARBs using clinical guidelines that are developed with stakeholder consultation, derived from expert opinion backed by analysis of Medicare data, and include a program size estimate. In addition, the clinical guidelines (also referred to as the ''OMS criteria'') are based on the acquisition of FADs from multiple prescribers, multiple pharmacies, the level of FADs used, or any combination of these factors, or a history of opioid-related overdose.

PARBs are the Part D beneficiaries who CMS believes are potentially at the highest risk of opioid-related adverse events or overdose. The current minimum OMS criteria [31] identifies PARBs who (1) use opioids with an average daily morphine milligram equivalents (MME) of greater or equal to 90 mg for any duration during the most recent six months, who have received opioids from 3 or more opioid prescribers and 3 or more opioid dispensing pharmacies, *or* from 5 or more opioid prescribers regardless of the number of dispensing pharmacies (also referred to as ''MIN1'' minimum OMS criteria), or (2) have a history of opioid-related overdose, with a medical claim with a primary diagnosis of opioid-related overdose within the most recent 12 months and a Part D opioid prescription (not including Medication for Opioid Use Disorder [32] (MOUD)) within the most recent 6 months (also referred to as ''MIN2'' minimum OMS criteria). Sponsors may use the current supplemental OMS criteria 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. These are (1) use of opioids (regardless of average daily MME) during the most recent 6 months; AND (2) 7 or more opioid prescribers OR 7 or more opioid dispensing pharmacies.

In 2019, CMS assigned the Health Federally Funded Research and Development Center (FFRDC) to develop evidence-based recommendations for improving the OMS criteria for the future. The Health FFRDC conducted a literature review, facilitated a Technical Expert Panel (TEP), and performed data analyses. All three activities served as inputs into the evidence-based recommendations. The Health FFRDC recommended that the results of the literature review and data analysis support the continued inclusion of average MME, number of opioid dispensing pharmacies, and number of opioids prescribers as indicators for PARBs. In addition, they recommended that further data analysis would be necessary to determine which additional criteria would be appropriate to potentially adopt. CMS conducted subsequent literature reviews and analysis.

In recent years, there has been a marked decrease in Part D prescription opioid overutilization, but opioid-related overdose deaths continue to be

[31] April 20, 2023 HPMS memorandum, CORRECTION—Contact Year 2023 Drug Management Program Guidance available at: *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/rxutilization.*

[32] Referred to as medication-assisted treatment (MAT) in past guidance.

a growing problem throughout the United States.[33] While the CDC found synthetic opioids (other than methadone) to be the main driver of opioid overdose deaths, accounting for 82 percent of all opioid-involved deaths in 2020,[34] we must remain vigilant regarding the risks of prescription opioids including misuse, opioid use disorder (OUD), overdoses, and death. CMS tracks prevalence rates for Part D beneficiaries with an OUD [35] diagnosis and beneficiaries with an opioid poisoning (overdose). While overall opioid-related overdose prevalence rates among Part D enrollees have declined over the period from contract year 2017 through 2021 at about 6.5 percent per annum, overall opioid-related overdose prevalence rates increased by 1.0 percent between 2020 and 2021. Furthermore, about 1.6 percent of all Part D enrollees had a provider diagnosed OUD in Contract Year 2021, and the OUD prevalence rate has grown by 3.2 percent per annum since contract year 2017.

A past overdose is the risk factor most predictive for another overdose or suicide-related event.[36] CMS finalized regulations to implement section 2004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act to include beneficiaries with a history of opioid-related overdose as PARBs in DMPs. While the implementation of the SUPPORT ACT enables identification of beneficiaries with a history of opioid-related overdose and continues to identify PARBs who receive high levels of opioids through multiple providers who may be more likely to misuse prescription opioids,[37] CMS is working on alternative methods to identify beneficiaries potentially at risk before their risk level is diagnosed as an OUD or the person experiences an opioid-related overdose.

A recently published article that evaluated the use of machine learning algorithms for predicting opioid overdose risk among Medicare beneficiaries taking at least one opioid prescription concluded that the machine learning algorithms appear to perform well for risk prediction and stratification of opioid overdose especially in identifying low-risk groups having minimal risk of overdose.[38] Machine learning is a method of data analysis that automates analytical model building, based on the idea that systems can learn from data, identify patterns and make decisions with minimal human intervention.

While we did not propose changes to the clinical guidelines or OMS criteria in the November 2023 proposed rule, we provided information on our data analysis to date and welcome feedback for future changes. Using predictor variables identified through the literature reviews, CMS performed a data analysis to determine the top risk factors for Part D enrollees at high-risk for one of two outcomes: (1) having a new opioid poisoning (overdose) or (2) developing newly diagnosed OUD. Since Part D enrollees with a known opioid-related overdose are already identified in OMS, CMS focused on individuals at high risk for a new opioid-related overdose or OUD. We anticipated no additional sponsor burden since we did not propose regulatory changes and solicited feedback.

In the analysis, we utilized Medicare data and traditional logistic regression as well as machine learning models like Random Forest, Least Absolute Shrinkage and Selection Operator (LASSO), and Extreme Gradient Boosting (XGBoost) [39] Cross Validation (CV) to examine and evaluate performance in predicting risk of opioid overdose and OUD. The models were compared based on the following criteria: Area Under the Curve (AUC), sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and number needed to examine (NNE). An XGBoost model with CV performed best according to the specified criteria and was selected as the model of choice for predicting a beneficiary with a new opioid overdose or OUD diagnosis.

The model population included 6,756,152 Medicare beneficiaries contemporaneously enrolled in Part D and Parts A, B, or C during the period from January to June 2019, who were prescribed at least one non-MOUD prescription opioid during the measurement period and did not have a DMP exemption (that is, cancer, sickle cell disease, hospice, LTC facility resident, palliative care, or end-of-life care). We excluded beneficiaries with a prior opioid-related overdose or an OUD diagnosis in the year prior to the prediction period. The training dataset used to build the model consisted of a random 75 percent sample of the study population (5,067,114). The remaining 25 percent of the population (1,689,038) was used for validating the prediction performance of the model. The measurement period to obtain information for the predictor variables (for example, opioid use patterns, demographics, comorbidities, etc.) was from January 1 to June 30, 2019, and the prediction period we used to identify beneficiaries with a new opioid overdose event or new OUD diagnosis was from July 1 to December 31, 2019.

The following risk factors [40] were incorporated into the XGBoost model:

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[33] Spencer, Merianne R. et al. (2022). Drug Overdose Deaths in the United States, 2001–2021. (457).

[34] *https://www.cdc.gov/drugoverdose/deaths/synthetic/index.html.*

[35] CMS used a modified version of the Chronic Condition Warehouse (CCW) definition that excludes undiagnosed OUD beneficiaries such as those with an opioid OD event and also limits analysis to the particular measurement period instead of the prior two years.

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

[37] Over 30,000 Part D enrollees met the minimum OMS criteria and were reported to sponsors through OMS reports in 2022 (18 percent met the level of opioid use though multiple provider criteria, and 82 percent met the history of history of opioid-related overdose criteria).

[38] Lo-Ciganic WH, Huang JL, Zhang HH, Weiss JC, Wu Y, Kwoh CK, Donohue JM, Cochran G, Gordon AJ, Malone DC, Kuza CC, Gellad WF. Evaluation of Machine-Learning Algorithms for Predicting Opioid Overdose Risk Among Medicare Beneficiaries With Opioid Prescriptions. JAMA Netw Open. 2019 Mar 1;2(3):e190968. doi: 10.1001/jamanetwork open.2019.0968. Erratum in: JAMA Netw Open. 2019 Jul 3;2(7):e197610. PMID: 30901048; PMCID: PMC6583312.

[39] Extreme Gradient Boosting (XGBoost) model—data mining technique that is similar to Random Forest that combines multiple decision trees into a single strong prediction model, but it differs in doing so in an iterative manner by building one tree at a time and optimizing a differentiable loss function.

[40] Multicollinearity tests were undertaken in order to ensure that there was no collinearity among the explanatory variables used in the model.

TABLE CN-1: Risk factors used for the XGBOOST MODEL

Risk Factor Flag	Description
Age	Beneficiary age in years
Sex	Female or Male sex
Race	White, Black, Asian, Hispanic, Native American, Other or Unknown race/ethnicity
LIS	Beneficiary low-income subsidy status
Dual	Beneficiary dual-eligibility status
Current Medicare Entitlement	Beneficiary current Medicare entitlement: ESRD (1) / non-ESRD (2)
MME	Average daily morphine milligram equivalents (MME)
Number of Opioid Pharmacies	Number of different pharmacies with an opioid prescription drug event (PDE) claim
Number of Opioid Prescribers	Number of different opioid prescribers
Number of Short-Acting Opioid Fills	Number of short-acting opioid PDEs
Number of Long-Acting Opioid Fills	Number of long-acting opioid PDEs
Number of Different Prescription Opioids	Number of different opioids prescribed (GPI-14[41])
Number of MOUD Days	Number of Medication-Assisted Treatment (MOUD) days
Hepatitis	Hepatitis diagnosis
Cervical nerve injury	Cervical nerve injury diagnosis
Lumbar nerve injury	Lumbar nerve injury diagnosis
Thoracic nerve injury	Thoracic nerve injury diagnosis
Neuropathy	Neuropathy diagnosis
Other chronic pain	Other chronic pain diagnosis
Number of Mental Health Conditions	Number of mental health conditions (ADHD, anxiety, bipolar, depression, PTSD, personality disorder, schizophrenia) diagnosed
Number of Substance Use Disorders	Number of substance use disorders (alcohol, cannabis, hallucinogen, inhalant, non-psychoactive, psychoactive, sedative, stimulant) diagnosed

[41] The Generic Product Identifier (GPI) designates any or all of a drug's group, class, sub-class, name, dosage form, and strength.

Risk Factor Flag	Description
	hallucinogen, inhalant, non-psychoactive, psychoactive, sedative, stimulant) diagnosed
Antianxiety Drug Fill	PDE claim for antianxiety drug
Antipsychotic Drug Fill	PDE claim for antipsychotic drug
Anticonvulsant Drug Fill	PDE claim for anticonvulsant drug
Concurrent use of opioid and benzodiazepine (1 or more days)	Concurrent PDE for opioid and benzodiazepine (1+ day overlap)
Concurrent use of opioid and benzodiazepine (30 or more days)	Concurrent PDE for opioid and benzodiazepine (30+ day overlap)
Codeine Fill	PDE opioid claim for codeine (GPI-10)
Fentanyl Fill	PDE opioid claim for fentanyl (GPI-10)
Methadone Fill	PDE opioid claim for methadone (GPI-10)
Morphine Fill	PDE opioid claim for morphine (GPI-10)
Oxycodone Fill	PDE opioid claim for oxycodone (GPI-10)
Oxymorphone Fill	PDE opioid claim for oxymorphone (GPI-10)
Tramadol Fill	PDE opioid claim for tramadol (GPI-10)
Hydrocodone Fill	PDE opioid claim for hydrocodone (GPI-10)
Hydromorphone Fill	PDE opioid claim for hydromorphone (GPI-10)
Other Opioid Fill	PDE opioid claim for other opioid (GPI-10)

We evaluated the performance of the model using the confusion matrix generated by applying the prediction model to the validation dataset to calculate various metrics.

TABLE CN-2: Confusion Matrix for the XGBoost Model

Actual New OUD or Opioid-Related Overdose Diagnosis:	Predicted New OUD or Opioid-Related Overdose Diagnosis: No	Predicted New OUD or Opioid-Related Overdose Diagnosis: Yes	Total
No	1,154,395	513,551	1,667,946
Yes	3,920	17,172	21,092
Total	1,158,315	530,732	1,689,038

TABLE CN-3: Performance Metrics for the XGBoost Model

Criteria	Result
AUC	0.8253
Sensitivity	81.41 Percent
Specificity	69.21 Percent
PPV	3.24 Percent
NPV	99.66 Percent
NNE	31
Probability Threshold	0.474

The top 15 risk factors that were highly associated with a new OUD or opioid-related overdose diagnosis were:

TABLE CN-4: Top 15 Risk Factors

Rank	Risk Factor Variable	Gain
1	Number of Short-Acting Opioid Fills	0.3853
2	MME*	0.1256
3	Age	0.0882
4	Number of Long-Acting Opioid Fills	0.0729
5	Number of Mental Health Conditions	0.0539
6	Number of Substance Use Disorders	0.0298
7	Anticonvulsant Drug Fill	0.0294
8	Number of Different Prescription Opioids	0.0234
9	Oxycodone Fill	0.0230
10	Other Opioid Fill	0.0227
11	Dual	0.0200
12	Number of Opioid Prescribers*	0.0148
13	Concurrent use of opioid and benzodiazepine (30 or more days)	0.0134
14	Morphine Fill	0.0112
15	LIS	0.0102

*Part of current minimum OMS criteria.

The number of short-acting prescription opioid fills and the average daily MME were found to contribute most to XGBoost model predictions of a new OUD or opioid-related overdose diagnosis. Risk was present across a range of MME levels and increased with higher MME levels. The risk of developing a new OUD or opioid-related overdose diagnosis also increased with the number of diagnosed mental health or substance use disorders. Utilization of opioids with other high-risk medications like anticonvulsants, benzodiazepines, anti-psychotics, and anti-anxiety medications were positively associated with higher risk. Also, utilization of opioids like oxycodone and morphine were positively associated with higher risk, while utilization of codeine, tramadol, and opioids in the other category were positively associated with lower risk.

Lastly, we applied our finalized model to data from October 1, 2021 through March 31, 2022 to predict future new opioid-related overdose events and OUD diagnoses during the period from April 1, 2022 to September 30, 2022 to understand program size estimates and NNE values.

TABLE CN-5: Risk Probability Thresholds and Performance Metrics

Risk Probability Threshold	Number of Beneficiaries with Predicted New OUD or Opioid-Related Overdose Diagnosis	Number of True Positives*	PPV (Percent)	NNE
Top 1 percent**(Validation Data)	16,862	1,860	11.01	9
Top 1 percent	62,571	5,445	8.70	11
Top 50,000	50,000	4,562	9.12	11
Top 40,000	40,000	3,792	9.48	11
Top 30,000	30,000	2,996	9.99	10
Top 20,000	20,000	2,168	10.84	9
Top 10,000	10,000	1,219	12.19	8
Top 5,000	5,000	679	13.58	7
Top 1,000	1,000	150	15.00	7

*True Positives are beneficiaries that were categorized into the given risk probability threshold group based on data from the October 1, 2021 to March 31, 2022 measurement period, then were subsequently found to have experienced a new opioid OD/OUD during the April 1, 2022 to September 30, 2022 prediction period.
**Validation data: random 25 percent sample of total population: January 1, 2019 to June 30, 2019 measurement period, and July 1, 2019 to December 31, 2019 prediction period.

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Between 9 percent and 15 percent of the beneficiaries with a predicted new opioid-related overdose/OUD actually experienced a new overdose or OUD diagnosis during the evaluation period (April 1, 2022, through September 30, 2022) depending on the Risk Probability Threshold. The Top 1 percent threshold (n = 62,571) reported the lowest precision score, while the Top 1,000 threshold showed the highest precision. Among those who had a new opioid-related overdose/OUD in the evaluation period, about 92 percent developed a new OUD; the proportion with a new opioid overdose increased from 10 percent to 17 percent as the risk probability threshold increased from the Top 1 percent to the Top 1,000; and, as the risk probability threshold increased, about 2 percent to 8 percent had both a new opioid overdose and were identified as having a newly diagnosed OUD. Among the different Risk Probability Thresholds, between 93 to 98 percent of the correctly predicted new overdoses/OUDs do not meet the current OMS criteria. The percentage that meets the current OMS criteria decreases as the Risk Probability Threshold becomes more restrictive. Thus, our analysis shows that there is very little overlap between the population identified through this model and beneficiaries already identified through the OMS.[42] Furthermore, our analysis confirms that machine learning models can analyze large datasets and identify complex patterns that are not easily discernible by current non-statistical approaches. This makes them a powerful tool for identifying new opioid-related overdose or OUD risk and capturing an additional population of potential at-risk beneficiaries who have not been identified through our current OMS criteria.

In the November 2023 proposed rule, we discussed that CMS next plans to assess risk in the model, validate the stability of the model as new data become available, and develop guidelines on how to feasibly implement the model into the existing DMP and OMS processes. We solicited feedback on the following:

- Potentially using such a model to enhance the minimum or supplemental OMS criteria in the future (either in addition to the current criteria or as a replacement).
- How to avoid the stigma and/or misapplication of identification of a PARB at high risk for a new opioid-related overdose or OUD using the variables in the model.
- Implementation considerations, such as effectively conducting case management, as described in 423.153(f)(2), with prescribers of PARBs identified by the model; opportunities to promote MOUD, co-prescribing of naloxone, or care coordination; or potential unintended consequences for access to needed medications.
- Other factors to consider.

Comment: Commenters supported our machine learning model approach or further testing. Several commenters encouraged CMS to provide a demographic breakdown or the fairness analysis used to evaluate the model. Several commenters suggested that CMS use clearly defined risk factors that foster case management, ensure correctness of the risk factors used, or focus on distinguishing factors to identify at-risk beneficiaries and to minimize misapplication of the criteria for beneficiaries with low risk of overdose or OUD. One commenter recommended methods to better identify overdose risk such as removing beneficiaries who do not show continuous use of opioids after an overdose event and shortening look back windows.

Response: We thank the commenters for their support of our machine learning model approach and thoughtful input. CMS will consider the feedback, and we will proceed with further testing to improve the model and risk factors.

[42] CMS also notes that historically, only about 1.6 percent of the beneficiaries meeting the history of opioid-related overdose (MIN2) OMS criteria also meet the (MIN1) minimum OMS criteria.

The model focused on Part D beneficiaries at high-risk of one of two outcomes: (1) having a new opioid poisoning (overdose) or (2) developing newly diagnosed OUD. Since Part D beneficiaries with a known opioid-related overdose are already identified in OMS, CMS focused on individuals at high risk for a new opioid-related overdose or OUD. CMS also excluded beneficiaries with a prior opioid-related overdose or an OUD diagnosis in the year prior to the prediction period. Also, we did include demographic factors in the initial model and a few of the factors were highly associated with a new OUD or opioid-related overdose diagnosis as described above and in the November 2023 proposed rule. We will look for opportunities to provide additional details or output from the analysis after we conduct more testing.

Comment: Some commenters recommended that CMS assess whether any new criteria resulting from the use of such model could unintentionally lead providers to be less likely to diagnose someone with OUD, as that, in turn, would decrease access to MOUD.

Response: We will evaluate unintentional consequences of using updated criteria that may affect the likelihood of diagnosing beneficiaries with OUD. We encourage sponsors and prescribers to promote co-prescribing of naloxone, MOUD, or other treatment referrals through the DMP case management process.

Comment: Some commenters requested sufficient lead time and proper communication language be in place before CMS implements any changes.

Response: We did not propose changes to the clinical guidelines or OMS criteria in the November 2023 proposed rule. Changes would be proposed through a future notice of proposed rulemaking with sufficient lead time and guidance, if finalized.

M. Codification of Complaints Resolution Timelines and Other Requirements Related to the Complaints Tracking Module (CTM) (42 CFR 417.472(l), 422.125, 423.129, and 460.119)

CMS maintains the CTM in the Health Plan Management System (HPMS) as the central repository for complaints received by CMS from various sources, including, but not limited to the Medicare Ombudsman, CMS contractors, 1–800–MEDICARE, and CMS websites. The CTM was developed in 2006 and is the system used to comply with the requirement of section 3311 of the Affordable Care Act for the Secretary to develop and maintain a system for tracking complaints about MA and Part D plans received by CMS, CMS contractors, the Medicare Ombudsman, and others. Complaints from beneficiaries, providers, and their representatives regarding their Medicare Advantage (MA) organizations, Cost plans, Programs of All-inclusive Care for the Elderly (PACE) organizations, and Part D sponsors are recorded in the CTM and assigned to the appropriate MA organization (MAO), Cost plan, PACE organization, and Part D sponsor if CMS determines the plan, organization, or sponsor is responsible for resolving the complaint. Unless otherwise noted, ''plans'' applies to MAOs, Part D sponsors, Cost plans, and PACE organizations for purposes of this section.

We proposed to codify existing guidance for the timeliness of complaint resolution by plans in the CTM. Currently, §§ 422.504(a)(15) and 423.505(b)(22) require MAOs and Part D sponsors to address and resolve complaints received by CMS against the MAO and Part D sponsor through the CTM; we proposed to codify the expectation in guidance that Cost plans and PACE organizations also address and resolve complaints in the CTM. We proposed to codify the existing priority levels for complaints based on how quickly a beneficiary needs to access care or services and to codify a new requirement for plans to make first contact with individuals filing non-immediate need complaints within 3 calendar days. This timeframe will not apply to immediate need complaints because those complaints need to be resolved within two calendar days.

CMS codified the requirement for MAOs and Part D sponsors to address and resolve complaints in the CTM at §§ 422.504(a)(15) and 423.505(b)(22) in the ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' (76 FR 21431), which appeared in the April 15, 2011 **Federal Register** (hereafter referred to as the ''April 2011 final rule''). As described in the April 2011 final rule, the regulation requires that MAOs and Part D sponsors provide a summary of the resolution in the CTM when a complaint is resolved. (76 FR 21470)

As Part D sponsors, Cost plans and PACE organizations that offer Part D coverage have been required to comply with § 423.505(b)(22). We proposed to add language to §§ 417.472(l) and 460.119 to codify in the Cost plan regulations and PACE regulations, respectively, the requirement that Cost plans and PACE organizations address and resolve complaints in the CTM. This proposed new requirement will apply to all complaints in the CTM for Cost plans and PACE organizations, not just complaints about Part D.

In addition, CMS has issued guidance describing our expectations for how complaints should be handled. In the Complaints Tracking Module Plan Standard Operational Procedures (CTM SOP), the most recent version of which was released on May 10, 2019, via HPMS memo,[43] CMS provides detailed procedures for plans to use when accessing and using the CTM to resolve complaints. This includes describing the criteria CMS uses in designating certain complaints as ''immediate need'' or ''urgent'' (all other complaints are categorized ''No Issue Level'' in the CTM), setting forth our expectation that plans should review all complaints at intake, and documentation requirements for entering complaint resolutions in the CTM. The CTM SOP defines an ''immediate need complaint'' for MAOs, Cost plans, and PACE organizations as ''a complaint where a beneficiary has no access to care and an immediate need exists.'' For Part D sponsors, ''an immediate need complaint is defined as a complaint that is related to a beneficiary's need for medication where the beneficiary has two or less days of medication remaining.'' The CTM SOP defines an ''urgent complaint'' for MAOs, Cost plans, and PACE organizations as a complaint that ''involves a situation where the beneficiary has no access to care, but no immediate need exists.'' For Part D sponsors, ''an urgent complaint is defined as a complaint that is related to the beneficiary's need for medication where the beneficiary has 3 to 14 days of medication left.''

In Chapter 7, section 70.1 of the Prescription Drug Benefit Manual, ''Medication Therapy Management and Quality Improvement Program,'' [44] CMS requires Part D sponsors to resolve any ''immediate need'' complaints within two (2) calendar days of receipt into the CTM and any ''urgent'' complaints within seven (7) calendar days of receipt into the CTM. Chapter 7, section 70.1 also sets forth CMS's expectation that Part D sponsors promptly review CTM complaints and notify the enrollee of the plan's action as expeditiously as the case requires based on the enrollee's health status.

[43] Available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ctm%20plan%20sop%20eff053019.pdf.*

[44] Available at *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/dwnlds/chapter7pdf.*

Requirements for resolution of complaints received in the CTM do not override requirements related to the handling of appeals and grievances set forth in 42 CFR part 422 subpart M (which apply to cost plans as well as MAOs per § 417.600), Part 423 subpart M, for Part D sponsors, and §§ 460.120–460.124 for PACE organizations. Rather, CTM requirements supplement the appeals and grievance requirements by specifying how organizations must handle complaints received by CMS in the CTM and passed along to the plan. The requirement for organizations to enter information on the resolution of complaints in the CTM within specified time periods allows CMS to track and ensure accountability for complaints CMS itself received, either directly from beneficiaries or via entries in the CTM from the Medicare ombudsman, CMS contractors, or others. A beneficiary who filed a complaint directly with CMS may later contact CMS to find out the status of the complaint and the plan's use of the system will allow CMS to answer the beneficiaries inquires more expeditiously. In order to comply with the applicable regulations, plans must handle any CTM complaint that is also an appeal or grievance within the meaning of the regulation in such a way that complies with the notice, timeliness, procedural, and other requirements of the regulations governing appeals and grievances.

We proposed to codify the timeliness requirements for MAOs and Part D plans at new §§ 422.125 and 423.129, both titled ''Resolution of Complaints in Complaints Tracking Module.'' We proposed to codify these requirements for Cost plans and PACE organizations at §§ 417.472(l) and 460.119 by adopting §§ 422.504(a)(15) and 422.125 by reference into the requirements for Cost plans and PACE organizations, respectively.

Specifically, we proposed to codify at §§ 422.125(a) and 423.129(a) the definitions of ''immediate need'' and ''urgent'' complaints in substantially the same way as they are currently defined in guidance for MA and Part D-related complaints. However, we proposed to specify that immediate need and urgent complaints for MA plans (as well as Cost plans, and PACE) also include situations where a beneficiary has access to enough of a drug or supply to last fewer than 2 days or from 3 to 14 days, respectively, as part of the definition that these complaints are about situations that prevent the beneficiary from accessing care or a service. This proposed change recognizes that some complaints to an MAO (or Cost plan or PACE organization) may overlap with Part D access, such as when a beneficiary reports a problem with their enrollment in an MA–PD plan that is blocking access to Part D coverage. The change also recognizes that non-Part D MA, Cost plan, and PACE complaints relate not just to access to physician services but to drugs and supplies that may be covered by the MA plan, Cost plan, or PACE organization's non-Part D benefit (for example, Part B drugs or diabetic test strips covered under the medical benefit of an MA plan). Further, MA plans, Cost plans, and PACE also cover Part B drugs.

We also proposed to codify at §§ 422.125(b) and 423.129(b) the current timeframes reflected in section 70.2 of Chapter 7 of the Prescription Drug Benefit Manual for resolving immediate need and urgent complaints. A two (2) calendar day deadline for resolving plan-related immediate need complaints is both consistent with current practice by plans and logically follows from the definition of an ''immediate need'' complaint. By its nature, an immediate need complaint requires swift action. Because we define immediate need, in part, as a situation where a beneficiary has access to two or fewer days' worth of a drug or supply they need, a timeline greater than two calendar days for resolving a complaint would represent an unacceptable risk to beneficiaries.

Similarly, a 7 calendar day deadline for ''urgent'' complaints reflects the importance of not delaying resolution of a situation that is preventing access to care or services a beneficiary needs. Because we define ''urgent'' in part as a situation where a beneficiary has 3 to 14 days' worth of a drug or supply they need, allowing more than a week to elapse before resolving the complaint will put beneficiaries at unacceptable risk of not receiving replacement drugs or supplies timely.

For all other Part D and non-Part D complaints in the CTM, we proposed requiring resolution within 30 days of receipt. This is consistent with current practice and the guidance in section 70.2 of Chapter 7 of the Prescription Drug Benefit Manual, and we believe will prevent complaints from lingering for months without resolution in the CTM. Further, a 30-day timeframe for resolving complaints in the CTM aligns with the 30-day period provided in §§ 422.564(e) and 423.564(e) for resolution of grievances. Although those regulations permit an extension of up to 14 days for resolving the grievance if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee, we do not believe that including the authority to extend the deadline to resolve complaints in the CTM is appropriate because complaints received into the CTM are often the result of failed attempts to resolve issues directly with the plan. Allowing plans to further extend the time to resolve the complaint only allows further delays in addressing beneficiary concerns. Moreover, recent evidence indicates that the vast majority of non-immediate need or urgent complaints are resolved within 30 days—98 percent of such complaints were resolved by plans within 30 days in 2022.

All timeframes for resolution will continue to be measured from the date a complaint is assigned to a plan in the CTM, rather than the date the plan retrieves the complaint from the CTM. This is consistent with current guidance and practice. Measuring the timeframe in this manner is the best way to protect beneficiaries from delayed resolution of complaints and encourages organizations to continue retrieving CTM complaints in a timely manner so that they have sufficient time to resolve complaints.

We do not anticipate that plans will have difficulty meeting these timeframes. The vast majority of complaints are currently resolved in the timelines specified for the priority level of the complaint. For example, in 2022, plans resolved 97 percent of complaints within the required time frames for the level of complaint. Plans resolved 94 percent of immediate need complaints within two (2) calendar days, 97 percent of urgent complaints within seven (7) calendar days, and 98 percent of complaints with no issue level designated within thirty (30) calendar days. Codifying the timeframes as proposed merely formalizes CMS's current expectations and the level of responsiveness currently practiced by plans.

We also proposed to create a new requirement for plans to contact individuals filing non-immediate need complaints. At §§ 422.125(c) and 423.129(c), we proposed to require plans to contact the individual filing a complaint within three (3) calendar days of the complaint being assigned to a plan. While current guidance generally includes the expectation that organizations inform individuals of the progress of their complaint, CMS has never specified a timeframe for reaching out to a complainant. CMS has observed that, particularly for complaints that are not assigned a priority level, plans sometimes wait until the timeframe for resolution has almost elapsed to contact the complainant. Because the timeframe

for resolving uncategorized complaints is 30 days, an individual who files a complaint may wait weeks to hear back from the plan responsible for resolving it. We believe that such delays cause unnecessary frustration for beneficiaries and are inconsistent with the customer service we expect from plans.

We acknowledge that our proposed timeframe for reaching out to the complainant concerning a CTM complaint is more specific than our requirement at §§ 422.564(b) and 423.564(b) for plans to ''promptly inform the enrollee whether the complaint is subject to its grievance procedures or its appeals procedures.'' We proposed a specific timeframe for contacting the beneficiary regarding a CTM complaint because, unlike with complaints received by the plans outside the CTM, the complainant has not reached out directly to the plan and may not know that their complaint has been passed on to the plan by CMS via the CTM. Moreover, as previously noted, CMS monitors the handling of complaints it receives through the CTM in real time. Part of handling CTM complaints through the CTM, as required by §§ 422.504(a)(15) and 423.505(b)(22), is entering information into the CTM when the plan reaches out to the complainant. CMS will therefore be able to monitor whether a plan has reached out to a beneficiary within the required timeframe and follow up with the plan well before timeframe for resolving the complaint has elapsed.

We proposed a three (3) calendar day timeframe for reaching out to the individual filing the complaint because it will provide a timely update to individuals filing both urgent and uncategorized complaints without delaying resolution of immediate need complaints. We expect that a plan will indicate in this communication that the plan has received and is working on the complaint, and that they provide contact information that the individual filing the complaint could use to follow up with the plan regarding the complaint. We solicited comment on whether this timeframe is appropriate and whether a longer or shorter timeframe will better balance the needs of beneficiaries with the capacity of plans to respond to complaints.

We also proposed conforming changes to §§ 422.504(a)(15) and 423.505(b)(22) to incorporate the proposed new requirements into the existing contractual requirements for MAOs and Part D sponsors. The proposed revisions to §§ 417.472(l) and 460.119 incorporate both the requirements in proposed § 422.125 and the requirement for a contract term for resolving complaints received by CMS through the CTM for Cost plans and PACE organizations and their contracts with CMS.

We received comments on the proposal and our responses to the comments are below.

Comment: Several commenters supported the proposed rule, with one noting that they support any effort to improve the timeliness and transparency associated with enrollee complaints to MA plans. One organization was particularly appreciative of CMS's goal to ensure that beneficiaries receive a timely response to complaints. Another commenter likewise expressed the need to codify a timeline for letting complainants know that the plan had received the complaint, stating that beneficiaries and their representatives frequently have no idea if a plan has received and is addressing the complaint.

Response: We appreciate the support for our proposal. We agree that establishing clear timelines for MA plans, Cost plans, PACE organizations and Part D plans to respond to CTM complaints is important.

Comment: A few comments supported the proposal and suggested that CMS adopt measures to promote greater transparency and accountability for beneficiary and provider complaints. Specifically, they suggested making CTM complaints publicly available on Medicare Plan Finder or elsewhere, carefully monitoring trends in CTM complaints and use them to focus CMS audits, creating an online portal for all stakeholders to enter complaints about plans, and creating a provider hotline similar to 1–800–MEDICARE specifically for providers to submit complaints.

Response: We appreciate the commenter's support. While the commenter's suggestions are out of scope for the proposed rule, we will consider them as we continue to explore ways to improve transparency and accountability. We already closely monitor CTM complaints and that complaint rates are used to calculate Star Ratings for MA and Part D plans.

Comment: A commenter supported the proposal, but expressed concern that many CTM complaints appear to be the result from MAO attempts to shield denials of coverage from review by the Independent Review Entities (IREs) that handle reconsiderations of adverse appeals and coverage determination decisions by MAOs and Part D sponsors. The commenter was particularly concerned that CMS does not appear to have an effective mechanism to monitor what should have been sent to the IRE for review but was not.

Response: This comment is out of scope for this proposal, but we appreciate the commenter's concern. We agree it is critical for MAOs, Part D sponsors and cost plan organizations (which must comply with the MA appeal regulations per § 417.600) to send all of the cases to the IRE that should be sent to the IRE. See section VII.E of this rule for a discussion of our revision to the process for identifying data completeness issues at the IRE and calculating scaled reductions for the Part C appeals measures to help ensure that all of the cases that should be sent to the IRE are sent.

Comment: A commenter expressed concern with CMS's statements that CTM complaints must be handled as appeals or grievances when appropriate. The commenter stated that treating all CTM complaints as appeals or grievances would result in conflicting timeframes for resolution and duplicative communications to members. The commenter requested clarification of whether CMS expects all complaints to be treated as appeals or grievances and, if not, whether complaints that are appeals or grievances would be held to the CTM timeframes in addition to the appeals and grievance timeframes.

Response: We understand the commenter's concern. We wish to clarify that CTM complaints should only be treated as appeals or grievances when they otherwise meet the definition of appeals or grievances under the applicable regulations. We note that MA and Part D appeals and grievances must be resolved ''as expeditiously as the case requires'' and that this would require resolution of the appeal or grievance within the proposed timeframe for immediate need and urgent complaints if the appeal or grievance involved a service or drug for which the beneficiary has a need that meets the definition of ''immediate need'' or ''urgent'' that we proposed and are finalizing in §§ 422.125 and 423.129. See §§ 422.564(e)(1), 422.630(e) and 423.564(e)(1) regarding the timeline for responses to enrollee appeals and grievances. Although the regulations at §§ 422.564(e)(2), 422.630(e)(2), and 423.564(e)(2) permit the 30-day timeframe resolution of grievances to be extended by up to 14 days if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee, the stricter timing requirements for CTM complaints addressed in §§ 422.125 and 423.129

will control where a CTM complaint has been filed.

Similarly, PACE service determinations and appeals must be resolved as ''expeditiously as the participant's condition requires'', but no later than three days after the request is received for service determinations, 30 days after the request is received for appeals, and 72 hours after the appeal request is received for expedited appeals. See §§ 460.121(i), 460.122(c)(6), and 460.122(f) regarding the timelines for response to PACE participant service determination requests and appeals and the definition of expedited appeals. Pursuant to provisions of this rule, PACE grievances must also be resolved as ''expeditiously as the case requires,'' but no later than 30 calendar days after the PACE organization receives the grievance. See section XI.H of this rule, adopting changes to § 460.120, including a timeline for resolution of PACE grievances at § 460.120(g). Immediate need complaints that also qualify as PACE grievances, service determination requests, appeals, or expedited appeals therefore need to be resolved within two days under both PACE requirements and the requirements of this rule. Although the regulations at §§ 460.121(i)(1) and 460.122(f)(3) allow the timeline for resolution of service determination requests and expedited appeals to be extended by five days or 14 days, respectively, under certain circumstances, the stricter timing requirements for CTM complaints addressed in §§ 422.125 and 423.129 will control where a CTM complaint has been filed in the same way they would for MA and Part D grievances.

Because existing CMS regulations explicitly permit extension for MA and Part D appeals and grievances, we do not think it is appropriate to penalize an organization for extending the resolution of a non-immediate need and non-urgent CTM complaint that meets the definition of an MA or Part D appeal or grievance. Therefore we are adding a new paragraph (4) to §§ 422.125(b) and 423.129(b) to allow organizations to extend the timeline to respond to a CTM complaint if the complaint is also a grievance within the scope of §§ 422.564, 422.630 or 423.564 *and* if it meets the requirements for an extension of time under §§ 422.564€(2), 422.630(e)(2), or 423.564(e)(2) as applicable. (Depending on the type of organization—MA plan, applicable integrated plan, Part D plan, or cost plan the specific regulation that governs the time frame for responding to a grievance will vary.) This extension will not be available for any complaint that meets the definition of an immediate need complaint or urgent complaint or that requires expedited treatment under §§ 422.564(f), 422.630(d), or 423.564(f) because such a delay would present an unacceptable risk of harm to the beneficiary. PACE organizations are not permitted to extend the 30-day timeframe for resolution grievances under the revisions to § 460.120 finalized in this rule or for non-expedited appeals under § 460.122(c)(6) and service determinations must be resolved within eight days even with the permitted five-day extension under § 460.121(i), so it is not necessary to allow an extension of the 30-day timeline for non-immediate need and non-urgent complaints that also qualify as PACE grievances, service determination requests, or appeals.

We also acknowledge the potential conflict between the timelines for resolving immediate need complaints or urgent complaints and the requirement for organizations to respond within 24-hours to MA and Part D grievances that meet the definition of ''expedited grievances'' under §§ 422.564(f), 422.630(d), and 423.564(f). Similarly, there is a potential conflict between the timeline for resolving urgent complaints and the three days and 72 hours permitted to respond to PACE service determination requests and expedited appeals under §§ 460.121(i) and 460.122(f)(2). We did not intend to allow organizations to take longer to resolve an expedited MA or Part D grievance or PACE service determination request or expedited appeal than is currently required under the regulation merely because the grievance, service determination request, or appeal was received as a CTM complaint. Therefore, we are adding a new paragraph (5) to §§ 422.125(b) and 423.129(b) to make clear that organizations must comply with the shortest applicable timeframe for resolving a CTM complaint when the complaint also qualifies as a grievance, PACE service determination request, or PACE appeal. By shortest applicable timeframe, we mean the timeframe that (1) applies under this new CTM provision for the type of complaint (that is, immediate need complaint, urgent complaint, or other type of CTM complaint), the grievance regulation (that is §§ 422.56, 422.630, 423.564, or 460.120), or the PACE service determination or appeals regulation (that is §§ 460.121 or 460.122) and (2) is the shortest of those two applicable time frames. So, if a CTM complaint qualifies as both an urgent complaint and an expedited MA or Part D grievance, the organization responsible for responding to the complaint would be required to do so within 24 hours, as required by §§ 422.564(f), 422.630(d), and 423.564(f), and not within the seven days permitted under §§ 422.125(b)(2) and 423.129(b)(2) for urgent complaints. Similarly, with respect to the requirement for organizations to contact the individual making the complaint in the CTM within a specific timeframe, we expect that organizations will meet this timeframe for CTM complaints that also meet the definition of MA, Part D, or PACE grievances. To the extent that the requirement in §§ 422.564(b) and 423.564(b) to ''promptly inform the enrollee whether the complaint is subject to its grievance procedures or its appeals procedures'' would permit organizations to take longer than seven days to notify enrollees, §§ 422.125(c) and 423.129(c) would nevertheless require organizations to contact individuals who file a complaint that qualifies as a grievance in the CTM within seven days.

Comment: A commenter recommended shorter timeframes for resolving complaints submitted in the CTM. The commenter urged CMS to require that immediate need complaints be resolved within 24 hours and that all other cases be resolved within 72 hours. The commenter noted that this would reflect timelines for the appeals processes for Part B drugs and Part D benefits, which require that decisions be made ''as soon as the beneficiary requires'' but not later than 72 hours for standard requests (§§ 422.568 and 423.568) and 24 hours for expedited requests (§§ 422.572 and 423.572). The commenter noted that a seven-day resolution timeline for urgent complaints in which patients have three to fourteen days of treatment left would potentially leave patients without needed care for four days.

Response: We acknowledge that some complaints may require quicker resolution than the timeframes currently required for CTM complaints. As previously discussed, we expect organizations to treat complaints that meet the definition of appeals or grievances in a manner consistent with the requirements prescribed in the regulation for handling appeals and grievances. When a CTM complaint is actually an appeal, the organization must comply with the appeal regulations; nothing in the new regulations we are finalizing to address handling of CTM complaints changes or creates an exception to the appeal regulations that apply to cost plans, MA plans (including applicable integrated plans), Part D plans or PACE

organizations. We are finalizing a new paragraph (b)(4) as part of §§ 422.125 and 423.129 to make clear that organizations should comply with the shortest timeline called for in the applicable regulations when the timeliness requirements related to CTM complaints and grievances both apply. Therefore, an organization would have to respond to an immediate need complaint that also meets the definition of an expedited grievance within the 24 hours required by §§ 422.564(f), 422.630(d), or 423.564(f). Similarly, if an urgent complaint meets the definition of a grievance under §§ 422.561 and 423.560, or a PACE service determination request or appeal under §§ 460.121 and 460.122, and involves a beneficiary with only four days of medication remaining, the organization would be required to resolve the issue within four days because §§ 422.564I(1), 422.630(e), 423.564(e)(1), 460.121(i), and 460.122(c)(6) require organization notify an enrollee of its decision on a grievance (or PACE service determination request or appeal) ''as expeditiously as the case requires'' based on the enrollee's health status.

The resolution timeframes of two days for immediate need complaints, seven days for urgent complaints, and 30 days for all other CTM complaints have been in effect for many years and we do not have evidence that beneficiaries entitled to quicker resolutions under the regulations for grievances have had those resolutions delayed as a result. We are finalizing the resolution timeframes for CTM complaints as proposed in §§ 422.125 and 423.129 with the modifications described for §§ 422.125(b)(4) & (5) and 423.129(b)(4) & (5), but we will continue to monitor CTM complaint resolutions and appeals and grievances procedures and records for evidence that the CTM resolution timeframes are causing unnecessary delays in the resolution of appeals and grievances.

Comment: A commenter supported the proposed requirement to contact complainants within three days of filing a CTM complaint but recommended that CMS require organizations to provide beneficiaries with the CTM complaint ID number in addition to the plan contact information. The commenter also recommended that CMS require plans to document the contact within one to two business days of making the contact.

Response: We appreciate the commenter's support. We agree that organizations should provide the complainant with the CTM complaint ID number when reaching out to them regarding the complaint. However, we do not believe that it is necessary to codify this expectation at this time. Individuals filing CTM complaints receive the complaint ID number when they call 1–800–MEDICARE, and we do not think organizations reaching out to complainants would ordinarily fail to provide this information when contacting the individual to update them on the status of the complaint. We also agree that organizations should update the CTM promptly when contacting complainants and resolving complaints. We currently monitor CTMs on an ongoing basis and our experience is that organizations meet this expectation. Therefore, we do not believe that it is necessary to codify this expectation at this time.

Comment: A commenter noted that their State guidance requires health plans to acknowledge a complaint within ten days. They questioned whether there was a way to align the CMS requirement with the State requirement.

Response: We recognize that States may have different expectations with respect to handling complaints. However, State insurance laws other than licensure and solvency do not apply to MA plans under section 1856(b)(3) of the Act, and we do not believe that it is necessary or practical to allow organizations a longer time to contact complainants or resolve complaints merely because a State may permit longer timeframes for other types of health plans. We expect and will continue to expect MA plans, cost plans, Part D plans, and PACE organizations to meet the federal timeframes for beneficiary contact and complaint resolution adopted here (or in other applicable laws).

Comment: A commenter was generally supportive of the proposal but noted that complaints related to D–SNPs may require action from State Medicaid agencies, which may require longer to resolve. The commenter recommended that CMS modify the proposal to account for the need to involve State Medicaid agencies in the resolution of D–SNP complaints.

Response: We appreciate the commenter's support and acknowledge that some complaints for D–SNPs may require action by or input from State agencies or others that are not bound by CMS requirements. However, we do not believe a modification related to potential involvement of a State Medicaid agency to the requirements we proposed and are finalizing in this rule is necessary. Some CTM complaints have always required action by or input from outside agencies. This has not caused any significant delays in complaint resolution. Our experience is that most States recognize the need to resolve urgent complaints and immediate need complaints quickly and that States rarely take longer than 30 days to respond to other complaints. Isolated complaints may take longer to resolve as a result of inaction by outside agencies, but we do not believe that it is necessary to extend the timeframe for resolution to account for these outlier events. Rather, we will continue to exercise its discretion to take into account such outliers when determining whether compliance or enforcement actions are necessary in a particular circumstance.

Comment: A few commenters expressed concern that CMS would expect organizations to actually make contact with beneficiaries within the required timeframes, rather than requiring them to attempt to make contact. They requested that CMS clarify whether an attempt to make contact within the specified timeframe would satisfy the requirement. They also requested that CMS clarify the means by which the organization make contact.

Response: We recognize that beneficiaries are not always available to receive calls when plans reach out to them. We are therefore finalizing the proposed regulations at §§ 422.125(c) and 423.129(c) rule with a modification to clarify that organizations *attempt* to make contact with individuals filing complaints in the CTM within the specified timeframe. We believe that this ensures that plans will reach out to complainants in a timely manner without creating an unrealistic expectation that plans be able to reach complainants who may not be available to receive calls or other communications within the specified timeframes.

We also recognize that plans have many ways to contact beneficiaries, including by phone or mail. We expect plans to attempt to contact complainants regarding time sensitive matters by the most expeditious means available. We also expect that plans would generally use the same method to reach out to complainants as the complainants used to file complaints. Generally, this would require that plans attempt to contact complainants by phone, since this is the way the vast majority of complaints are made and the quickest way to reach individuals in real time. Our experience operating the CTM indicates that organizations do attempt to contact complainants by phone. We therefore do not believe that it is necessary to explicitly codify this expectation at this time. However, we

will continue to monitor CTM complaints to ensure that organizations continue to observe best practices for reaching out to complainants.

Comment: Several commenters requested greater flexibility in the timeframes for resolving CTM complaints and reaching out to individuals filing complaints. Some requested that CMS use a business day standard rather than a calendar day standard, stating that it would allow PACE organization to better manage communications outside of weekends and holidays. One commenter suggested extending the time period for contacting a complainant to five calendar days as an alternative to a business day standard to balance the need for timely communication against PACE organizations' need for flexibility. Another commenter was concerned that contacting the complainant within three calendar days of filing a complaint does not guarantee that the individual will get meaningful feedback and may result in beneficiary confusion regarding the status of their complaint. Some commenters believe that requiring contact within three calendar days for a complaint that MAOs and Part D sponsors have 30 days to resolve would negatively impact the resources needed to investigate and resolve immediate need and urgent cases. They noted that they already strive to reach out within four to seven days for urgent and uncategorized complaints. One commenter also noted that beneficiaries often express frustration with receiving calls at inopportune times, such as on holidays, especially when the complaint is not an immediate need complaint.

Response: We appreciate the commenters' desire for greater flexibility and the difficulty plans may experience in meeting a 3-calendar day timeframe for reaching out to beneficiaries. However, we do not believe that switching from a calendar day to a business day standard would be the best way to balance the needs of the beneficiary for transparency with the plans' needs for flexibility. The need for health care services can occur at any time, regardless of holidays or business schedules. Moreover, different states and territories celebrate different holidays, making it difficult for us to hold plans accountable to a uniform standard that is based on business days. We have long applied a calendar day standard to requirements related to complaints, as well as to appeals and grievances. It would therefore be inconsistent to switch to a business day standard when codifying CTM resolution requirements.

We also do not share the commenter's concern that contacting complainants before a complaint has been resolved would be premature or confusing. As discussed previously, one of the major purposes of requiring organizations to contact individuals filing complaints before the complaint has been resolved is to ensure that the complainant knows that the organization has received and is working to resolve the complaint. We do not believe such communications would be confusing for beneficiaries.

However, we do recognize that a three-calendar day requirement to contact beneficiaries is a new requirement that may prove difficult for organizations to adhere to and that it may not significantly improve the beneficiary experience such that burden is sufficiently outweighed. Based on these comments, we are finalizing a slightly longer deadline by which organizations must attempt to contact individuals filing non-immediate need complaints as finalized §§ 422.125(c) and 423.129(c) require organizations to attempt to contact the complainant within 7 calendar days of the organization being assigned the complaint from the CTM. We believe that this strikes a balance between providing individuals timely information regarding the handling of their complaints with plans' valid concerns about being able to meet a shorter timeframe. We also believe that this will address commenter's concerns about the difficulty of contacting beneficiaries on non-business days—it is unusual for an organization to have more than two or three consecutive non-business days in a 7-day period, so organizations should be able to meet the longer 7-day timeframe regardless of whether a complaint was received immediately before a weekend or holiday.

Final Decision: We thank commenters for their input. We note that comments were generally supportive, with many commenters representing plans requesting more flexibility and some commenters representing beneficiaries and providers requesting more stringent requirements and improved transparency. We received several comments requesting greater public transparency for CTM complaints and increased scrutiny of plans' handling of appeals and grievances that were out of scope for the proposal, but which we will take into account as we continue to monitor plan performance in these areas. Based on the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed rule with four significant modifications: (1) changing the requirement to make contact to a requirement to attempt contact, (2) adding language that permits the extension of time to resolve non-immediate need and non-urgent complaints that also qualify as non-expedited grievances in a manner consistent with the extension permitted for grievances under §§ 422.564, 422.630, and 423.564, (3) adding language that requires organizations to adhere to the shortest timeframe required by the regulation for CTM complaints and grievances when a CTM complaint also qualifies as a grievance; and (4) requiring that organizations contact individuals filing complaints within 7 calendar days rather than 3 calendar days.

N. Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products (§§ 423.4, 423.100, 423.104, 423.120, 423.128, and 423.578)

Section 1860D–11(e)(2) of the Act provides that the Secretary may only approve Part D plans if certain requirements are met, including the provision of qualified prescription drug coverage. Section 1860D–11(e)(2)(D) of the Act specifically permits approval only if the Secretary does not find that the design of the plan and its benefits, including any formulary and tiered formulary structure, are likely to substantially discourage enrollment by certain Part D eligible individuals. Section 1860D–4(c)(1)(A) of the Act requires ''a cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate.'' Lastly, section 1860D–4(b)(3)(E) of the Act requires Part D sponsors to provide ''appropriate notice'' to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists before removing a covered Part D drug from a formulary or changing the preferred or tiered cost-sharing status of such a drug.

In section III.Q., Changes to an Approved Formulary, of the December 2022 proposed rule, we proposed regulations related to (1) Part D sponsors obtaining approval to make changes to a formulary already approved by CMS, including extending the scope of immediate formulary substitutions (also generally referred to as immediate substitutions herein);[45] and (2) Part D

[45] In the subsequent November 2023 proposed rule, we noted the distinction between formulary substitutions made by a plan sponsor and product substitutions made by a pharmacist at the point of dispensing. As we described in section III.F.2.a.(2) of the November 2023 proposed rule, state laws

Continued

sponsors providing notice of such changes.

For reasons discussed therein, the December 2022 proposed rule proposed regulatory changes on how to obtain approval to make changes to a formulary already approved by CMS and to provide notice of such changes. We proposed to codify, with some revisions, longstanding sub-regulatory guidance and terminology specifying when and how Part D sponsors can obtain approval to make negative formulary changes and the enrollees to whom these changes would apply.

Approval of formulary changes: Specifically, we proposed to codify our existing practice with respect to CMS review and approval of negative formulary changes by proposing in § 423.120(e) that Part D sponsors may not make any negative formulary changes to the CMS-approved formulary except as specified in the regulation. We proposed to codify longstanding policy at proposed § 423.120(e)(3)(i), to permit each Part D sponsor that has submitted a maintenance change request to assume that CMS has approved the request if it does not hear back from CMS within 30 days of submission, and at § 423.120(e)(3)(ii) to specify that Part D sponsors must not implement any non-maintenance changes until they receive notice of approval from CMS. We also proposed to codify our longstanding policy that affected enrollees are exempt from approved non-maintenance changes for the remainder of the contract year at § 423.120(e)(3)(ii).

In support thereof, we proposed to define ''negative formulary changes'' to Part D drugs in § 423.100 to include drug removals, moves to higher cost-sharing tiers, and adding or making more restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements. We proposed to specify that negative formulary changes can be classified in one of three categories, which we also proposed to define in that same section as—

- ''Maintenance changes,'' which we proposed to define to encompass seven types of changes including drug substitutions that do not meet our requirements of immediate substitutions under § 423.120(e)(2)(i); changes based on particular events such as certain FDA actions, long-term shortages, and new clinical guidelines or information, or to promote safe utilization; or adding PA to help determine Part B versus Part D coverage;
- ''Non-maintenance changes,'' which we proposed to define as negative formulary changes that are not maintenance changes or immediate negative formulary changes; or
- ''Immediate negative formulary changes,'' a newly coined term that we proposed to encompass all types of immediate substitutions or market withdrawals under § 423.120(e)(2)(i) or (ii) respectively.

As an exception to the general rule requiring prior CMS approval of formulary changes, our current regulations permit immediate generic substitutions and the removal of drugs ''deemed unsafe'' by FDA or ''removed from the market by their manufacturer.'' We proposed in the December 2022 proposed rule to move and incorporate that regulation text as follows: In § 423.120(e)(2)(i), we proposed to permit ''immediate substitutions,'' meaning Part D sponsors could make immediate generic substitutions as well as substitute a new ''interchangeable biological product'' for its corresponding reference product; a new ''unbranded biological product'' for its corresponding brand name biological product; and a new ''authorized generic'' for its corresponding brand name equivalent. We proposed to support this proposal by defining the above quoted terms in § 423.4; identifying the corresponding relationships (including the previously permitted generic substitutions) in our definition of a ''corresponding drug'' in § 423.100; and also defining ''biological product,'' ''brand name biological product,'' and ''reference biological product'' in § 423.4. In proposing in § 423.120(e)(2)(ii) to continue to permit plans to immediately remove from their formulary any Part D drugs deemed unsafe by FDA or withdrawn from sale by their manufacturer, we proposed to newly describe these changes as ''market withdrawals.'' Under § 423.120(e)(2), as proposed in the December 2022 proposed rule, Part D sponsors meeting our requirements for immediate substitutions and market withdrawals would be able to make these changes immediately without submitting negative change requests to CMS. However, proposed § 423.120(f)(2) and (3) would require Part D sponsors to provide advance general notice of such changes and to submit specific changes with their next required or scheduled CMS formulary updates.

We proposed in respective §§ 423.120(b)(3)(i)(B) and 423.120(e)(4) to conform our regulations such that the same transition and timing rules would apply for all immediate negative formulary changes: as proposed, all immediate negative formulary changes could take place at any time (previously this exception only applied to immediate generic substitutions and market withdrawals) and Part D sponsors would not need to provide a transition supply (previously we only specified in regulation that this exception applied to immediate generic substitutions).

We also proposed to update and move to a new place the current regulation at § 423.120(b)(6), which prohibits Part D sponsors from making certain changes from the start of the annual enrollment period to 60 days after the beginning of the contract year. We proposed to update such regulation at § 423.120(e)(4) to specify that plans cannot make negative formulary changes during the stated time period except, as noted earlier, for immediate negative formulary changes (that is, immediate substitutions or market withdrawals).

We also proposed miscellaneous changes in § 423.100 in support of the previously described changes, including updating the definition of ''affected enrollee'' to encompass beneficiaries affected by all negative formulary changes and moving our current regulatory description of ''other specified entities'' from § 423.120(b)(5)(1) to be a standalone definition of the term in § 423.100.

Permitted formulary changes and the IRA: We also proposed in the December 2022 proposed rule a change related to the Inflation Reduction Act of 2022 (IRA). Section 11001 of the IRA added section 1860D–4(b)(3)(I)(i) of Act to require, starting in 2026, Part D sponsors to include on their formularies each covered Part D drug that is a selected drug under section 1192 of the Act for which a maximum fair price is in effect with respect to the plan year. Section 1860D–4(b)(3)(I)(ii) of the Act clarifies that nothing in clause (i) shall be construed as prohibiting a Part D sponsor from removing such a selected drug from a formulary if such removal would be permitted under § 423.120(b)(5)(iv) or any successor regulation. We proposed to identify § 423.120(e)(2)(i) as the successor regulation to § 423.120(b)(5)(iv) for purposes of section 1860D–4(b)(3)(I)(ii) of the Act.

Notice of formulary changes: We proposed to move, with some revisions and streamlining, current regulations on

govern the ability of pharmacists to substitute biological products at the point-of-dispensing. By contrast, the Secretary's statutory authority under section 1860D–11(e)(2) of the Act governs approval of, and by extension any changes to, Part D formularies. The provisions we describe herein strictly apply to changes to Part D formularies made by plan sponsors, and do not apply to substitutions made by pharmacists at the point of dispensing.

notice of changes, and align them with our proposed approval requirements. Specifically, in § 423.120(f)(1) we proposed to specify that maintenance and non-maintenance negative formulary changes would require 30 days' advance notice to CMS, other specified entities, and in written form to affected enrollees. We proposed to retain and move to § 423.120(f)(1) an alternative option for Part D sponsors to provide a month's supply with notice at the point of sale as specified. We also proposed to move and extend our existing requirements for immediate generic substitutions to include immediate substitutions of corresponding drugs and market withdrawals, by requiring advance general notice of immediate negative formulary changes at § 423.120(f)(2), followed by written retrospective notice required under § 423.120(f)(3) to affected enrollees. We proposed that this retrospective notice be provided to affected enrollees as soon as possible after a specific change, but by no later than the end of the month following any month in which a change takes effect. We proposed at § 423.120(f)(4) to reorganize and renumber our current requirements for the contents of the direct written notice, and to provide more flexibility by no longer restricting appropriate alternative drugs to those in the same therapeutic category or class or cost-sharing tier. Our proposed revision aimed to make clear that the contents of the written notice would be largely the same regardless of the timing: whether Part D sponsors were providing notice before making a particular change (for maintenance and non-maintenance changes under § 423.120(f)(1)) or after (for negative immediate changes under § 423.120(f)(3) as proposed). Section 423.120(f)(5) proposed to newly specify how to provide advance general notice and specific notice of changes other than negative formulary changes.

We also proposed conforming amendments to update § 423.128(d)(2)(iii) to require online notice of ''negative formulary changes'' and to update cross citations in §§ 423.104(d)(2)(iv)(A)(6) and 423.128(e)(6) to reflect the fact we proposed to move the bulk of our requirements on formulary changes from § 423.120(b)(5) and (6) to § 423.120(e) and (f). We proposed to revise text at § 423.120(b)(5) and (6) to indicate that Part D sponsors must provide notice of formulary changes and can only make changes to CMS-approved formularies as specified, respectively, in § 423.120(f) and (e).

After receiving comments on the December 2022 proposed rule, we identified a limited number of changes that we wanted to make to that proposed regulatory text, which we proposed in the November 2023 proposed rule. We noted that the November 2023 proposed rule reflected our intent to consider the formulary change proposals in section III.Q. of the December 2022 proposed rule, as updated by the limited changes proposed in the November 2023 proposed rule, for inclusion in future rulemaking.

In the November 2023 proposed rule, we noted that commenters on section III.Q. of the December 2022 proposed rule did not agree on the requirements that should apply to formulary substitutions of Food and Drug Administration (FDA) approved and licensed biosimilar biological products. Different commenters submitted divergent requests that formulary substitutions of biosimilar biological products other than interchangeable biological products be treated as immediate substitutions, be treated as maintenance changes, or not be permitted whatsoever. Our proposed regulatory text in the December 2022 proposed rule only addressed substitution of interchangeable biological products and unbranded biological products, and did not specify how Part D sponsors could treat substitution of biosimilar biological products other than interchangeable biological products. We stated that we believed, in part because of the interest in the topic, it would be appropriate to propose changes then to solicit comment directly on the subject.

Accordingly, we proposed in the November 2023 proposed rule to update the regulatory text we proposed in the December 2022 proposed rule to the extent necessary to permit Part D sponsors to treat substitutions of biosimilar biological products other than interchangeable biological products as ''maintenance changes,'' as defined in the December 2022 proposed rule. We also proposed to define a new term, ''biosimilar biological product,'' distinct from our previously proposed term ''interchangeable biological product.'' We also proposed some technical changes to the term ''interchangeable biological product.'' We believe these proposals from the November 2023 proposed rule add to the December 2022 proposed rule to increase access to biosimilar biological products in the Part D program, consistent with the Biden-Harris Administration's commitment to competition as outlined in Executive Order (E.O.) 14306: ''Promoting Competition in the American Economy.'' [46]

We specifically proposed to define biosimilar biological products consistent with sections 351(i) and (k) of the Public Health Service Act (PHSA) to include interchangeable biological products. As we noted in section III.F.2.b.(1) of the November 2023 proposed rule, in section III.Q of the December 2022 proposed rule, we originally proposed to permit maintenance changes and immediate substitutions involving interchangeable biological products. In the November 2023 proposed rule, we also proposed to allow substitution of biosimilar biological products other than interchangeable biological products for reference products as a maintenance change. To ensure clarity, we proposed in the November 2023 proposed rule to address the application of these policies to interchangeable biological products and to biosimilar biological products other than interchangeable biological products in separate paragraphs of the proposed definition of maintenance change in § 423.100.

Further, in considering a comment on immediate formulary substitutions we received on the December 2022 proposed rule, we also determined it would be appropriate to propose in the November 2023 proposed rule to provide Part D sponsors with additional flexibility with respect to the timing requirements for maintenance changes and immediate substitutions than as originally proposed in the December 2022 proposed rule. Rather than requiring a Part D sponsor to add a ''corresponding drug'' and make a ''negative formulary change'' (as both such terms are defined in the December 2022 proposed rule) to its related drug ''at the same time'' for a maintenance change, we proposed in the definition of maintenance change in § 423.100(1) in the November 2023 proposed rule to allow Part D sponsors to make a negative formulary change to the related drug within 90 days of adding the corresponding drug. We made similar changes in § 423.100(2) requiring negative formulary changes be made to a reference product within 90 days of adding a biosimilar biological product other than an interchangeable biological product. This means that the same flexibility is available when Part D sponsors make any biosimilar biological product substitutions that are maintenance changes. Lastly, we also

[46] *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.*

proposed to make similar adjustments to the timing requirements for immediate substitutions of corresponding drugs in § 423.120(e)(2)(i). Specifically, as proposed in the November 2023 proposed rule, Part D sponsors would be able to make negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug (as such terms are defined in the December 2022 proposed rule, as updated by the November 2023 proposed rule).

Additionally, we also proposed in the November 2023 proposed rule a technical change to our proposed definition of ''corresponding drug'' in § 423.100 included in the December 2022 proposed rule to specify that the reference to an ''unbranded biological product of a biological product'' is intended to refer to ''an unbranded biological product marketed under the same BLA [Biologics License Application] as a brand name biological product.''

Lastly, we proposed in the November 2023 proposed rule to address a technical change to the regulatory text proposed in the December 2022 proposed rule to specify in introductory language to the § 423.100 proposed definition of ''maintenance change'' that maintenance changes apply with respect to ''a covered Part D drug.''

As discussed earlier, we noted in the November 2023 proposed rule that we intended to consider section III.Q. of the December 2022 proposed rule, as updated by the limited proposed changes discussed in that November 2023 proposed rule, for inclusion in future rulemaking. Even though we acknowledged in the November 2023 proposed rule at a high level some comments regarding the December 2022 proposed rule that informed the limited changes we proposed in the November 2023 proposed rule, we stated that if we were to move forward in future rulemaking, we would respond to comments received in response to section III.Q. of the December 2022 proposed rule, as well as comments received in response to the changes proposed in section III.F. of the November 2023 proposed rule. We summarize those comments, and our responses as follows:

Comment: Many commenters voiced general and specific support for the proposals both in the December 2022 and November 2023 proposed rules. Somewhat fewer commenters offered criticism, in whole or in part, including some commenters who generally supported the proposals but had concerns with specific parts.

Response: We thank supporters for their support and all commenters for providing us with their feedback. We address specific comments about the proposals in more detail below.

Comment: Several commenters supported that our proposal in the December 2022 proposed rule codified rules on formulary changes in one place, with a few appreciating the clarity. A few supporters also specifically supported certain proposed definitions such as ''negative formulary change''; ''maintenance change'' and ''non-maintenance change''; and ''affected enrollee.'' Conversely, a few commenters suggested that we change certain definitions (as discussed in specific comments and responses below). Another commenter stated that the policy was too complex and required streamlining rather than a discussion in two preambles, and suggested we use a chart and that we not only explain the relationship of our proposals to Chapter 6 of the Prescription Drug Benefit Manual [47] but also update that manual chapter. A few other commenters stated that the proposed regulation did not conform to the guidance in Chapter 6.

Response: We thank those commenters who supported our proposal and specific definitions. One of our major goals with this proposal was to codify in one place guidance that had long stood apart from related regulations and conform the two in a reorganized regulation. We acknowledge that the policy related to changes to an approved formulary has been and remains intricate and that the December 2022 proposed rule and November 2023 proposed rule addressed a wide range of issues related to formulary changes, including with respect to conforming current regulations and longstanding guidance, while proposing new policies (for example, related to substitutions of biosimilar biological products). We will take the chart suggestion under consideration for any future updates to guidance and Chapter 6, but we do not think that the final rule is the appropriate location for such a chart. Where there is a conflict between the regulations and the manual chapter, the regulations supersede and take precedence. We discuss substantive issues related to interpretations of manual guidance later in these responses.

Comment: A commenter stated that CMS should not distinguish between authorized generic drugs and unbranded biological products in formulary placement policy because they are approved or licensed (respectively) under the same New Drug Application (NDA) or BLA as the brand name drug and, other than the fact that they are not labeled with a brand name on their label, they are the branded product. A product that is identical in all respects because it is approved or licensed under the same NDA or BLA should not be considered a ''negative'' formulary change, immediate or otherwise.

Response: While the commenter is technically correct that we could look at formulary replacement of a branded drug product with its authorized generic or unbranded biological product, as applicable, as not being a formulary change at all, we do not think this would be a meaningful distinction for enrollees.

When an enrollee goes to the pharmacy, they would not know the difference between an authorized generic drug or a generic drug as those terms will be defined in § 423.4. Similarly, if the name changes from the branded biological product to an unbranded biological product licensed under the same BLA, an enrollee might not know the difference between the unbranded biological product and a biosimilar of the branded biological product. Consequently, to avoid enrollee confusion, we are finalizing a rule that treats all these replacements as substitutions.

Comment: A commenter thanked CMS for the steps we proposed to take to eliminate ''barriers'' for patients to access lower-cost treatment options by permitting plans to add biosimilar biological products to formularies as they become available, while another commenter suggested that requiring 30 days' notice before the effective date of maintenance changes was an unnecessary ''barrier'' to patients getting the exact treatment they need.

Response: There have never been any barriers to Part D sponsors adding at any time to their formularies any Part D drugs that they think their enrollees need for treatment (such as new biosimilar biological products) or from adding those drugs on lower cost-sharing tiers or with fewer restrictions than those that apply to related drugs already on the formulary (such as reference products). Our guidance in section 30.3.3.1 of Chapter 6 of the Prescription Drug Benefit Manual states that Part D sponsors may add any Part D drug to their formularies at any time. We note, however, that we have and continue to maintain approval and notice requirements that Part D sponsors must follow when they seek to remove

[47] *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.*

a drug or make negative formulary changes to drugs already on the formulary and that enrollees may currently be taking.

Comment: Several commenters stated we should not permit any midyear changes to formularies because enrollees enroll in plans with the expectation that they will have access to the same drugs for the entirety of the plan year and to permit any changes is tantamount to a bait and switch. A few commenters suggested that CMS should not permit any midyear formulary changes because enrollees cannot leave plans midyear, with one commenter requesting a special enrollment period (SEP) for enrollees to join other plans midyear following formulary changes.

Response: We do not agree that formularies should be static for the plan year. As discussed more fully in section III.Q.2.a. of the December 2022 proposed rule, section 1860D–4(b)(3)(E) of the Act itself contemplates that Part D sponsors may make changes to formularies during a plan year. For example, there is a need for certain changes to an approved formulary to reflect the availability of new drug therapies as well as for Part D sponsors to take advantage of opportunities to improve safety and quality and lower costs.

We understand that enrollees sign up for plans with the expectation of continued access to their drugs. Accordingly, we have established, and are codifying in this final rule, approval and notice requirements for different kinds of formulary changes. We are permitting the following changes to drugs currently provided on a formulary: (i) immediate substitutions of corresponding drugs, such as new generic drugs for brand name drugs and interchangeable biological products for reference products; (ii) immediate removal of drugs withdrawn from sale by their manufacturer or that FDA determines to be withdrawn for safety or effectiveness reasons; (iii) maintenance changes, which include substitutions of generic drugs for brand name drugs that are not being made on an immediate substitution basis; substitutions of interchangeable biological products for their reference products; and removals based on long term shortage and market availability; (iv) non-maintenance changes, which can only be made if CMS provides explicit approval and which do not apply to enrollees currently taking the applicable drug; and (v) enhancements to the formulary (for instance, Part D sponsors can add a drug to the formulary or lower its cost-sharing), which can be made at any time.

We believe these requirements strike the appropriate balance between protecting enrollees by ensuring they have adequate notice of changes to their plan's formulary, while ensuring Part D sponsors have the flexibility to ensure formularies reflect the latest market developments and clinical guidelines. We monitor negative change request submissions and changes to HPMS formularies as a matter of standard operations, and we are not aware of widespread complaints from beneficiaries stating they have been subject to formulary changes without proper notice. Part D sponsors submit all maintenance and non-maintenance changes to CMS for approval and, even if approved, non-maintenance changes do not apply to enrollees currently taking a drug for the remainder of the plan year. In addition, enrollees can avail themselves of the formulary exception process if the enrollee or their physician believes it is necessary that the enrollee remain on a drug that is subject to a midyear change. The request for a SEP based on a midyear formulary change is out of scope.

Comment: A few commenters specifically supported the time periods within which we required specific notice. A few other commenters pointed to the fact that section 30.3.4.1 of Chapter 6 of the Prescription Drug Benefit Manual requires 60 days' advance direct notice and asked that we conform any final regulation to that guidance.

Response: We appreciate commenters' support for the specific notice time periods that we proposed. Our intent in the December 2022 proposed rule was to codify much of our longstanding guidance. However, while Chapter 6 of the Prescription Drug Benefit Manual specifies a requirement for 60 days' advance direct notice, the current § 423.120(b)(5)(i) has required Part D sponsors to provide 30 days' notice rather than 60 days' notice for formulary changes since the effective date of the ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' final rule, which appeared in the April 16, 2018 **Federal Register** (hereinafter referred to as the April 2018 final rule). Where there is a conflict between the regulations and the manual chapter, the regulations supersede and take precedence. The same considerations for adopting a 30-day requirement that we discussed in the November 2017 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 56413) (hereafter referred to the November 2017 proposed rule), and which led us to finalize the April 2018 final rule, strike us as applicable today. Additionally, we have several years of operational experience with the requirements of the April 2018 final rule, for which we have not received widespread complaints.

As discussed in section II.A.14 of the November 2017 proposed rule, we believe the 30 days' notice provides the necessary beneficiary protections and affords enrollees sufficient time to either change to a covered alternative drug or to obtain needed prior authorization or an exception for the drug affected by the formulary change. CMS regulations establish robust beneficiary protections in the coverage determination and appeals processes. CMS requires at § 423.568(b) that standard coverage determinations are completed within 72 hours and at § 423.572(a) that expedited coverage determinations for exigent circumstances are completed within 24 hours. If an initial coverage determination is unfavorable, the enrollee or prescriber can request a standard redetermination, which in accordance with § 423.590(a) must be completed within 7 days of receipt of the request, or an expedited redetermination, which in accordance with § 423.590(d)(1) must be completed within 72 hours. (See a later response addressing comments supporting and opposing the advance direct notice requirements we would require for Part D sponsors seeking formulary to substitution of biosimilar biological products for reference products as maintenance changes.)

Comment: A commenter suggested that we no longer require any notification of immediate substitutions because it would be confusing to send a notice about a change that already took effect. In contrast, another commenter suggested that permitting sponsors to provide notice as late as almost two months after an immediate formulary substitution takes effect is too long a time period and asked that we not finalize the requirement to provide notice ''no later than the end of the month following any month in which a change takes effect.'' They suggested that such notice be provided on or before the effective date of the change. A few other commenters recommended that there should be advance direct notice for any changes made to a

formulary, including immediate substitutions.

Response: We disagree with the suggestion to do away entirely with requiring direct notice to affected enrollees of immediate substitutions. It is still important that affected enrollees learn about formulary changes made to the drugs they take, even in the context of immediate substitutions that may have already taken effect. For immediate substitutions, under proposed § 423.120(f)(2), and under current § 423.120(b)(5)(iv)(C), permitting immediate substitutions of generic drugs for brand name drugs, Part D sponsors must provide advance general notice in beneficiary communications materials describing the types of changes that can be made without giving advance direct notice of specific changes, including to enrollees currently taking a drug subject to substitution. Part D sponsors must specify in this advance general notice that affected enrollees will receive direct notice of any specific changes made to drugs they take, which may arrive after the change is effective, and that will explain steps they may take to request coverage determinations, including exceptions. Proposed § 423.120(f)(3) and current § 423.120(b)(5)(iv)(E) require that Part D sponsors provide retrospective direct notice to affected enrollees. Additionally, § 423.128(d)(2)(ii) requires Part D sponsors to update their online formulary monthly. However, we decline to require that notice be provided in advance or at the same time as the effective date of an immediate substitution. A central reason that we do not require advance direct notice of specific changes in these cases is to support and encourage Part D sponsors to add corresponding drugs to their formularies as soon as possible. We are not aware of a notable volume of enrollee complaints related to the notice requirements for immediate substitutions of generic drugs under the current § 423.120(b)(5)(iv), which we finalized in the April 2018 final rule to permit Part D sponsors to send retrospective direct notice of immediate generic substitutions to affected enrollees after such changes take effect. We do not believe that extending similar rules to immediate substitutions of authorized generics, interchangeable biological products, and unbranded biological products will have different results for enrollees and, therefore, we decline to change that regulation now or to require different notice requirements for immediate substitutions of products that qualify as corresponding drugs other than generics.

Comment: A commenter stated that there was a technical error in our definition of maintenance change proposed in § 423.100 because it failed to indicate that corresponding drugs must be newly available to align with sub-regulatory guidance at Chapter 6, section 30.3.3.1, of the Prescription Drug Benefit Manual, which the commentor interprets as requiring that maintenance changes involving brand-name drugs being substituted with generic drugs to be limited to newly available generic drugs only.

Response: The comment pointing to a technical error with respect to maintenance changes misinterprets our guidance. While section 30.3.3.1 of Chapter 6 provides an example of a maintenance change involving a new generic drug, our sub-regulatory guidance has not limited maintenance changes to only newly approved generic drugs. Notably, section 30.3.3.2 states that ''CMS will generally give positive consideration to the following types of formulary changes'' including ''[r]emoval or placement in a less preferred tier of a brand name drug upon the availability and addition of an A-rated generic or multi-source brand name equivalent, at a tier with lower cost to the beneficiary.'' It does not require that generic drugs added to the formulary as part of maintenance changes be newly available. However, to make an immediate substitution, the generic drug being added to the formulary must be newly available.[48] Although some sponsors might choose to make maintenance changes only to substitute newly marketed generics, we do not want to preclude sponsors from making maintenance changes to add generics that are not newly available because there are other appropriate factors that Part D sponsors could consider when determining when to make such formulary substitutions. For example, a Part D sponsor might not make a formulary substitution when a generic first becomes available on the market because there may not be a significant price difference between the first generic and brand name drug. However, as more generics are introduced to the market, the price of all generic drugs may decrease to the point a Part D sponsor could later decide a formulary change would be advantageous.

Comment: A few commenters supported all or parts of our proposal, as updated in the November 2023 proposed rule, to require Part D sponsors to remove, or otherwise apply a negative formulary change to, a brand name drug, reference product, or brand name biological product within 30 days of adding a corresponding drug as part of an immediate substitution (under proposed § 423.120(e)(2)(i)) or within 90 days of adding a corresponding drug or biosimilar biological product as part of a maintenance change (under subparagraphs (1) and (2), respectively, of the proposed § 423.100 definition of maintenance change). A few commenters did not support the change as proposed but had differing views on what the policy should be. One commenter stated that we must continue to require immediate substitutions to take place ''at the same time'' because there was no evidence that the existing requirement created a problem that needs to be fixed. A few other commenters asked that we provide more time than a 30- or 90-day window within which to apply a negative formulary change to a brand name drug or reference product after adding a corresponding drug or biosimilar biological product other than an interchangeable biological product to the formulary. Another commenter said that we should apply the same 90-day window to both types of changes because implementing different time frames within which to complete immediate substitutions and maintenance changes could be burdensome for Part D sponsors and confuse enrollees, pharmacies, and providers. Another commenter stated that the 30- and 90-day windows did not provide enough time for Part D sponsors to evaluate new products' attributes and availability in the marketplace, update systems, and consider market condition for pricing changes (for instance, whether a generic price will drop even more after additional entries). Another commenter asked that we monitor this flexibility on an annual basis to ensure providing more time to complete immediate substitutions would not permit Part D sponsors to game the system by delaying coverage for generic drugs.

Response: We appreciate comments on both sides of the issue. We think 30- and 90-day limits to make negative formulary changes after adding a drug as part of an immediate substitution or maintenance change under

[48] Section 423.120(b)(5)(iv) requires in part that, ''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.'' In the proposed regulatory reorganization, this requirement would appear at § 423.120(e)(2)(i) and would apply to immediate substitutions of corresponding drugs.

§ 423.120(e)(2)(i) or subparagraphs (1) and (2) of the definition of a maintenance change in § 423.100, respectively, are reasonable. As for evidence to support our proposal, we proposed these flexibilities in our November 2023 proposed rule in response to a comment we received in response to our December 2022 proposed rule that stated it was difficult to make substitutions ''at the same time''. The commenter suggested that while they could quickly add a drug to the formulary, before removing or making negative formulary changes to a drug currently on the formulary they needed time to, for instance, evaluate new product attributes such as formulation, interchangeability, and pricing; determine sufficient availability in the marketplace; communicate changes; and update systems. In response to our November 2023 proposed rule, the original commenter repeated its concerns and a couple of other commenters also asked for more time. Additionally, a couple of commenters specified that they supported the 90-day window. We believe these comments, as well as our appreciation of formulary management considerations and the practicalities of programming internal systems, provide sufficient evidence to support the proposed timeframes.

To respond to commenters to the November 2023 proposed rule that asked for longer times frames within which to make negative changes to the drug on the formulary, the purpose of immediate substitutions is to support quick action, in which Part D sponsors put a newer corresponding drug on the formulary right away and remove the drug it replaces as soon as possible. To encourage this quick action, we permit Part D sponsors implementing immediate substitutions to provide notice to affected enrollees of the specific changes after they have taken effect. For that reason, we continue to encourage that immediate substitutions take place ''at the same time.'' Extending the time within which to remove a brand name drug, brand name biological product, or reference product past 30 days would negate the concept of an ''immediate'' change.

While maintenance changes are not as urgent a matter, it would be challenging for CMS to monitor negative formulary changes that take place more than 90 days after adding a corresponding drug or biosimilar biological product other than an interchangeable biological product.[49] Further, the more days that pass after a Part D sponsor adds a replacement drug and before it removes or makes another other negative formulary change to the drug on the formulary it will replace, the more the two actions seem less like a substitution of one drug for another so much as two unrelated formulary changes.

In response to the concern that implementing different time frames to make immediate substitutions versus maintenance changes creates a burden for Part D sponsors, they are not required to take advantage of the flexibility offered. The respective 30- and 90-day timeframes to make a negative formulary change after adding a corresponding drug to the formulary are limits, not requirements. Under the proposal, a Part D sponsor could decide to ensure all immediate substitutions and maintenance changes take place ''at the same time.''

We have carefully considered the commenter's concern that implementing different windows could confuse enrollees, providers, and pharmacies. It is possible that Part D sponsors are currently removing brand name drugs after the date they add corresponding generic drugs. As discussed in our November 2023 proposed rule, there has been a longstanding operational limitation that Part D sponsors remove a brand name drug from the formulary within 90 days of adding a generic drug. We also do not believe that enrollees will be aware of the exact moment that a Part D sponsor decides to add a drug. Rather, affected enrollees will most likely learn that their plan will be making, or already has made, a formulary substitution either when they receive direct notice or request a refill on a brand name drug or reference product. We are not aware that the current limitation has resulted in undue confusion and do not expect that to be the case with this rule. We will also continue to review beneficiary complaints in our Complaint Tracking Module, should any complaints arise related to confusion about the different timeframes.

Lastly, we do not believe that monitoring immediate substitutions on an annual basis would provide a means to determine or address if Part D sponsors are gaming the system by delaying coverage for generic drugs because this provision has not and will not require Part D sponsors to offer generic drugs.

[49] Please note that the definition of corresponding drug in § 423.120 includes interchangeable biological products.

Comment: A commenter asked that we clarify whether we mean business or calendar days in all instances that apply a number of days to a requirement.

Response: For regulations related to notice and approval of changes to approved formularies, any requirements that refer to days are a reference to calendar days. This includes § 423.120(b)(5) and (6) and proposed (e) and (f) and related definitions including ''maintenance changes'' as defined in § 423.100. We believe the use of calendar days for regulations related to notice and approval of changes to approved formularies is appropriate because they are easier for CMS, plan sponsors, enrollees, and others to track.

Comment: Several commenters stated that maintenance changes did not require prior approval from CMS, with a commenter characterizing such changes as ''near-immediate.''

Response: While it is technically true that Part D sponsors may not receive explicit notice of approval of a negative change request for a maintenance change, the proposed § 423.120(e)(3)(i) would codify longstanding sub-regulatory guidance from Chapter 6, section 30.3.3.2, of the Prescription Drug Benefit Manual, under which Part D sponsors may assume a maintenance change request has been approved if they do not hear from CMS within 30 days of submission. This is in contrast to our longstanding policy for non-maintenance changes, which we proposed to codify at § 423.120(e)(3)(ii), under which Part D sponsors must not implement non-maintenance changes until they receive explicit notice of approval of the negative change request from CMS. Regardless of whether approval can be assumed after a period of time, contrary to the commenters' assertions, both longstanding guidance and our proposal require Part D sponsors to submit maintenance and non-maintenance change requests to CMS for approval. Moreover, it is important to note that approval of maintenance changes is not automatic. While we noted in our preamble to the November 2023 proposed rule that most such requests are routinely approved, CMS endeavors to review all requests and we have denied maintenance change requests, albeit infrequently, before the end of the 30-day approval period. Furthermore, we have instituted edits within the HPMS Negative Change Request module which can raise flags on issues that require our review or in some cases will prevent Part D sponsors from submitting a negative change request that would not meet CMS requirements. Lastly, should a Part D sponsor make a change to their HPMS

formulary file that is inconsistent with an approved (or assumed approved) negative change request, CMS may deny the formulary change via the line-level review process.

Comment: A couple of commenters asked CMS to expand the proposed definition of maintenance changes to include as additional categories of maintenance changes (1) applying PA to exclude non-Part D drugs or to reflect new indications or (2) placing PA or ST on protected class drugs specified under section 1860D–4(b)(3)(G)(iv) of the Act to ensure they are used for protected indications. Another commenter requested that CMS allow prescribers to continue to prescribe the reference product to an enrollee currently taking the affected product without a lengthy prior authorization requirement.

Response: We did not propose to permit the midyear addition of PA to prevent use of drugs for excluded uses, when a new indication is approved, or to permit Part D sponsors to cover only protected indications for protected class drugs. We appreciate commenters raising these issues, and we may take some of these suggestions into consideration for future rulemaking. Generally, we expect Part D sponsors to submit such PA or ST requirements for review and approval with their annual formulary submissions. Additionally, under current policy, Part D sponsors can submit these types of requests midyear as non-maintenance change requests for consideration by CMS. In the absence of a PA requirement on a particular drug, Part D plans may conduct retrospective review under § 423.153(c)(3) to confirm that a dispensed drug is being used for a medically accepted indication. We note that non-protected indications for protected class drugs are not excluded from Part D coverage as long as the use is for a medically accepted indication, as defined in section 1860D–2(e)(4) of the Act.

Our intent is to allow Part D sponsors to promote utilization of biosimilar biological products. We believe the current PA process continues to be the appropriate mechanism for providers to provide the necessary justification for continuing on a reference product.

Comment: A few commenters offered divergent views on our proposal that the list of alternative drugs, which we require under the current § 423.120(b)(5)(ii)(D) to be provided as part of the written notice of a formulary change, no longer be limited under our proposed § 423.120(f)(4)(iv) to alternative drugs in the same therapeutic category or class as the drug to which the negative formulary change applies. A couple of commenters were concerned that Part D plans would use this flexibility to switch patients under the immediate substitution rules to drugs with different forms or modes of therapeutic action. In contrast, a supporter noted that drugs may span multiple therapeutic categories and appreciated the extra flexibility provided for Part D sponsors to negotiate discounts and reduce overall prescription drug spending. Another supporter asked that we permit clinical experts outside of the P&T committee to identify appropriate formulary alternatives because P&T committees only meet quarterly.

Response: We appreciate commenters' support. For commenters that did not support our proposed policy, we clarify that the current requirement that Part D sponsors list alternative drugs in § 423.120(b)(5)(ii)(D) addresses a different topic than does the current regulation § 423.120(b)(5)(iv), which specifies drugs that can be immediately substituted. Section 423.120(b)(5)(ii) addresses the content that must be included in notices of change—including a list of alternatives—but, contrary to the commenters' suggestions, does not govern what types of drugs can be substituted or the conditions for making such changes. Rather, § 423.120(b)(5)(iv) governs what types of drugs can be immediately substituted and the conditions for making such changes.

While § 423.120(b)(5)(ii) does not govern the types of drugs that can be substituted, it requires Part D sponsors to list alternatives. We believe provision of this list could affect treatment in that it might provide alternatives that an enrollee and their provider have not considered, or steer the enrollee to certain drugs on that list given their coverage on their formulary. An enrollee and their provider can consider the list of alternatives to the drug that is being removed or otherwise subject to a negative formulary change as they decide whether to try the new drug added to the formulary, try another drug that appears on the list of alternatives, or to request an exception for coverage of the removed drug. As we noted in our proposal, there can be multiple drug options to treat the same condition and we believe that the list of alternatives should not limit possibilities of treatment by a strict adherence to class and category, particularly since Part D sponsors are not required to use a particular classification system for their Part D formularies. Therefore, we are finalizing § 423.120(f)(4)(iv) as proposed.

As to the question regarding who can determine what drug alternatives exist, we do not believe it is appropriate for Part D sponsors to outsource consideration of formulary alternatives to clinical experts outside of the P&T committee. Section 423.120(b)(1) specifies that a P&T committee must develop and revise the formulary. Applying a negative formulary change to a drug is a formulary revision, and we believe that consideration of the formulary in its entirety is part and parcel of any formulary revision decision. We do not see how, for example, a decision could be made to remove or apply utilization management restrictions to a drug without examining which drugs are being added to or are already on the formulary that could treat the same conditions as the drug subject to the negative formulary change.

Comment: A couple of commenters supported our proposal in the December 2022 proposed rule to identify § 423.120(e)(2)(i) as the successor regulation to § 423.120(b)(5)(iv) under section 1860D–4(b)(3)(I)(ii) of the Act, as added by the IRA. Another commenter asked us to clarify expectations for when a Part D drug that is a selected drug under section 11001 of the IRA is removed from the formulary and give plans the flexibility to determine lowest price on a drug-by-drug basis.

Response: We thank the commenters for their support. Section 1860D–4(b)(3)(I)(i) of the Act requires Part D sponsors to include on their formularies each covered Part D drug that is a selected drug under section 1192 of the Act for which a maximum fair price is in effect with respect to the plan year. Because maximum fair prices will not take effect until 2026, the formulary inclusion requirement in section 1860D–4(b)(3)(I)(i) of the Act does not apply in 2025. As a result, we are not finalizing the proposed language in § 423.120(b)(5) to identify a successor regulation for purposes of section 1860D–4(b)(3)(I)(ii) of the Act at this time.

It is not within the scope of this provision on formulary changes to address the request for flexibility to determine the lowest price of the drug.

Comment: A commenter pointed out that our regulation assumes all enrollees receive and comprehend notices of midyear formulary changes, whereas in reality enrollees may experience low health literacy, language barriers, or cognitive impairments that impede their understanding of such notices. Furthermore, the commenter noted that enrollees from socioeconomically disadvantaged communities and those experiencing major health challenges

such as rare diseases may not be capable of navigating the exceptions process. The commenter suggested that, by ignoring health disparities, our proposed policy for formulary substitution of biosimilar biological products as maintenance changes could cause disproportionate harm to vulnerable patient communities.

Response: We certainly appreciate that the health care system, along with all its complexities, presents significant challenges for those experiencing health care and other disparities. CMS continues to take action to address those disparities. However, we do not believe that our biosimilar biological product policy on maintenance changes widens health care disparities. In fact, our intent is quite the opposite. For example, if this proposal improves access to more biosimilar biological products in the Part D program, it could lead to greater utilization of lower price biosimilar biological products that have been determined by FDA to be just as safe and effective as their reference products.

CMS has implemented various requirements to help protect enrollees, address disparities, and mitigate confusion and burdens for enrollees, especially those with low health literacy, language barriers, and cognitive and other health care impairments. For example, under § 423.2267(a), we require Part D sponsors to provide: translated materials proactively in any non-English language that at least 5 percent of the beneficiaries in their service area speak, and materials in alternative formats (such as recordings and braille) to beneficiaries who are visually impaired. Furthermore, pursuant to § 423.128(d), we require all plans to have call centers to respond to current and prospective enrollee requests for assistance, and § 423.128(d)(1)(iii) also requires Part D sponsors to provide interpreters for non-English speaking and limited English proficient (LEP) individuals at their call centers. States also have established State Health Insurance Assistance Programs (SHIPs) that can assist enrollees in navigating their options. Enrollees can also designate a person to speak to plans on their behalf.

Comment: A commenter requested that we permit Part D sponsors to immediately substitute a brand name drug for an authorized generic, and an authorized generic drug for a generic drug, including within the same plan year. Another commenter asked that we make clear there could be only one maintenance change for a reference product within a single plan year to avoid confusion and potential disruption of care. A few other commenters asked us either to clarify or make sure that § 423.120(e)(2)(i) only permitted substitution of an interchangeable biological product for a reference product and not substitution of an interchangeable biological product for another interchangeable biological product that has the same reference product. Another commenter asked that we clarify that maintenance changes would only be allowed for biosimilar biological products for their reference products and not among different biosimilar biological products that have the same reference product. Without identifying them all, a commenter asked for guidance specific to 36 different permutations of formulary change types it counted among branded and unbranded versions of reference products and biosimilar biological products. In contrast, another commenter asked generally how Part D sponsors should treat enrollees taking a biosimilar biological product that is not the biosimilar biological product that is covered by the plan.

Response: We would not permit the immediate substitution of a brand name drug for an authorized generic (that is, applying a negative formulary change to an authorized generic already on the formulary and adding a brand name drug to the formulary). Our proposed regulation is not written to support that substitution. The proposed § 423.120(e)(2)(i) allows Part D sponsors to apply immediate negative formulary changes to a ''brand name drug. . . . within 30 days of adding a corresponding drug.'' The proposed definition of ''corresponding drug'' in § 423.100 refers in part to ''a generic or authorized generic of a brand name drug.'' Therefore, an immediate substitution would not allow a Part D sponsor to make a negative formulary change to an authorized generic within 30 days of adding a brand name drug. We do not support modifying our proposal in this way because the intent of our generic substitution policy is to encourage plans to make substitutions as soon as new generic drugs or authorized generic drugs are marketed to provide beneficiaries with access to lower cost therapeutically equivalent drugs. Moreover, it is unlikely that a brand name drug would be marketed after an authorized generic and, therefore, it would not fit within the structure of our proposed regulation, which contemplates the substitution within the plan year of a brand name drug to be removed or subject to a negative formulary change with a drug that is marketed (after CMS approves an initial formulary).

Likewise, our proposed regulation would not permit Part D sponsors to immediately substitute a generic for an authorized generic or an authorized generic for a generic as an immediate substitution under § 423.120(e)(2)(i). Nevertheless, an authorized generic and a generic of the same brand name drug generally are represented by the same RxCUI, as assigned by the National Library of Medicine's RxNorm.[50] In other words, one RxCUI can represent multiple NDCs. As more NDCs become available and assigned to an RxCUI, to the extent there is not a different RxCUI to submit on the formulary file, Part D sponsors cannot submit NDC-specific formulary changes in the HPMS system. Further, we note that it is not inconsistent with CMS policy for Part D sponsors not to cover every NDC associated with an RxCUI for a generic drug. Accordingly, a Part D sponsor can adjust which NDCs for a generic drug and authorized generic of the same brand name reference drug are covered on its formulary in a manner that would not be considered a formulary change subject to the requirements of this final rule.

With respect to interchangeable biological products, the proposed § 423.120(e)(2)(i) likewise would not permit immediate substitutions among interchangeable biological products—that is, we would not permit Part D sponsors to immediately substitute an interchangeable biological product for another interchangeable biological product as an immediate substitution under § 423.120(e)(2)(i). This is because § 423.120(e)(2)(i) would be limited to immediate substitutions of interchangeable biological products for their reference products, not for other interchangeable biological products that may be interchangeable with the same reference product. However, in contrast to generic drugs and authorized generic drugs of the same brand name drug sharing the same RxCUI, every biosimilar biological product is assigned its own distinct RxCUI. Therefore, a Part D sponsor cannot adjust which NDCs for interchangeable biological products with the same reference product are covered on its formulary in a manner that would not be considered a formulary change subject to the requirements of this rule. We believe this is in line with FDA's approach that approves biosimilar biological products in relation to reference products. For instance, our definition of a ''biosimilar

[50] *https://www.nlm.nih.gov/research/umls/rxnorm/overview.html.*

biological product'' at § 423.4 cites section 351(i)(2) of the PHSA (42 U.S.C. 262(i)(2)), which establishes similarity of a biological product compared to the reference product and not with respect to other biosimilar biological products. Similarly, our definition of an ''interchangeable biological product'' at § 423.4 cites section 351(k)(4) of the PHSA (42 U.S.C. 262(k)(4)), which provides that interchangeability is determined with respect to a reference product and not with respect to other interchangeable biological products.

Our proposed definition of a maintenance change at § 423.100 would not permit substitutions among biosimilar biological products that share a reference product as maintenance changes, nor would our proposed definition of immediate substitutions at § 423.120(e)(2)(i) permit maintenance changes among interchangeable biological products that share a reference product. For interchangeable biological products, § 423.100 would define a maintenance change at subparagraph (1) as making any negative formulary change to a drug within 90 days of adding a corresponding drug as specified. Section 423.100 would define a corresponding drug to include ''an interchangeable biological product of a reference product''. For biosimilar biological products other than interchangeable biological products, § 423.100 would define a maintenance change at subparagraph (2) as ''making any negative formulary changes to a reference product within 90 days of adding a biosimilar biological product other than an interchangeable biological product of that reference product.'' This definition does not include making negative formulary changes to a biosimilar biological product after adding a different biosimilar biological product for the same reference product.

With respect to the commenter's question about how to treat enrollees taking a biosimilar biological product that is not the biosimilar biological product on the formulary, this situation would be treated the same as any other situation where an enrollee is taking a non-formulary drug. If the plan only has biosimilar biological product A on the formulary and then an enrollee who has been taking biosimilar biological product B enrolls in the plan, the enrollee would need a new prescription for the biosimilar biological product A.

We do not prohibit multiple maintenance changes with respect to the same drug within the same plan year, and our review process considers each such request on its own merit. We think multiple maintenance changes within the same year would be rare given the type of changes we allow but not impossible. For example, a plan may add a therapeutically equivalent generic drug to the formulary and add a PA to the brand name drug. If the brand name drug then becomes subject to a long-term shortage, a maintenance change to remove the brand name drug from the formulary altogether may be appropriate.

It is beyond the scope of this regulation to address every hypothetical scenario provided by the commenter, but we will take them into account when providing guidance in the future.

Finally, we note that, regardless of whether Part D sponsors are permitted to replace an existing drug, they can always add the generic or authorized generic, or biosimilar biological product or unbranded biological product, to their formulary.

Comment: Several commenters, including a few concerned only about the proposed expansion of immediate substitutions to include interchangeable biological products for reference products, asked that we require transition supplies for immediate substitutions, including for some generic substitutions of brand name drugs. Additionally, a few commenters, including commenters concerned that we would now permit as maintenance changes substitution of biosimilar biological products other than interchangeable biosimilar biological products for reference products, asked that we require Part D sponsors to provide transition supplies for midyear maintenance changes. A commenter asked that we explain how our rules apply to hypothetical transition scenarios.

Response: We do not agree with the commenters asking us to apply the transition process to immediate substitutions or maintenance changes. The current § 423.120(b)(3) provides that Part D sponsors must provide a transition process for specified enrollees. In the April 2018 final rule, we finalized the current § 423.120(b)(3)(i)(B) to provide that Part D sponsors do not need to provide a transition supply when a Part D sponsor immediately substitutes a generic drug for a brand name drug under § 423.120(b)(5)(iv). We are not aware of widespread complaints regarding this policy and therefore do not see a reason to undo a policy that has been in place for several years or to apply different rules to other kinds of immediate substitutions or to maintenance changes permitted under this proposal.

In the December 2022 proposed rule, we proposed to move the current regulation on immediate generic substitutions, § 423.120(b)(5)(iv), to § 423.120(e)(2)(i) and to expand it to include among other products, interchangeable biosimilar biological products. We also proposed in the December 2022 proposed rule to change the reference in § 423.120(b)(3)(i)(B) to now refer to § 423.120(e)(2), which would mean we would not require Part D sponsors to provide a transition supply, for instance, when replacing a reference product with an interchangeable biological product within the requirements of § 423.120(e)(2)(i). Similar to our decision in the April 2018 final rule not to provide transition supplies for immediate generic substitutions under § 423.120(b)(5)(iv), we are not convinced there is a need to require transition supplies for immediate substitutions of interchangeable biological products, authorized generics, or unbranded biological products under the proposed § 423.120(e)(2)(i). Requiring transition supplies for one type of immediate substitution but not others would introduce an unnecessary level of operational complexity for Part D sponsors and inconsistent policies.

With respect to requiring transition supplies for maintenance changes, we did not propose to change the existing transition policy. Maintenance changes require 30 days advance notice to affected enrollees under § 423.120(f)(1). That 30 days' advance notice serves the same function as the transition policy to provide affected enrollees time to consider a formulary alternative or pursue a formulary or tiering exception for the drug they are taking that will be subject to the negative formulary change. As a reminder, the transition regulation at § 423.120(b)(3)(i)(B) requires 30 days' notice and a month's supply. Similarly, affected enrollees getting 30 days advance notice of a maintenance change who have refills or obtain a new prescription can go to the pharmacy and request a refill before the maintenance change becomes effective.

It is beyond the scope of this regulation to address every hypothetical transition scenario, but we will take them into account when providing guidance in the future to reflect regulatory changes.

Comment: While many commenters generally supported greater use of biosimilar biological products, they were generally divided into three main groups regarding our specific proposals relating to biosimilar biological product substitutions (which we mean to describe generally as a formulary change in which a Part D sponsor would add a biosimilar biological product and either

remove or apply a negative formulary change to its reference product).

The first group of commenters supported some or all of our specific proposals regarding biosimilar biological product substitutions, under which we would permit immediate substitutions of interchangeable biological products for their reference products under proposed § 423.120(e)(2)(i) and also permit Part D sponsors to treat as maintenance changes all biosimilar biological product substitutions under subparagraphs (1) and (2) of the definition of maintenance changes proposed in § 423.100. They stated, for instance, that the proposed policies would result in more uptake of biosimilar biological products by switching enrollees taking reference products to biosimilar biological products, a move they felt could improve the overall affordability of the Part D program to enrollees due to the lower cost of biosimilar biological products as compared to reference products. They stated, for instance, that because a distinction is made between interchangeable biological products and biosimilar biological products other than interchangeable biological products, with respect to pharmacy-level substitutions, CMS had struck the right balance by proposing to provide 30 days' advance notice to enrollees to get a new prescription or to ask for an exception before a Part D sponsor substitutes a biosimilar biological product other than an interchangeable biological product for their reference product.

The second group of commenters did not support some or all of the proposed flexibilities for biosimilar biological product substitutions to occur as immediate substitutions or maintenance changes, including interchangeable biological products. These commenters stated, for instance, that switching from biosimilar biological products to reference products was not the same as switching from generic drugs to brand name drugs and that any biosimilar biological product substitutions could disrupt patient treatment. They posited that biosimilar biological products, being complex molecules made from living organisms, are different than small molecule drugs that are chemically synthesized and that even minor differences in manufacturing processes could cause variations leading to clinical differences in a given patient's experience or reaction. They pointed out that biosimilar biological products are often used to treat patients with complex chronic conditions, whom they believe would be less well prepared to deal with adverse effects resulting from changes to the drugs they take.

The final group of commenters did not feel CMS went far enough in providing flexibilities to promote greater use of biosimilar biological products and recommended that we permit immediate substitutions of all biosimilar biological products regardless of whether they are licensed as interchangeable biological products or not. They pointed to the fact that FDA had found all biosimilar biological products to be highly similar and to have no clinically meaningful differences from reference products in safety and effectiveness and pointed out that FDA's recently proposed labeling changes would reduce the visibility of a product's interchangeability status. These commenters stated that interchangeability is only meaningful in that it allows substitution at the pharmacy counter. A commenter stated that treating biosimilar biological products other than interchangeable biological products as maintenance changes would not go far enough to make a major difference in terms of savings because the regulation would still require 30 days' advance notice, time in which the product could already have been switched. A few of these commenters acknowledged that if we did not move towards more flexibility, they supported what we had proposed.

Response: We appreciate the time all commenters took to explain many different points of view regarding biosimilar biological products, which are a relatively new category of products on the market. We appreciate the first group of commenters who supported our proposals to permit immediate substitutions of interchangeable biological products and maintenance changes of all biosimilar biological products. As explained in section III.F.2.b.(1) of the November 2023 proposed rule, our proposal accounts for the current PHSA delineation between interchangeable biological products, which may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product (also called pharmacy-level substitution), and biosimilar biological products which do not meet the standards for interchangeability. However, substitution in terms of the conditions and requirements that must be met for a pharmacist to dispense a biosimilar biological product in place of its reference product without a new prescription is subject to state pharmacy law. Our review of state requirements with respect to pharmacy-level substitutions involving biosimilar biological products indicates that currently states overwhelmingly require that a biosimilar biological product is an interchangeable biological product for a pharmacist to make such a substitution for a reference product without the intervention of the health care provider who prescribed the reference product, among other conditions and requirements.[51] [52] [53] Our goal is to promote greater use of biosimilar biological products, and for that reason we expanded our original December 2022 proposal in the November 2023 proposed rule to include as maintenance changes substitutions of biosimilar biological products other than interchangeable biological products for their reference products. Since in most cases a pharmacist would not be permitted to make a pharmacy-level substitution involving biosimilar biological products other than interchangeable biological products without the intervention of the prescriber, we maintain our decision that substitutions of biosimilar biological products other than interchangeable biological products should be maintenance changes with 30-days advance notice to provide enrollees with time to obtain new prescriptions for the biosimilar biological products other than interchangeable biological products or obtain formulary exceptions for the reference products.

We do not agree with commenters in the second group that did not support permitting any formulary changes for biosimilar biological products. We believe that the emerging biosimilars market provides too great an opportunity for potential savings and that prohibiting plan sponsors from making such formulary changes would fail to acknowledge FDA determinations that such products are as safe and effective as their reference products and could discourage greater use of biosimilar biological products.

As to the last group of commenters, we disagree that our proposals did not go far enough in providing plan sponsors with flexibilities to promote greater use of biosimilar biological products. With respect to the comment that treating formulary substitutions for reference products of biosimilar

[51] *https://www.cardinalhealth.com/content/dam/corp/web/documents/publication/Cardinal-Health-Biosimilar-Interchangeability-Laws-by-State.pdf.*

[52] *https://www.mintz.com/sites/default/files/media/documents/2019-02-08/State%20Legislation%20on%20Biosimilars.pdf* n.

[53] *https://www.nacds.org/pdfs/government/2021/State-Substitution-Practices-for-Biological-Drugs-chart-July-2021.pdf.*

biological products other than interchangeable biological products as maintenance changes would not make much of a difference in savings, we note that our proposed policy is still a significant change from our current sub-regulatory policy. Current policy treats biosimilar biological product substitutions as non-maintenance changes, and exempts such biosimilar biological product substitutions from applying to enrollees currently taking an affected drug for the remainder of the plan year, which limits the potential cost savings of any such formulary change.

Comment: A commenter specifically supported our definition of ''biosimilar biological product.'' A few commenters each respectively asked that we: (i) revise the definition of ''unbranded biological product'' in our proposed § 423.4 to be modeled on the definition of ''authorized generic drug'' found in section 505(t) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)), which includes a description of distribution; (ii) provide an explanation of the meaning of the word ''potency'' as used in our proposed definition of a ''biosimilar biological product'' in § 423.4; and (iii) revise our definition in § 423.4 to define ''interchangeable biological product'' in order that it resemble the statutory definition in 42 U.S.C. 262(i)(3). Another commenter asked that we add biological products to the existing definition of ''brand drug'' in § 423.4 (more precisely, ''brand name drug'') to be more like our current definition of ''covered Part D drug'' in § 423.100 includes both small molecule drugs and biological products.

Response: While we appreciate the comments, we disagree with the suggestions to change our proposed definitions. Specifically, we are not revising the proposed definition of ''unbranded biological product'' to conform it to a statutory definition of ''authorized generic drug.'' Our proposed definition is consistent with how the FDA considers the unbranded biological product to be the same product as the brand name biological product, but marketed without the brand name on its label.[54] Nor do we think it is necessary for the purpose of CMS regulations to redefine what potency means for ''biosimilar biological products.''

We are persuaded to revise our proposed definition of ''interchangeable biological product'' in § 423.4 to include language that links the standards described in 42 U.S.C. 262(k)(4) to the definition of interchangeability at 42 U.S.C. 262(i)(3), since this is more descriptive while maintaining the accuracy of the proposed definition. We will therefore modify our proposed definition of ''interchangeable biological product'' in this final rule by adding the following language to the end: ''which in accordance with section 351(i)(3) of the Public Health Service Act (42 U.S.C. 262(i)(3)), may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.''

We decline to revise our definition of brand name drug given that we are finalizing a definition of ''brand name biological product'' in § 423.4, as proposed.

Comment: Several commenters who did not agree with our policy proposals contended that CMS was undermining the work of the FDA. For instance, a commenter stated that it is the role of FDA to decide what biosimilar biological products are interchangeable. In their opinion, if CMS were to permit Part D plans to substitute any biosimilar regardless of a determination of interchangeability, this is tantamount to disregarding the distinction between interchangeable biological products and biosimilars other than interchangeable biological products as set forth in the PHSA. On the other hand, several commenters that supported our proposed policies believed our policies were consistent with those of FDA. Several commenters on all sides of the issue looked to FDA publications and studies to support their positions, with a few citing the Biologics Price Competition and Innovation Act (BPCIA) or the PHSA. A few commenters also asked CMS to work with FDA, and one commenter specifically requested that the two agencies come to a consensus on the definitions and data surrounding biosimilarity and interchangeability, and the need for any more studies to support interchangeability determinations.

Response: We disagree that our proposals interfere with FDA's review of biosimilar biological products. CMS, among other things, works in partnership with the entire health care community to improve quality, equity, and outcomes in the health care system.[55] This includes regulation of Part D sponsors. FDA's mission, among other things, is to protect the public health by assuring the safety, efficacy, and security of human drugs and biological products.[56] It has long been the case that both agencies have had overlap on some issues, and both agencies have undertaken complementary initiatives under the Executive Order on Promoting Competition in the American Economy (E.O. 14306). Examples of such initiatives include FDA's work to continue to clarify and improve the approval framework for generic drugs and biosimilar biological products to make generic drug and biosimilar biological product approval more transparent, efficient, and predictable, including improving and clarifying the standards for interchangeability of biological products, as well as CMS's efforts to prepare for Medicare and Medicaid coverage of interchangeable biological products, and to develop payment models to support increased utilization of generic drugs and biosimilar biological products. This work includes issuing regulations codifying definitions specific to our missions and authorities. The policies being finalized in this rule are appropriate for the needs of the Part D program.

Comment: A commenter questioned the underlying premise for our proposed policies, noting that, as compared to brand name drugs and generics, biosimilar biological products were not priced at a significant savings from their reference products. Another commenter stated that treating substitutions of reference products with biosimilar biological products other than interchangeable biological products as maintenance changes would not make a major difference in terms of the uptake of biosimilar biological products because it would not cause manufacturers of reference products to provide lower prices or increase rebates. Another commenter posited that providing more flexibilities for biosimilar biological products other than interchangeable biological products could dampen manufacturer innovation by reducing the incentive to devote additional time and resources to interchangeable product development.

[54] See FAQ #11: How are ''unbranded biologics'' displayed in the Purple Book? *https://purplebooksearch.fda.gov/faqs#11.*

[55] *https://www.cms.gov/about-cms#:~:text=CMS%20is%20the%20federal%20agency,in%20the%20health%20care%20system.* ''CMS is the federal agency that provides health coverage to more than 160 million through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS works in partnership with the entire health care community to improve quality, equity and outcomes in the health care system.''

[56] *https://www.fda.gov/about-fda/what-we-do#mission* ''The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.''

Lastly, another commenter did not support our policy on the basis that allowing Part D sponsors to remove reference products from their formularies removes incentives for the biosimilar biological product to compete on price and could harm biologic competition, especially when only one or a few biosimilar biological products are currently on the market.

Response: These comments highlight a variety of factors that may influence the biological product market, but we do not speculate on every potential downstream effect of our proposal to permit substitutions of biosimilar biological products other than interchangeable biological products as maintenance changes. It is up to Part D sponsors to negotiate with manufacturers, and section 1860D–11(i) of the Act generally prohibits the Secretary from interfering with those negotiations. We believe that it is in the interest of the Part D program and Medicare beneficiaries to provide Part D sponsors with flexibilities that can be leveraged in negotiations with manufacturers to reduce costs to the government and Medicare beneficiaries. While we cannot estimate savings for our proposals with any certainty or predict whether fewer or more manufacturers will produce interchangeable biological products in the future, we clarify that the intent of this specific proposal has never been to affect decisions by manufacturers. Rather our goal is to promote greater access to and utilization of biosimilar biological products by providing more flexibility for Part D sponsors to substitute them for reference products than had previously been permitted. The introduction of biosimilar biological products to the market is relatively recent compared to generic small molecule drugs. We believe there is a potential for savings to the Medicare Trust Fund in the long term as acceptance of biosimilar biological products grows and increased competition drives down costs.

Comment: A commenter pointed out that CMS stated in the December 2022 proposed rule at pages 79536–7 with respect to another proposal on midyear benefit changes that such midyear changes violate uniformity and integrity of bids. A few commenters pointed out that we had stated in our December 2022 proposed rule that it was not appropriate to immediately substitute biosimilar biological products other than interchangeable biological products, and one commenter noted that we indicated in the April 2018 final rule that it could cause confusion if we were to define generic drugs to include biosimilar biological products. Pointing out that nothing had changed since that time, these commenters suggested we had no support to undertake what they reviewed as a reversal in policy.

Response: The commenter failed to note that in the December 2022 proposed rule, we drew a distinction between changes in ''bid-level'' cost sharing (for example, the cost sharing associated with an entire tier of drugs) and changes in the cost sharing for an individual drug (for example, when such drug moves from one tier to another). That discussion in the December 2022 proposed rule explained that section 1860D–4(b)(3)(E) of the Act contemplates that there will be midyear changes in cost sharing of individual formulary drugs. Since the beginning of the Part D program, we have allowed formulary changes that result in changes to the cost sharing for individual drugs (for example, moving a single drug to a different cost-sharing tier), but have declined to permit Part D sponsors to change their benefit designs or waive or reduce premiums, ''bid-level'' cost sharing (for example, the cost sharing associated with an entire tier of drugs), or cost sharing (for some or all enrollees) once plans are permitted to market for the following contract year (on October 1, consistent with § 423.2263(a)) on the grounds that such activities would be inconsistent with the CMS-approved bid.

We do not believe our previously finalized policies are inconsistent with our proposal to permit substitution of biosimilar biological products other than interchangeable biological products as maintenance changes. In the December 2022 proposed rule, we stated that we were not permitting the immediate substitution of biosimilar biological products other than interchangeable biological products as immediate substitutions, and our proposals in the November 2023 proposed rule did not propose to permit such immediate substitutions. (See the November 2023 proposed rule at III.F.2.(b)(1) for a detailed discussion.) In our April 2018 final rule, we noted that, to avoid confusion, we were not finalizing a proposed rule regarding the similar treatment of biosimilar biological products and generic drugs for purposes of LIS cost-sharing. We do not believe a concern about avoiding confusion in 2018 with respect to the separate issue of LIS cost-sharing is relevant to the policy proposals in our December 2022 and November 2023 proposed rules that involve the same type of products but in a different context.

We do not believe that finalizing our proposals regarding formulary substitution of biosimilar biological products precludes us from revisiting these policies in the future. Of course, in such instances, as is the case anytime that we feel it necessary to revisit regulatory policy, we would carefully consider all factors and issue proposals through rulemaking subject to public comment and response.

We also note we are finalizing our proposals to provide safeguards to mitigate potential confusion, including a requirement that Part D sponsors provide 30 days' advance notice requirement for substitutions of biosimilar biological products other than interchangeable biological products.

Comment: Several commenters requested that we exempt enrollees currently taking a reference product if we finalize a policy that permits Part D sponsors to treat as maintenance changes formulary substitutions of biosimilar biological products other than interchangeable biological products for reference products.

Response: We disagree with these commenters. As noted earlier, we believe the right course of action is to treat such substitutions as maintenance changes. These commenters appeared to support the feature of our current sub-regulatory policy on non-maintenance changes that exempts enrollees currently taking an affected product for the remainder of the plan year from substitution of reference products by biosimilar biological products other than interchangeable biological products. However, the non-maintenance policy also requires Part D sponsors to obtain explicit approval of such changes from CMS. We believe that to continue to require every Part D sponsor that seeks to substitute a biosimilar biological product other than an interchangeable biological product for a reference product to wait to obtain explicit permission before making any change and to continue to exempt enrollees currently taking the reference product would be counter to the goal of promoting the utilization of biosimilar biological products. Additionally, as noted previously in this section, the 30-day advance notice timeframe affords enrollees sufficient time to change to a covered alternative drug which could include biological products; to get a refill of the reference product to be replaced; or to obtain needed prior authorization or an exception for the reference product affected by the formulary change. Affected enrollees may still be able to access the reference

product through the plan's coverage determination and exceptions process.

Comment: Many commenters opposed ''non-medical switching'' formulary changes that are based on payer mandated reasons other than strict medical necessity (such as cost and coverage reasons). They stated that permitting biosimilar biological product substitutions for enrollees who are stable on reference products would disrupt treatment and undermine the doctor-patient relationship and central role of prescribers in determining the best course of treatment, leading to poor health outcomes and exacerbating health care disparities. Several commenters opposed to the proposal noted that biosimilar biological product substitutions could disrupt patient care or result in unexpected cost sharing. One commenter suggested that rather than finalizing this proposal, CMS should focus on policies that empower physicians when partnering with their patients, such as expanded access to real-time benefit tool (RTBT) use. A few commenters asked us to require Part D sponsors to send notice of specific changes to the prescribers of affected enrollees. Several commenters also noted the importance of having a robust exceptions process.

Response: We take seriously concerns that enrollees, especially those facing health challenges, may have when they are either switched from a drug they have been stable on or told their plan will no longer cover it, including for products such as biosimilar biological products that are relatively new to the market. However, as we discussed in our December 2022 proposed rule and the November 2017 proposed rule and as contemplated under section 1860D–4(b)(3)(E) of the Act, Part D sponsors may make changes to their formularies as specified during the year. As detailed in the November 2023 proposed rule, all biosimilar biological products have been determined by FDA to be safe and effective, and we believe that, over time, biosimilar biological products will gain more acceptance, as was the case with generic drugs as substitutes for brand name drugs. For instance, the FDA has stated:

Both [biosimilar biological products and reference products] are rigorously and thoroughly evaluated by the FDA before approval. For [biosimilar biological products] to be approved by the FDA, manufacturers must show that patients taking [biosimilar biological products] do not have any new or worsening side effects as compared to people taking the [reference products].

As it does with all medication approvals, the FDA carefully reviews the data provided by manufacturers and takes several steps to ensure that all [biosimilar biologic products] meet standards for patient use. The FDA's thorough evaluation makes sure that all [biosimilar biological products] are as safe and effective as their [reference products] and meet the FDA's high standards for approval. This means [consumers] can expect the same safety and effectiveness from the [biosimilar biological product] over the course of treatment as [they] would from the original product.[57]

We are not convinced that sending notices to prescriber offices, which serve a great many patients covered by many types of insurance and receive many communications, is an effective means to address enrollee concerns. Prescribers are more likely to respond to direct requests from their patients asking for a new prescription or help supporting an exception request. We agree with the commenter who noted the importance of RTBTs to provide prescribers with drug coverage and cost-sharing information for their patients at the point of prescribing. CMS does not require prescribers to use RTBTs, but requires at § 423.160(b)(7) that Part D sponsors implement at least one RTBT capable of integrating with at least one prescriber's e-prescribing system or electronic health record. See section III.L.5. of this final rule for a discussion of our proposals to enable more widespread access to RTBTs through the adoption of a standard.

Lastly, we agree with commenters about the importance of a robust exceptions process being available to affected enrollees. Since the start of the Part D program in 2006, CMS has had such a process in place. Under the coverage determination and appeal processes described in Part 423, subpart M, Part D enrollees and their prescribers have the right to request an exception to a plan coverage rule, including an exception to the plan's tiered cost-sharing structure or formulary utilization management (UM) criteria. Part D plan sponsors are required to make coverage decisions and notify the enrollee (and the prescriber, as appropriate) in writing in accordance with strict regulatory timeframes. Under § 423.578, a Part D plan must grant a tiering or formulary exception request (for example, provide coverage for a non-formulary drug or an exception to the UM criteria) when it determines that the requested drug is medically necessary, consistent with the prescriber's supporting statement indicating that preferred alternatives(s) would not be as effective and/or would have adverse effects. Enrollees have a statutory right to an expedited determination if the prescriber indicates that applying the standard timeframe may jeopardize the enrollee's health, and plans must issue all coverage decisions, except those seeking reimbursement only, as expeditiously as the enrollee's health condition requires. Any initial coverage request that the plan expects to deny based on a lack of medical necessity must be reviewed by a physician. If the Part D sponsor makes an adverse coverage determination, the required written notice must explain the specific reason(s) for the denial and include a description of the enrollee's right to a standard or expedited redetermination by the plan, and the right to request independent review. We require plans to conduct all redeterminations (first level appeals) using a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare criteria, if the initial denial was based on a lack of medical necessity. If a plan fails to make a coverage decision and notify the enrollee within the required timeframe, the request must be forwarded to the independent review entity to be adjudicated.

Moreover, while we do not treat a claim transaction as a coverage determination, we do require Part D sponsors to arrange with network pharmacies to provide enrollees with a written copy of the Office of Management and Budget (OMB)-approved standardized pharmacy notice (''Notice of Denial of Medicare Prescription Drug Coverage,'' CMS–10146) when the enrollee's prescription cannot be filled under the Part D benefit and the issue cannot be resolved at the point of sale. The notice instructs the enrollee on how to contact his or her plan and explains the enrollee's right to request a coverage determination. Thus, all beneficiaries immediately receive clear, concise instructions on how to pursue their appeal rights whenever a prescription cannot be filled. For additional information on the coverage determination, appeals, and grievance process, including information about the pharmacy notice, see 42 CFR part 423, subparts M and U, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals

[57] See FDA website entitled ''Biosimilar and Interchangeable Biologics: More Treatment Choices'' at: *https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices#:~:text=Biosimilars%20are%20a%20type%20of,macular%20degeneration%2C%20and%20some%20cancers.*

Guidance.[58] We believe these requirements are comprehensive enough to address issues that might arise related to any transition from a reference product to a biosimilar biological product.

Comment: Several commenters specifically noted that requiring 30 days' notice for maintenance changes would be sufficient time for an enrollee to communicate with their health care provider to get a new prescription for a biosimilar biological product other than an interchangeable biosimilar biological product. A commenter asked if patients taking a reference product could waive their 30 days' advance notice of maintenance changes and immediately switch to a substituted biosimilar biological product. Several commenters asked CMS to extend the advance direct notice period from 30 days to either 60 or 90 days. These commenters posited that biosimilar biological products were different than other drugs and that enrollees taking these drugs were likely to be sicker or experiencing a chronic illness. They stated that enrollees taking reference products would need to schedule appointments with their providers to discuss changing treatment to a biosimilar biological product and that average wait times may exceed a month. Another commenter suggested that given the level of concern many patients who have been on the same medication have regarding biosimilar biological products with which they may not be familiar, providing a longer time period would give enrollees and their prescribers more of an opportunity to feel comfortable making the transition. A commenter that opposed permitting Part D sponsors to treat the substitution of biosimilar biological products for their reference products as maintenance changes, noted that the 30-day notice period might not provide sufficient time for an enrollee to obtain the biosimilar biological product if it is subject to risk evaluation and mitigation strategies (REMS). In such instances, FDA may require manufacturers to restrict a drug's distribution or use only to patients with prescriptions from authorized physicians or pharmacies under specified conditions via one or more ''Elements to Assure Safe Use'' (ETASU).

Response: As noted earlier, the needs of enrollees are an important priority for CMS. However, we have required advance direct notice of maintenance changes since the beginning of the Part D program and are not convinced that there is anything unique about biosimilar biological products other than interchangeable biological products that justifies a change to that longstanding policy. CMS has for some time permitted maintenance changes; since our April 2018 final rule, Part D plans have been required to provide 30 days' notice to these enrollees of changes. We are not aware of widespread complaints regarding the 30 days' advance direct notice, and do not believe it is necessary to create a special rule for individuals taking reference products subject to biosimilar biological product maintenance changes. We believe it would add unnecessary complications and set a poor precedent to establish a different time period of advance direct notice for biosimilar biological products substituted as maintenance changes (be they interchangeable or other than interchangeable) relative to other Part D drugs. We find this level of complications unmerited because, as discussed in section III.F of the November 2023 proposed rule, we trust in FDA evaluations that have determined all biosimilar biological products are safe and effective. See our discussion in the proposed rule for more on this (88 FR 78518). Additionally, affected enrollees may still be able to access the reference product through the plan's coverage determination and exceptions process.

Section 1860D–4(b)(3)(E) of the Act requires ''appropriate notice'' of formulary changes; further, we view appropriate notice of change as an integral beneficiary right. Therefore, we disagree that we need to change the requirement for advance direct notice of maintenance changes or create more complexity by requiring plans to create a means for enrollees to waive formulary change notice on an individual basis. If a prescriber were to recommend a switch to a new biosimilar biological product to their patient, either they or the patient could call or otherwise reach out to the plan to see if the drug was available on the formulary ahead of receipt of any 30-day advance notice of drug change.

We appreciate that a REMS could cause complications relative to the 30-day notice period, for example, if the prescriber needs to enroll in a different REMS for a biosimilar biological product than for the reference product in order to be certified to prescribe the biosimilar biological product; however, we do not think this scenario is unique to biological products. The same scenario could occur under our current policy for maintenance changes involving generic substitutions for brand name drugs, because when a brand name drug has a REMS, the generic drug must also have a REMS and manufacturers may not have a shared system REMS.[59] We are not aware of complaints indicating that our current policy for substitutions of generic drugs for brand name drugs has been complicated by REMS for drugs involved. Consequently, we do not see a need to change the policies we have proposed for substitution of biosimilar biological products.

Comment: A few commenters suggested that if we were to permit plans to require patients stable on reference products to switch to biosimilar biological products to reduce costs for payers, those savings should be shared with enrollees. A few commenters requested that we require biosimilar biological products to be placed on lower cost-sharing tiers than the reference products they replaced.

Response: By encouraging Part D sponsors to introduce biosimilar biological products to their formularies more quickly, we believe enrollees may also be able to share in savings when negotiated prices for those products are lower than for the reference products, particularly in coinsurance-based benefit designs. CMS disagrees with the commenters' proposal to require biosimilar biological products to be placed on lower cost-sharing tiers than the reference products they replaced because it has been longstanding policy to require substitutions to apply to the same or lower tier. Moreover, most biological products qualify for the specialty tier, as defined at § 423.560. Unless the plan benefit structure includes two specialty tiers as permitted under § 423.104(d)(2)(iv)(D), requiring substituted biosimilar biological products to be placed on a lower tier than the reference product would in effect prohibit Part D sponsors from placing biosimilar biological products on the specialty tier if the reference product had been on the specialty tier.

Comment: While we received support for recognizing the role of education to advance uptake and acceptance of biological products, several commenters stressed that biosimilar biological products are a relatively new concept that could cause confusion and concern for enrollees who would prefer to continue taking drugs they are familiar with. They asked that we develop educational resources on biological products to better inform patients and

[58] *https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.*

[59] *https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems.*

health care professionals and urge plan sponsors to engage in robust education and utilize communications best practices. A commenter encouraged us to update the Medicare Plan Finder tool to identify coverage of and savings associated with biosimilar biological products.

Response: We plan to update our materials to reflect any regulatory changes regarding the provision of biosimilar biological products, as well as investigate options for identifying biosimilar biological product alternatives on Medicare Plan Finder. Likewise, we encourage Part D sponsors to educate their enrollees, including making sure that call center customer service representatives are trained to discuss biosimilar biological products. We note that the FDA also plays an important role in educating consumers on emerging drug therapies. FDA offers a variety of materials in multiple formats and languages to help promote understanding of biosimilar biological products and interchangeable biological products.[60]

Comment: A commenter asked us to ensure enrollees receive appropriate notifications of midyear changes, develop such notices with stakeholder feedback, and hold Part D sponsors responsible if timelines or other standards are not met. A commenter requested that if the rule is finalized, that we monitor enrollee and prescriber experiences with biosimilar biological products to determine whether notice is necessary, particularly as state laws regarding substitution evolve.

Response: We will keep this feedback in mind as we consider different monitoring options.

Comment: A few commenters were concerned that permitting immediate substitutions of interchangeable biological products for reference products and maintenance changes of all biosimilar biological products for reference products would impose a greater administrative burden upon pharmacists.

Response: While we certainly favor reducing unnecessary burdens on pharmacists, it is not clear to us how permitting immediate substitutions of interchangeable biological products under proposed § 423.120(e)(2)(i) will increase the administrative burden placed on pharmacists. State laws determine the requirements for pharmacists to make pharmacy-level substitutions of interchangeable biological products for their reference products and these pharmacy-level substitutions can take place even when a reference product remains on the formulary (that is, in the absence of any immediate substitution by the plan). We acknowledge that permitting Part D sponsors to substitute biosimilar biological products for reference products as maintenance changes means the claim will potentially be denied at the pharmacy (if the negative formulary change adds restrictions or removes the reference product from the formulary) or the enrollee will be faced with higher than expected cost-sharing (if the negative formulary change moves the reference product to a different cost-sharing tier). The changes may cause enrollees to ask the pharmacist questions at the point of sale. In some cases, a pharmacist might reach out to the patient or their prescriber to obtain a new prescription if, for example, a refill of a reference product that a patient has been taking is denied by the plan. However, the advance direct notice provided to affected enrollees is intended to prompt the enrollee to act before the formulary change takes place and before the next fill of the reference product at the pharmacy. We decline to make further changes to our proposal based on these comments.

Comment: A commenter was concerned that expanding immediate substitutions to include substitutions of authorized generics, interchangeable biological products, and unbranded biological products, as proposed in the December 2022 proposed rule, would allow plans to choose different specified products for coverage, such that facilities would have to stock every single product option or substitution, whereas currently, only one substitution needs to be stocked. Conversely, a few commenters were concerned that substituted drugs would have a different delivery form. A commenter on the November 2023 proposed rule shared concerns that, given that all biosimilar biological products are not necessarily available in all delivery forms, our proposed rule could mean enrollees would lose access to their current delivery form (for instance, be able to only obtain a vial when they currently use a pen cartridge).

Response: We appreciate the concern the commenter raised about the potential impact of our proposed policies on pharmacies that may need to stock multiple biosimilar biological products and the challenges that could create as more biosimilar biological products come to the market. However, that issue is not specific to Part D and is beyond the scope of our proposal to expand midyear substitutions. Regarding the concerns about changes in available delivery forms, under proposed § 423.120(e)(2)(i), we would only allow immediate substitutions of an interchangeable biological product that FDA has determined to be interchangeable with its reference product. Our annual formulary review process ensures that Part D plan formularies include adequate representation of drugs consistent with best practices of formularies currently in widespread use. Part D sponsors are not required to cover every dosage or delivery form of a particular drug; however, Part D sponsors are expected to cover widely available dosage and delivery forms so as to not unduly limit enrollee access. If a Part D sponsor has multiple dosage or delivery forms of a particular drug on their formulary, Part D sponsors implementing immediate substitutions will be expected to continue to offer a similar variety of dosage and delivery forms to meet the needs of patients. CMS will review changes submitted on the HPMS formulary file and take action as appropriate if it appears that any immediate substitutions are inappropriate. As for maintenance changes defined in § 423.100, these determinations are subject to our review on a case-by-case basis. CMS takes into consideration differences in available delivery forms when making decisions to approve or deny such negative change requests.

Comment: A few commenters opined that our policy conflates pharmacy substitutions and formulary coverage, and that there is a distinction between the ability of a pharmacist to substitute a product without prescriber intervention and a plan's decisions regarding formulary coverage of a product.

Response: We understand the decision by a Part D sponsor to provide formulary coverage of any given product is very different from the ability of a pharmacist to substitute a product for another drug. However, coverage decisions do not take place in a vacuum, and CMS cannot ignore practical realities despite these commenters' position that formulary design should not be affected by pharmacy substitutions policies. In contrast, CMS believes that to prevent enrollees from standing in line at the pharmacy counter unable to get the biosimilar biological product because they do not have a new prescription for it, our proposal to require 30 days' advance direct notice in § 423.120(f)(1) is appropriate.

Comment: A few commenters asked us to align our proposed regulations

[60] See the following FDA website on Multimedia Education Materials | Biosimilars: *https://www.fda.gov/drugs/biosimilars/multimedia-education-materials-biosimilars.*

with policies in certain other countries. Specifically, both a commenter that asked us to restrict immediate substitutions to interchangeable biological products and a few commenters that asked us to permit immediate substitutions of all biosimilar biological products for reference products cited policies in Europe to support their different views.

Response: We appreciate the comments but clarify that we are proposing policies on approval and notice of formulary changes for Part D plans in the United States independent of policies in other countries. As explained in detail in both the December 2022 and the November 2023 proposed rules, our policies are informed by another federal agency, FDA, which implements the statutory and regulatory framework for the review and approval of biosimilar biological products.

After consideration of the comments received on both the December 2022 and November 2023 proposals, and for the reasons set forth in the proposed rules and our responses to the comments in this final rule, we are finalizing the proposed regulation text changes at §§ 423.4, 423.100, 423.104, 423.120, and 423.128, with the minor modifications discussed below, in addition to other non-substantive organizational and editorial changes for clarity.

- In § 423.4, removing the word ''biological'' from the term ''reference biological product.''
- In § 423.4, adding the following language to the end of the definition of ''interchangeable biological product'': ''which in accordance with section 351(i)(3) of the Public Health Service Act (42 U.S.C. 262(i)(3)), may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.''
- In § 423.100, in the definition of ''maintenance change,'' revising and reordering language to provide more clarity by stating that drugs subject to removal include those ''that FDA determines to be withdrawn for safety or effectiveness reasons.''
- In § 423.120(b)(5), finalizing the requirement that Part D sponsors must provide notice of changes as specified in § 423.120(f), but removing a reference to selection of a successor regulation to § 423.120(b)(5)(iv) for purposes of section 1860D–4(b)(3)(I)(ii) of the Act.
- In § 423.120(e)(2)(ii), revising and reordering language on market withdrawals to provide more clarity by stating that drugs subject to removal include those ''that the Food and Drug Administration (FDA) determines to be withdrawn for safety or effectiveness reasons.''
- In § 423.120(f)(4)(iv), revising language requiring Part D sponsors to include in their written notice of change a list of formulary alternatives to specify that the alternative drugs be ''on the formulary'' to make clear these alternatives are on the formulary and can meet the definition of a Part D drug.
- In § 423.120(f)(4)(v), revising language specifying that Part D sponsors provide written notice of the coverage determinations and exceptions to make clear that an exception is a type of coverage determination and to correct the regulatory cross-reference.

Additionally, in the course of developing the final rule, it came to our attention that we had inadvertently omitted updating § 423.578(d) when proposing updates to the regulations to reflect the agency's proposals. Accordingly, we are making conforming changes in this final rule to the existing regulation text in § 423.578(d) to correspond with the changes we are finalizing in this rule to require Part D sponsors to provide notice regarding negative formulary changes under § 423.120(f).

O. Parallel Marketing and Enrollment Sanctions Following a Contract Termination (§§ 422.510(e) and 423.509(f))

Sections 1857(c)(2) and 1860D–12(b)(3)(B) of the Act provide CMS with the ability to terminate MA (including MA–PD) and PDP contracts if we determine that a contract(s) has met any of the following thresholds:

- Has failed substantially to carry out the contract
- Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of, respectively, Part C or Part D of Title XVIII of the Act (that is, the Medicare statute).
- No longer substantially meets the applicable conditions of the applicable part of the statute.

This termination authority is codified at 42 CFR 422.510(a)(1) through (3) and 423.509(a)(1) through (3), respectively. In addition, section 1857(g)(3) of the Act (incorporated for Part D sponsors under section 1860D–12(b)(3)(F) of the Act) specifies that intermediate sanctions and civil money penalties (CMPs) can be imposed on the same grounds upon which a contract could be terminated (63 FR 34968 and 70 FR 4193). CMS codified this authority at §§ 422.752(b) and 423.752(b) with respect to intermediate sanctions, and §§ 422.752(c)(1)(i) and 423.752(c)(1)(i) with respect to CMPs.

If CMS terminates an MA organization or Part D sponsor contract(s) during the plan year but the termination is not effective until January 1 of the following year, the MA organization or Part D sponsor could potentially continue to market and enroll eligible beneficiaries (as described in 422 Subpart B and 423 Subpart B) into plans under the terminating contract(s) unless CMS imposes separate marketing and enrollment sanctions on the terminating contract(s).[61] A terminating contract that continues to market to and enroll eligible beneficiaries will cause confusion and disruption for beneficiaries who enroll in the period of time between when the termination action is taken and the January 1 effective date of the termination.

For these reasons, we proposed to add paragraph (e) to § 422.510 and paragraph (f) to § 423.509 that, effective contract year 2025, marketing and enrollment sanctions will automatically take effect after a termination is imposed. At paragraph (e)(1) of § 422.510 and paragraph (f)(1) of § 423.509, we proposed to state that the marketing and enrollment sanctions will go into effect 15 days after CMS issues a contract termination notice. This timeframe is consistent with the number of days CMS often designates as the effective date for sanctions after CMS issues a sanction notice.

At paragraph (e)(2) of § 422.510 and paragraph (f)(2) of § 423.509, we proposed that MA organizations and Part D sponsors will continue to be afforded the same appeals rights and procedures specific to contract terminations under 42 CFR Subpart N of parts 422 and 423, however, there will not be a separate appeal for the sanction (in other words the appeal of the termination will include the associated marketing and enrollment sanctions). In addition, at paragraph (e)(3) of § 422.510 and paragraph (f)(3) of § 423.509 we proposed that if an MA organization or Part D sponsor appeals the contract termination, the marketing and enrollment sanctions will not be stayed pending the appeal consistent with §§ 422.756(b)(3) and 423.756(b)(3). Finally, at paragraph (e)(4) of § 422.510 and paragraph (f)(4) of § 423.509 we proposed that the sanction will remain in effect until the effective date of the termination, or if the termination decision is overturned on appeal, until

[61] Regulations in 42 CFR 422 Subpart B and 423 Subpart B permit enrollees to enroll in a plan mid-year during their initial election period or special election periods.

the final decision to overturn the termination is made by the hearing officer or Administrator.

CMS rarely terminates MA organization and Part D sponsor contracts and, on average, contract terminations affect less than one MA organization or Part D sponsor a year. Therefore, we anticipate that this proposal will not result in additional costs or additional administrative burden for affected MA organizations and Part D sponsors. For example, an MA organization and Part D sponsor will not be required to submit a corrective action plan, and if appealed there will only be one appeal rather than multiple. MA organizations and Part D sponsors will continue to be required to comply with existing regulations that require public and beneficiary notice that their contract is being terminated under this proposal.

Comment: Several commenters expressed support for this proposal.

Response: CMS appreciates commenters' support.

Final Decision: After consideration of the public comments received and for the reasons discussed here and in the proposed rule, we are finalizing this provision without modification.

P. Update to the Multi-Language Insert Regulation (§§ 422.2267 and 423.2267)

Individuals with limited English proficiency (LEP) experience obstacles to accessing health care in the United States. Language barriers negatively affect the ability of patients with LEP to comprehend their diagnoses and understand medical instructions when they are delivered in English and impact their comfort with post-discharge care regimens.[62] We further described the language barriers faced by individuals with LEP in the November 2023 proposed rule at 88 FR 78523. These barriers contribute to disparities in health outcomes for individuals with LEP, which likely worsened during the COVID–19 pandemic.[63]

The multi-language insert (MLI) currently required at §§ 422.2267(e)(31) and 423.2267(e)(33) is a standardized communications material that informs enrollees and prospective enrollees that interpreter services are available in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese. These were the 15 most common non-English languages in the United States when we reinstituted the MLI in the Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency final rule (87 FR 27704) (hereafter referred to as the May 2022 final rule). Additionally, §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i) require plans to provide the MLI in any non-English language that is the primary language of at least five percent of the individuals in a plan benefit package (PBP) service area but is not already included on the MLI. These regulations also provide that a plan may opt to include the MLI in any additional languages that do not meet the five percent threshold, where it determines that including the language would be appropriate. The current MLI states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' The issuance of the MLI is independent of the Medicare written translation requirements for any non-English language that meets the five percent threshold, as currently required under §§ 422.2267(a)(2) and 423.2267(a)(2), and the additional written translation requirements for fully integrated D–SNPs (FIDE SNPs) and highly integrated D–SNPs (HIDE SNPs) provided in §§ 422.2267(a)(4) and 423.3367(a)(4).[64] Additionally, we note that pursuant to CMS's authority in section 1876(c)(3)(C) to regulate marketing and the authority in section 1876(i)(3)(D) to specify new section 1876 contract terms, we have also established in § 417.428 that most of the marketing and communication regulations in subpart V of part 422, including the MLI requirement in § 422.2267(e)(31), also apply to section 1876 cost plans.

Section 1557 of the Patient Protection and Affordable Care Act (ACA)[65] provides that, except where otherwise provided in Title I of the ACA, an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964, *42 U.S.C. 2000d et seq.* (race, color, national origin), Title IX of the Education Amendments of 1972, *20 U.S.C. 1681 et seq.* (sex), the Age Discrimination Act of 1975, *42 U.S.C. 6101 et seq.* (age), or section 504 of the Rehabilitation Act of 1973, *29 U.S.C. 794* (disability), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance); any program or activity administered by the Department; or any program or activity administered by any entity established under Title I of the Act. On May 18, 2016, the Office for Civil Rights (OCR) published a final rule (*81 FR 31375;* hereinafter referenced to as the ''2016 section 1557 final rule'') implementing the requirement that all covered entities—any health program or activity that receives Federal financial assistance—include taglines with all ''significant communications.'' The sample tagline provided by the Department consisted of a sentence stating, in the 15 most common non-English languages in a State or States, ''ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–xxx–xxx–xxxx (TTY: 1–xxx–xxx–xxxx).'' On June 19, 2020, the Department published a new section 1557 final rule, 85 FR 37160 (2020 section 1557 final rule), rescinding the 2016 section 1557 final rule's tagline requirements, 84 FR 27860. That rule is currently in effect, save for a few provisions enjoined or set aside by the courts and pending OCR's new proposed rule for section 1557 of the ACA, published on August 4, 2022 (87 FR 47824).

None of the rulemaking impacting the various notifications of interpreter services changed the requirement that MA organizations, Part D sponsors, or cost plans must provide these services under applicable law. Plans have long been required to provide interpreters when necessary to ensure meaningful access to individuals with LEP, consistent with existing civil rights laws. In implementing and carrying out the Part C and D programs under

[62] Espinoza, J. and Derrington, S. ''*How Should Clinicians Respond to Language Barriers that Exacerbate Health Inequity?*'', *AMA Journal of Ethics* (February 2021) E109. Retrieved from *https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2021-02/cscm3-2102.pdf;* Karliner, L., Perez-Stable, and E., Gregorich, S. ''*Convenient Access to Professional Interpreters in the Hospital Decreases Readmission Rates and Estimated Hospital Expenditures for Patients with Limited English Proficiency*'', *Med Care* (March 2017) 199–206. Retrieved from *https://pubmed.ncbi.nlm.nih.gov/27579909/.*

[63] Lala Tanmoy Das et al., Addressing Barriers to Care for Patients with Limited English Proficiency During the COVID–19 Pandemic, Health Affairs Blog (July 29, 2020), *https://www.healthaffairs.org/do/10.1377/hblog20200724.76821/full/.*

[64] This proposal pertains only to the MLI requirements in §§ 422.2267(e)(31) and 423.2267(e)(33), not §§ 422.2267 and 423.2267 broadly.

[65] 42 U.S.C 18116(c).

sections 1851(h), 1852(c), 1860–1(b)(1)(B)(vi), 1860D–4(a), and 1860D–4(l) of the Act, CMS considers the materials required under §§ 422.2267(e) and 423.2267(e) to be vital to the beneficiary decision making process; ensuring beneficiaries with LEP are aware of and are able to access interpreter services provides a clear path for this portion of the population to properly understand and access their benefits.

In the May 2022 final rule, we noted that we gained additional insight regarding the void created by the lack of any notification requirement associated with the availability of interpreter services for Medicare beneficiaries (87 FR 27821). We stated that we consider the materials required under §§ 422.2267(e) and 423.2267(e) to be vital to the beneficiary's decision-making process. We also noted that we reviewed complaint tracking module (CTM) cases in the Health Plan Management System (HPMS) related to ''language'' and found a pattern of beneficiary confusion stemming from not fully understanding materials based on a language barrier. We noted that solely relying on the requirements delineated in the 2020 section 1557 final rule for covered entities to convey the availability of interpreter services is insufficient for the MA, cost plan, and Part D programs and is not in the best interest of Medicare beneficiaries who are evaluating whether to receive their Medicare benefits through these plans and who are enrolled in these plans. We stated that we believed that informing Medicare beneficiaries that interpreter services are available is essential to realizing the value of our regulatory requirements for interpreter services.

On August 4, 2022, OCR published a new proposed rule for section 1557 of the ACA (87 FR 47824) that proposed to require covered entities to notify the public of the availability of language assistance services and auxiliary aids and services for their health programs and activities at no cost using a notice of availability of language assistance services and auxiliary aids and services (Notice of Availability). Proposed 45 CFR 92.11(b) would require the Notice of Availability to be provided in English and at least in the 15 most common languages spoken by individuals with LEP in the relevant State or States, and in alternate formats for individuals with disabilities who request auxiliary aids and services to ensure effective communications. These proposed provisions would result in misalignment with the MLI requirement under §§ 422.2267(e)(31) and 423.2267(e)(33) which require that notice be provided in the 15 most common non-English languages in the United States.

In addition, under § 438.10(d)(2), States must require Medicaid managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), prepaid ambulatory health plans (PAHPs), and primary care case management programs to include taglines in written materials that are critical to obtaining services for potential enrollees in the prevalent non-English languages in the State explaining the availability of oral interpretation to understand the information provided, information on how to request auxiliary aids and services, and the toll-free telephone number of the entity providing choice counseling services in the State. Several States that use integrated Medicare and Medicaid materials for D–SNPs and Medicare-Medicaid Plans have contacted CMS and requested that we change the MLI to be based on the 15 most common languages in the State rather than the 15 most common languages nationally because the most common languages in the State are often not the same as the most common 15 languages nationally.

As a result of the MLI requirements at §§ 422.2267(e)(31) and 423.2267(e)(33) and the Medicaid requirement at § 438.10(d)(2), any applicable integrated plans (AIPs), as defined at § 422.561, that provide integrated Medicare and Medicaid materials for enrollees must currently include the MLI in the 15 most common languages nationally as well as the Medicaid tagline in the prevalent non-English languages in the State to comply with both Medicare and Medicaid regulatory requirements. Specifically, these plans that provide integrated materials must comply with the MLI requirements at §§ 422.2267(e)(31) and 423.2267(e)(33) and the Medicaid requirement at § 438.10(d)(2) to include taglines in written materials that are critical to obtaining services for potential enrollees in the prevalent non-English languages in the State. In the enrollee materials, this can result in a very long multi-page list of statements noting the availability of translations services in many languages. As discussed in greater detail below, we proposed to update §§ 422.2267(e)(31) and 423.2267(e)(33) to instead require that a Notice of Availability be provided in English and at least the 15 languages most commonly spoken by individuals with LEP of the relevant State; we articulated our expectation that this proposed policy would better align with the Medicaid translation requirements at § 438.10(d)(2).[66]

We believe rulemaking regarding a notice of the availability of language assistance services and auxiliary aids and services for individuals with LEP is needed to more closely reflect the actual languages spoken in the service area. We also believe it is in the best interest of enrollees for the requirements to align with the Medicaid translation requirements because it allows D–SNPs that are AIPs to provide a more applicable, concise Notice of Availability to enrollees that does not distract from the main purpose of the document. Further, alignment of Medicare and OCR rules would help to prevent confusion among MA organizations, Part D sponsors, and cost plans regarding which requirements they must comply with.

We proposed to amend §§ 422.2267(e)(31) and 423.2267(e)(33). First, we proposed to replace references to the MLI with references to a Notice of Availability. We proposed that this notice be a model communication material rather than a standardized communication material and thus that CMS would no longer specify the exact text that must be used in the required notice. Second, we proposed to change paragraphs (e)(31) and (e)(33) to require MA organizations and Part D sponsors to provide enrollees a Notice of Availability that, at a minimum, states that MA organizations and Part D sponsors provide language assistance services and appropriate auxiliary aids and services free of charge. Third, we proposed, in new paragraphs (e)(31)(i) and (e)(33)(i), that the Notice of Availability must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication. We noted in the proposed rule that this State-specific standard would ensure that a significant proportion of each State's particular LEP population receives key information in the appropriate languages. We cited the U.S. Census Bureau's ACS 2009–2013 multi-year data, which show that the top languages spoken in each State can

[66] We expect the 15 most common languages for a given State to include any language required by the Medicaid program at § 438.10(d)(2). Therefore, our NPRM would reduce burden on fully integrated dual eligible special needs plans and highly integrated dual eligible special needs plans, as defined at § 422.2, and applicable integrated plans, as defined at § 422.561, to comply with regulations at §§ 422.2267(a)(4) and 423.2267(a)(4).

vary significantly.[67] We concluded that State-specific language translations provide for flexibility to maximize access to care for individuals with LEP. Fourth, we proposed that the updated notice must also include a statement regarding the availability of appropriate auxiliary aids and services to reduce barriers to access for individuals with disabilities.

As discussed in the November 2023 proposed rule, we believe this proposal would make it easier for individuals to understand the full scope of available Medicare benefits (as well as Medicaid benefits available through the D–SNPs, where applicable), increasing their ability to make informed health care decisions, and promote a more equitable health care system by increasing the likelihood that MA enrollees have access to information and necessary health care. Additional benefits include mitigating the risk that §§ 422.2267(e)(31) and 423.2267(e)(33) could conflict with § 438.10(d)(2) and the forthcoming 1557 final rule, requiring applicable Medicare plans to comply with two, disparate sets of requirements. Further, requiring MA organizations and Part D sponsors to provide multiple sets of translated statements accompanying enrollee materials could lead to enrollee confusion and detract from the enrollee material message. Setting aside which specific policies are finalized in the forthcoming 1557 final rule, we generally continue to believe our proposed changes are appropriate given the benefits of a Notice of Availability for individuals with LEP and auxiliary aid and service needs more closely reflecting the actual languages spoken in the service area and aligning with the Medicaid translation requirements.

Additionally, we proposed in §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) that if there are additional languages in a particular service area that meet the 5 percent service area threshold, described in paragraph §§ 422.2267(a)(2) and 423.2267(a)(2), beyond the languages described in §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i), the Notice of Availability must also be translated into those languages, similar to the current MLI requirements at §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i). While §§ 422.2267(a)(2) and 423.2267(a)(2) apply to the Notice of Availability since it is a required material under §§ 422.2267(e) and 423.2267(e), we wanted to clarify this in the regulation text. MA organizations and Part D sponsors may also opt to translate the Notice of Availability in any additional languages that do not meet the 5 percent service area threshold at §§ 422.2267(a)(2) and 423.2267(a)(2), where the MA organization or Part D sponsor determines that such inclusion would be appropriate, which is also included in the current MLI requirements at §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i). It is possible that there may be a subpopulation in the plan benefit package service area that uses a language that does not fall within the top 15 non-English languages or meet the 5 percent service area threshold that the plan determines can benefit by receiving the notice. We noted that pursuant to CMS's authority in section 1876(c)(3)(C) to regulate marketing and the authority in section 1876(i)(3)(D) to specify new section 1876 contract terms, and as established in § 417.428, this proposal would also apply to section 1876 cost plans.

To assist plans with fulfilling their requirements under §§ 422.2267(a)(2) and 423.2267(a)(2) to translate required materials into any non-English language that is the primary language of at least five percent of the population of a plan service area, since 2009 CMS has provided plans with a list of all languages that are spoken by 5 percent or more of the population for every county in the U.S. Each fall, we release an HPMS memorandum announcing that MA organizations and Part D sponsors can access this list in the HPMS marketing review module.[68] However, plans can also use U.S. Census Bureau ACS data to determine the top languages spoken in a given State or service area. The September 2023 Medicare Part C & D Language Data Technical Notes[69] outlines our methodology for calculating the percentage of the population in a plan's service area speaking a language other than English and provides plans with instructions to make these calculations on their own.

We received the following comments on this proposal and respond to them below:

Comment: Many commenters supported CMS's plan to require MA and Part D plans to provide enrollees a Notice of Availability that, at a minimum, states that MA organizations and Part D sponsors provide language assistance services and appropriate auxiliary aids and services free of charge in English and at least the 15 languages most commonly spoken by individuals with LEP of the relevant State and languages that meet the 5 percent service area threshold. The Medicaid and CHIP Payment and Access Commission (MACPAC) noted that the change aligns with work they have underway, more closely aligns Medicare requirements with existing Medicaid standards, reduces administrative burden on health plans, and may reduce health disparities for beneficiaries whose primary language is not English. A commenter stated that integrated Medicare and Medicaid plans have been experiencing this conflict between Medicaid requirements and Medicare MLI requirements for many years. Another commenter stated that using the same standard as Medicaid will reduce administrative time and effort for State Medicaid agencies overseeing D–SNPs by enabling State Medicaid staff to enforce a standard consistent with their other Medicaid products.

Response: We appreciate the widespread support for our proposal. We believe that requiring a Notice of Availability to be provided in English and in at least the 15 most commonly spoken non-English languages and languages that meet the 5 percent service area threshold free of charge is more closely tailored to the needs of the population where the notice will be sent and will make it easier for individuals to understand the full scope of available Medicare benefits (as well as Medicaid benefits available through a D–SNP, where applicable), increasing their ability to make informed health care decisions. It will also promote a more equitable health care system by increasing the likelihood that MA enrollees have access to information and necessary health care.

Comment: A few commenters opposed the proposal noting that it would place an undue administrative burden on plans, including national subcontractors that work with multiple plans across multiple States. Some commenters raised concerns about providing a State-based notice for plans with multi-State service areas. A commenter stated that providing the Notice of Availability based on an

[67] *https://www2.census.gov/library/data/tables/2008/demo/language-use/2009-2013-acs-lang-tables-nation.xls.*

[68] We released the contract year 2024 version of this HPMS memorandum titled, ''Corrected Contract Year 2024 Translated Model Materials Requirements and Language Data Analysis'' on September 25, 2023. This memorandum can be retrieved at: *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-september-18-22.*

[69] Found in HPMS as described in the September 25, 2023 HPMS memo, ''Corrected Contract Year 2024 Translated Model Materials Requirements and Language Data Analysis.'' This memo can be retrieved at *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-september-18-22.*

enrollee's location would require plans to implement enrollee-level programming for every plan communication for all 50 States. A few commenters reported having employer-group waiver plans that covered more than one State.

Response: We thank the commenters for their thoughts. We believe that requiring the Notice of Availability to be provided in at least the 15 most common languages spoken by individuals with LEP where the notice will be sent will make it easier for individuals to understand the full scope of available Medicare benefits (as well as Medicaid benefits available through the D–SNPs, where applicable), increasing their ability to make informed health care decisions, and promote a more equitable health care system by increasing the likelihood that MA enrollees have access to information and necessary health care. Any subcontractors will need to work with the applicable plan to ensure that they are meeting this requirement.

However, we share the concerns raised by commenters about plans that have a service area covering multiple States and the potential burden associated with determining the State of residence for enrollees within the plan. We also agree that requiring such plans to include the Notice of Availability in at least the top 15 non-English languages in each State in the plan's service area, potentially resulting in many more than 15 languages, may cause enrollee confusion and undue administrative and financial burden to the plan. As a result, we are updating the regulation to require the Notice of Availability to be provided in at least the top 15 languages most commonly spoken by individuals with LEP within the State or States associated with the plan benefit package service area, consistent with the section 1557 proposed rule. This approach would allow plans to aggregate the populations with LEP across all States in the plan's service area to determine the 15 languages in which it must provide the Notice of Availability. For example, if a plan's service area is New York, the Notice of Availability must include at least the top 15 languages spoken by individuals with LEP in New York, based on guidance published by the Secretary. If the plan's service area includes Connecticut, New Jersey, and New York, the plan may aggregate the populations with LEP across Connecticut, New Jersey, and New York to determine the 15 languages in which it must provide the Notice of Availability, based on guidance published by the Secretary. If the service area does not include an entire State, the plans should still use the top 15 languages for the entire State. If the service area is national, the plan may use the top 15 languages nationally for the Notice of Availability, based on guidance published by the Secretary.

Comment: Another commenter questioned whether, if CMS finalizes the proposal as a model communication material, plans can use each State's required tagline and language for the Notice of Availability.

Response: Since D–SNPs are State-specific at the plan level this will still allow D–SNPs to comply with § 438.10(d)(2) and use the State-specific tagline to satisfy the Notice of Availability requirements at §§ 422.2267(e)(31) and 423.2267(e)(33) as long as it states, at a minimum, in at least the 15 most common non-English languages and any language that meets the 5 percent service area threshold, that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge, since the Notice of Availability does not require standardized language. The D–SNP will not need to include multiple notices to meet these Medicaid and Medicare regulatory requirements.

Comment: A few commenters requested that we publish annually the 15 most common languages spoken by individuals with LEP in each State and nationally. Other commenters requested that we expand the list beyond 15 languages such as to the top 20 languages most commonly spoken by individuals with LEP in each State. They stated that including the top 20 languages on the list would help advocates identify languages that may meet the plan coverage area threshold even if they are not on the list of the top 15 for the State.

Response: We appreciate commenters' requests for CMS to publish lists of the top languages in each State and note that HHS will provide a list of the top 15 non-English languages most commonly spoken by individuals with LEP in each State and nationally based on the U.S. Census Bureau's American Community Survey (ACS) data. Additionally, since 2009, CMS has provided plans with a list of all languages that are spoken by five percent or more of the population for every county in the U.S. Each fall, we release an HPMS memorandum announcing that MA organizations and Part D sponsors can access this list in the HPMS marketing review module.[70] Further, the HPMS memorandum notes that plans can also use U.S. Census Bureau ACS data to determine the top languages spoken by individuals with LEP in a given State or service area. The September 2023 Medicare Part C & D Language Data Technical Notes[71] outlines our methodology for calculating the percentage of the population in a plan's service area speaking a language other than English and provides plans with instructions to make these calculations on their own.

We also appreciate commenters asking us to publish more than the 15 top languages spoken by individuals with LEP in each State. Plans will be able to identify the top 15 languages most commonly spoken by individuals with LEP in any State based on guidance published by the Secretary. Plans may opt to include additional languages, for which the U.S. Census Bureau's ACS data would be a helpful data source. We will consider expanding the list of languages provided in HPMS for MA and Part D plans in a future HPMS update.

Comment: A few commenters requested that we provide our methodology for determining the top 15 languages spoken by individuals with LEP in a State.

Response: We will provide guidance explaining our methodology for determining the top 15 languages spoken by individuals with LEP in each State and nationally based on ACS data.

Comment: A commenter encouraged CMS to clarify that the languages available be based on the ''plan State'' and not the enrollee's State of residence.

Response: We clarify that the requirement is based on the State or States associated with the plan benefit package service area rather than where an organization is located. To improve clarity, we are updating the regulation text at §§ 422.2267(e)(31) and 423.2267(e)(33) to, ''State or States associated with the plan's service area.''

Comment: We received a few comments asking us to clarify which communications a Notice of Availability must accompany and the frequency with which the Notice of Availability is sent to enrollees. A commenter suggested we develop a targeted list of

[70] We released the contract year 2024 version of this HPMS memorandum titled, ''Corrected Contract Year 2024 Translated Model Materials Requirements and Language Data Analysis'' on September 25, 2023. This memorandum can be retrieved at: *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-september-18-22.*

[71] Found in HPMS as described in the September 25, 2023 HPMS memo, ''Corrected Contract Year 2024 Translated Model Materials Requirements and Language Data Analysis.'' This memo can be retrieved at *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-september-18-22.*

materials with which to include the Notice of Availability while another commenter requested that we limit the types of documents that a Notice of Availability must accompany to those documents sent less frequently. Another commenter urged that we make the Notice of Availability an annual mailing instead of requiring inclusion in all materials and allow it to be suppressed if an enrollee has indicated a language of preference.

Response: While we acknowledge the comments suggesting we reduce the frequency with which we require the Notice of Availability, we believe it is important to continually make enrollees aware of the availability of language assistance services in all required materials under §§ 422.2267(e) and 423.2267(e). The requirement to include notice of available interpreter services and auxiliary aids and services with all required materials is an established policy that is already provided for in CMS regulations. CMS did not propose any amendments to this aspect of its policy as enrollee language and format preferences and needs may change over time. We also note that §§ 422.2267(e)(31) and 423.2267(e)(33) include provisions, such as allowing for a single copy of the requisite notice to be included in a mailing of multiple required documents, that ease burden and offer plans some flexibility, where practicable.

Comment: Several commenters requested that we work with OCR and Medicaid to ensure consistency between our proposal, the OCR section 1557 final rule, and Medicaid regulations.

Response: We thank the commenters recommending we better align our regulations with other relevant regulations. We strive to achieve this goal by better aligning Medicare regulations at 42 CFR 422.2267(a)(2) and 423.2267(a)(2) with OCR regulations at 45 CFR 92.11 and Medicaid regulations at 42 CFR 438.10(d)(2). We note that we have continued to work closely with OCR, the CMS Center for Consumer Information and Insurance Oversight (CCIIO), and other offices throughout the drafting of our rule to ensure alignment of regulations and mitigate burden on plans.

Comment: Several commenters opposed the use of a model notice instead of standardized language for the Notice of Availability. However, another commenter specifically noted support for the model communication approach and urged CMS to routinely review plans' Notices of Availability for compliance. A commenter requested that we work with States to publish a national Notice of Availability and any associated disclaimers, which aligns with all State requirements and accommodates all multi-plan materials by June of every year to reduce complexity and prevent enrollee confusion. Another commenter asked that we use specific notice language to ensure that all enrollees receive a full explanation of their rights while another commenter expressed concern that a model notice may result in more errors. Finally, another commenter recommended we collaborate with relevant stakeholders to develop a single, uniform Notice of Availability that can be used by health plans and providers without customization in the top 31 languages spoken nationally to accommodate 99 percent of the LEP population.

Response: We appreciate the commenters' concerns that a model Notice of Availability rather than standardized language may result in more errors and the concern with ensuring enrollees receive a full explanation of their rights. We also appreciate the support in making the Notice of Availability a model communication.

To mitigate errors in messaging, we specified that the content of the Notice of Availability must include at minimum, a statement that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge. In addition, for the purpose of compliance with section 1557 of the Affordable Care Act, OCR will be providing model language translated into the 15 languages most commonly spoken by individuals with LEP in every State and nationally that plans can use as a template to comply with the proposed CMS notice requirements. Also, allowing the use of a model Notice of Availability provides flexibility for D–SNPs in States that may require the use of a specific tagline or Notice language so that they do not have to include additional language in materials. We believe that allowing this flexibility along with the OCR model language outweighs the risk of errors in messaging.

We also thank the commenter for the recommendation to develop a Notice of Availability list translated in the top 31 languages spoken nationally. However, we believe that a list of 31 languages would be too long. As we explained in the proposed rule (88 FR 78525), States with AIP D–SNPs contacted CMS concerned that compliance with Medicaid requirements at § 438.10(d)(2) and Medicare requirements at §§ 422.2267(e)(31) and 423.2267(e)(33) would require D–SNPs to include a Notice with a long list of languages in the required materials. One State described how their current list of languages to comply with Medicare and Medicaid requirements for D–SNPs was over four pages. We noted this as a reason for updating this regulation in the proposed rule. As the commenter points out, lengthy notices can dilute the primary message, making it more difficult for enrollees to receive critical information. Lengthy inserts can also increase costs for plans.

Comment: A commenter encouraged us to promote flexibility for plans to send materials digitally as nearly a quarter of the commenter's plan enrollees selected to receive plan materials electronically. The commenter suggested we require MA organizations to ask enrollees for email address and cell phone information as part of the enrollment application.

Response: We clarify that plans may send the Notice of Availability digitally with required materials as described and permitted in proposed §§ 422.2267(e)(31)(vii) and 423.2267(e)(33)(vii) which we have renumbered as §§ 422.2267(e)(31)(ii)(G) and 423.2267(e)(33)(ii)(G) in this final rule that the notice may be provided electronically when a required material is provided electronically as permitted under §§ 422.2267(d)(2) and 423.2267(d)(2). We also note that the model MA enrollment form includes a section where enrollees can note materials they would like to receive via email and the option to add their email address. Enrollees may also include their cell phone number in the application.

Comment: A commenter questioned if the reference to ''auxiliary aids'' in the CMS proposal equates to what CMS traditionally considered alternate formats: audio, large print, and braille. Another commenter requested that braille be exempt from the requirement because plans know that an enrollee's preference is braille if the enrollee is already receiving documents in braille.

Response: We thank the commenter for the question and clarify that, in alignment with OCR, we define ''auxiliary aids'' as written in 45 CFR 92.102.[72] As noted, plans must provide the Notice of Availability in alternate formats, if requested. If an enrollee indicates a preference for receiving materials in braille, the plan should also provide that enrollee with the Notice of Availability text in English braille, and then—not in braille—include the text in the 15 languages most commonly

[72] *https://www.ecfr.gov/current/title-45/section-92.102.*

spoken by individuals with LEP in the State or States associated with the plan benefit package service area, informing them of the availability of verbal translation services as well as alternate formats. If an enrollee requests materials in large print, then the plan should provide them with the Notice of Availability text in English in large print and in at least the 15 languages most commonly spoken by individuals with LEP in the State or States associated with the plan benefit package service area. Plans must also comply with section 504 of the Rehabilitation Act and section 1557 of the Affordable Care Act, which may include providing the Notice of Availability in an alternate format or providing another auxiliary aid or service such as braille. Thus, if an enrollee is in need of the Notice of Availability in an alternate format or through another auxiliary aid or service, the enrollee's plan would likely already be required to provide the Notice of Availability in the requested medium, to comply with section 504 and section 1557.

Comment: Some commenters recommended that we delay the effective date or enforcement of the requirement to CY 2026 or until OCR's final rule is released to ensure consistency and prevent what they characterize as undue burden to plans. A commenter stated a concern with being able to include the associated costs in their 2024 MA bids and the time required to make the administrative updates.

Response: We appreciate the commenters' concerns about the timing of our proposal and OCR's section 1557 final rule. We have worked closely with OCR to eliminate potential conflicts with the section 1557 final rule.

We also understand that MA organizations may need to make some administrative adjustments to comply with this requirement. CMS will provide a list of the top 15 languages most commonly spoken by individuals with LEP in each State and nationally, and OCR will provide translations of the model Notice of Availability in those languages. In addition, in this final rule we have updated §§ 422.2267(e)(31) and 423.2267(e)(33) to allow plans to continue using the MLI until the beginning of contract year 2026 marketing on September 30, 2025. However, plans will also have the choice, starting at the beginning of marketing for contract year 2025 on September 30, 2024, of using the Notice of Availability described in subparagraphs 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) to satisfy the MLI requirement, as provided in §§ 422.2267(e)(31)(i)(G) and 423.2267(e)(33)(i)(G). This flexibility will allow D–SNPs in States requiring a State-specific tagline to use the State tagline for contract year 2025 marketing and communications without also having to include the MLI as well. It will also allow those plans that want to provide a State-specific notice for contract year 2025 marketing and communications to do so. Per §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii), all plans will be required to use the Notice of Availability for CY 2026 marketing and communications beginning September 30, 2025.

Comment: A commenter requested that all levels of government adopt policies ensuring that individuals with LEP have adequate language access to their health care provider. The commenter also recommended we work to ensure that professional language service providers are adequately trained, certified, and compensated, and that opportunities are made available for Medicare beneficiaries, family caregivers, and trained interpreters to provide input on the language used in the model communication materials.

Response: We appreciate the commenter's perspective that professional language service providers should be adequately trained, certified, and compensated. We agree that these are important issues, although matters of compensation are beyond the scope of this rulemaking. We note that OCR will provide model language based on beneficiary testing. In addition, we encourage MA organizations to consult with Medicare beneficiaries, family caregivers, and trained interpreters if they decide to include translations of the Notice of Availability in languages other than those provided by OCR.

Comment: A few commenters recommended that we provide all standard model materials in the top 15 languages that are on the current MLI.

Response: We appreciate the commenters' recommendation, but the requests for CMS to provide translations of all standard model materials are out of scope. Our proposal pertains to notifying enrollees of the availability of verbal translation services, not the translations of written model materials themselves. However, we note that in contract year 2024, CMS did translate the Annual Notice of Changes (ANOC), Evidence of Coverage (EOC), EOC errata, Explanation of Benefits (EOB), Provider Directory, Pharmacy Directory, Formulary, Low-Income Subsidy (LIS) Rider, and Part D transition letter in Chinese, Korean, Spanish, and Vietnamese. We also remind commenters that OCR will provide translations of the model Notice of Availability in the 15 languages most commonly spoken by individuals with LEP in each State and nationally. Additionally, we note that §§ 422.2267(a)(3) and 423.2267(a)(3) obligate plans to provide required materials to enrollees on a standing basis in any of the non-English languages identified in §§ 422.2267(a)(2) or (a)(4) and 423.2267(a)(2) or (a)(4) or in an accessible format, when an enrollee makes a request to receive these materials in a non-English language or accessible format.

Comment: A few commenters stated that the 5 percent service area threshold is not inclusive enough and recommended that we set a threshold of either 5 percent or 1,000 people, whichever is lower, in a service area. Another commenter requested that there be an undefined standard to ensure that smaller language communities receive the Notice of Availability in their preferred language.

Response: We appreciate the commenters' perspectives on this issue, but changes to the threshold for the translation requirement are beyond the scope of this regulation. We believe policy making on this issue would benefit from further study and engagement with interested parties, including notice to the public and the opportunity to submit comments on this topic.

Comment: A commenter strongly encouraged us to minimize future modifications to the Notice of Availability as such fluctuations over the years have created administrative burden and increased costs for plans.

Response: We agree with the commenter that limiting future modifications to regulations regarding notification of the availability of language assistance services and auxiliary aids and services would help reduce burden. We will work to limit future changes. Moreover, we anticipate the policy we are finalizing, which better aligns Medicare translation requirements with Medicaid and OCR requirements, will mitigate the need for future updates.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing revisions to paragraphs at §§ 422.2267(e)(31) and 423.2267(e)(33) as follows: We are allowing plans a choice in the applicability date for the updates to §§ 422.2267(e)(31) and 423.2267(e)(33). Plans may implement the changes for contract year 2026 marketing and communications beginning September

30, 2025, or contract year 2025 marketing and communications beginning September 30, 2024. As a result, we are adding the heading *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability)* at §§ 422.2267(e)(31) and 423.2267(e)(33) and modifying sections §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i) to read, ''Prior to contract year 2026 marketing on September 30, 2025, the notice is referred to as the *Multi-language insert (MLI).* This is a standardized communications material which states, 'We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.'' We are then inserting the former rule sections §§ 422.2267(e)(31)(i)–(vi) and 423.2267(e)(33)(i)–(vi) and renumbering them as §§ 422.2267(e)(31)(i)(A)–(F) and 423.2267(e)(33)(i)(A)–(F). We are also including a clarification in §§ 422.2267(e)(31)(i)(B) and 423.2267(e)(33)(i)(B) to incorporate the exception that we are finalizing in §§ 422.2267(e)(31)(i)(G) and 423.2267(e)(33)(i)(G), which will allow plans to utilize the new model notice described in §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) to satisfy the existing MLI requirement during contract year 2025. We are also adding § 422.2267(e)(31)(i)(G) stating, ''At plan option for CY 2025 marketing and communications beginning September 30, 2024, the plan may use the model notice described in subparagraph 422.2267(e)(31)(ii) to satisfy the MLI requirements set forth in this subparagraph (i).'' We are adding an identical provision at § 423.2267(e)(33)(i)(G) except with a reference to subparagraph 423.2267(e)(33)(ii).

We are modifying sections §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) to state, ''For CY 2026 marketing and communications beginning September 30, 2025, the required notice is referred to as the *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability).* This is a model communications material through which MA organizations must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge.'' We are then redesignating sections §§ 422.2267(e)(31)(i)–(vi) and 423.2267(e)(33)(i)–(vi) as new paragraphs §§ 422.2267(e)(31)(ii)(A)–(G) and 423.2267(e)(33)(ii)(A)–(G). For the redesignated paragraphs (e)(31)(ii)(A) and (e)(33)(ii)(A) we are adding ''or States associated with the plan's service area'' between the proposed language ''relevant State'' and ''and must be provided . . .'' to reduce the burden on organizations with plan benefit packages that operate in more than one State and conform with the section 1557 proposed rule, and to clarify that the requirement is based on the plan benefit package service area. Paragraph (A) will specify that this notice of availability of language assistance services and auxiliary aids and services must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States associated with the plan's service area and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

Q. Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310)

Section 1853(a) of the Act requires CMS to risk-adjust payments made to Medicare Advantage (MA) organizations. In order to carry out risk adjustment, section 1853(a)(3)(B) of the Act requires submission of data by MA organizations regarding the services provided to enrollees and other information the Secretary deems necessary. The implementing regulation at § 422.310(b) requires that MA organizations submit to CMS ''the data necessary to characterize the context and purposes of each item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner.'' Currently, § 422.310(d)(1) provides that MA organizations submit risk adjustment data equivalent to Medicare fee-for-service (FFS) data to CMS as specified by CMS. MA encounter data, which are comprehensive data equivalent to Medicare FFS data, are risk adjustment data.[73]

Section 1106(a)(1) of the Act authorizes the Secretary to adopt regulations governing release of information gathered in the course of administering programs under the Act. In addition, section 1856(b) of the Act authorizes CMS to adopt standards to carry out the MA statute, and section 1857(e)(1) of the Act authorizes CMS to add contract terms that are not inconsistent with the Part C statute and are necessary and appropriate for the program. The regulation at § 422.310(f)(1) establishes permissible CMS uses of MA encounter data (referred to as ''risk adjustment data'' in the regulation), while § 422.310(f)(2) and (f)(3) establish rules for CMS release of data. Prior to 2008, § 422.310(f) provided for CMS to use MA risk adjustment data to risk adjust MA payments and, except for any medical record data also collected under § 422.310, for other purposes. Over time, we subsequently refined the regulatory language describing the scope of permissible uses and releases of the MA risk adjustment data, including MA encounter data, to (i) risk adjusting MA payments, (ii) updating risk adjustment models, (iii) calculating Medicare disproportionate share hospital percentages, (iv) conducting quality review and improvement activities, (v) for Medicare coverage purposes, (vi) conducting evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related purposes, (vii) for activities to support administration of the Medicare program, (viii) for activities to support program integrity, and (ix) for purposes authorized by other applicable laws (70 FR 4588; 73 FR 48650 through 48654; 79 FR 50325 through 50334).

Section 422.310(f)(2) permits the release of MA encounter data to other HHS agencies, other Federal executive branch agencies, States, and external entities, and § 422.310(f)(3) of our current regulation specifies circumstances under which we may release MA encounter data for the purposes described in § 422.310(f)(1). Existing regulations allow release of the data after risk adjustment reconciliation for the applicable payment year has been completed, under certain emergency preparedness or extraordinary circumstances, and when CMS determines that releasing aggregated data before reconciliation is necessary and appropriate for activities to support the administration of the

[73] See System of Records Notices for the CMS Encounter Data System (EDS), System No. 09–70–0506, published June 17, 2014 (79 FR 34539), as amended at February 14, 2018 (83 FR 6591); and for the CMS Risk Adjustment Suite of Systems (RASS), System No. 09–70–0508, published August 17, 2015 (80 FR 49237), as amended at February 14, 2018 (83 FR 6591).

Medicare program (finalized in the CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program final rule (88 FR 79400)). We noted in the November 2023 proposed rule that further expanding MA encounter data sharing to include support for the Medicaid program would be consistent with the goals of the Federal Coordinated Health Care Office, as established in statute (88 FR 78527).

MA enrollment has grown to approximately half of all Medicare beneficiaries; a trend also seen in the enrollment of dually eligible individuals. For example, 51 percent of all dually eligible individuals were enrolled in an MA plan in 2021 (up from 12 percent in December 2006).[74] [75] Such individuals experience the health care system and incur health outcomes as individuals regardless of which health care program pays for the service, but currently, the States' ability to obtain MA encounter data for program analysis and evaluations or program administration for dually eligible individuals enrolled in an MA plan is limited to support of a Medicare-Medicaid demonstration. Our current regulation text does not specify that we may make MA encounter data available to States for Medicaid program administration or to conduct evaluations and other analyses for the Medicaid program, with the exception of those evaluations and analyses used to support demonstrations. Therefore, previous rulemaking limited opportunities for States to effectively perform functions such as coordination of care, quality measure design, and program evaluation and analysis by allowing them access to MA encounter data for these activities only for those dually eligible individuals enrolled in Medicare-Medicaid demonstrations.

We proposed changes to § 422.310(f) to improve States' access to MA encounter data, including making a specific exception to the timing of sharing MA encounter data. We noted that we did not intend for our proposals to impact the terms and conditions governing CMS release of MA risk adjustment data as described in § 422.310(f)(2), in accordance with applicable Federal laws and CMS data sharing procedures. As discussed in the August 2014 final rule, CMS data sharing procedures require each recipient of data from CMS to sign and maintain a CMS data sharing agreement, ''which addresses privacy and security for the data CMS discloses'' and ''contains provisions regarding access to and storage of CMS data to ensure that beneficiary identifiable information is stored in a secure system and handled according to CMS's security policies,'' which encompasses the limitations for additional disclosure of CMS data (79 FR 50333). We noted that such provisions would similarly apply to States that receive MA encounter data under our proposed amendments to § 422.310(f).

As stated in the August 2014 final rule, the data described in paragraphs (a) through (d) would include those elements that constitute an encounter data record, including contract, plan, and provider identifiers, with the exception of disaggregated payment data (79 FR 50325). In accordance with § 422.310(f)(2)(iv), we aggregate payment data to protect commercially sensitive information.

1. Expanding and Clarifying the Programs for Which MA Encounter Data May Be Used for Certain Allowable Purposes

As we stated in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program proposed rule (hereafter referred to as the May 2014 proposed rule; 79 FR 27978), using MA encounter data enables us, our contractors, and external entities to support Medicare program evaluations, demonstration designs, and effective and efficient operational management of the Medicare program, encourages research into better ways to provide health care, and increases transparency in the administration of the Medicare program (79 FR 28281 through 28282). However, because States lack access to MA encounter data, States' ability to conduct activities for dually eligible individuals enrolled in MA plans is limited. As Medicare is the primary payer for dually eligible individuals, States generally lack comprehensive data on care provided to dually eligible individuals enrolled in MA. Over the years, various States have requested that CMS share MA encounter data for dually eligible individuals to better coordinate care, conduct quality improvement activities, support program design, conduct evaluations, and improve efficiency in the administration of the Medicaid program.

Our current regulation text at § 422.310(f)(1)(vi) (evaluations and analysis to support the Medicare program) and (vii) (activities to support administration of the program) specifies that, for these purposes, the encounter data must be used for the Medicare program. Therefore, though § 422.310(f)(2) permits CMS to release MA encounter data to States for the purposes listed in paragraph (f)(1), § 422.310(f)(1)(vi) and (vii) do not clearly permit CMS to release MA encounter data to States to support Medicaid program evaluations and analysis or to support administration of the Medicaid program.

We proposed to add ''and Medicaid program'' to the current MA encounter data use purposes codified at § 422.310(f)(1)(vi) and (vii) and explained that these additions would enable CMS to use the data and release it (in accordance with § 422.310(f)(2) and (3)) for the purposes of evaluation and analysis and program administration for Medicare, Medicaid, or Medicare and Medicaid combined purposes. We stated our belief that our release of MA encounter data for data use purposes that support the Medicare and Medicaid programs would generally be to the States and would support our responsibility to improve the quality of health care and long-term services for dually eligible individuals; improve care continuity, ensuring safe and effective care transitions for dually eligible individuals; improve the quality of performance of providers of services and suppliers under the Medicare and Medicaid programs for dually eligible individuals; and support State efforts to coordinate and align acute care and long-term care services for dually eligible individuals with other items and services furnished under the Medicare program.

We noted in the November 2023 proposed rule that, as stated above, CMS's usual data sharing procedures apply to the release of MA encounter data in accordance with § 422.310(f)(2) and address access to and storage of CMS data to ensure that beneficiary identifiable information is protected. We explained that we make other data available to external entities, including

[74] 2023 Medicare Trustees Report *https://www.cms.gov/oact/tr.*

[75] *https://www.cms.gov/files/document/managedcareenrollmenttrendsdatabrief2012-2021.pdf.*

States, in accordance with CMS data sharing procedures and Federal laws, including but not limited to the Privacy Act of 1974. We further explained that we review data requests for appropriate use justifications, including updated or amended use justifications for existing data requests, and we employ data sharing agreements, such as a Data Use Agreement and Information Exchange Agreement, that limit external entities to CMS-approved data uses and disclosure of CMS data. For example, States that request data from CMS for care coordination and program integrity initiatives may disclose the data to State contractors, vendors, or other business associates for those activities. In accordance with CMS data sharing agreements, these State contractors, vendors, or other business associates must also follow the terms and conditions for use of the CMS data, including limiting use of the CMS-provided data only for approved purposes. We explained that this would mean that, under our proposal, a State receiving MA encounter data for care coordination may disclose MA encounter data to Medicaid managed care plans to coordinate services for enrolled dually eligible individuals. We noted that comments submitted on the August 2014 final rule cited concerns that access to MA encounter data by competitors of the various MA organizations that are required to submit data could permit a competitor to gain an advantage by trending cost and utilization patterns over a number of years. We explained that § 422.310(f)(2)(iv) provides for aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data and that any release of MA encounter data to States would comply with applicable statutes, regulations, and processes including those described above, and we expressed our belief that concern around potential competitive advantage would be mitigated if the risk exists at all. We noted that, as stated in the August 2014 final rule, we believe that CMS data sharing procedures and review of use justifications ''strikes an appropriate balance between the significant benefits of furthering knowledge'' and the concerns regarding the release of risk adjustment data, including about beneficiary privacy or commercially sensitive nature of encounter information submitted by MA plans (79 FR 50328). Consistent with what we stated in the August 2014 final rule, CMS data sharing agreements have enforcement mechanisms, and data requestors acknowledge these mechanisms. For example, penalties under section 1106(a) of the Social Security Act [42 U.S.C. 1306(a)], including possible fines or imprisonment, and criminal penalties under the Privacy Act [5 U.S.C. 552a(i)(3)] may apply, as well as criminal penalties that may be imposed under 18 U.S.C. 641 (79 FR 50333). Requestors of CMS data, such as States, are responsible for abiding by the law, policies, and restrictions of the data sharing agreements—which extends to any downstream disclosures of the data to State contractors, vendors, or other business associates—as a condition of receiving the data. We noted our intent to only approve requests for MA encounter data that have clear written data use justifications and identify any downstream disclosure—such as to State contractors, vendors, or other business associates—for each requested purpose. We have not identified any issues regarding competitive harm or disadvantage in our current data sharing programs.

As stated in the November 2023 proposed rule, this proposal would allow us to use MA encounter data and disclose it—subject to the other limitations and protections specified in § 422.310(f) and other applicable laws and regulations—to States to perform evaluations and analysis, which would include program planning for dually eligible individuals. Currently, States generally only receive Medicare FFS data from CMS under current authorities, which results in an incomplete assessment of the dually eligible population. Under our proposal, we noted that States could request MA encounter data for all of the dually eligible enrollees they serve and include this growing portion of the dually eligible population in their data analysis and efforts to improve outcomes for low-income older adults and people with disabilities who are enrolled in the Medicaid program.

In the August 2014 final rule, we stated that, in addition to use of these data for review of bid validity and MLR, we expected there would be additional potential uses for these data as part of the program administration purpose, such as the development of quality measures (79 FR 50326). Consistent with our expectation at that time, we clarified in the November 2023 proposed rule that care coordination would be an allowable use for these data as part of the purpose currently codified at § 422.310(f)(1)(vii)—for activities to support the administration of the Medicare program—which includes activities that are not within the scope of the other permitted uses defined at § 422.310(f)(1). Similar to quality measure development, a use we explicitly named, care coordination is critical to ensuring that individuals receive effective and efficient care, especially when services may be covered under multiple health care programs, as is the case for dually eligible individuals who are enrolled in Medicaid and an MA plan. We also stated our belief that use and release of MA encounter data to States to support administering the Medicaid program, including to coordinate care and improve quality of care for Medicaid-covered individuals, is appropriate. We provided the example that, in administering the Medicaid program, a State may need MA encounter data to coordinate care for dually eligible individuals, which may include identification of individuals at high risk of institutional placement or other undesirable outcomes based on past service utilization; coordination of services from the MA plan's coverage of an inpatient stay to Medicaid coverage of subsequent home and community-based services; coordination of Medicaid-covered services in a skilled nursing facility for a dually eligible individual after reaching the limits of the individual's coverage through the MA plan; monitoring nursing facility quality of care, including through tracking rates of hospitalization and emergency room visits; and coordination of physical health services with behavioral health services, where Medicaid coverage differs from the MA plan's coverage.

2. Adding an Additional Condition Under Which MA Encounter Data May Be Released Prior to Reconciliation

Section 422.310(f)(3) describes the circumstances under which we may release MA encounter data. Specifically, the current regulation provides that MA encounter data will not become available for release unless the risk adjustment reconciliation for the applicable payment year has been completed, we determine it is necessary for certain emergency preparedness purposes, we determine that extraordinary circumstances exist, or we determine that releasing aggregated data is necessary and appropriate to support activities and authorized uses in the administration of the Medicare program. Section 422.310(g) specifies the deadlines that we use to determine which risk adjustment data submissions we will use to calculate risk scores for a given payment year. This section also establishes a reconciliation process to adjust payments based on additional data from the data collection period

(meaning the year the item or service was furnished to the MA enrollee) so long as we receive the submissions before the established final risk adjustment data submission deadline for the payment year, which is no earlier than January 31 of the year following the payment year. This submission window provides MA organizations an opportunity to update or submit encounter data records and chart review records to be considered for risk adjustment and payment in the applicable payment year. Section 422.310(b) requires MA organizations to submit data for all items and services provided to an MA enrollee; therefore, MA organizations must continue to submit encounter data records and data corrections after the final risk adjustment data submission deadline when timely data submissions are determined to be inaccurate, incomplete, or untruthful (see § 422.310(g)(2)(ii) for limitations on which submissions after the final risk adjustment data submission deadline may be used for additional payment). We explained that the timing limitation on release of MA encounter data in our current regulation is tied to the established final risk adjustment data submission deadline for a given payment year, and it results in a data lag of at least 13 months after the end of the MA risk adjustment data collection period (that is, the year during which the item or service was furnished to the MA enrollee), before CMS may release the MA risk adjustment data for the purposes described in § 422.310(f)(1). In the November 2023 proposed rule, we stated our belief that there will be increased utility of MA encounter data for Medicaid programs if the data is released before final risk adjustment reconciliation for coordination of care under the allowable purpose in § 422.310(f)(1)(vii) and that the reasons and concerns we identified when adopting the delay in release of MA encounter data can be sufficiently taken into account by CMS as part of evaluating a request to use the data for specific purposes and determining whether to release the data. Further, in many cases, those reasons and concerns likely do not sufficiently apply in the context of care coordination to require a delay in releasing the data, the further discussion of which we recount below.

In order to improve utility of MA encounter data for certain approved purposes, we proposed to add a new paragraph (f)(3)(v) to § 422.310 to authorize MA encounter data to be released to States for the purpose of coordinating care for dually eligible individuals when CMS determines that releasing the data to a State Medicaid agency before the final risk adjustment reconciliation for a relevant year is necessary and appropriate to support activities and uses authorized under paragraph (f)(1)(vii). As discussed in the November 2023 proposed rule, the proposed amendment to § 422.310(f)(1)(vii) would expand the scope of that provision to include using the data to support administration of the Medicaid program, and in our discussion, we clarified that coordination of care activities are within the scope of activities that support administration of these health care programs. We specified care coordination in our discussion of the proposal for release of MA encounter data prior to final risk adjustment reconciliation, because, as we explained in the November 2023 proposed rule, we believe providing States access to this more timely data is critical to effectively coordinating care which is directly tied to our responsibility to support States' efforts to coordinate and align care and services for dually eligible individuals and furthers our goal to improve care continuity and ensure safe and effective care transitions for dually eligible individuals (see 42 U.S.C. 1315B) while accommodating the concerns that led us to adopt the time limits in § 422.310(f)(3). Together, the proposed changes to § 422.310(f)(1)(vii) and (f)(3)(v) would improve the timeliness of the MA encounter data we make available to States for coordination of care for dually eligible individuals. For care coordination activities, States rely more on timely data about service utilization than on complete data. We stated our belief that improving access to timely MA encounter data and ensuring Medicaid programs can coordinate care for dually eligible individuals supports our goal of providing dually eligible individuals full access to the benefits to which they are entitled (42 U.S.C. 1315B(d)).

As discussed above, States cannot effectively coordinate care for individuals using data that is more than one or two years old. We recognize that the MA encounter data may be subject to edits before final risk adjustment reconciliation given the final risk adjustment data submission deadline for submission of risk adjustment data under § 422.310(g)(2)(ii), which states that the final risk adjustment data submission deadline is a date no earlier than January 31 of the year following the payment year. Therefore, data from some MA organizations or for some enrollees may not be available as quickly as data from or for others. However, we explained that we believe that earlier release of MA encounter data to States for the purpose of care coordination for dually eligible individuals would be appropriate and, as stated above, many of the reasons and concerns to require a delay releasing MA encounter data likely do not sufficiently apply in the context of care coordination. Care coordination activities require States, or their contractors, to identify and contact individuals who have received or are in need of services from their providers. We explained that as States would use the MA encounter data to identify opportunities for care improvement such as improving transitions of care or promoting the use of underutilized services, we did not foresee any risk to individuals from States using data that may be subject to change in the future. States would be able to use the data to identify more dually eligible individuals who are potentially in need of Medicaid-covered services. States are not required to act on the data and can address potential data concerns arising from using MA encounter data before final risk adjustment reconciliation as States have experience using Medicare data that may not be final for effective care coordination. We noted that many States already obtain timely Medicare FFS claims with a lag between 14 days to 3 months, depending on the data file, for uses such as care coordination, quality improvement, and program integrity. These Medicare FFS claims may also be subject to change subsequent to the States' receipt of the data, yet we are not aware of any problems in these use cases caused by CMS sharing data that is still subject to change. Because the MA encounter data released to States would be for care coordination purposes, we do not anticipate any negative impacts from any potential subsequent changes to the encounters. MA encounter data made available to States prior to final risk adjustment reconciliation would not contain disaggregated payment information, in accordance with § 422.310(f)(2)(iv). Additionally, States will not use the pre-reconciliation MA encounter data for plan payment. Under our proposal, release of the MA encounter data for care coordination purposes must be necessary and appropriate to support administration of the Medicaid program; we stated our belief that it would not be appropriate or necessary to use the MA data released on this accelerated schedule for payment purposes (88 FR 78530).

As we explained in the November 2023 proposed rule, coordination of care is a clear situation where more timely MA encounter data is needed for effective intervention without invoking risks that we have cited in the past about sharing MA risk adjustment data before final risk adjustment reconciliation. The timing limits in § 422.310(f)(3) were adopted in the August 2014 final rule in response to comments expressing concern about release of the MA risk adjustment data (79 FR 50331 through 50332). In that prior rulemaking, some commenters cited concerns about release of MA encounter data submitted in the initial years due to concerns regarding systems development and submission challenges. We stated our belief that these concerns were mitigated by the subsequent years since the implementation of the August 2014 final rule that have resulted in accumulation of experience submitting, reviewing, and using MA encounter data in accordance with § 422.310(f). We noted that, in addition, CMS maintains several checks and edits in the encounter data system to minimize duplicate, incomplete, or inappropriate data stored in the encounter data system. In the November 2023 proposed rule, we reiterated that our proposed amendment to paragraph (f)(3) would only permit the release of MA encounter data to State Medicaid agencies for care coordination for dually eligible individuals.

We also explained that we had noted in prior rulemaking that our approach to reviewing requests for MA encounter data from external entities would incorporate the Medicare Part A/B and Part D minimum necessary data policy, with additional restrictions to protect beneficiary privacy and commercially sensitive information of MA organizations and incorporated that limitation into paragraph (f)(2) (79 FR 50327). Further, we noted that this limitation would also apply when reviewing State requests for MA encounter data under the proposed expansion of § 422.310(f)(1)(vi) and (vii), and to any State requests for MA encounter data before the reconciliation deadline to support coordination of care. We explained that CMS data sharing procedures include a review team that assesses data requests for minimum data necessary and appropriate use justifications for care coordination, and we would only approve release of MA encounter data for any data requests where the requestor has sufficiently demonstrated that the request satisfies all requirements of § 422.310(f). We noted that other commenters on the August 2014 final rule had expressed concerns that MA organizations are able to delete, replace, or correct MA encounter data before the reconciliation deadline, which could potentially result in inaccurate or incomplete MA encounter data and that incomplete or inaccurate data should not be used or released for the purposes outlined in § 422.310(f). Additionally, CMS makes available technical assistance to States to help with State use and understanding of Medicare data. In the November 2023 proposed rule, we expressed our intent to extend this technical assistance to States requesting MA encounter data to mitigate issues arising from non-final data, and to evaluate the potential concerns arising from using MA encounter data before final reconciliation when determining whether to release MA encounter data to States for care coordination activities for dually eligible individuals to support administration of the Medicare and Medicaid programs.

Finally, we proposed that these amendments to § 422.310(f) would be applicable upon the effective date of the final rule. As outlined in section I.A. of the November 2023 proposed rule, the majority of our proposals were proposed to be applicable beginning January 1, 2025. We stated that we do not believe delaying the applicability of these proposed amendments beyond the effective date of the final rule is necessary because these proposals address CMS's authority to use and share MA encounter data but do not impose any additional or new obligations on MA organizations.

We received the following comments on these two proposals and respond to them below:

Comment: Numerous commenters, including the vast majority who commented on these proposals, expressed support for CMS proposals to expand the allowable MA encounter data uses by adding ''and Medicaid'' to existing uses at § 422.310(f)(1)(vi) and (vii) and our proposal to share MA encounter data with States in advance of reconciliation for the purpose of care coordination for dually eligible individuals. These commenters agreed that these changes would improve States' ability to understand and improve service delivery for dually eligible individuals. Many comments also included additional perceived benefits, such as: identification of unaligned dually eligible individuals (that is, individuals enrolled in one MA plan and a separate, unaligned Medicaid managed care plan); D–SNP program planning; assessing supplemental benefit use; facilitating development of a long term services and supports dashboard to inform policy and quality improvement efforts; ensuring proper payment for services and determination of third party liability with minimal disruption to providers; focusing outreach for service provision by Medicaid managed care plans; analysis for required reporting on managed care network adequacy and service access; eliminating potentially duplicative evaluations; and providing continuity within both primary and specialty care for dually eligible individuals.

Response: We appreciate the comments and support.

Comment: A commenter requested clarification on how the facilitation of the data exchange may occur and if this requires data exchange agreements, three-way contracts, business associate agreements, or other contractual arrangements.

Response: To effectuate encounter data sharing with States, we would utilize our existing pathways for new data requests, including the existing data transfer mechanisms and data sharing agreements that we currently hold with the States for the disclosure of Medicare data. As stated in the proposed rule, we ''review data requests for appropriate use justifications, including updated or amended use justifications for existing data requests'' and ''employ data sharing agreements, such as a Data Use Agreement and Information Exchange Agreement, that limit external entities to CMS-approved data uses and disclosure of CMS data'' (88 FR 78528).

Comment: Many commenters supported CMS's intent to provide technical assistance and emphasized its importance. A few of those commenters provided suggestions on technical assistance that we could provide to States for encounter data, including sharing information on best practices for utilizing the data; content and limitations of the data set; data request processes and timelines; disclosure parameters and suggested uses for the data; purposes not permitted; data linkage; and building data infrastructure for use of MA encounter data.

Response: We thank these commenters for their suggestions. We agree that technical assistance to States would be an important aspect of sharing MA encounter data. As we noted in our proposal, we intend to provide technical assistance to States, such as the CCW Medicare Encounter Data User Guide (*https://www2.ccwdata.org/web/guest/user-documentation*), to help them make the most effective use of MA

encounter data, including ways to mitigate issues arising from non-final data, potential concerns arising from using MA encounter data before final reconciliation, and what disclaimers are appropriate to provide to requestors, to help them understand the limitations of the MA encounter data (88 FR 78531). We will take these suggestions into consideration when developing our technical assistance approach.

Comment: A commenter provided additional suggestions for our communication around sharing of MA encounter data with States. These suggestions included notifying plans when MA encounter data is shared with a State, guidance to States on how to communicate with plans and address anomalies, particularly when the State is analyzing and interpreting these data for performance evaluation and quality reporting, and publishing a report following 2 years of implementation that provides the industry with information on how the sharing of MA encounter data has facilitated greater coordination, integration, and quality measure alignment.

Response: We thank the commenter for these suggestions. We will take them into consideration as we establish operational processes to support sharing MA encounter data with States.

Comment: A commenter supported CMS proposals and suggested CMS include other data collected from or submitted by MA organizations, such as data obtained from chart reviews, lab results, EMR records, and other clinical documents, in addition to MA encounter data in the data that is shared with States under § 422.310(f).

Response: We note that current regulation at § 422.310(f) specifies the purposes and procedures according to which we may use and release the MA risk adjustment data, which is defined in § 422.310(a) and includes encounter data and other data submitted by MA organizations for risk adjustment purposes (such as chart review records, which are reports of diagnoses, and may be sourced from chart reviews, lab results, EMR record or other clinical documents). However, aside from the chart review records, any clinical documentation that CMS may have access to will not be released. The regulation at § 422.310(f) excludes the use and release of the data described at § 422.310(e) for validation of risk adjustment data; this means that the medical records or other clinical documents that MA organizations submit to validate their risk adjustment submissions are not released under § 422.310(f). CMS did not propose any changes to expand data sharing to include medical records or other clinical documents; therefore, CMS is not finalizing any regulatory changes related to sharing such information.

Comment: Some commenters stressed the importance of establishing strong measures to ensure data privacy and security when disclosing MA encounter data, including limiting access to medical records to protect the trust and security of the physician-patient relationship and the safety of the patient.

Response: We appreciate these comments underscoring the importance of protecting data privacy and security. In the proposed rule, we stated that we disclose data in accordance with applicable Federal laws and CMS data sharing procedures that include privacy and security measures for data sharing to protect individuals' PHI and PII, (88 FR 78527). We also noted in our proposed rule the following additional CMS data sharing processes to protect the safety of the individual: we review data requests for appropriate use justifications, employ data sharing agreements that limit data requestors to CMS-approved data uses and disclosure of CMS data, and include enforcement mechanisms; and data requestors acknowledge these mechanisms and that they will abide by the law, policies, and restrictions of the data sharing agreements as a condition of receiving the data (88 FR 78528). We will only approve data requests that are within the allowable uses of MA risk adjustment data (generally MA encounter data) as detailed in § 422.310(f)(1). With regard to the comment about limiting access to medical records, as discussed in a prior response to a public comment, § 422.310(f) does not authorize the release of medical records or other records submitted by an MA organization under § 422.310(e) to validate its risk adjustment data submissions.

Comment: Some commenters underscored the importance of data quality and provided recommendations to ensure data accuracy and completeness. These recommendations included suggesting that CMS continue to seek ways to improve the completeness of encounter data, including considering MedPAC's 2019 recommendation on MA encounter data completeness; considering ways to ensure that data is as accurate as possible when shared to avoid incorrect care planning and potential patient harm; and providing further clarity on how this data will be communicated. Additionally, a commenter recommended CMS avoid any changes that may impact data quality or how MA organizations currently report to CMS and State Medicaid programs.

Response: We thank these commenters for the recommendations to ensure data quality and accuracy. We reiterate our intent to provide technical assistance and necessary resources for data requestors, including appropriate disclaimers to help requestors understand the limitations of the MA encounter data (88 FR 78531). We stated in the proposed rule that we do not foresee any potential patient harm from States using data that may be subject to change in the future since States would use the MA encounter data to identify opportunities for care improvement, such as improving transitions of care or to promote the use of underutilized services, and that States are not required to act on the data. We also explained that States have experience using Medicare data that may not be final for effective care coordination (88 FR 78530). We appreciate MedPAC's 2019 recommendations and note that we have been working with MA plans to ensure that the accuracy and completeness of MA encounter data improve over time. We note that we have released the *Request for Information: Medicare Advantage Data* to solicit feedback ''on all aspects of data related to the MA program—both data not currently collected as well as data currently collected,'' including ''precise detail and definitions on the data format, fields, and content that would facilitate comprehensive analyses of any publicly released MA data, including comparisons with existing data sets'' and ''recommendations related to operational considerations as part of this effort'' (89 FR 5907 through 5908).

Additionally, we confirm that our proposal does not impact how MA plans submit MA encounter data to CMS. As mentioned above, we will utilize our existing pathways for new MA encounter data requests, including the existing data transfer mechanisms.

Comment: A commenter raised the concern that in order for the proposed policies to be meaningful, States would need necessary resources and infrastructure in place to utilize MA encounter data effectively. The commenter also explained that it is important to coordinate with States to understand their current and planned capacity for ingesting and utilizing the MA encounter data before proceeding. The commenter further stressed that without sufficient IT supports and specific plans for how to leverage MA encounter data, providing the data as proposed would not achieve CMS's goals. Another commenter suggested

that MA encounter data be available at the discretion of the State, as with other Medicare data sharing, as not all State systems are sophisticated enough to use this data.

Response: We appreciate the comments regarding States' capabilities for intake and analysis of the MA encounter data. Many States have extensive history with encounter data through their Medicaid managed care programs. Many also have experience working with Medicare FFS and MA encounter data. For example, since 2011, we have disclosed Medicare data to States to support the dually eligible population, and over 30 States have requested and used, or are still using, these data. Another example is that numerous States currently receive and use MA encounters directly from MA plans in accordance with the terms of a demonstration or as detailed by the contract held by a D–SNP with the State. Additionally, our data sharing agreements require States attest to certain requirements regarding appropriate administrative technical and physical safeguards to protect the integrity, security, and confidentiality of the data as well as system security requirements in order to request data from us. Nonetheless, capacity and experience vary across States, and we confirm our stated intention in the proposed rule that MA risk adjustment data would be available, consistent with § 422.310(f) as amended, when the State requests such data; a State's request for MA encounter data from CMS would be voluntary.

Comment: A few commenters raised questions regarding duplicative data sharing practices and the requirements in some State Medicaid agency contracts (SMACs) for D–SNPs to submit MA encounter data directly to States. A commenter asked how the proposed change would impact existing SMAC requirements, which may currently require such data sharing between D–SNPs and the State, and whether our proposal would create redundancies, inefficiencies, or simply obviate the need for such data sharing. A commenter wished to avoid duplicating any data sharing practices currently in place, and suggested we collaborate with MA plans and States to determine if data sharing can be streamlined through one process. Another commenter suggested removing the requirement for D–SNPs to submit MA encounter data directly to States and, instead, CMS would create a uniform set of MA encounter data available from a central organization, eliminating 50 different systems that collect data in different ways, formats, and times.

Response: We appreciate the interest in streamlining data sharing processes and will consider these comments as we implement the final rule. However, nothing in our final rule imposes any additional or new obligations on MA organizations (88 FR 78531) or creates any additional data sharing or data reporting burden for MA plans. These comments relate to MA encounter data that D–SNPs submit to States in accordance with SMACs established under § 422.107(d)(1). Changes to SMAC requirements about data sharing or data access are outside the scope of our current proposals and are subject to negotiation between the MA organization (or D–SNP) and the State; our current proposals do not directly impact these SMAC requirements or data sharing processes.

Comment: A commenter suggested that CMS provide additional resources for MA organizations on collecting encounter data, citing burdens associated with collecting, processing, and submitting the data. Another commenter suggested that CMS encourage MA plans to submit more timely, higher quality, and uniform MA encounter data directly to States to improve usability for time-sensitive care coordination.

Response: We believe that these suggestions for additional resources for MA organizations to collect MA encounter data and encouraging MA plans to submit more timely, higher quality data directly to States are beyond the scope of this rule. However, as mentioned above, we released the *Request for Information: Medicare Advantage Data* to solicit additional feedback on all aspects of data related to the MA program, including ways that we could improve our current MA data collection and release methods (89 FR 5907).

Comment: A commenter recommended CMS create data sharing agreements to exclude downstream disclosure of MA encounter data to commercial entities. Another commenter expressed concern that changes made by Congress or CMS could expand the type of information captured by MA encounter data in the future to include competitively sensitive information that should not be shared with States. This commenter said that CMS should create an explicit exclusion of payment and pricing data and other competitively sensitive information, indicating that only MA encounter data necessary to support coordination of care, quality measure design, and program evaluation and analysis be shared with States.

Response: As stated in the proposed rule, we intend to only approve requests for MA encounter data that have clear written data use justifications and identify any downstream disclosure—such as to State contractors, vendors, or other business associates—for each requested purpose (88 FR 78528). Also, consistent with what we stated in the August 2014 final rule, CMS data sharing agreements have enforcement mechanisms, and data requestors acknowledge these mechanisms. For example, penalties under section 1106(a) of the Social Security Act [42 U.S.C. 1306(a)], including possible fines or imprisonment, and criminal penalties under the Privacy Act [5 U.S.C. 552a(i)(3)] may apply, as well as criminal penalties may be imposed under 18 U.S.C. 641 (79 FR 50333). Requestors of CMS data, such as States, are responsible for abiding by the law, policies, and restrictions of the data sharing agreements—which extends to any downstream disclosures of the data to State contractors, vendors, or other business associates—as condition of receiving the data. Additionally, we note that current regulation at § 422.310(2)(iv) limits CMS release of MA encounter data ''(s)ubject to the aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data.'' We stated in the proposed rule that—given that § 422.310(f)(2)(iv) provides for aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data and that any release of MA encounter data to States would comply with applicable statutes, regulations, and processes including those described above—we believe that concern around potential competitive advantage is mitigated, if the risk exists at all. We have not identified any issues regarding competitive harm or disadvantage in our current data sharing programs, including current disclosure of MA encounter data (88 FR 78528).

Finally, we note that in the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the

Medicare Promoting Interoperability Program final rule (hereinafter referred to as the January 2024 final rule), we finalized a requirement for impacted payers to employ a Payer-to-Payer API by January 1, 2027 to satisfy two requirements: first, for transfer of data from a previous payer to a current payer for a new enrollee, and second, for quarterly exchange of data between two concurrent payers. Impacted payers include States, Medicaid managed care plans, and MA plans, and therefore would apply to individuals dually enrolled in two or more of these payers—such as between an MA organization and a Medicaid managed care plan (89 FR 8759).

Comment: We received a comment on our discussion in section XI of the November 2023 proposed rule (88 FR 78605), which provided examples where the commenter felt we inadequately justified the need for rulemaking. Specific to our MA encounter data use proposals in this section, the commenter suggested that we include the number of States that have requested such data and provide more specific information about how the wording of the current rule has harmed coordination and quality of care.

Response: As described in the proposed rule, 51 percent of all dually eligible individuals were enrolled in an MA plan in 2021, but previous rulemaking limited opportunities for States to effectively perform functions such as coordination of care, quality measure design, and program evaluation and analysis by allowing them access to MA encounter data for these activities only for those dually eligible individuals enrolled in Medicare-Medicaid demonstrations (88 FR 78527). We also noted in the proposed rule that ''(a)s Medicare is the primary payer for dually eligible individuals, States generally lack comprehensive data on care provided to dually eligible individuals enrolled in MA'' and that ''(o)ver the years, various States have requested that CMS share MA encounter data for dually eligible individuals to better coordinate care, conduct quality improvement activities, support program design, conduct evaluations, and improve efficiency in the administration of the Medicaid program'' (88 FR 78527). We further clarify here that while we do not have a definitive list of all the States that would have requested MA encounter data if it were made available, our contractor conducted an informal poll in 2017 of the States that requested Medicare FFS data and found that 14 out of 15 respondents were interested in requesting MA encounter data if made available. Additionally, during 2022, four States directly asked us for MA encounter data to support specific projects related to dually eligible individuals. In 2023, 26 States (and the District of Columbia) requested Medicare data for dually eligible individuals for care coordination, quality improvement, program planning, and program integrity data uses. The remaining 25 States that did *not* request Medicare data for such uses had various levels of engagement and interaction with our program. Over the previous decade, some of those 25 non-participating States with high managed care penetration cited the lack of MA encounter data as the reason the State did not request Medicare FFS data via our data sharing program.

In the proposed rule, we provided numerous examples of ways States could use MA encounter data. These examples included identification of individuals at high risk of institutional placement or other undesirable outcomes based on past service utilization; coordination of services from the MA plan's coverage of an inpatient stay to Medicaid coverage of subsequent home and community-based services; coordination of Medicaid-covered services in a skilled nursing facility for a dually eligible individual after reaching the limits of the individual's coverage through the MA plan; monitoring nursing facility quality of care, including through tracking rates of hospitalization and emergency room visits; and coordination of physical health services with behavioral health services, where Medicaid coverage differs from the MA plan's coverage (88 FR 78528). As the current regulation at § 422.310(f) does not permit CMS to disclose MA encounter data to States for these data uses, we believe there is harm incurred when States are unable to conduct these activities for dually eligible individuals. We note that we do not know the full extent of States that would have requested MA encounter data if current regulation permitted, the exact data uses for which the States would have used the data, or the number of dually eligible individuals impacted by such data-driven initiatives. However, based on our experience and observations, we believe that it is appropriate to conclude that access to MA risk adjustment data on an accelerated timeframe could support State efforts to coordinate care for dually eligible individuals who are in MA plans.

Finally, as stated in the proposed rule, we believe disclosure for the purpose of improving States' ability to understand and improve care provided to dually eligible individuals is appropriate and consistent with our intention in prior rulemaking regarding uses of MA risk adjustment data and proposed changes to regulation to support our intention (88 FR 78526).

Comment: A commenter recommended additional data sharing efforts for CMS to undertake to improve care coordination for dually eligible individuals. The commenter suggested CMS establish a database with Medicare data for all dually eligible individuals—including Medicare program and contract enrollment data, as well as their Medicare claims data—and disclose to States and plans for coordination across payers. The commenter also suggested requiring States to share standard elements (for example, Medicare program enrollment, Medicare contract number) to Medicaid managed care plans in standard benefit enrollment and maintenance files to facilitate coordination for dually eligible individuals.

Response: We appreciate the suggestions, but they are outside of the scope of our proposal.

After considering the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed amendment to add ''and Medicaid program'' to the current MA encounter data use purposes at § 422.310(f)(1)(vi) to conduct evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related research, and § 422.310(f)(1)(vii) for activities to support the administration of the Medicare program. We are also finalizing without modification our proposed addition of new § 422.310(f)(3)(v) to allow for MA encounter data to be released to States for the purpose of coordinating care for dually eligible individuals when CMS determines that releasing the data to a State Medicaid agency before reconciliation is necessary and appropriate to support activities and uses authorized under paragraph (f)(1)(vii). These amendments to § 422.310(f) will be applicable upon the effective date of this final rule as outlined in section I.A. of this final rule. As explained in the proposed rule, delaying the applicability of these proposed amendments beyond the effective date of the final rule is not necessary because these proposals address CMS's authority to use and share MA risk adjustment data but do

not impose any additional or new obligations on MA organizations.

3. Solicitation of Comments on Use of MA Encounter Data To Support Required Medicaid Quality Reporting

We requested comments on making MA encounter data available to States to support Child and Adult Core Set reporting as efficiently as possible while complying with § 422.310(f) and balancing considerations related to the timeliness of quality reporting with accuracy and completeness. While States are required to include all Medicaid and CHIP beneficiaries in certain mandatory Child and Adult Core Set reporting, including dually eligible individuals, States lack access to the Medicare utilization data needed to report on dually eligible individuals enrolled in MA plans. We discussed these mandatory Core Set reporting requirements and the timing limitations posed by our current regulations in the November 2023 proposed rule (88 FR 78531).

Several commenters supported CMS sharing MA encounter data to States prior to reconciliation for quality review and improvement use. A commenter suggesting alternative options to using MA encounter data prior to reconciliation. We appreciate the support and suggestions for our efforts to improve both the utility of MA encounter data and support of State requirements for quality reporting. We will consider comments and suggestions received as we move forward.

T. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) Appeals Process

In this final rule, we are revising certain timing issues in terms of when RADV medical record review determination and payment error calculation appeals can be requested and adjudicated. Specifically, we proposed that Medicare Advantage (MA) organizations must exhaust all levels of appeal for medical record review determinations before the payment error calculation appeals process can begin. We believed that this clarification was necessary because RADV payment error calculations are directly based upon the outcomes of medical record review determinations. We also proposed several other changes to our regulatory appeals process to conform with these proposed revisions.

Section 1853(a)(1)(C) of the Act requires that CMS risk-adjust payments made to MA organizations. Risk adjustment strengthens the MA program by ensuring that accurate payments are made to MA organizations based on the health status and demographic characteristics of their enrolled beneficiaries, and that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees who are expected to incur lower health care costs, and more for less healthy enrollees who are expected to incur higher health care costs). Making accurate payments to MA organizations also ensures we are safeguarding Federal taxpayer dollars.

Contract-level RADV audits are CMS's main corrective action for overpayments made to MA organizations when there is a lack of documentation in the medical record to support the diagnoses reported for risk adjustment. CMS conducts RADV audits of MA organization-submitted diagnosis data from a selection of MA organizations for specific payment years to ensure that the diagnoses they submitted are supported by their enrollees' medical records. CMS can collect the improper payments identified during CMS and Department of Health and Human Services Office of Inspector General (HHS–OIG) audits, including the extrapolated amounts calculated by the OIG. The RADV audit appeals process, as outlined in 42 CFR 422.311, is applicable to both CMS and HHS–OIG audits and is therefore referred to as the ''MA RADV audit appeals process.'' Additional information regarding CMS's contract level RADV audits was outlined in the RADV final rule, CMS–4185–F2, published on February 1, 2023.[76]

1. Current MA RADV Appeals Process

CMS previously established a process after notice and comment rulemaking for MA organizations to appeal RADV audit findings as outlined by provisions at 42 CFR 422.311(c)(6)–(c)(8). Once review of the medical records submitted by MA organizations to support audited HCCs is completed and overpayment amounts are calculated, HHS (CMS or HHS–OIG) issues an audit report to each audited MA organization contract. In accordance with § 422.311(b)(1), this audit report includes the following:

- Detailed enrollee-level information relating to confirmed enrollee HCC discrepancies.
- The contract-level RADV-payment error estimate in dollars.
- The contract-level payment adjustment amount to be made in dollars.
- An approximate timeframe for the payment adjustment.
- A description of the MA organization's RADV audit appeal rights.

The MA RADV audit appeals process begins once MA organizations are notified of their audit findings via a RADV audit report. MA organizations have 60 days from the date of issuance of a RADV audit report to file a written request for appeal and must follow the Secretary's RADV audit appeals procedures and requirements under § 422.311. MA organizations may appeal RADV medical record review determinations and/or the MA RADV payment error calculation and must specify which findings the MA organization is appealing when requesting an appeal of a RADV audit finding.

Under CMS's existing RADV audit appeals regulations under 42 CFR 422.311(c)(6)–(8), the MA RADV administrative audit appeals process consists of three levels: reconsideration, hearing, and CMS Administrator review. Below is a summary of the three levels of appeal for background information only. This regulation is not revising the basic structure of these three levels of appeal.

a. Reconsideration

Reconsideration is the first stage of the RADV audit appeals process. When appealing a medical record review determination, the MA organization's written request must specify the audited HCC(s) that it wishes to appeal and provide a justification of why the audited HCC(s) should not have been identified as an error. When appealing a payment error calculation, the MA organization's written request must include its own RADV payment error calculation that clearly indicates where HHS' payment error calculation was erroneous, as well as additional documentary evidence pertaining to the calculation of the error that the MA organization wishes the reconsideration official to consider. For payment error calculation appeals, a third-party who was not involved in the initial RADV payment error calculation reviews the HHS and MA organization's RADV payment error calculations and recalculates, as appropriate, the payment error using the appropriate payment error calculation method for the relevant audit.

The reconsideration official issues a written reconsideration decision to the MA organization, and this decision is considered final unless the MA organization disagrees with the reconsideration official's decision and submits a valid request for CMS hearing officer review. A new audit report is

[76] *https://www.federalregister.gov/documents/2023/02/01/2023-01942/medicare-and-medicaid-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare.*

subsequently issued for either a medical record review determination reconsideration or a payment error calculation reconsideration only if the reconsideration official's decision is considered final.

b. Hearing Officer Review

An MA organization that disagrees with the reconsideration decision may request a hearing officer review in accordance with procedures and timeframes established by CMS under 42 CFR 422.311(c)(7). If the MA organization appeals the medical record review reconsideration determination, the written request for RADV hearing must include a copy of the written decision of the reconsideration official, specify the audited HCC(s) that the reconsideration official confirmed as being in error, and explain why the MA organization disputes the reconsideration official's determination. If the MA organization appeals a RADV payment error calculation, the written request for RADV hearing must include a copy of the written decision of the reconsideration official and the MA organization's RADV payment error calculation that clearly specifies where the MA organization believes the Secretary's payment error calculation was erroneous.

The hearing officer has the authority to decide whether to uphold or overturn the reconsideration official's decision and, pursuant to this decision, sends a written determination to CMS and the MA organization explaining the basis for the decision. If necessary, a third party who was not involved in the initial RADV payment error calculation recalculates the RADV payment error and issues a new RADV audit report to the MA organization. For MA organizations appealing the RADV payment error calculation only, a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization and CMS. The hearing officer's decision is final unless the decision is reversed or modified by the CMS Administrator.

c. CMS Administrator Review

Under the existing RADV audit appeals regulation at 42 CFR 422.311(c)(8), a request for CMS Administrator review must be made in writing and filed with the CMS Administrator within 60 days of receipt of the hearing officer's decision. After receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or decline to review the hearing officer's decision. If the CMS Administrator elects to review the hearing decision, the CMS Administrator then will acknowledge the decision to review the hearing officer's decision in writing and notify CMS and the MA organization of their right to submit comments within 15 days of the date of the notification. The CMS Administrator renders his or her final decision in writing to the parties within 60 days of acknowledging his or her decision to review the hearing officer's decision. The decision of the hearing officer becomes final if the CMS Administrator declines to review the hearing officer's decision or does not render a decision within 60 days.

2. Proposed Policies

In this final rule, we are revising the timing of when a medical record review determination and a payment error calculation appeal can be requested and adjudicated. Specifically, we proposed that MA organizations must exhaust all levels of appeal for medical record review determinations before beginning the payment error calculation appeals process. We believed that this change was necessary because RADV payment error calculations are based upon the outcomes of medical record review determinations and the current regulatory language is somewhat ambiguous regarding this point. Adjudicating medical record review determination appeals prior to payment error calculation appeals alleviates operational concerns for CMS and burden on MA organizations by preventing unnecessary appeals of payment error calculations that will be moot if revisions must be made to payment error calculations based on medical record review determination appeal decisions.

Section 422.311(c)(5)(iii) states that, ''for [MA organizations] that appeal both medical record review determination appeal and RADV payment error calculation appeal [,] (A) the Secretary adjudicates the request for the RADV payment error calculation following conclusion of reconsideration of the MA organization's request for medical record review determination appeal.'' The regulations also state that, for cases in which an MA organization requests both a medical record review determination appeal and payment error calculation appeal, ''. . . (B) an [MA organization's] request for appeal of its RADV payment error calculation will not be adjudicated until appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are *final for that stage of appeal*'' [emphasis added]. This language arguably addresses both those cases in which the final adjudication is reached during the reconsideration phase, as well as those that proceed to the second and third level of appeal. We proposed to delete § 422.311(c)(5)(ii)(C), which requires MA organizations requesting both a medical record review determination appeal and payment error calculation appeal to file their written requests for both appeals within 60 days of the issuance of the RADV audit report before the reconsideration level of administrative appeal. Instead, we proposed that MA organizations may request only a medical record review determination appeal or payment error calculation appeal for purposes of reconsideration, and not both at the same time. We proposed to amend § 422.311(c)(5)(iii) by providing that MA organizations who request a medical record review determination appeal may only request a payment error calculation appeal after the completion of the medical record review determination administrative RADV appeal process.

An MA organization may also choose to only appeal the payment error calculation, and therefore, no preceding medical record review determination appeal will occur. MA organizations choosing to only file a payment error calculation appeal will not be able to file a medical record review determination appeal after the adjudication of payment error calculation appeal. At § 422.311(c)(5)(ii)(B), we proposed to specify that MA organizations will forgo their medical record review determination appeal if they choose to only file a payment error calculation appeal, because medical record review appeals decisions need to be final prior to adjudicating a payment error calculation appeal.

At § 422.311(c)(5)(iii)(A) *and (B),* we proposed to specify that this process is complete when the medical record review determination appeals process has been exhausted through the three levels of appeal, or when the MA organization does not timely request a medical record review determination appeal at the hearing officer or CMS Administrator review stage. At proposed § 422.311(c)(5)(iii)(B), we proposed that an MA organization whose medical record review determination appeal has been completed has 60 days from the issuance of a revised RADV audit report to file a written request for payment error calculation appeal, which specifies the issues with which the MA organization disagrees and the reasons for the disagreements. If, as a result of the medical record review determination appeals process, no

original determinations are reversed or changed, then the original audit report will be reissued, and the MA organization will have 60 days from the date of issuance to submit a payment error calculation appeal if it so chooses.

We also proposed to revise § 422.311(c)(6)(i)(A) to clarify that an MA organization's request for medical record review determination reconsideration must specify any and all audited HCCs from an audit report that the MA organization wishes to dispute. The intent of this revision is to permit an MA organization to submit only one medical record review determination reconsideration request per audited contract, which includes all disputed audited HCCs, given that the results of all audited HCCs for a given audited contract are communicated as part of a single audit report.

We also proposed to revise § 422.311(c)(6)(iv)(B) to clarify that the reconsideration official's decision is final unless it is reversed or modified by a final decision of the hearing officer as defined at § 422.311(c)(7)(x).

We also proposed to add § 422.311(c)(6)(v) to clarify that the reconsideration official's written decision will not lead to the issuance of a revised audit report until the decision is considered final in accordance with § 422.311(c)(6)(iv)(B). If the reconsideration official's decision is considered final in accordance with § 422.311(c)(6)(iv)(B), the Secretary will recalculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

We also proposed to revise § 422.311(c)(7)(ix) to clarify that if the hearing officer's decision is considered final in accordance with § 422.311(c)(7)(x), the Secretary will recalculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports for the specific MA contract audit. Once the medical record review determination decision of the adjudicator is final, we believe the same entity that issued the audit report will be able to revise the audit report by applying any medical record review determination findings that may have changed through the medical record review determination appeal process and issue a revised audit report in the most efficient and streamlined manner. Issuing a revised audit report is a standard process and neutrally applies the final adjudicator's medical record review determination findings. This process is consistent with other long standing CMS appeals program, such as the Provider Reimbursement Review Board (PRRB), where post-adjudication revised determinations are issued by the same entity (*e.g.,* the Medicare Administrative Contractor for PRRB cases) that issued the original determination.

- We also proposed the following to provide clarity to the Administrator's level of appeal: To revise § 422.311(c)(8)(iii) to add a requirement that if the CMS Administrator does not decline to review or does not elect to review within 90 days of receipt of either the MA organization or CMS's timely request for review (whichever is later), the hearing officer's decision becomes final.
- To revise § 422.311(c)(8)(iv)(A) to clarify that CMS and the MA organization may submit comments within 15 days of the date of the issuance of the notification that the Administrator has elected to review the hearing decision.
- To revise § 422.311(c)(8)(v) to clarify that the requirement of the Administrator to render a final decision in writing within 60 days of the issuance of the notice acknowledging the decision to elect to review the hearing officer's decision and the 60-day time period is determined by the date of the final decision being made by the Administrator, not by the date it is delivered to the parties.
- To revise § 422.311(c)(8)(vi) to clarify the scenarios in which the hearing officer's decision becomes final after a request for Administrator review has been made.
- To add new § 422.311(c)(8)(vii) that states once the Administrator's decision is considered final in accordance with § 422.311(c)(8)(vi), the Secretary will recalculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

We also proposed to add new § 422.311(c)(9) to specify what actions related to the RADV audit appeals process constitute final agency action. Specifically, in cases when an MA organization appeals a payment error calculation subsequent to an MRRD appeal that has completed the administrative appeals process, the MRRD final decision and the payment error calculation final decision will not be considered a final agency action until the related payment error calculation appeal has completed the administrative appeals process and a final revised audit report has been issued.

We also proposed to revise § 422.311(a) to remove the word ''annually'' for clarity, as the Secretary may conduct RADV audits on differing cadences between the CMS and HHS–OIG RADV audits.

3. Summary of Public Comments

We invited public comment on these proposals and received several comments. Specifically, we received numerous comments regarding our proposals related to the timing of requesting and adjudication of MRRD and PEC appeals. We did not receive any comments specifically addressing our proposals related to the finality of decisions at each level of appeal of appeal, nor the requirements for revised or reissued audit reports. We did not receive any comments specifically addressing our proposals related to the requirements affecting the elective Administrator review process. We did not receive any comments specifically related to our proposal concerning the definition of final agency action. A discussion of these comments, along with our responses follows.

Comment: Commenters generally expressed support for our proposed policies regarding the timing of MRRD and PEC appeals. Commenters stated that these proposals will provide needed clarity in the RADV audit appeals process and that by disallowing MRRD appeals and PEC appeals from being adjudicated concurrently, we will avoid potential administrative complications. Commenters generally agreed that these changes will create uniformity and consistency in the appeals process. One commenter, in addition to supporting our proposed appeals policies, encouraged CMS to consider larger scale reforms to reduce substantial overpayments to MA organizations and recover improper payments.

Response: We thank these commenters for their support of our RADV audit program and our appeals proposals. We agree that the proposals will create uniformity and consistency, as well as avoid administrative complications in the appeals process.

Comment: A commenter requested clarification regarding whether completion of the MRRD appeals process is distinct if an MA organization does not have a medical record to review.

Response: Any valid medical record that is reviewed as part of a RADV audit and found to not substantiate the audited diagnosis may be appealed if the MA organization disagrees with the audit finding. If an MA organization does not wish to appeal any of the medical record review determinations or does not request an appeal by the deadline, the MA organization may

proceed with a PEC appeal. If the commenter is asking whether there are MRRD appeal rights when an MA organization does not submit a medical record to substantiate a diagnosis during an audit, pursuant to § 422.311(c)(3)(iv) MA organizations may not appeal RADV errors that result from failure to submit a valid medical record.

Comment: A commenter requested that we alter the proposal to support uniformity between the RADV appeals process and the OIG audit process.

Response: The RADV audit appeals provisions being finalized in this rule are applicable to appeals of RADV audit findings resulting from both CMS and OIG audits. As stated in § 422.311(a), RADV audits are conducted by the Secretary and the results of any such audit by CMS or OIG are appealable pursuant to § 422.311(c). Appeal rights to audit findings based on either CMS or OIG RADV audits begin with the issuance of an audit report that details audit findings.

4. Comments Out of Scope of the Proposed Policies

We received several comments that were beyond the scope of the proposed rule. Commenters sought additional clarification and made recommendations related to the underlying risk adjustment payment model, aspects of the RADV audit methodology related to sampling and extrapolation, and the need for monetary penalties to be applied to providers or other actors that contributed to a negative RADV finding.

We thank commenters for making broad recommendations for changes to the risk adjustment payment model and for the application of monetary penalties; however, the scope of this rule is limited to the RADV audit appeals process.

Regarding the use of extrapolation and other aspects of RADV audit methodology, the RADV audit appeals process is limited to medical record review determinations and payment error calculations communicated to MA organizations in an audit report. Pursuant to § 422.311(c)(3)(iii), the Secretary's medical record review determination methodology and payment error calculation methodology are ineligible for appeal under this process. While MA organizations may appeal individual medical record review determinations and the resulting payment error calculation, they may not appeal the underlying audit methodology.

5. Final Policy

After consideration of the public comments received, we are finalizing these policies as proposed. As noted above, we did not receive comments on some proposals and are finalizing those policies as proposed.

IV. Benefits for Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Part C and Part D Midyear Benefit Changes (§§ 422.254, 423.265)

1. Overview and Summary

In our proposed rule titled ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications,'' (*87 FR 79452*) which appeared in the December 27, 2022 issue of the **Federal Register** (hereinafter referred to as the ''December 2022 proposed rule''), we proposed two provisions that, if finalized, would restrict changes to the benefits offered by plans (inclusive of MA, MA–PD, and Part D) within the contract year.

We proposed these provisions to codify our longstanding policy prohibiting midyear benefit changes (MYBCs), previously referred to as midyear benefit enhancements (MYBEs), for MA and Part D plans. Specifically, we proposed to prohibit changes to non-drug benefits, premiums, and cost sharing by an MA organization after plans are permitted to begin marketing prospective contract year offerings on October 1 (consistent with § 422.2263(a)) of each year for the following contract year and until the end of the applicable contract year. Similarly, we proposed to codify our longstanding policy prohibiting Part D sponsors from making midyear changes to the benefit design or waiving or reducing premiums, bid-level cost sharing (for example, the cost sharing for an entire formulary tier of Part D drugs), or cost sharing for some or all of a Part D plan's enrollees. This prohibition applies after plans are permitted to begin marketing prospective contract year offerings on October 1 (consistent with § 423.2263(a)) of each year for the following contract year and until the end of the applicable contract year.

2. Medicare Advantage Prohibition on Midyear Benefit Changes (§ 422.254)

In a 2008 final rule titled, ''Medicare Program; Prohibition of Midyear Benefit Enhancements for Medicare Advantage Organizations'' (*73 FR 43628*), which appeared in the **Federal Register** on July 28, 2008, and is hereinafter referred to as the ''July 2008 final rule,'' we prohibited MA organizations from making any midyear changes in benefits, premiums, or cost sharing, even under the circumstances in which these types of changes had been permitted previously.[77] We have enforced this policy to the present day. It is necessary to prohibit benefit changes after bids are submitted and after marketing is permitted to begin in order to maintain the integrity of the bidding process. MA organizations are still allowed to make changes during the bidding process when permitted by CMS to remain in compliance with the requirements set forth at § 422.254 and when permitted by § 422.256. Per § 422.2263, following the start of marketing on October 1 of each year, MA organizations may begin to market and publicize their plan offerings for the following contract year, such that organizations may compare their approved plans against competitors in order to make advantageous changes. However, allowing MYBCs undermines the integrity of the bidding process because it would allow MA organizations to alter their benefit packages after the bidding process is complete. Finally, MA organizations may use MYBCs to misrepresent their actual costs and noncompetitively revise their benefit packages later in the year (*69 FR 46899, 70 FR 4301, 71 FR 52016*).

Altering an approved plan to include new benefits after marketing has started may also give MA organizations an unfair advantage over competitors when beneficiaries are selecting their plans during the initial coverage elections period (ICEP). We articulated in the July 2008 final rule that we believe enrolling newly age-eligible enrollees is attractive to MA organizations because of their relatively low health care utilization, as these individuals tend to be healthier compared to older beneficiaries (*73 FR 43631*). Therefore, to prevent MA organizations from inappropriately changing bids to appeal to low-utilization enrollees, an MA organization must provide the benefits

[77] HHS Secretary Xavier Becerra Statement on End of the COVID–19 Public Health Emergency, *https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html.*

described in the MA organization's final plan benefit package (PBP) (as defined in § 422.162(a)) until the end of the applicable contract year. The July 2008 final rule reiterated these points. Despite the July 2008 final rule, we have continued to receive inquiries from MA organizations requesting changes to PBPs after the contract year has begun.

We also noted in the December 2022 proposed rule that CMS has interpreted MYBCs after the start of the contract year to violate the uniformity requirements set forth at § 422.100(d)(ii), which require that an MA organization must offer a plan to all beneficiaries in a service area ''at a uniform premium, with uniform benefits and level of cost sharing throughout the plan's service area, or segment of service area as provided in § 422.262(c)(2).'' Altering the non-prescription drug benefits, premiums, or cost sharing midyear violates this requirement, even if the new benefit, premium, or cost sharing is offered to all of the plan's enrollees, because some enrollees would have paid for such benefits, premiums, or cost sharing already, and might not be eligible for reimbursement of these costs. In other words, some plan enrollees would have paid higher or lower amounts for the same benefits or services than other plan enrollees who paid depending on when the MYBC was put in effect.

Furthermore, we noted in the December 2022 proposed rule that Employer Group Waiver Plans (EGWPs) exclusively enroll the members of the group health plan sponsored by the employer, labor organization (that is, union) or trustees of funds established by one or more employers or labor organizations to furnish benefits to the entity's employees, former employees, or members or former members of the labor organizations; these plans generally have ''800 series'' MA contracts with CMS. We stated that these EGWPs are not currently subject to this prohibition on MYBCs under existing CMS waivers for EGWPs and will not be subject to the new regulation prohibiting MYBCs. However, we stated, an MA organization is subject to the prohibition on MYBCs if the MA organization offers an MA plan that enrolls both individual beneficiaries and employer or union group health plan members (that is, a plan open to general enrollment); for those types of plans, the employer or union sponsor may make mid-year changes to offer or change only non-MA benefits that are not part of the MA contract (that is, are not basic benefits or MA supplemental benefits). (*See 73 FR 43630* and Chapter 9, section 20.3, of the Medicare Managed Care Manual, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c09.pdf*.)

We proposed to add new paragraph § 422.254(a)(5) explicitly prohibiting MYBCs and specifying when this prohibition applies. Specifically, we proposed to clarify in regulatory text that any changes to non-prescription drug benefits, cost sharing, and premiums are prohibited starting after plans are permitted to begin marketing prospective contract year offerings on October 1 of each year for the following contract year (consistent with § 422.2263(a)) and through the end of the applicable contract year, except for modifications in benefits required by law.

3. Part D Prohibition on Midyear Benefit Changes (§ 423.265)

In the December 2022 proposed rule (*87 FR 79452*), we proposed to add new paragraph § 423.265(b)(5), which states that once a Part D sponsor is permitted to market prospective plan year offerings for the following contract year (consistent with § 423.2263(a)), it may not change the benefits described in its CMS-approved plan benefit package (PBP) (as defined at § 423.182(a)) for the contract year, except where a modification in benefits is required by law.

In part, section 1860D–11(e)(2)(C) of the Act, codified at § 423.272(b)(1), requires that CMS may only approve a bid if it determines that the portions of the bid attributable to basic and supplemental prescription drug coverage are supported by the actuarial bases provided and reasonably and equitably reflect the revenue requirements (as used for purposes of section 1302(8)(C) of the Public Health Service Act) for benefits provided under that plan. MYBCs indicate that the plan bid was overstated and render the bid meaningless, while waiving or reducing the premiums, cost sharing, or both, that are reflected in the approved bid would indicate that the amounts provided in the bid were not necessary for the provision of coverage. In our final rule titled ''Medicare Program; Medicare Prescription Drug Benefit'' (*70 FR 4194*), which appeared in the January 28, 2005 issue of the **Federal Register** (hereinafter referred to as the ''January 2005 Part D final rule''), we stated in the preamble that in order to maintain the integrity of the bidding process, we believed it was not appropriate to allow either MA organizations or Part D sponsors to waive premiums or offer midyear benefit changes, as these would be de facto adjustments to benefit packages for which bids were submitted earlier in the year. We also stated that these adjustments would be de facto acknowledgement that the revenue requirements submitted by the plan were overstated, and further, that allowing premium waivers or midyear benefit enhancements would render the bid meaningless (*70 FR 4301*). In other words, waiving or reducing the premiums and/or cost sharing that are reflected in the approved bid would indicate that the amounts provided in the bid do not reasonably and equitably reflect the revenue requirements of the expected population for the plans' benefits as required.

In the December 2022 proposed rule, we drew a distinction between changes in ''bid-level'' cost sharing (for example, the cost sharing associated with an entire tier of drugs) and changes in the cost sharing for an individual drug (for example, when such drug moves from one already approved tier of the benefit to another already approved tier of the benefit). Section 1860D–4(b)(3)(E) of the Act, as codified at § 423.120(b)(5), requires that Part D sponsors provide appropriate notice before any removal of a covered Part D drug from a formulary and ''any change in the preferred or tiered cost-sharing status'' of such a drug. Thus, the statute contemplates midyear changes in cost sharing of individual formulary drugs. Consequently, since the beginning of the Part D program, we have allowed formulary changes that result in changes to the cost sharing for individual drugs (for example, moving a single drug to a different cost-sharing tier). However, CMS has declined to permit Part D sponsors to change their benefit designs, or waive or reduce premiums, ''bid-level'' cost sharing (for example, the cost sharing associated with an entire tier of drugs), or cost sharing (for all or individual enrollees) once plans are permitted to market for the following contract year (on October 1, now reflected in § 423.2263(a)) on the grounds that such activities would be inconsistent with the CMS-approved bid.

As we noted in our proposed rule titled, ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (*74 FR 54633*), which appeared in the October 22, 2009 issue of the **Federal Register** (hereinafter referred to as the ''October 2009 proposed rule''), a Part D sponsor's waiver of cost sharing midyear violates the uniform benefit requirements because such a waiver results in plans not providing the same coverage to all eligible beneficiaries

within their service area (*74 FR 54690*). The CMS-approved benefit cannot be varied for some or all of the plan's enrollees at midyear because that would violate the uniform benefit provisions set forth in § 423.104(b). Even if the plan changed the benefit midyear for all of the plan's enrollees, this would still violate the uniform benefit provision because some of the plan's enrollees would still have paid for benefits prior to the change. For example, because drug costs are often not evenly distributed over the course of a year, a midyear reduction in cost sharing could provide unequal benefit to enrollees who had the same drug costs but in different phases of their Part D benefit.

We received the following comments on the proposed Medicare Advantage and Part D prohibitions on midyear changes to be added at §§ 422.254 and 423.265, and our responses follow:

Comment: Most of the comments received discussed midyear benefit changes broadly, without specific reference to the MA or Part D provisions. Most commenters took a positive or neutral stance on the two proposals, but a few were opposed to them. A commenter asked that CMS allow midyear benefit changes when plans attempt to improve their benefit packages. Another commenter stated that CMS should make an exception when new products are released to market, particularly pointing to new drugs that receive FDA approval.

Response: As discussed in the proposed rule, changes in bid-level cost sharing or benefits after bids have been submitted could undermine the integrity of the bidding system, disincentivize plans from submitting complete and accurate bids on time, provide competitive advantages to plans that make such changes, undermine CMS's ability to provide accurate comparative information to beneficiaries about plan benefits and costs, and potentially violate the uniform benefit requirements. Both the MA and Part D bid submissions rely on applying a consistent set of criteria for evaluating the suitability and reasonableness of an MA organization or Part D sponsor's estimated costs for the contract year. Allowing plans to make benefit changes after the bid submission deadline would compromise the integrity of that process by introducing new variation between the costs estimated at the bid submission deadline and the actual costs incurred. A sophisticated MA organization or Part D sponsor may attempt to analyze their population during the contract year and determine which benefit changes could improve their overall costs, causing their bid projections to be distorted relative to a different organization or plan sponsor's bids and costs. Similarly, an organization or plan sponsor that sees lower than expected membership could try to adjust their benefits within the year to be more enticing. They may decide, with the availability of the contract year emerging experience, to change their competitive position by adjusting benefits. This would be inconsistent with the standardized bidding process set forth in statute and regulation, which requires plans to bid using only the information available to them at that time. The bid process ensures that MA organizations and Part D sponsors are assuming the risk for the contract year on an equitable basis and receiving fair reimbursement for that risk.

In addition, the potential distortion between the bid amounts and the actual costs after a mid-year benefit change could reduce the accuracy of information based on the bids that is released by CMS. For example, if Part D sponsors are making changes during the contract year that would have resulted in higher bids, that would mean that the release of the national average monthly bid amount is artificially low. This, in turn, would mean that all downstream payments relying on the national average would be inaccurate as well.

The proposed regulatory provisions would restrict changes to the fundamental aspects of plan benefit package design. Under our proposal, MA plans would not be prohibited from making adjustments to their own rules on such matters as prior authorization or referral policies, or from making changes to their provider network, so long as these adjustments or network changes remain within the bounds of existing regulatory requirements and are consistent with the approved plan benefit package. *See,* for example, § 422.111(d) and (e). Likewise, Part D plans would continue to be allowed to make midyear formulary changes that result in cost sharing changes for individual drugs, but they would not be allowed to change cost sharing for entire tiers of drugs or adjust premiums.

In addition, we clarify that the prohibition on MYBCs, which has been longstanding CMS policy, does not and will not prohibit Part D plans (including MA–PD plans) from enhancing their formularies to add coverage of new FDA-approved products. Section 1860D–4(b)(3)(C)(iii) of the Act (echoed in regulation at § 423.120(b)(4)) specifically allows an exception to the rules prohibiting changes to the therapeutic classes and categories of a formulary in order ''to take into account new therapeutic uses and newly approved covered Part D drugs.'' Nothing in our proposed policy overrides the statutory requirement or the equivalent language in existing regulation. In addition, because MA plans must cover all Part A and Part B benefits (subject to limited exclusions as outlined at § 422.100(c)), changes in items and services covered under Parts A and B due to changes in the law, new or changed NCDs, and advances in medical technology or new healthcare services that are newly covered by Traditional Medicare under existing benefit rules must be covered for MA enrollees as well. See § 422.109 for more information on how NCD and legislative changes in benefits are incorporated into the coverage for MA enrollees.

Comment: Some commenters indicated that they appreciated a number of the waivers and flexibilities pertinent to midyear changes that CMS implemented during the COVID–19 public health emergency. One commenter highlighted several of the pharmacy access and cost-sharing flexibilities as particularly helpful in the midst of the emergency. The commenters who expressed appreciation for the COVID–19 waivers and flexibilities also requested that CMS extend those flexibilities through the end of 2023 to allow plans time to transition.

Response: We thank the commenters for providing their input. The waivers and flexibilities for which these commenters requested extensions ended with the conclusion of the Public Health Emergency on May 11, 2023.[78] We do not believe it is necessary or appropriate to continue those flexibilities outside of the context of the PHE. As discussed in the proposed rule (*87 FR 79514 through 79517*) and in the prior response, there are important policy considerations and statutory compliance issues served by the prohibition on MYBCs.

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments, we are finalizing the proposed new provisions at §§ 422.254(a)(5) and 423.265(b)(5) without substantive modification. We have made minor modifications to clarify the text.

[78] HHS Secretary Xavier Becerra Statement on End of the COVID–19 Public Health Emergency, *https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html.*

AA. Failure To Collect and Incorrect Collections of Part D Premiums and Cost Sharing Amounts (§§ 423.293 and 423.294)

In the December 2022 proposed rule *(87 FR 79452),* we proposed requirements for Part D sponsors to: (1) refund incorrect collections of premiums and cost sharing, and (2) recover underpayments of premiums and cost sharing. We also proposed to establish both a lookback period and timeframe to complete overpayments and underpayment notices, as well as a de minimis threshold for associated refunds and recoveries. We solicited comments regarding the addition of similar requirements in MA, specifically regarding establishing a lookback period and de minimis threshold for refunding incorrect collections.

Part D sponsors' failure to attempt to collect cost sharing or premiums is a violation of statutory and regulatory requirements. Part D sponsors' incorrectly high or low collections of cost sharing and premiums would have the effect of making the benefit non-uniform and would violate the uniform premium and benefit requirements of section 1860D–2(a) of the Act and § 423.104(b). Existing language at § 423.104(b) mirrors the language at § 422.100(d)(1) and (2)(i) with regard to uniform premiums and cost sharing. Similarly, whether done in a small number of instances or to all members enrolled of a plan, the excess collection of premiums is the basis for intermediate sanctions, as stated in section 1857(g)(1)(B) of the Act, covering Medicare Advantage organizations, and 1860–12(b)(3)(E), for Part D sponsors. However, although CMS adopted a regulation for the MA program at § 422.270 to address incorrect collections of premiums and cost sharing in the final rule titled ''Medicare Program; Establishment of the Medicare Advantage Program'' (*70 FR 4640*), which appeared in the **Federal Register** on January 28, 2005, the regulations in Part 423 have not previously addressed Part D sponsor requirements regarding incorrect collections of premiums and cost sharing. In the December 2022 proposed rule, we proposed to add a new regulation at § 423.294 to establish new Part D requirements that generally align with the existing MA requirements in § 422.270 for incorrect collections and to establish new Part D requirements regarding failure to collect premiums and cost sharing amounts.

Specifically, in order to align Part D with the existing MA requirements in § 422.270 we proposed to add a new regulation at § 423.294, which at paragraph (c) would require a Part D sponsor to make a reasonable effort to collect monthly beneficiary premiums under the timing established in § 422.262(e) (made applicable to Part D premiums in § 423.293(a)(2)) and ensure collection of cost sharing at the time a drug is dispensed. If for some reason the Part D sponsor fails to collect or ensure collection in a timely manner, the Part D sponsor would be required to make a reasonable effort to bill for and recover the premium or cost sharing amount after the fact. Any adjustments to the premium or cost sharing amount that occur based on subsequently obtained information would be made within the same timeframe for coordination of benefits as established at § 423.466(b), which is 3 years from the date on which the monthly premium was due or on which the prescription for a covered Part D drug was filled. We also proposed to add new § 423.294(b)(2) to require a Part D sponsor to make a reasonable effort to identify all amounts incorrectly collected and to pay any other amounts due during the timeframe for coordination of benefits as established at § 423.466(b).

In addition, we proposed new Part D requirements for the management of incorrect collections. First, we proposed to clarify that the 3-year lookback period established in § 423.466(b) for coordination of benefits applies to retroactive claim or premium adjustments that result in refunds and recoveries at § 423.294(b)(2) and (4) and § 423.294(c)(2), respectively. Part D sponsors have been required to process retroactive claims adjustments within 45 days of receiving complete information, per § 423.466(a), but there has been no requirement for the timing of retroactive premium adjustments. Although § 423.466(b) allows 3 years for coordination of benefits, there was no limit in the regulation for how far back a Part D sponsor must look to determine whether retroactive premium adjustments or claims adjustments unrelated to coordination of benefits must be made. For example, if a Part D sponsor in 2022 identifies an error in their prior years' drug pricing files that resulted in beneficiaries being charged incorrect cost sharing from 2015 to 2020, the current regulation might require them to refund and/or recover amounts for prescriptions beneficiaries received as far back as seven years ago. This is not only inconsistent with our coordination of benefits requirements, which only require adjustments for the past 3 years, but is potentially confusing to beneficiaries. By establishing a 3-year lookback period in § 423.294(b)(2) and (4) and § 423.294(c)(2), we would align the timeframe established in § 423.466(b) for coordination of benefits with the timeframe for premium adjustments and claims adjustments unrelated to coordination of benefits. This 3-year period coincides with the timeframe established in § 423.466(b) for coordination of benefits with State Pharmaceutical Assistance Programs (SPAPs), other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf. A Part D sponsor would not be required to make a premium or claims payment adjustment if more than 3 years have passed from the date of service, just as a Part D sponsor is required to coordinate benefits for a period of 3 years.

Second, we proposed in §§ 423.294(b)(2) and (4) and 423.294(c)(2), respectively, that the 45-day timeframe in § 423.466(a) applies to the processing of refunds and recoveries for both claims and premium adjustments. This would make the timeframes for the refund or recovery of premium adjustments the same as the timeframes for claims adjustments, refunds, and recoveries related to the low-income subsidy program (which, under § 423.800(e), are the same as the requirements of § 423.466(a)). In other words, whenever a Part D sponsor receives, within the 3-year lookback period, information that necessitates a refund of enrollee overpayment of premiums and/or cost sharing, or recovery of underpayments of premiums and/or cost sharing, the Part D sponsor would be required to issue refunds or recovery notices within 45 days of the Part D sponsor's receipt of such information. Nothing in this proposal would alter the requirements of § 423.293(a)(4) with respect to the options a Part D sponsor must provide Part D enrollees for retroactive collection of premiums.

Finally, we proposed to apply a de minimis amount, calculated per Prescription Drug Event (PDE) transaction for cost sharing or, for premium adjustments, per month, for these refunds and recoveries. Specifically, we proposed in § 423.294(b) and (c)(1) that if a refund or recovery amount falls below the de minimis amount set for purposes of § 423.34(c)(2) for the low-income subsidy (currently set at $2), the Part D sponsor would not be required to issue a refund or recovery notice. For example, if a plan sponsor in 2025 discovered that it had charged incorrect premiums amounts to certain beneficiaries for a 12-month period from

January through December of 2022 and the de minimis amount for 2025 is $2, the sponsor would not have to issue recovery notices to any beneficiary who owed $24 or less for the 12-month period.

The proposed rule preamble also noted that we are not making any changes to the Medical Loss Ratio (MLR) requirements under §§ 422.2420(c) and 423.2420(c), which provide that uncollected premiums that could have been collected are treated as revenue and are included in the MLR denominator.

In addition, the proposed rule noted that current MA regulations set forth at § 422.270 do not contain allowances for de minimis amounts or limits to the lookback periods for MA organizations to refund or recover incorrect collections of cost sharing or premiums. On the contrary, § 422.270(b) states that an MA organization must agree to refund all amounts incorrectly collected from its Medicare enrollees, or from others on behalf of the enrollees, and to pay any other amounts due the enrollees or others on their behalf. With regard to timing of recovering underpayments when an enrollee is not at fault, § 422.262(h) provides that an enrollee may make payments in equal monthly installments spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the Medicare Advantage organization. In the proposed rule, we solicited comments on adding requirements regarding a de minimis amount and lookback periods for recovering or refunding incorrect collections in MA that would mirror the proposed requirements in Part D.

We also proposed to implement a technical change to existing regulation text related to the Part D retroactive collection of monthly beneficiary premiums. Specifically, we proposed to amend § 423.293(a)(4) by replacing ''Medicare Advantage organization'' with ''Part D sponsor'' to be consistent with the terminology used in the rest of § 423.293.

We received comments in response to the proposed new regulatory text at §§ 423.293 and 423.294. A summary of the comments received and our responses follow.

Comment: A commenter stated that the collection of cost sharing is materially different from premium collection and stated that CMS should not proceed with the proposal to codify the collection of cost sharing and premiums together under § 423.294. They noted that premiums are collected by the plans, but collection of cost sharing is managed by pharmacies and should not be described as the plans' responsibility. This commenter believed it was inappropriate for the proposal codifying our interpretation of the uniform benefit requirement to include cost sharing because plans are not the parties that fail to collect beneficiary cost sharing. The commenter stated that plans would only have control over cost sharing in the case of retroactive adjustments and asked that the provision be revised to either explicitly state that the requirement only applies to plans in the case of retroactive adjustments, or to exclude language regarding cost sharing.

Response: We recognize that there is a fundamental difference between the collection of Part D cost sharing and premiums under normal circumstances. Pharmacies, not plans, collect cost sharing at the point of sale, and therefore plan oversight of cost sharing is more resource intensive in the case of retroactive adjustments. Pharmacies may also have certain autonomy when it comes to the collection of cost sharing. Pharmacies, as outlined at § 1001.952(k)(3), may choose to waive cost sharing under specific, but limited, circumstances (for example, in the circumstances outlined at 42 CFR § 1001.952(k)(3)). With those limitations in mind, the preamble of the December 2022 proposed rule *(87 FR 79517)* makes clear that we anticipate retroactive adjustments to be the primary circumstance in which plans will handle cost sharing directly.

However, the uniform benefit requirement at § 423.104(b)(2) requires Part D plan sponsors to offer ''a uniform premium, with uniform benefits and level of cost sharing throughout the plan's service area.'' As noted in the October 2009 proposed rule *(74 FR 54690),* CMS has consistently interpreted the uniform benefit requirement to prohibit Part D sponsors from varying cost sharing and premiums within its service area. While plan sponsors will primarily manage cost sharing directly in the case of retroactive adjustments, our existing regulations have placed significant responsibility for the correct collection of cost sharing on plan sponsors. For example, plans may exercise authority through their network participation agreements to define pharmacies' responsibility to collect cost sharing, per regulations at § 423.104(g). The proposed regulation merely codifies a portion of the obligations that plans have already been required to uphold.

Comment: A commenter stated that the proposed 3-year lookback period for incorrect collections does not align with the six-year overpayment lookback period. They proposed that CMS should revise the proposed provision to clarify that it would only require plan sponsors to refund or collect cost sharing created through retroactive adjustments. Alternatively, they asked CMS to clarify whether CMS would adjust its payments to plans outside of the 3-year lookback period but refuse to allow plans to initiate reimbursements or recoveries in that same period.

Response: While the commenter is correct that the proposed lookback period for incorrect collections would not align with the six-year overpayment lookback period (defined in regulation at § 423.360(f)), it was not our intention to align these lookback periods. It was our stated goal to clarify that the lookback period for Part D incorrect collections should be understood as covered by the lookback period outlined in regulation for coordination of benefits (at § 423.466(b)). While the overpayment lookback period in § 423.360(f) pertains to the reporting and returning of CMS overpayments by plans, our proposed incorrect collections provision better aligns with other aspects of coordination of benefits that are relevant to beneficiary or third-party payments to plans and pharmacies. For example, CMS payments to plans and the associated plan payment reconciliation processes are not closely related to the repayment to, or recovery of funds from, individuals. The incorrect collection of cost sharing and the adjustments that can be made in the coordination of benefits process, however, are inherently related. Furthermore, while the provision does not require plans to provide adjustments beyond the 3-year lookback window, there is nothing that would prohibit plans from voluntarily issuing refunds for premium or cost sharing overpayments, so long as they did so in a uniform manner.

Comment: A commenter stated that they were opposed to the 45-day timeframe for processing refunds and recoveries for premium adjustments proposed at § 423.294(b)(2). Because the adjustment process can be complicated, they indicated that a 90-day timeframe would be preferable instead.

Response: First, we note that the 45-day timeframe is meant for the beneficiary's benefit and is not related to record keeping. Furthermore, as stated in the December 2022 proposed rule *(87 FR 79517),* we are aligning the adjustment of retroactive premium adjustments with the timeline for processing retroactive claims adjustments. Part D sponsors are already required to process retroactive claims adjustments within 45 days of receiving

complete information, per § 423.466(a), and the proposal would simply impose a similar requirement for premium adjustments. While the process for refunding or recovering premiums may be complicated, we do not consider it to be substantially more complicated than final processing of retroactive claims adjustments. Furthermore, as noted earlier in this section, plan sponsors are already required to make claims adjustments for refunds and recoveries related to the low-income subsidy program within a 45-day window (per § 423.800(e)). Finally, we also believe it to be in the beneficiary's interest to resolve refunds and recoveries in a timely manner. As explained, the 45-day window has been used for adjustments in the past, and we consider it to be still most appropriate in this circumstance.

Comment: Commenters were divided in their opinions of the proposed de minimis amount for incorrect collections of Part D premiums and cost sharing. While some commenters were supportive, others expressed opposition to the proposal. A commenter suggested that the proposed de minimis regulation could be interpreted to be optional, but they argued that it should be made mandatory across all plans in order to prevent enrollee confusion. Another commenter suggested that the proposal, which they understood to be mandatory, would deprive plans of existing flexibility to determine on their own the financial thresholds that are appropriate for collection.

Response: We clarify that CMS has not previously provided Part D sponsors with flexibility to pursue or return incorrect collections only when they deem the funds sufficient to be worth the time and effort. As noted in the October 2009 proposed rule *(74 FR 54690),* CMS has interpreted a failure to attempt to collect premiums and cost-sharing as a violation of the uniform benefit requirement. Plans are already required to ensure correct payment of premiums and cost-sharing, consistent with current regulations and guidance, which do not define a minimum amount below which the obligation to provide a refund to enrollees (or to collect from enrollees) does not apply. We proposed and are finalizing at § 423.294(b) and (c)(1) that it is not mandatory for Part D sponsors to collect or refund amounts below the de minimis threshold established in the regulation.

Furthermore, there will be little financial difference to enrollees whether plans adopt the de minimis requirement or continue to refund or recover all incorrectly collected amounts. For instance, the de minimis amount for premium adjustments for 2024 will amount to $2 per month. Thus, under the proposed rule, plans would only be permitted to forego premium adjustments less than or equal to $24 for a calendar year. In the case of one-time errors or errors that took place over a small number of instances, the amounts involved may be less than the postage required to send a refund or recovery notice to a beneficiary. In combination with the 3-year lookback period, we believe that our proposed de minimis amount provision would enable plans to minimize their own burden while also limiting beneficiary confusion over minor adjustments to previously paid premiums and cost-sharing.

Comment: A commenter requested clarification regarding whether recoupment of underpayments will apply to dually eligible beneficiaries, noting that the dually eligible population often faces obstacles that limit their ability to make unexpected payments. The commenter also stated their belief that CMS had not previously required Part D sponsors to attempt to recover underpayments of premiums and cost-sharing and refund overpayments.

Response: Under current regulations and guidance, plan sponsors are already required to recover underpayments and refund overpayments, regardless of the amount. Our proposal elaborated on existing regulations applying to incorrect collections of premiums and cost sharing. As explained in the October 2009 proposed rule *(74 FR 54690)* and reiterated here, we have interpreted failure to attempt to collect premiums and cost sharing as a violation of the existing uniform benefit requirement at § 423.104(b). In addition, there is at present no clear limit to the lookback period for premium and cost-sharing adjustments. While our proposed policy would apply to dually eligible enrollees, the abbreviation of the lookback period and inclusion of de minimis amount regulation may serve to decrease the frequency with which plans attempt to recover incorrect collections from dually eligible enrollees. Existing regulation and guidance provide further protections for dually eligible enrollees. In the case of retroactive premium collections in which the enrollee is without fault, § 423.293(a)(4) instructs sponsors to offer the enrollee the opportunity to make payment by lump sum, by equal monthly installments spread out over at least the same period over which the payments were due, or through other arrangements mutually acceptable to the enrollee and the sponsor Similar recommendations can be found in section 70.3.1 of Chapter 13 of the Prescription Drug Benefit Manual, which covers refunds and recoupments for the premium and cost-sharing subsidies for low-income individuals and would apply to all full dually eligible enrollees and individuals eligible for a Medicare Savings Program as a Qualified Medicare Beneficiary, Specified Low Income Medicare Beneficiary, or a Qualifying Individual.

Comment: A commenter responded to CMS's request for feedback about aligning elements of the process for MA incorrect collections with those in the December 2022 proposed rule *(87 FR 79517)* for Part D. The commenter believed that the process for collecting cost sharing is more complex for MA plans than for Part D plans. The lag in payments and collections involved in, for example, clinical and hospital visits necessitates substantial differences between the incorrect collections policies of the two programs.

Response: We appreciate the commenter's feedback. We decline to revise § 422.270 at this time to: (1) apply a threshold for a de minimis amount below which refunds of excess MA cost sharing or excess MA premiums are not required, or (2) adopt lookback periods to limit the obligation for MA organizations to recover or refund incorrect collections of such payments. We may revisit these policies for the MA program at a later date.

After consideration of the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the changes to §§ 423.293 and 423.294 as proposed with minor grammatical and formatting changes.

B. Definition of ''Basic Benefits'' (§ 422.2)

Section 1852(a)(1)(B)(i) of the Act defines the term ''benefits under the original Medicare Fee-for-Service program option'' for purposes of the requirement in subparagraph (a)(1)(A) that each MA organization provide enrollees such benefits. Section 17006(c)(1) of the 21st Century Cures Act (Pub. L. 114–255) (hereafter referred to as ''the Cures Act'') amended section 1852(a)(1)(B)(i) of the Act by inserting ''or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)'' after ''hospice care.'' Per section 17006(c)(3) of the Cures Act, this amendment applies with respect to plan years beginning on or after January 1, 2021. Thus, effective January 1, 2021, MA plans no longer cover organ acquisitions for kidney transplants, including the costs for

living donors covered by Medicare pursuant to section 1881(d) of the Act.

In the April 2019 final rule [79] and the January 2021 final rule, we amended the definition of ''basic benefits'' at § 422.100(c)(1) to exclude coverage for organ acquisitions for kidney transplants, effective beginning in 2021, in addition to the existing exclusion for hospice care. In the June 2020 final rule, we also amended several regulations to address coverage of organ acquisition for kidney transplants for MA enrollees, with amendments to §§ 422.258, 422.322, and 422.306. However, we inadvertently omitted making the same type of revision to the ''basic benefits'' definition at § 422.2. We proposed to correct the definition of basic benefits at § 422.2 to add the exclusion of coverage for organ acquisitions for kidney transplants to § 422.2.

Specifically, we proposed to revise the ''basic benefits'' definition at § 422.2 to change the phrase ''all Medicare-covered benefits'' to ''Part A and Part B benefits'' and correct the phrase ''(except hospice services)'' to include, beginning in 2021, organ acquisitions for kidney transplants (which includes costs covered under section 1881(d) of the Act).

This provision is a technical change to align the definition of basic benefits with existing law; therefore, neither an economic impact beyond current operating expenses nor an associated paperwork burden are expected.

We invited public comment on this proposal and received a comment in support of our proposal and an out-of-scope comment. We thank the commenter for their support.

For the reasons outlined in the proposed rule and summarized in this rule, we finalize the revisions to the definition of basic benefits at § 422.2 as proposed.

C. Standards for Determining Whether Special Supplemental Benefits for the Chronically Ill (SSBCI) Have a Reasonable Expectation of Improving the Health or Overall Function of an Enrollee

The Balanced Budget Act (BBA) of 2018 included new authorities concerning supplemental benefits that may be offered to chronically ill enrollees in Medicare Advantage (MA) plans. We addressed these new supplemental benefits extensively in the Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program (hereafter referred to as ''June 2020 final rule'') (85 FR 33796, 33800–05), where we referred to them as Special Supplemental Benefits for the Chronically Ill (SSBCI).

As we summarized in the June 2020 final rule, we interpreted the intent of this new category of supplemental benefits as enabling MA plans to better tailor benefit offerings, address gaps in care, and improve health outcomes for chronically ill enrollees who meet the definition established by the statute. Section 1852(a)(3)(D)(ii)(II) of the Act authorizes the Secretary to waive the uniformity requirements generally applicable to the benefits covered by MA plans with respect to SSBCI. Therefore, CMS may allow MA plans to offer SSBCI that are not uniform across the entire population of chronically ill enrollees in the plans but that are tailored and covered for an individual enrollee's specific medical condition and needs (83 FR 16481–82).

In addition to limiting the eligibility of enrollees who can receive SSBCI to chronically ill enrollees, section 1852(a)(3)(D)(ii)(I) of the Act requires that an item or service offered as an SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. We codified this statutory requirement as part of the definition of SSBCI at § 422.102(f)(1)(ii).

As we provided in a Health Plan Management System (HPMS) memorandum dated April 24, 2019 [80] (''2019 HPMS memo'' hereafter), SSBCI can be in the form of:

- Reduced cost sharing for Medicare-covered benefits;
- Reduced cost sharing for primarily health-related supplemental benefits;
- Additional primarily health-related supplemental benefits; and/or
- Non-primarily health-related supplemental benefits.

As we described in the November 2023 proposed rule, to offer an item or service as an SSBCI to an enrollee, an MA plan must make at least two separate determinations with respect to that enrollee in order to satisfy the statutory and regulatory requirements for these benefits. First, the MA plan must determine that an enrollee meets the definition of ''chronically ill enrollee.'' Section 1852(a)(3)(D)(iii) of the Act defines ''chronically ill enrollee'' as an individual enrolled in the MA plan who meets all of the following: (I) has one or more comorbid and medically complex chronic conditions that is life-threatening or significantly limits the overall health or function of the enrollee; (II) has a high risk of hospitalization or other adverse health outcomes; and (III) requires intensive care coordination. Per § 422.102(f)(1)(i)(B), CMS may publish a non-exhaustive list of conditions that are medically complex chronic conditions that are life-threatening or significantly limit the overall health or function of an individual. This list is currently the same as the list of chronic conditions for which MA organizations may offer chronic condition special needs plans, which can be found in section 20.1.2 of Chapter 16b of the Medicare Managed Care Manual. We require, currently at § 422.102(f)(3)(i), the MA plan to have written policies for making this determination and to document each determination that an enrollee is a chronically ill enrollee. Documentation of this determination must be available to CMS upon request according to § 422.102(f)(3)(ii) (to be redesignated to § 422.102(f)(4)(ii)).

Second, the MA plan must determine that the SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the enrollee. Currently § 422.102(f)(3)(iii) provides that the MA plan ''must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and must document these criteria.'' We also require the MA plan to document ''each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request'' at § 422.102(f)(3)(iv). (See later in this section for how paragraph (f)(3) of § 422.102 is redesignated and revised in this final rule.)

We noted in the November 2023 proposed rule that we do not define or definitively interpret the phrase ''has a reasonable expectation of improving or maintaining the health or overall function of the enrollee'' in regulation or policy guidance. Rather, in the 2019 HPMS memo, we provided MA plans with ''broad discretion in determining what may be considered 'a reasonable expectation' when choosing to offer specific items and services as SSBCI.'' We stated that we granted MA plans this discretion so that they might effectively tailor their SSBCI offerings and the eligibility standards for those offerings to the specific chronically ill population upon which the plan is focusing.

[79] ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021,'' final rule (84 FR 15680).

[80] ''Implementing Supplemental Benefits for Chronically Ill Enrollees'' *https://www.cms.gov/medicare/health-plans/healthplansgeninfo/downloads/supplemental_benefits_chronically_ill_hpms_042419.pdf* (April 24, 2019).

We further indicated that ''CMS will provide supporting evidence or data to an MA organization if CMS determines that an MA plan may not offer a specific item or service as an SSBCI because it does not have a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee.'' In other words, we placed the burden on CMS, and not the MA plan, to generate evidence demonstrating whether the ''reasonable expectation'' standard—a standard that we granted broad discretion for an MA plan to determine—has been met (or not met) when offering items or services as SSBCI.

As we described in the November 2023 proposed rule, supplemental benefits, including SSBCI, are generally funded using MA plan rebate dollars.[81] When submitting an annual bid to participate in the MA program, an MA organization includes in its bid a Plan Benefit Package (PBP) and Bid Pricing Tool for each of its plans, where the MA organization provides information to CMS on the premiums, cost sharing, and supplemental benefits (including SSBCI) it proposes to offer. Since issuing the 2019 HPMS memo, the number of MA plans that offer SSBCI—and the number and scope of SSBCI offered by an individual plan—has significantly increased. We have observed these trends in reviewing PBPs from MA plans submitted in the past few years.

In the November 2023 proposed rule, we noted that based on our internal data, 101 MA plans offered a food and produce benefit in contract year 2020, while 929 MA plans were offering this as an SSBCI in contract year 2023.[82] Similarly, 88 MA plans offered transportation for non-medical needs as an SSBCI in contract year 2020. In contract year 2023, 478 MA plans were offering this as an SSBCI.[83] MA plans are also continuing to identify items or services as SSBCI that were not included as examples in the 2019 HPMS memo. When an MA plan is offering such a benefit, the plan indicates it in the PBP [84] that is submitted with its bid. The MA plan categorizes the benefit within our PBP submission system as an ''other'' SSBCI (a benefit designation within the PBP submission system) and describes the proposed new benefit in a ''free text'' field. While 51 MA plans offered an ''other'' non-primarily health-related supplemental benefit in contract year 2020, 440 plans are offering at least one ''other'' non-primarily health related SSBCI in contract year 2023—and 226 plans are offering at least two.[85]

Through SSBCI, MA organizations can design and implement benefits, including non-primarily health-related benefits, that may be able to holistically address various needs of chronically ill enrollees. We provided in the November 2023 proposed rule that, as these benefits become a more significant part of the MA program, we believe it is important to update our processes for reviewing and approving SSBCI to manage the growth and development of new SSBCI offerings, as well as to ensure compliance with the statutory requirements at section 1852(a)(3)(D). Additionally, section 1854(b)(1)(C) of the Act requires that MA plans offer the value of MA rebates back to enrollees in the form of payment for supplemental benefits, cost sharing reductions, or payment of Part B or D premiums. As an increasing share of Medicare dollars is going toward MA rebates that plans are using to offer SSBCI, we believe that revising the regulation to adopt greater review and scrutiny of these benefits is important for CMS to maintain good stewardship of Medicare dollars, including the MA rebates used to pay for these benefits, and for ensuring that the SSBCI offered are consistent with applicable law and those most likely to improve or maintain the health or overall function of chronically ill enrollees. Therefore, we proposed to update our rules and processes to simultaneously ensure effective program administration and oversight, while enabling MA organizations to offer SSBCI and improve health outcomes for chronically ill enrollees.

Currently, the burden is on CMS to review SSBCI included in an MA organization's bid and determine whether sufficient evidence or data exists to demonstrate that it has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. Given the growth in the quantity and type of SSBCI offerings and given the associated burden increase on CMS in reviewing and approving bids that include SSBCI, we believe that it would be more efficient for the MA organization, rather than CMS, to demonstrate that the reasonable expectation standard has been met.

When CMS provides MA organizations with broad latitude in offering items or services as SSBCI and in establishing what a ''reasonable expectation'' means for a given SSBCI, we believe that it is appropriate for the MA organization, rather than CMS, to identify supporting evidence or data to support an SSBCI and to establish compliance with the applicable law.

We proposed that an MA organization that includes an item or service as SSBCI in its bid must be able to demonstrate through relevant acceptable evidence that the item or service has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. As part of shifting responsibility this way, we proposed, as relevant to an MA organization that includes SSBCI in its bid, to: (1) require the MA organization to establish, by the date on which it submits its bid, a bibliography of ''relevant acceptable evidence'' related to the item or service the MA organization would offer as an SSBCI during the applicable coverage year; (2) require that an MA plan follow its written policies (that must be based on objective criteria) for determining eligibility for an SSBCI when making such determinations; (3) require the MA plan to document denials of SSBCI eligibility rather than approvals; and (4) codify CMS's authority to decline to accept a bid due to the SSBCI the MA organization includes in its bid and to review SSBCI offerings annually for compliance, taking into account the evidence available at the time. In addition, we proposed to make a technical edit to § 422.102(f)(1)(i)(A)(*2*) to correct a typographical error. We describe each proposal in greater detail below.

First, we proposed to redesignate what is currently § 422.102(f)(3) to (f)(4), and to address, at new § 422.102(f)(3), new requirements for each MA plan that includes an item or service as SSBCI in its bid. The MA organization must be able to demonstrate, through relevant acceptable evidence, that the item or service to be offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee and must, by the date on which it submits its bid to CMS, establish a bibliography of all ''relevant acceptable evidence'' concerning the impact that the item or service has on the health or overall function of its recipient. The bibliography must be made available to CMS upon request. As part of this

[81] MA plan rebates are a portion of the amount by which the bidding benchmark or maximum MA capitation rate for a service area exceeds the plan's bid; MA plans are obligated to use the MA rebates for the purposes specified in 42 CFR 422.266: payment of supplemental benefits (including reductions in cost sharing) or reductions in Part B or Part D premiums.

[82] Taken from CMS internal data.

[83] Taken from CMS internal data.

[84] A PBP is a set of benefits for a defined MA (or Prescription Drug Plan) service area. The PBP is submitted by MA organizations and PDP sponsors to CMS for benefit analysis, marketing, and beneficiary communication purposes.

[85] Taken from internal data.

proposal, an MA organization would be required to include, for each citation in its written bibliography, a working hyperlink to or a document containing the entire source cited. This proposal would apply only to SSBCI offered in the form of additional primarily health-related supplemental benefits or SSBCI offered in the form of non-primarily health-related supplemental benefits. It would not apply to an SSBCI offered in the form of reduced cost sharing, regardless of the benefit for which it is offered. We stated that we intended to exclude from this policy supplemental benefits offered under the Value-Based Insurance Design (VBID) Model administered by the Center for Medicare and Medicaid Innovation (CMMI), unless CMMI incorporates this policy within the VBID Model.

We also proposed, in new paragraph (f)(3)(iv), that the MA organization must make its bibliography of relevant acceptable evidence available to CMS upon request. CMS may request and use this bibliography, without limitation, during bid review to assess whether SSBCI offerings comply with regulatory requirements, or during the contract year as part of CMS's oversight activities. We noted that CMS does not intend at this time to require MA organizations to submit these bibliographies as a matter of course in submitting bids.

We proposed that the term ''relevant acceptable evidence'' would include large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to investigate whether the item or service (that is proposed to be covered as an SSBCI) impacts the health or overall function of a population, or large systematic reviews or meta-analyses summarizing the literature of the same. We further proposed that the MA plan would need to include in its bibliography all relevant acceptable evidence published within the 10 years preceding the month in which the MA plan submits its bid. Ideally, relevant acceptable evidence should include studies and other investigations specific to the chronic conditions for which the MA organization intends to target the SSBCI, but we are not proposing to make this a requirement at this time. We are concerned that relevant acceptable evidence applicable to many SSBCI will already be limited, and that requiring a bibliography be limited to only studies concerning certain chronic conditions would discourage the development of new SSBCI. Similarly, to the extent there exists sufficient relevant acceptable evidence that the item or service meets the reasonable expectation standard for a sample of a population, an MA organization may still offer an SSBCI to enrollees with a specific chronic condition even in the absence of any studies addressing the connection between an item or service and its effect on the health or overall function of individuals with that condition.

We proposed that, in the absence of publications that meet these standards, ''relevant acceptable evidence'' for purposes of the MA plan's bibliography could include case studies, federal policies or reports, and internal analyses or any other investigation of the impact that the item or service has on the health or overall function of its recipient. By ''bibliography,'' we mean a list, and not a description, of scholarly publications or other works, as we describe below.

In our April 2023 final rule, we discussed what constituted sufficiently high-quality clinical literature in the context of an MA organization establishing internal clinical criteria for certain Medicare basic benefits (88 FR 22189, 22197). We believe that those standards are also applicable for identifying ''relevant acceptable evidence'' in the context of supporting whether an item or service offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. Therefore, our proposal for § 422.102(f)(3)(ii) largely tracked the language in § 422.101(b)(6) describing acceptable clinical literature for purposes of establishing internal coverage criteria, but with revisions to be specific to the context of SSBCI and the reasonable expectation standard.

As we noted in the November 2023 proposed rule, literature that CMS considers to be ''relevant acceptable evidence'' for supporting an SSBCI offering include large, randomized controlled trials or cohort studies or all-or-none studies with clear results, published in a peer-reviewed journal, and specifically designed to answer a question relevant to the requirements for offering and covering SSBCI and how the MA plan will implement the coverage—such as the impact of structural home modifications on health or overall function. Literature might also include that which involves large systematic reviews or meta-analyses summarizing the literature specifically related to the subject of the SSBCI—such as meal delivery, availability of certain food or produce, or access to pest control—published in a peer-reviewed journal with clear and consistent results. Under this proposal, an MA organization would be required to cite all such available evidence in its bibliography, and not just studies that present findings that are favorable to its SSBCI offering.

We also proposed that, in the absence of literature that conforms to these standards for relevant acceptable evidence, an MA organization would be required to include in its bibliography any other investigations of the impact of the item or service which may include evidence that is unpublished, is a case series or report, or derived solely from internal analyses within the MA organization. In this way, our proposed policy would deviate from the standard we established for the type of evidence necessary to support an MA organization's internal coverage criteria for Medicare basic benefits. We noted in our proposal that we believe this deviation is appropriate as there is relatively less research into the impact of the provision on items or services commonly offered as SSBCI on health or overall function of chronically ill individuals.

We did not propose that relevant acceptable evidence must directly address whether there is a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee with a specific chronic illness or condition (conditions that the MA plan would have identified in its PBP submission), but such materials may be more persuasive than materials that only describe the impact of certain items and services—particularly non-primarily health-related items and services—on healthier individuals or populations. Further, our proposal was limited to SSBCI offered as additional primarily health-related supplemental benefits and non-primarily health-related supplemental benefits. We did not propose to require a bibliography for SSBCI that are exclusively cost sharing reductions for Medicare-covered benefits or primarily health-related supplemental benefits, so the regulation text was limited to SSBCI that are items or services. Although we did not propose to apply this new documentation requirement to cost sharing reductions offered as SSBCI, that type of SSBCI must also meet the reasonable expectation standard to be offered as SSBCI.

We believe that this proposal for new paragraph (f)(3) (which we are finalizing without modification, as discussed in the responses to public comments in the following pages) will serve our goal of ensuring that SSBCI regulatory standards are met—specifically, that an item or service covered as an SSBCI has a reasonable expectation of improving or maintaining the health or overall

function of a chronically ill enrollee. As we explained in the November 2023 proposed rule, we expect that rigorous research like that we describe above might be limited, and that some studies may not produce results favorable to the offering of an SSBCI. However, when there are also favorable studies, the existence of such unfavorable studies does not necessarily mean that there could not be a ''reasonable expectation'' that the SSBCI would improve or maintain the health or overall function of a chronically ill enrollee. And it is not our goal that mixed results in current literature—or the lack of rigorous research at all—would reduce innovation in SSBCI offerings. We wish to continue to see MA organizations identify new ways to deliver helpful benefits to chronically ill enrollees that can address their social needs while also improving or maintain the health or overall function of these chronically ill enrollees. Our goal is to ensure that SSBCI innovation occurs in a manner that is grounded to the extent possible in research, and that MA organizations and CMS alike are tracking to the most current research relevant to SSBCI offerings. We believe this policy will continue to promote SSBCI innovation while helping to ensure that when Medicare funds are used to offer SSBCI, such offerings meet statutory requirements.

We solicited comments on our proposed requirement that an MA organization that includes an item or service as SSBCI in its bid must, by the date on which it submits its bid to CMS, establish in writing a bibliography of all relevant acceptable evidence concerning the impact that the item or service has on the health or overall function of its recipient. We also solicited comments on our definition of ''relevant acceptable evidence,'' including the specific parameters or features of studies or other resources that would be most appropriate to include in our definition. We also solicited comments on our proposal that, for each citation in the written bibliography, the MA organization would be required to include a working hyperlink to or a document containing the entire source cited. Additionally, we solicited comments on whether we should apply this requirement to all items or services offered as SSBCI, or whether there are certain types or categories of SSBCI for which this requirement should not apply. We address comments received and our responses at the end of this section.

Second, for clarity, we proposed to explicitly require at redesignated § 422.102(f)(4)(iii) that an MA plan apply its written policies, which must be based on objective criteria, that it establishes for determining whether an enrollee is eligible to receive an SSBCI. The regulation currently requires MA organizations to have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and must document these criteria. While we anticipate that MA plans are already applying their written policies that identify the eligibility criteria when making these determinations, we proposed to make clear that an MA plan must apply its written policies when making SSBCI eligibility determinations.

We stated that we were considering whether to exclude the policies required by current § 422.102(f)(3) (that is, the requirements we are proposing to redesignate to new paragraph (f)(4)) from the general rule reflected in § 422.111(d) that MA plans may change plan rules during the year so long as notice is provided to enrollees. We solicited comments on whether CMS should permit changes in SSBCI eligibility policies during the coverage year, and, if so, the limitations or flexibilities that CMS should implement that would still allow CMS to provide effective oversight over SSBCI offerings. As we explained in our proposal, the ability to change plan rules during the year does not permit changes in benefit coverage but would include policies like utilization management requirements, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations.

Third, we proposed to amend redesignated paragraph (f)(4)(iv) to require that an MA plan document each instance wherein the plan determines that an enrollee is ineligible to receive an SSBCI. Denials of coverage when an enrollee requests an SSBCI are organization determinations subject to the rules in Subpart M, including the requirements related to the timing and content of denial notices in § 422.568. By fully documenting denials as required by this proposal, MA organizations should be better placed to address any appeals, including when an adverse reconsideration must be sent to the independent review entity for review. Similarly, requiring robust documentation of denials of SSBCI by MA organizations will make oversight and monitoring by CMS easier and more productive, should CMS request documentation.

We solicited comments on our proposal to require an MA plan to document its findings that a chronically ill enrollee is ineligible, rather than eligible, for an SSBCI.

Fourth, we proposed to add § 422.102(f)(5) to codify CMS's authority to decline to approve an MA organization's bid, if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting. We clarified that while this proposal would establish a specific basis on which CMS may decline to approve an MA organization's bid, our authority to enforce compliance with other regulations and to negotiate bids (see section 1854(a) of the Act and Subpart F) would not be limited by this provision. As described in section 1854(a)(5)(C) of the Act, CMS is not obligated to accept any or every bid submitted by an MA organization, and CMS may reject bids that propose significant increases in cost sharing or decreases in benefits offered under the plan. Similarly, CMS's authority to review benefits to ensure non-discrimination is not limited or affected under this proposal. Our proposal was intended to clarify and establish that CMS's review of bids that include SSBCI could include specific evaluation of SSBCI and that CMS may decline to approve bids based on a lack of relevant acceptable evidence in support of the SSBCI offering the MA organization includes in its bid.

We also proposed to codify that, regardless of whether an SSBCI offering was approved in the past, CMS may annually review the items or services that an MA organization includes as SSBCI in its bid for compliance with all applicable requirements, considering the relevant acceptable evidence applicable to each item or service at the time the bid is submitted. Under this proposal, CMS would have clear authority to evaluate an SSBCI included in a bid each year based on the evidence available at that time. CMS would not be bound to approve a bid that contains a certain SSBCI only because CMS approved a bid with the same SSBCI in the past. We believe this provision, if finalized, would help ensure sound use of Medicare dollars by establishing a clear connection between an SSBCI and the most current evidence addressing whether there is a reasonable expectation that the SSBCI will improve or maintain the health or overall function of a chronically ill enrollee.

We believe that codifying that CMS may decline to approve a bid for an MA

organization to offer certain SSBCI is appropriate to support CMS's programmatic oversight function. CMS already possesses the authority to negotiate and reject bids under Section 1854 of the Act, and to establish certain minimum requirements related to SSBCI under Section 1852 of the Act. We can rely on these bases as well as the requirements for SSBCI in the statute and regulations to decline to approve bids that include SSBCI that lack evidence to support the MA organization's expectations related to the SSBCI, but, as we noted in the November 2023 proposed rule, we believe it prudent to establish clearly how our evaluation of individual SSBCI offerings and the evidence supporting these offerings fit within our bid negotiation and approval authority. We believe that SSBCI provide a critical source of innovation, and we wish to see MA organizations continue to develop impactful benefits tailored to their chronically ill enrollees. However, we must also ensure that benefits offered within the MA program comply with all applicable statutory and regulatory standards. We believe it is critical for effective program administration that CMS be able to obtain, upon request, relevant acceptable evidence from an MA organization to support CMS's review of SSBCI each year considering the information and evidence available at that point in time.

We solicited comment on this proposal to codify CMS's authority to decline to approve an MA organization's bid if the MA organization fails to demonstrate, through relevant acceptable evidence, that an SSBCI included in the bid has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting.

The policies proposed in this section, which we are finalizing with modifications detailed further below, will work together to place the burden of showing whether an item or service offered as SSBCI has a reasonable expectation of improving the health or overall function of a chronically ill enrollee onto the MA organization. Implementing these proposals changes the policy set forth in the 2019 HPMS memo requiring CMS to provide supporting evidence or data to an MA organization if CMS determines that an MA plan may not offer a specific item or service as an SSBCI because it has not met the reasonable expectation standard. Under these proposals, the MA organization must, in advance of including an SSBCI in its bid, have already conducted research on the evidence establishing a reasonable expectation that the item or service would improve or maintain the health or overall function of the recipient of the item or service. By the time the MA organization submits its bid, it must be able to show CMS, upon request, the relevant applicable evidence that supports the reasonable expectation that the item or service would improve or maintain the health or overall function of the chronically ill enrollees it is targeting. We expect that MA plans are already proactively conducting similar research and establishing written policies for implementing SSBCI based on this research when designing them. Additionally, MA plans may seek guidance from CMS regarding SSBCI items or services not defined in the PBP or in previous CMS guidance prior to bid submission. However, plans should note that such guidance provided in advance of the bid submission process is not a guarantee that CMS will approve the bid. As such, we believe this proposal, if implemented, would create efficiency while imposing relatively little burden on MA plans.

In addition, we proposed at § 422.102(f)(3)(iv) that MA plans will be required to document and submit to CMS upon request each determination that an enrollee is not eligible to receive an SSBCI. We believe that requiring an MA organization to support its SSBCI offerings with a written bibliography of relevant acceptable evidence and an MA plan to document denials of SSBCI work together to ensure that SSBCI are being implemented in an evidence-based, non-discriminatory, and fair manner. The evidence base established by an MA organization could serve to inform an MA plan's objective criteria for determining eligibility. By requiring an MA plan to document instances of SSBCI denials, we believe this proposal will improve the experience of MA plans, enrollees, and CMS in managing and oversight of appeals of such denials. Further, it will help ensure that MA plans are not denying access to SSBCI based on factors that are biased or discriminatory or unrelated to the basis on which the SSBCI are reasonably expected to improve or maintain the health or overall function of the chronically ill enrollees. For example, researchers have identified that certain algorithms that have been used to decide who gets access to additional services can have clear racial bias, when factors such as expected future cost or expected future utilization are incorporated into the algorithm.[86] By codifying CMS' authority to decline to approve a bid that includes an SSBCI not supported by evidence, this proposal also serves to ensure appropriate program administration and oversight.

Finally, we proposed to make a technical edit to § 422.102(f)(1)(i)(A)(*2*) to correct a typographical error. In our June 2020 final rule, we noted that section 1852(a)(3)(D)(ii) of the Act, as amended, defines a chronically ill enrollee as an individual who, among other requirements, ''[h]as a high risk of hospitalization or other adverse health outcomes[.]'' We then indicated that ''we propose to codify this definition of a chronically ill enrollee'' at § 422.102(f)(1)(i). However, our regulation at § 422.102(f)(1)(i)(A)*(2)* currently reads: ''Has a high risk of hospitalization of other adverse outcomes[.]'' We proposed to substitute ''or'' for the second ''of'' in this provision, such that it aligns with the statutory language that we intended to codify in our regulation.

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses follows.

Comment: Commenters were overall very supportive of our efforts to improve SSBCI offerings and ensure that these benefits provided value to enrollees. Commenters expressed support for our stated goals of ensuring that SSBCI were supported by evidence, and that MA rebate dollars were used to benefit enrollees.

Response: We appreciate the support of our proposal.

Comment: Some commenters expressed support for the degree of flexibility CMS proposed to include as part of its relevant acceptable evidence standard. However, several commenters sought clarification regarding aspects of our proposal. Specifically, several commenters sought clarification about whether CMS would request bibliographies as part of the bidding process, expressing concern that plans would have very little time to address any deficiencies.

Response: We appreciate commenter's support and reassert that we did not propose to require plans to submit their bibliographies with their bids. The provision proposed and finalized at § 422.102(f)(3)(iv) gives CMS the necessary flexibility to request to see

[86] *See, e.g.,* Ziad Obermeyer et al., Dissecting racial bias in an algorithm used to manage the health of populations. *Science* 366, 447–453 (2019). DOI:10.1126/science.aax2342.

plans' bibliographies at any time during the bidding process or during the contract year; this may be helpful or even necessary to ensure compliance with the statutory and regulatory requirements for SSBCI. Our oversight of the MA program is enhanced by having access to bibliographies upon request and will lead to more effective and useful SSBCI offerings for Medicare beneficiaries. We will also provide time for plans to respond to any concerns CMS raises about SSBCI evidence bases during the bid process to allow plans to address any concerns expressed about submitted bibliographies and the associated benefits and make modifications to their bids as needed.

Comment: We received some comments which expressed opposition to our proposed SSBCI evidentiary standard, specifically the requirement that plans provide ''all relevant acceptable evidence.'' Commenters were largely in agreement that the proposed requirement would be too burdensome. Some commenters were concerned that the requirement would stifle innovation, especially for SSBCI benefits, which may not have a large evidence base. Some commenters felt that the standard should be limited to a certain minimum number of sources or to information from specific sources. Additionally, some commenters asked that CMS recognize a good faith effort in collecting ''all relevant acceptable evidence.'' They proposed that instead of ''all'' evidence, CMS accept a ''comprehensive'' or ''reasonable'' bibliography. A commenter suggested, to limit burden on plans, that CMS identify a singular research resource from which plans would be required to source published literature.

Response: We appreciate these comments, and we share this desire to foster continued innovation in benefits that are reasonably expected to maintain or improve the health or overall function of chronically ill enrollees. While we anticipate that plans have been identifying or developing evidence to support their SSBCI each year, toward ensuring compliance with the reasonable expectation standard and further ensuring that administering the SSBCI offerings makes business sense, we do not wish to have the unintended effect of limiting SSBCI offerings or stifling innovation. We recognize that for some benefits, which are more commonly offered or generally agreed upon to have a positive impact on the health of an individual, there may be a large number of studies, reports, and other sources of evidence available. Collecting and listing all such evidence produced within the last 10 years with assurances that no relevant citations were missed may be unrealistic.

To this end, we are modifying our proposed language at § 422.102 (f)(3)(ii) to require plans to include in their bibliographies ''a comprehensive list'' of relevant acceptable evidence published within the 10 years prior to the June immediately preceding the coverage year during which the SSBCI will be offered. We proposed requiring plans to include ''all relevant acceptable evidence'' in these bibliographies. We intend that this change to the final rule will allow plans, especially those offered by smaller MA organizations or organizations with more limited resources, to meet the requirements without exhaustive efforts to find evidence from every available source. However, we note that plans must demonstrate genuine efforts to be thorough and inclusive of evidence related to the SSBCI offered. We also reiterate that plans must provide any available negative evidence and literature, which means including studies beyond those which present findings favorable to its SSBCI offering. Plans must demonstrate best efforts in including all evidence which adheres to the requirements proposed at § 422.102 (f)(3).

We are not limiting the sources from which plans may pull their evidence base as suggested by a commenter as we wish to provide flexibility for plans to cull from sources they deem acceptable to comply with the standards proposed. Additionally, we are not imposing a minimum number of bibliographic citations for a certain SSBCI. However, we expect that for more established items or services, plans are accordingly including a greater number of citations as there are likely to be a greater number of studies and investigations into the impact such items or services have on the studied sample group. Further, instituting such a minimum number of citations may be limiting for plans offering SSBCI which are less established and may not be able to meet such an arbitrary requirement. We note, however, that CMS may propose such a requirement in future rulemaking if it becomes evident that plans are not making a good faith effort in complying with the requirements or are allowing for SSBCI items or services with little to no evidence which do not meet the ''reasonable expectation'' standard.

While, as modified in this final rule, requirements about the standards for the evidence used to support SSBCI, creation of a bibliography, and making the bibliography available to CMS may require plans to conduct further research than they currently do, we anticipate that the new burden will be manageable to the extent that the plans are building on existing efforts to ensure that their SSBCI offerings meet the ''reasonable expectation'' standard in the statute and currently at § 422.102(f)(1)(ii). As noted in the preamble, we expect that MA plans are already proactively conducting similar research and establishing written policies for implementing SSBCI based on this research when designing them. Additionally, MA plans may seek guidance from CMS regarding SSBCI items or services not defined in the PBP or in previous CMS guidance prior to bid submission. However, plans should note that such guidance provided in advance of the bid submission process is not a guarantee that CMS will approve the bid. To the extent that plans must conduct research anew to support novel, innovative SSBCI, we note that plans must only do so in the absence of large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, or large systematic reviews or meta-analyses summarizing the literature of the same (as proposed at § 422.102(f)(3)(i)), as well as any other evidence including case studies, federal policies or reports (as proposed at § 422.102(f)(3)(iii)).

Comment: Several commenters expressed concern about the timing of implementation for this proposal and requested that CMS delay implementation of proposed § 422.102(f)(3) until calendar year 2026, or until bidding for CY2026.

Response: While we appreciate that MA organizations may wish for additional time to collect evidence which adheres to the requirement, as noted in this preamble, plans should already have an evidence base to support their current benefit offerings. The reasonable expectation standard is not changing under this final rule and MA plans have been submitting bids for and offering SSBCI on the basis that the items and services are reasonably expected to improve or maintain the health or overall function of chronically ill enrollees for several years. Therefore, it is not necessary to delay implementation of the requirements about the standards for the evidence used to support SSBCI, creation of a bibliography, and making the bibliography available to CMS. We believe that plans should already have evidence to show their benefit offerings have a reasonable expectation of improving or maintaining the health or overall function of their chronically ill enrollees, and therefore collating information sufficient to comply with

our standard as proposed will not be an undue burden that warrants a delay in implementation. Therefore, we are finalizing these changes to § 422.102(f)(3) for coverage beginning on and after January 1, 2025, and will apply these standards in evaluating bids for 2025.

Comment: Several commenters expressed concerns that CMS' proposed standards for bibliographies are too strict, and that CMS should accept alternative research or studies beyond those explicitly mentioned. Some commenters expressed concern that the proposed standard would be particularly burdensome on MA Special Needs Plans (SNPs) that serve a wide variety of chronic conditions. Some commenters also identified certain types of services, such as home-based services, or services for certain enrollees, such as those receiving residential treatment, which they felt would be more challenging to fit into our proposed standard.

Response: Our proposed requirements were purposefully broad and flexible in what evidence would be acceptable to support a given SSBCI. As we are finalizing in this final rule, plans must first present a comprehensive list of literature published in a peer-reviewed journal, including large, randomized controlled trials or prospective cohort studies with clear results, systematic reviews, and meta-analyses—the evidence we described in proposed (and finalized) § 422.102(f)(3)(i). Per the finalized language at § 422.102(f)(3)(ii), the bibliography must include a comprehensive list of relevant acceptable evidence published within the 10 years prior to June preceding the start of the contract year, including any available negative evidence and literature. Requiring a broad scope of relevant acceptable evidence is necessary so that CMS may be apprised of both positive and negative research related to a specific item or service that an MA plan proposes to cover as an SSBCI. When studies are not available, an MA plan may include in its bibliography such items as case studies, Federal policies or reports, and internal analyses that investigate the impact that the item or service has on the health or overall function of its recipient—the evidence we described in proposed 42 CFR 422.102(f)(3)(iii). As proposed and finalized, paragraph (f)(3)(iii) does not require an MA plan to include evidence in these other types of case studies, federal policies or reports, internal analyses, or other investigation about the item or service that the MA plan proposes to cover as an SSBCI; the standard to provide a comprehensive list of relevant evidence is limited to the specific, more reliable materials described in paragraph (f)(3)(i). In the absence of studies described in paragraphs (f)(3)(i) and (ii), plans must include in their bibliographies the types of evidence described in § 422.102(f)(3)(iii), as proposed and finalized.

It is not necessary for CMS to be overly prescriptive in listing every type of acceptable evidence that a plan may collect and submit. As noted in this preamble, CMS does not wish to hamper innovation in offering new benefits. At the same time, we are concerned that any further broadening of this standard may make the requirement meaningless when keeping in mind that this proposal is meant to ensure quality care for chronically ill individuals. We will consider in future rulemaking whether it should refine this standard, including but not limited to being more prescriptive regarding the acceptable sources of evidence. For now, we believe it appropriate to promote flexibility in demonstrating that a given SSBCI offering complies with the reasonable expectation standard.

To that end, while we recognize that providing ''a comprehensive list of relevant acceptable evidence'' may sometimes mean a large number of studies are collected for a single benefit, gathering this evidence base is critical for greater review and scrutiny of these benefits in order for CMS to maintain good stewardship of Medicare dollars, and for ensuring that the SSBCI offered are consistent with applicable law and those most likely to improve or maintain the health or overall function of chronically ill enrollees. Requiring a broad scope of relevant acceptable evidence over a specified period of time is necessary so that CMS may be apprised of both positive and negative research related to a specific item or service that an MA plan proposes to cover as an SSBCI.

Additionally, we reassert that the relevant acceptable evidence need not necessarily relate to a specific chronic condition. We note there are some conditions for which there is little evidence relating to non-medical services which may benefit an individual. As we noted in this preamble, while ideally the evidence would include the specific chronic condition used by the MA plan in its SSBCI eligibility criteria and how the specific item or service would address that specific chronic condition, we are not making this a requirement at this time. We also note that relevant acceptable evidence does not necessarily have to be related to Medicare eligible populations. Acceptable studies or other sources of evidence may focus on other groups, including individuals in specific geographies or underserved communities. Since plans may consider social determinants of health (SDOH) as a factor to help identify chronically ill enrollees whose health or overall function could be improved or maintained with SSBCI (42 CFR 422.102(f)(2)(iii)), we recognize that some relevant acceptable evidence may also be focused on certain communities that share a characteristic other than Medicare eligibility status. We therefore do not agree that specific types of MA plans, like SNPs, or services like residential treatment noted by the commenter would have difficulty meeting the requirement for the above reasoning.

Comment: Several commenters noted that some SSBCI services are generally accepted as regular supplemental benefits as well and recommended that such services be exempt from the requirement. Alternatively, some commenters suggested CMS make a list of specific items or services that may be offered as SSBCI and associated supporting bibliographies publicly available, such that plans could access them when choosing to provide those services. Many commenters recommended that CMS identify SSBCI that are supported by a robust evidence base and exempting those items or services from these requirements.

Response: While we agree there are some SSBCI which are offered by a large number of plans, and for which a large evidence base exists, we are not finalizing such a list at this time. Additionally, while we requested comment on specific items or services for which this requirement should not apply, commenters did not provide specific examples beyond a suggestion that CMS develop a ''core list'' of approved-and therefore exempt-SSBCI services. Therefore, we are finalizing this proposal that the MA plan develop a bibliography of specific types of evidence related to the proposed SSBCI without modification. CMS may consider developing and publishing a core list of SSBCI which are exempt from the requirement in future rulemaking should we determine that some services have a sufficiently robust evidence base. In addition, even for items and services that meet the standard of being primarily health related in § 422.100(c)(2), when an MA plan offers those benefits as SSBCI, the MA plan is necessarily limiting the coverage to specific chronically ill enrollees; it is appropriate to ensure that

the basis for that limitation is grounded in relevant acceptable evidence.

Comment: Some commenters suggested that, in the absence of any relevant acceptable evidence, CMS accept a rationale statement or allow plans to offer services for 1–2 years while the plan gathers internal data to support the continued offering of the benefit.

Response: While we reiterate our wish that MA plans continue to innovate and offer solutions to enrollees in the form of SSBCI, MA plans must use appropriate resources to test these benefits. Offering SSBCI where there is not a sufficient basis to conclude that the statutory and regulatory standards for such benefits under section 1852(a)(3)(D) of the Act and § 422.102(f) have been met is not appropriate. We decline to create an exception in our final rule for items and services which do not meet the ''relevant acceptable evidence'' criteria, a standard which CMS believes is sufficiently broad and flexible to accommodate less established SSBCI. Indeed, CMS proposed to allow plans to support SSBCI offerings through internal analyses in the absence of other established evidence. We note, however, that in addition to providing at least an internal analysis for an SSBCI for a current plan year, plans may leverage their experience in offering SSBCI to refine internal analyses for future plan years.

Comment: Some commenters were concerned that plans would not wish to devote the necessary resources to establish the bibliography at the time the bid is submitted and would instead pass this responsibility on to the businesses or organizations that provide the specific SSBCI benefits. These commenters expressed concern that these entities may not have the resources to do so or would be overburdened by the requirement. A few commenters requested clarification regarding the use of hyperlinks in the bibliography, including how to address internal analyses or when research is behind a ''paywall.''

Response: As with certain other programmatic requirements, MA plans may delegate functions to first tier, related, or downstream entities, subject to MA program rules such as § 422.504(i), and these requirements are no exception. MA plans are ultimately responsible for ensuring compliance with all federal law, including these new requirements, regardless of whether plans gather studies or conduct research directly or outsource those functions first tier, related or downstream entities. As it relates to our hyperlink requirement, plans must ensure that CMS can access completely each resource cited in the bibliography for an SSBCI. If the study is behind a ''paywall,'' is an internal analysis, or is otherwise not accessible through a hyperlink, the plan must provide such evidence directly to CMS upon request.

Comment: We received mixed comments regarding exclusion from the new requirements proposed and finalized in § 422.102(f)(3) (that is, the requirements about the standards for the evidence used to support SSBCI, creation of a bibliography, and making the bibliography available to CMS) of SSBCI that are reductions in cost-sharing for Parts A and/or B benefits, or reductions in cost sharing for other supplemental benefits which are not SSBCI. Some commenters were supportive of this exclusion while others felt that excluding cost-sharing benefits would mean plans offer fewer benefits which are not reductions in cost-sharing. Additionally, a commenter requested that CMS exclude from the requirement primarily-health related SSBCI that are substantially similar to mandatory supplemental benefits.

Response: We appreciate this feedback. At this time we are not extending the requirements about the standards for the evidence used to support SSBCI, creation of a bibliography, and making the bibliography available to CMS to apply as well to SSBCI that are reductions in cost-sharing, as we intend for this proposal to focus on the evidence base for SSBCI that are additional primarily health-related supplemental items and services and non-primarily health-related supplemental items and services, and not the level of cost borne by enrollees in accessing other covered benefits. We may consider in future rulemaking whether to subject SSBCI offered as cost sharing to these evidentiary requirements. However, we note that MA plans must still be able to explain how the SSBCI reduction in cost sharing meets the applicable statutory and regulatory standards, including the reasonable expectation standard.

We are also not exempting any particular SSBCI beyond those which are cost-sharing reductions. While some plans may choose to cover services which are substantially similar to already approved mandatory supplemental benefits, at this time, we are not making a distinction between services which are ''substantially'' similar to mandatory supplemental benefits, which vary by plan, and those which are not ''substantially'' similar.

Comment: We received several comments regarding our request for feedback on whether to codify a requirement that plans must follow their written policies for determining SSBCI eligibility. These comments were overwhelmingly supportive and additionally suggested that CMS require plans publish their written requirements for SSBCI eligibility on a public-facing website.

Response: We appreciate this feedback and support. We noted in this preamble that we anticipated plans were already following their written policies for determining SSBCI eligibility, policies which are a current regulatory requirement. We therefore believe amending the regulation to more clearly require compliance with the written policies is a logical next step and should not present a change in practice for plans. We are finalizing this aspect of the proposal without modification by finalizing the changes to redesignated paragraph (f)(4)(iii) as proposed.

We also appreciate the suggestion that plans publish their written SSBCI eligibility requirements, and while we are not finalizing such a requirement at this time, we may consider this in future rulemaking. We note that currently plans are expected to include SSBCI eligibility criteria in their Evidence of Coverage (EOC) and Annual Notice of Change (ANOC) documents. We stated in the June 2020 final rule ''[. . .]It is our expectation that plans communicate information on SSBCI to enrollees in a clear manner about the scope of SSBCI that the MA plan covers and who is eligible for those benefits.''

Comment: Some commenters supported our proposed change that plans must document SSBCI eligibility denials rather than approvals. Many commenters further suggested CMS require documentation of approvals as well as denials, rather than the CMS proposal to document only denials. A commenter also suggested CMS require additional data collection such as demographic information about the enrollee when a plan collects information for approval or denial of eligibility for an SSBCI benefit. Further, a commenter noted that by capturing both approvals and denials, CMS may be able to compare statistics of approvals and denials across plans.

Response: We appreciate this feedback and are finalizing paragraph (f)(4)(iv) (redesignated from existing paragraph (f)(3)(iv) with changes) with changes to require MA plans to document both approvals and denials of SSBCI eligibility. We agree that documenting both approvals and denials will give a more complete and comprehensive understanding of how plans are implementing coverage of SSBCI. In addition, this information

may assist us in evaluating how MA plans are marketing their benefits and exercising necessary oversight of their offerings. Since plans are already required to document approvals at current § 422.102(f)(3)(iv), we do not feel that this change should present a significant alteration of burden for plans from what we proposed in the November 2023 proposed rule.

We originally proposed documenting denials of SSBCI eligibility not only to increase ease of monitoring and oversight by CMS of whether benefits are being furnished consistent with how MA plans describe them but also to better position plans should enrollees appeal their SSBCI eligibility denials. However, commenters rightly pointed out that without the full picture of both approvals and denials, CMS may not be able to fully understand how plans are using their resources as it relates to SSBCI. If, for example, there are many denials as compared to approvals, it may alert the plan and CMS to an improper marketing of the benefit, or of overly broad recommendations of the benefit by a physician. Further, we agree with the commenter that by capturing both approvals and denials, CMS may be able to compare statistics of approvals and denials across MA plans, which, over time, may allow CMS to better determine if plans are improperly denying or approving SSBCI eligibility for plan enrollees. These additional capabilities and insights, which will be possible when there is adequate documentation of both approvals and denials, may allow for CMS to further refine SSBCI policy in future rulemaking to improve the enrollee experience and improve CMS's stewardship over Medicare dollars.

For these reasons, we are finalizing the proposal to require that MA plans document its eligibility determinations with a modification to require MA organizations to document both approvals and denials of eligibility for an enrollee to receive a particular SSBCI in § 422.102(f)(4)(iv).

Additionally, we are not requiring plans to report to CMS documentation regarding the approvals or denials on a regular basis at this time. However, CMS may request this data on a case by case or ad hoc basis or may incorporate this into regular reporting by MA organizations under §§ 422.504(f)(2) or 422.516(a). We also acknowledge concerns about equity and equitable treatment of enrollees, concerns which we share. It is our belief, through the modification of this proposal to include documentation of both approvals and denials, that MA plans will be additionally mindful of these concerns when making determinations. We note that plans may choose to include additional information, including demographic information about the enrollee, when documenting approvals and denials; however, CMS is not requiring plans to collect or submit this information as part of § 422.102(f). We may consider implementing such requirements in future rulemaking. We note that CMS has addressed some concerns regarding health equity and social risk factors elsewhere in this final rule. In the section titled ''Annual Health Equity Analysis of Utilization Management Policies and Procedures'' CMS sets forth additional requirements related to prior authorization determinations and their impact on health equity for MA organizations.

Comment: We solicited feedback on whether to exempt SSBCI from the general rule reflected in § 422.111(d) that MA plans may change certain plan rules during the year so long as notice is provided to enrollees. Some commenters urged that plans should not be allowed to change the eligibility requirements at all, while others suggested that the requirements should only be changed if eligibility were expanded to allow for more enrollees to benefit from services offered. A few commenters expressed concern about prohibiting changes in SSBCI eligibility policies during the coverage year as it may limit plan flexibility.

Response: We appreciate this feedback and the desire of commenters to preserve benefits available to enrollees and reduce confusion regarding plan requirements. This is a desire we share. We agree with commenters who expressed concern that changes during the coverage year to evidentiary standards or the objective criteria applied when determining eligibility for an SSBCI may disrupt or undermine a chronically ill enrollee's access to SSBCI. As commenters noted, changes in eligibility criteria and standards during the coverage year may be used to limit chronically ill enrollees' access to benefits. Most comments received on this topic urged us to exempt SSBCI from our general rule permitting changes in plan rules during the coverage year so long as notice is provided to enrollees. While some commenters suggested allowing changes only if such changes would expand access to the SSBCI, we believe that prohibiting changes to eligibility criteria and evidentiary standards for SSBCI altogether would minimize the potential for confusion and disagreement regarding whether a change does in fact expand access to a benefit. Moreover, this policy is consistent with another policy we are finalizing related to SSBCI eligibility disclaimers; ensuring that the disclaimers on marketing during the annual enrollment period are as accurate later in the coverage year as when beneficiaries are making enrollment decisions will improve the usefulness and applicability of the disclaimer. Taken together, these policies serve our goal of minimizing enrollee confusion regarding eligibility for certain SSBCI.

For these reasons, we are also adding new paragraph (f)(4)(v) as part of the changes we are finalizing to § 422.102(f) in this rule. New paragraph (f)(4)(v) requires that an MA plan offering SSBCI must maintain without modification for the full coverage year for the SSBCI offered, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, and the specific objective criteria used by an MA plan as part of SSBCI eligibility determinations.

While CMS considered additionally prohibiting plans from making changes to their utilization management policies related to SSBCI during the coverage year, we are not finalizing such a prohibition at this time. It is important that plans have the flexibility to relax utilization management criteria and policies in the event of extraordinary circumstances. For example, during the COVID–19 public health emergency, CMS encouraged plans in the HPMS memo titled ''Information Related to Coronavirus Disease 2019—COVID–19'' to waive or relax prior authorization policies in order to facilitate enrollees' access to services with less burden on beneficiaries, plans and providers. We wish to allow plans continued flexibility to address such extraordinary circumstances, including disasters, declarations of state of emergency or public health emergencies, through changes made to utilization management policies as appropriate.

Comment: A commenter requested CMS not allow plans to change eligibility criteria for SSBCI during the plan year. However, the commenter requested that if CMS permitted plans to change eligibility criteria, or utilization management policies during the plan year, CMS should create a Special Enrollment Period (SEP) that allows enrollees to disenroll from the MA plan based on changes to plan rules.

Response: We appreciate this comment. We agree that changing eligibility criteria policies for SSBCI, benefits which may be heavily marketed to potential enrollees, could cause difficulties for chronically ill enrollees, especially if they relied on information about the availability of SSBCI benefits

in making a plan election. We do not wish these enrollees to come to rely on such services, only to be unable to access them during the plan year, or to be surprised by service denials or unexpected high service costs. In this final rule, CMS is prohibiting plans from making changes to eligibility requirements for SSBCI by requiring that plans offering SSBCI maintain without modification for the full coverage year, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI and the specific objective criteria used by an MA plan as part of SSBCI eligibility determinations. Due to this change, an SEP is not necessary.

Comment: A commenter requested additional clarity about the bibliography review process, suggesting that CMS codify its process for reviewing bibliographies.

Response: While we appreciate the commenter's concerns regarding the timeline and review process CMS will use in reviewing the bibliographies prepared by MA organizations, we are not finalizing any formal process at this time. We believe that plans which offer SSBCI should already have strong evidence to support that such benefits will provide value to the enrollees by improving or maintaining the health or overall function of the enrollees. Therefore, we do not feel it is necessary to codify a formal review process which may be overly burdensome for plans, and overly restrictive on CMS. However, after initial years of implementation of this requirement, we may reevaluate this position about when and the extent to which CMS should request and review the bibliographies that this final rule requires. If there are indications that plans have not been responsibly offering benefits and generally adhering to requirements or if we determine that a more pro-active or formal approach to SSBCI review is necessary, we may consider future changes.

Comment: A commenter recommended CMS allow studies older than 10 years old, as they believed that some services would not be the subject of more current research such that there would be sufficient evidence to support the benefit.

Response: Under our proposal, MA plans are permitted to include studies published over 10 years ago in their bibliography. We are finalizing that MA plans are required to include a comprehensive list of studies constituting relevant acceptable evidence published within the past 10 years, including any available negative evidence and literature.

Comment: A commenter noted that the lack of clinical codes for these benefits made tracking outcomes difficult as enrollees may use different ''variations'' of a service, and it is difficult to prove that a specific SSBCI makes an impact without a reliable control group.

Response: We appreciate that measuring the impact of non-primarily health related benefits may be challenging in the absence of standard clinical codes. That said, our proposal does not require plans to prove that their specific SSBCI improved or maintained the health or overall function of the specific chronically ill enrollees who received the benefit. Instead, we are further implementing the existing statutory standard, under which an SSBCI must have a reasonable expectation of improving or maintaining the health or overall functioning of a chronically ill enrollee, and establishing requirements to ensure that the statutory requirements are met when SSBCI are included in MA bids. While evidence regarding the impact of a specific SSBCI on a specific sample of chronically ill enrollees might be valuable in demonstrating compliance with the reasonable expectation standard, this is not a requirement we are imposing as part of this final rule.

Comment: Some commenters recommended changes to the relevant acceptable evidence aspect of the proposal as it relates to SNPs. A commenter recommended that CMS change the policy for D–SNPs specifically. They recommend that, in instances where an SSBCI benefit overlaps with a Medicaid benefit, the plan should provide additional evidence to show that the benefit has a reasonable expectation of improving the health outcome of the D–SNP enrollees. Another commenter recommended that CMS require D–SNP plans to provide evidence that their SSBCI provides unique value to a substantial portion of their expected enrollee population eligible for SSBCI and will not be duplicative of other benefits they would already receive.

Response: We appreciate these comments. While we share the commenter's concern for D–SNP enrollees, specifically that these enrollees be able to access both Medicare and Medicaid benefits as necessary, we did not propose and are not adopting specific Medicare-Medicaid benefit coordination rules for SSBCI. The requirements we proposed and are finalizing in § 422.102(f)(3) are intended to ensure that there is relevant acceptable evidence on which to conclude that specific items and services that an MA plan intends to cover as SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. We note that CMS already expects that D–SNPs use flexibility to design their benefits in a way that adds value for the enrollee by augmenting and/or bridging a gap between Medicare and Medicaid covered services and are therefore not modifying our requirements regarding SSBCI bibliographies to reflect any additional burden or requirement on D–SNPs specifically.

Comment: A commenter recommended CMS allow plans to include studies that focus on ''different sites of care'' or ''methods of implementation'' from those proposed for the plan benefit.

Response: Under our proposal, plans may cite studies that concern different sites of care or methods of implementation compared to how plans intend to implement their specific SSBCI. While ideally, relevant acceptable evidence will include studies that align with how plans will implement their SSBCI, and to whom the plans target their SSBCI, we recognize that most relevant studies will vary in the exact benefit and population studied. We believe studies that consider a benefit design and implementation similar to but not precisely the same as that proposed by the plan is still relevant for demonstrating compliance with our reasonable expectation standard.

After consideration of the comments, and for the reasons provided in our November 2023 proposed rule, we are finalizing our proposed revisions to § 422.102(f) with three modifications. First, we are finalizing our proposals to redesignate current paragraph § 422.102(f)(3) to § 422.102(f)(4). We are finalizing at § 422.102(f)(3) our proposed policy requiring the MA organization to be able to demonstrate through relevant acceptable evidence that the item or service to be offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee and must, by the date on which it submits its bid to CMS, establish a bibliography of ''relevant acceptable evidence'' concerning the impact that the item or service has on the health or overall function of its recipient.

We are further finalizing our proposal, at paragraph (f)(3)(i) that relevant acceptable evidence includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to

investigate whether the item or service impacts the health or overall function of a population, or large systematic reviews or meta-analyses summarizing the literature of the same.

We are modifying our proposal at § 422.102(f)(3)(ii) that an MA organization must include in its bibliography ''all relevant acceptable evidence'' published within the 10 years prior to the June immediately preceding the coverage year during which the SSBCI will be offered. Instead, in response to comments received, we are finalizing that an MA organization must include in its bibliography ''a comprehensive list of relevant acceptable evidence [. . .] including any available negative evidence and literature.''

We are finalizing at § 422.102(f)(3)(iii) that, if no evidence of the type described in paragraphs (f)(3)(i) and (ii) of this section exists for a given item or service, then MA organization may cite case studies, Federal policies or reports, internal analyses, or any other investigation of the impact that the item or service has on the health or overall function of its recipient as relevant acceptable evidence in the MA organization's bibliography.

Second, we are also finalizing our proposal to explicitly require at § 422.102(f)(4)(iii) that MA plans must apply their written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI. We are effectuating this policy by adding ''and apply'' to redesignated paragraph (f)(4)(iii)(A) as we proposed. Further, based on comments received, we are finalizing an exemption to the general rule reflected at § 422.111(d) that MA plans may change plan rules for SSBCI during the coverage year. Specifically, we are finalizing at new § 422.102(f)(3)(v) that an MA plan offering SSBCI must maintain without modification for the full coverage year evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, and the specific objective criteria used by an MA plan as part of SSBCI eligibility determinations.

Third, after considering comments received, we are modifying our proposal that MA plans would need to document denials of SSBCI eligibility instead of approvals. Instead, we are adopting a requirement that MA plans must document both approvals and denials of SSBCI eligibility. Specifically, we are modifying proposed § 422.102(f)((4)(iv) to say ''Document each SSBCI eligibility determination, whether eligible or ineligible, to receive a specific SSBCI and make this information available to CMS upon request.''

Fourth, we are finalizing our proposal without modification to add § 422.102(f)(5) to codify CMS's authority to decline to approve an MA organization's bid, if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting. We are additionally finalizing our proposal that CMS may annually review the items or services that an MA organization includes as SSBCI in its bid for compliance with all applicable requirements, taking into account updates to the relevant acceptable evidence applicable to each item or service. We are further finalizing our clarification that this provision does not limit CMS's authority to review and negotiate bids or to reject bids under section 1854(a) of the Act and subpart F of this part nor does it limit CMS's authority to review plan benefits and bids for compliance with all applicable requirements.

Finally, we are finalizing our technical edit proposed at § 422.102(f)(1)(i)(A)(*2*) to correct a typographical error. Specifically, we are substituting ''or'' for the second ''of'' in § 422.102(f)(1)(i)(A)(*2*), such that it reads ''Has a high risk of hospitalization or other adverse health outcomes.''

D. Mid-Year Notice of Unused Supplemental Benefits (§§ 422.111(l) and 422.2267(e)(42))

Per CMS regulations at § 422.101, MA organizations are permitted to offer mandatory supplemental benefits, optional supplemental benefits, and special supplemental benefits for the chronically ill (SSBCI). When submitting an annual bid to participate in the MA program, an MA organization includes a Plan Benefit Package (PBP) (OMB 0938–0763) and Bid Pricing Tool (BPT) (OMB 0938–0944) for each of its plans where the MA organization provides information to CMS on the premiums, cost sharing, and supplemental benefits (including SSBCI) it proposes to offer. The number of supplemental benefit offerings has risen significantly in recent years, as observed through trends identified in CMS's annual PBP reviews as well as external reports. The 2023 Medicare Trustees Report showed that in the last decade, MA rebates quintupled from $12 billion in 2014 to $67 billion estimated for 2024, resulting in a total of over $337 billion going towards MA rebates over that time period. This increase, which was due to both the increase in MA enrollment and per MA beneficiary rebate growth, which included 27%–30% jumps each year from 2019 to 2023.[87] At the same time, CMS has received reports that MA organizations have observed low utilization of these benefits by their enrollees, and it is unclear whether plans are actively encouraging utilization of these benefits by their enrollees, which could be an important part of a plan's overall care coordination efforts.

CMS remains concerned that utilization of these benefits is low and has taken multiple steps to obtain more complete data in this area. For example, in the May 2022 final rule, we finalized expanded Medical Loss Ratio (MLR) reporting requirements, requiring MA organizations to report expenditures on popular supplemental benefit categories such as dental, vision, hearing, transportation, and the fitness benefit (87 FR 27704, 27826–28).[88] In addition, in March 2023, as a part of our Part C reporting requirements, we announced our intent to collect data to better understand the utilization of supplemental benefits, which was finalized, and beginning CY2024 requires MA plans to report utilization and cost data for all supplemental benefit offerings.[89] This data is collected in the information collection request Part C Medicare Advantage Reporting OMB 0938–1054.[90] Currently, there is no specific requirement for MA organizations, beyond more general care coordination requirements, to conduct outreach to enrollees to encourage utilization of supplemental benefits.

CMS understands that projected supplemental benefit utilization, that is, the extent to which an MA organization expects a particular supplemental benefit to be accessed during a plan year, is estimated by an MA organization in part by the type and extent of outreach conducted for the benefit.[91] [92] We are concerned that

[87] *https://www.cms.gov/oact/tr/2023.*

[88] Available at *https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and.*

[89] Available at: *https://www.cms.gov/medicare/enrollment-renewal/health-plans/part-c* and *https://www.cms.gov/files/document/cy2024-part-c-technical-specifications-01092024.pdf.*

[90] *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-10261.*

[91] U.S. Government Accountability Office (GAO). ''MEDICARE ADVANTAGE Plans Generally Offered Some Supplemental Benefits, but CMS Has Limited Data on Utilization.'' Report to Congressional

Continued

beneficiaries may make enrollment decisions based on the allure of supplemental benefits that are extensively marketed by a given MA plan during the annual election period (AEP) only to not fully utilize, or utilize at all, those supplemental benefits during the plan year. This underutilization may be due to a lack of effort by the plan to help the beneficiary access the benefits or a lack of easy ability to know what benefits have not been accessed and are still available to the enrollee throughout the year. Such underutilization of supplemental benefits may nullify any potential health value offered by these extra benefits.

Additionally, section 1854(b)(1)(C) of the Act requires that MA plans offer the value of MA rebates back to enrollees in the form of payment for supplemental benefits, cost sharing reductions, or payment of Part B or D premiums. Therefore, CMS has an interest in ensuring that MA rebates are provided to enrollees in a way that they can benefit from the value of these rebate dollars. For example, analysis indicates that while supplemental dental benefits are one of the most widely offered supplemental benefits in MA plans, enrollees in these plans are no more likely to access these services than Traditional Medicare enrollees.[93]

As discussed, MA organizations are given the choice of how to provide MA rebates to their enrollees. Organizations may, instead of offering supplemental benefits in the form of covering additional items and services, use rebate dollars to further reduce Part B and Part D premiums, reduce cost sharing for basic benefits compared to cost sharing in Traditional Medicare, and reduce cost sharing in other ways, such as reducing maximum out-of-pocket (MOOP) amounts.

Over the last several years, CMS has observed an increase in (1) the number and variety of supplemental benefits offered by MA plans, (2) plan marketing activities by MA organizations, and (3) overall MA enrollment; we presume that an enrollee's plan choice is influenced, at least in part, by the supplemental benefits an MA plan offers because the absence or presence of a particular supplemental benefit represents a distinguishable and easily understood difference between one plan and another. We are also concerned that some MA plans may be using these supplemental benefits primarily as a marketing tool to steer enrollment towards their plan and are not taking steps to ensure that their enrollees are using the benefits being offered or tracking if these benefits are improving health or quality of care outcomes or addressing social determinants of health. We believe targeted communications specific to the utilization of supplemental benefits may further ensure that covered benefits (including those that are heavily marketed) are accessed and used by plan enrollees during the plan year. This outreach, in conjunction with the improved collection of utilization data for these supplemental benefits through MLR and through Part C reporting requirements, should help inform whether future rulemaking is warranted.

Finally, CMS is also working to achieve policy goals that advance health equity across its programs and pursue a comprehensive approach to advancing health equity for all, including those who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Several studies have pointed to disparities in health care utilization. For example, a Kaiser Family Foundation (KFF) study [94] found that there are significant racial and ethnic disparities in utilization of care among individuals with health insurance. Additionally, underserved populations tend to have a disproportionate prevalence of unmet social determinants of health needs, which can adversely affect health. We believe that the ability to offer supplemental benefits provides MA plans the unique opportunity to use Medicare Trust Fund dollars (in the form of MA rebates) to fill in coverage gaps in Traditional Medicare, by offering additional health care benefits or SSBCI that address unmet social determinants of health needs, and as such, all eligible MA enrollees should benefit from these offerings. Targeted outreach to enrollees that is specific to the utilization of supplemental benefits may also serve to further ensure more equitable utilization of these benefits.

The establishment of a minimum requirement for targeted outreach to enrollees with respect to supplemental benefits that have not been accessed by enrollees would standardize a process to ensure all enrollees served under MA are aware of and utilizing, as appropriate, the supplemental benefits available to them. Section 1852(c)(1) of the Act requires, in part, that MA organizations disclose detailed descriptions of plan provisions, including supplemental benefits, in a clear, accurate, and standardized form to each enrollee of a plan at the time of enrollment and at least annually thereafter. We proposed to use our authority to establish standards under Part C in section 1856(b)(1) of the Act to ensure adequate notice is provided to enrollees regarding supplemental benefits coverage. This proposal will further implement the disclosure requirement in section 1852(c)(1)(F) of the Act. Specifically, we proposed that MA organizations must provide a model notification to enrollees of supplemental benefits they have not yet accessed. We proposed to implement this by adding new provisions at §§ 422.111(l) and 422.2267(e)(42) to establish this new disclosure requirement and the details of the required notice, respectively.

This proposed requirement will ensure that a minimum outreach effort is conducted by MA organizations to inform enrollees of supplemental benefits available under their plan that the enrollee has not yet accessed. We proposed that, beginning January 1, 2026, MA organizations must mail a mid-year notice annually, but not sooner than June 30 and not later than July 31 of the plan year, to each enrollee with information pertaining to each supplemental benefit available during that plan year that the enrollee has not begun to use. We understand that there may be a lag between the time when a benefit is accessed and when a claim is processed, so we would require that the information used to identify recipients of this notice be as up to date as possible at the time of mailing. MA organizations are not required to include supplemental benefits that have been accessed, but are not yet exhausted, in this proposed mid-year notice.

Understanding that not all Medicare beneficiaries enroll in an MA plan during the AEP, we specifically sought comment on how CMS should address the timing of the notice for beneficiaries that have an enrollment effective date after January 1. One possible approach we described as under consideration was requiring the notice to be sent six months after the effective date of the enrollment for the first year of enrollment, and then for subsequent years, revert to mailing the notice between the proposed delivery dates of June 30 and July 31. Another option was to not require the notice to be mailed for

Committee, 31 Jan. 2023, p. 20, *www.gao.gov/products/gao-23-105527.*

[92] U.S. Government Accountability Office (GAO). ''MEDICARE ADVANTAGE Plans Generally Offered Some Supplemental Benefits, but CMS Has Limited Data on Utilization.'' Report to Congressional Committee, 31 Jan. 2023, p. 20, *www.gao.gov/products/gao-23-105527.*

[93] *https://www.cms.gov/research-statistics-data-and-systems/research/mcbs/data-briefs/dental-coverage-status-and-utilization-preventive-dental-services-medicare-beneficiaries-poster.*

[94] *https://www.kff.org/report-section/racial-and-ethnic-disparities-in-access-to-and-utilization-of-care-among-insured-adults-issue-brief/.*

the first year of enrollment for those beneficiaries with an effective date of May 1 or later, as they would be receiving their Evidence of Coverage (EOC) around this same timeframe but may not have had sufficient time to access these benefits. Those enrollees who would be exempt from the mailing, based on their enrollment effective date, would then receive the notice (if applicable because one or more supplemental benefits have not been accessed by the enrollee) between June 30 and July 31 in subsequent enrollment years.

For each covered mandatory supplemental benefit and optional supplemental benefit (if the enrollee has elected) for which enrollee is eligible, but has not accessed, the MA organization must list in the notice the information about each such benefit that appears in EOC. For SSBCI, MA organizations must include an explanation of the SSBCI covered under the plan (including eligibility criteria and limitations and scope of the covered items and services) and must also provide point-of-contact information for eligibility assessment (which can be the customer service line or a separate dedicated line), with trained staff that enrollees can contact to inquire about or begin the SSBCI eligibility determination process and to address any other questions the enrollee may have about the availability of SSBCI under their plan. When an enrollee has been determined by the plan to be eligible for one or more specific SSBCI benefit but has not accessed the SSBCI benefit by June 30 of the plan year, the notice must also include a description of the SSBCI benefit to which the enrollee is entitled and must describe any limitations on the benefit. In the proposed rule, we noted the proposal to amend § 422.2267(e)(34) (discussed in section VI.B of this final rule), if finalized, would require specific SSBCI disclaimers for marketing and communications materials that discuss the limitations of the SSBCI benefit being offered; we also proposed that this mid-year notice must include the SSBCI disclaimer to ensure that the necessary information provided in the disclaimer is also provided to the enrollee in the notice.

Furthermore, we proposed that each notice must include the scope of the supplemental benefit(s), applicable cost sharing, instructions on how to access the benefit(s), applicable information on the use of network providers for each available benefit, list the benefits consistent with the format of the EOC, and a toll-free customer service number including, as required, a corresponding TTY number, to call if additional help is needed. We solicited public comment on the required content of the mid-year notice.

We also requested public comment on our proposal to require MA plans to provide enrollees with mid-year notification of covered mandatory and optional supplemental benefits (if elected) that have not been at least partially accessed by that enrollee, particularly the appropriate timing (if any) of the notice for MA enrollees who enroll in the plan mid-year. A discussion of these comments, along with our responses follows.

Comment: Some supporters of this provision expressed a belief that the Mid-Year Notice is not strong enough to support the needs of enrollees or should be amended for other reasons. A commenter suggested that an annual cycle was insufficient, and that the notice should be mailed monthly. Several commenters suggested the notice be sent quarterly. A commenter suggested the notice be sent three months after enrollment for anyone with an effective date before September 1st, and for the enrollee to receive it during the annually established timeframe in subsequent years. A commenter suggested the notice be sent after the first quarter of the plan year. Another commenter suggested that the notice should be mailed soon after an enrollee's coverage is effectuated, regardless of whether the effectuation date is January 1st or after, and should include all supplemental benefits available under the plan. Another commenter stated that partially utilized benefits should be included in the notice.

Response: We thank these commenters for their support and attention to detail. We are finalizing § 422.111(l) (requiring the Mid-year Notice to be sent and the timing) and § 422.2267(e)(42) (the content requirements for the Mid-Year Notice) as proposed. The purpose of the notice is to inform those enrolled in an MA plan about supplemental benefits that have not been accessed, rather than to inform them of all available supplemental benefits. We believe the EOC is the appropriate communication for informing beneficiaries of all supplemental benefits offered under a particular plan. We also note that it is important to give beneficiaries ample time to access the benefits before providing notice of unused supplemental benefits. We believe the timeframes set forth in this rule provide sufficient time. In addition, monthly or quarterly reminders may be burdensome or lose their effectiveness in providing a reminder to enrollees about the benefits available to them. However, after assessing the efficacy of this provision over time, we may make amendments to the Mid-Year Notice and its requirements in future rulemaking.

Comment: We received many comments that expressed concern about burden and complexity, specifically regarding the proposed annual deadline (July 31) and cost of providing personalized information to each enrollee. With respect to the annual deadline a commenter asked CMS to extend the deadline to August 15, and another believed they would need up to 8 weeks following June 30 to complete the process of printing and mailing. For various reasons, some commenters believed CMS underestimated the costs associated with printing and mailing documents that consist of personalized information; for example, a commenter stated their printing costs were always higher for personalized materials; some commenters estimated average document lengths would be much higher than the CMS estimate, from 18 to over 20 pages.

Response: The Mid-Year Notice of Unused Supplemental Benefits is intended to be a concise and user-friendly document, and we are committed to the formulation of a model design that is both informative and succinct. The length of the document will ultimately vary from enrollee to enrollee, depending on the number of supplemental benefits offered under the plan, the number and scope of supplemental benefits each enrollee may be eligible to receive, and individual utilization. As proposed and finalized, the notice must only include information about supplemental benefits that the enrollee has not yet begun to use by June 30.

Further, MA organizations have their own unique processes in place for compiling, printing, and disseminating information, and this may lead to variations in cost. Stakeholders will have further opportunity to comment directly on the model notice during the Paperwork Reduction Act process. We also believe that the notice will create an incentive for MA organizations to improve their education and outreach efforts regarding supplemental benefit access and utilization through their marketing and communication materials, during the enrollment process, and into the plan year. We believe that as supplemental benefits are better understood and utilized by enrollees in the first half of the year, the shorter the Mid-Year Notice will become.

Further, the requirement to notify enrollees about their unused supplemental benefits can provide MA organizations with the opportunity to glean useful information to further tailor their PBPs. CMS believes MA organizations could gain valuable insights into their enrollees' healthcare needs and preferences based on the data needed to send these individualized notifications, if MA organizations choose to analyze this data. This notice can benefit MA organizations by encouraging them to thoughtfully reassess which supplemental benefits they choose to offer so they can steer away from unpopular types of supplemental benefits in the future, leading to a more impactful use of resources, including Medicare dollars.

Comment: Some commenters stated that our proposal lacks scope. A commenter believed that CMS should have defined ''supplemental benefits'' for the purpose of determining inclusion in the Notice. Another commenter stated the requirements of SSBCI and information needed were not clear. Another commenter asked CMS to clarify whether quarterly allowance benefits should be included in the Notice.

Response: To clarify, supplemental benefits include reductions in cost sharing and additional items and services that are not covered under Medicare Parts A, B and D. Per § 422.100(c), supplemental benefits must meet specific requirements in addition to not being covered by Medicare Parts A, B or D. The terms ''mandatory supplemental benefits'' and ''optional supplemental benefits'' are defined in § 422. SSBCI are supplemental benefits that are offered only to eligible enrollees with chronic conditions and are defined at § 422.102(f). Certain limitations on how and when MA plans may offer supplemental benefits are addressed in §§ 422.100(c) and 422.102 that we do not summarize in depth here.

For purposes of the Mid-Year Notice requirement, all unused supplemental benefits that are offered by the MA plan must appear in the Mid-Year Notice regardless of whether the benefits are categorized on the PBP as mandatory, optional, or SSBCI. The only supplemental benefit that does not need to be included in the notice is cost-sharing reduction, and this change has been reflected in the final regulation text for clarification.

The regulation we proposed and are finalizing at § 422.2267(e)(42) lists the information that is required about the unused supplemental benefits. For each mandatory supplemental benefit an enrollee has not used, the MA organization must include the same information about the benefit that is provided in the Evidence of Coverage. For each optional supplemental benefit an enrollee has not used, the MA organization must include the same information about the benefit that is provided in the Evidence of Coverage.

For SSBCI, the Mid-Year Notice must include the SSBCI disclaimer specified at § 422.2267(e)(34) and additional information about the SSBCI. When an enrollee has not been deemed eligible, MA organizations must include an explanation of the SSBCI covered under the plan consistent with the format of other unused supplemental benefits, eligibility criteria for the SSBCI, and point-of-contact information for eligibility assessments, such as a customer service line or a separate dedicated line, to reach trained staff that can answer questions and initiate the SSBCI eligibility determination process. When an enrollee has been determined by the plan to be eligible for one or more specific SSBCI—but has not accessed the SSBCI benefit by June 30 of the plan year—the Mid-Year Notice for that enrollee must also include a description of the SSBCI to which the enrollee is entitled and must describe any limitations on the benefit, consistent with the format of other unused supplemental benefits.

In addition, as specified in § 422.2267(e)(42)(ii)(D), the Mid-Year Notice must include the following about each unused supplemental benefit listed in the Notice to each enrollee:

(*1*) Scope of benefit.

(*2*) Applicable cost-sharing.

(*3*) Instructions on how to access the benefit.

(*4*) Any applicable network information.

(E) Supplemental benefits listed consistent with the format of the EOC.

(F) A customer service number, and required TTY number, to call for additional help.

We believe that the regulation is sufficiently clear as to the scope and required content of the notice.

Comment: Some commenters believed CMS could meet the stated goal of increasing supplemental benefit utilization through non-regulatory means by encouraging MA organizations to use their existing resources to promote supplemental benefit usage. Examples included the incorporation of supplemental-benefit-focused abstracts into MA organizations' newsletters, reminders to enrollees to read their EOCs, and the addition of articles and reminders on plan websites.

Response: We encourage MA organizations to use other outlets available to them to inform enrollees of their supplemental benefits. This Notice provision represents a required minimum effort on the part of each MA organization and should not be understood to preclude other forms of outreach.

Comment: Several commenters believed there is much potential for enrollees to become confused, frustrated, and ultimately dissatisfied with their plans because they are ineligible to use a particular benefit. An example provided was meal delivery being available only post-surgery.

Response: As discussed in the proposal, MA organizations are required to provide descriptions of supplemental benefits clearly and accurately. Here, MA organizations must describe the scope of and include instructions on how to access each listed supplemental benefit, similar to how these benefits are described in the EOC. If the benefit is only made available under limited circumstances, this must be evident in the Mid-Year Notice. Moreover, we feel strongly that the risk of confusion or frustration is far outweighed by the benefits of informing enrollees of supplemental benefits that can be useful to improving or maintaining their health.

Comment: Some commenters suggested CMS adopt a non-personalized format that summarizes all supplemental benefits available under a plan regardless of whether the enrollee has used them. Reasons for this suggestion commonly included burden reduction for MA organizations and decreased likelihood of confusion for enrollees.

Response: We believe that a non-personalized summary of all supplemental benefits available under a plan could confuse enrollees and add unnecessary length to the Mid-Year Notice. Further, as discussed above, the purpose of the notice is to inform those enrolled in an MA plan about supplemental benefits that they have not accessed, rather than to inform them of all supplemental benefits available. Providing information on supplemental benefits that the enrollee has not used will focus the enrollee on the items and services that are covered by the plan that the enrollee has not accessed, but may still have time to access, during the remainder of the year. We believe the EOC is the appropriate communication for informing beneficiaries of all supplemental benefits offered under a particular plan.

Comment: Many commenters believed this provision will drive an uptick in

the utilization of supplemental benefits. A commenter expressed concern that the Mid-Year Notice may impact expected utilization in uncertain ways, threatening the integrity of what MA organizations project in their bids. Another commenter stated that MA organizations generally have an expectation that not all enrollees will use every benefit, including supplemental benefits. This commenter expressed concern that promoting use of supplemental benefits could result in unanticipated expenses for an MA organization and result in higher premiums.

Response: We believe that the Mid-Year Notice will generate an increase in the use of supplemental benefits. However, MA organizations should not presume enrollees are overutilizing or will over utilize benefits as we believe most enrollees will use their benefits only when they need them. We expect organizations to establish reasonable safeguards that ensure enrollees are appropriately directed to care.[95] Further, MA organizations regularly make determinations to manage utilization as is the case with SSBCI where they must have written policies for determining enrollee eligibility and must document its determination whether an enrollee is chronically ill (42 CFR 422.102). Section IV.C. of this final rule includes discussion of new SSBCI rules that could help to mitigate unnecessary utilization.

Comment: Some commenters stated the proposal does not strike an appropriate balance between administrative burden and enrollee impact—that the proposal adds confusion, complexity, and cost without any clear value or benefit; further, some believed the proposal is based on assumptions rather than data. For example, a commenter stated that the proposal indicates that utilization of supplemental benefits is low but does not specify the basis for that position. The commenter requested that CMS provide further evidence and explanation to support the claim that there is low supplemental benefit utilization, and that the cause is lack of enrollee awareness of benefits as opposed to the enrollee not needing or wanting to use the benefit. In addition, the commenter asked that CMS demonstrate that a Mid-Year Notice is the most suitable means to address low supplemental benefit utilization under the rulemaking framework of the Administrative Procedure Act.

Response: In the proposed rule, we did not claim that the only cause of low supplemental benefit utilization was lack of enrollee awareness of benefits as the commenter suggested. Rather, we noted that it is unclear whether plans are actively encouraging utilization of these benefits by their enrollees, including as part of a plan's efforts in care coordination or otherwise. In addition, while we cited reports of low supplemental benefit utilization, we also noted that more complete data is needed in this area and provided examples of how CMS has taken multiple steps to obtain such data through both MLR and Part C reporting requirements. We stated that we will use findings obtained from this outreach requirement, in conjunction with the improved collection of supplemental benefit utilization data, to inform whether additional *future* rulemaking is warranted. Identifying and addressing potential underutilization of benefits funded in large part by the government through MA rebates is appropriate for us to ensure appropriate use of Medicare Trust Fund dollars. Further, to the extent that underutilization of supplemental benefits is not an issue and these benefits are widely accessed by enrollees, the number of Mid-Year Notices would decrease as proposed and finalized, our rule only requires a notice to individual enrollees about supplemental benefits that enrollees have not accessed.

As discussed in the proposal, the recent significant increase in the number and variety of supplemental benefit offerings combined with marketing activities and an increase in overall MA enrollment has led CMS to believe that an enrollee's plan choice is influenced, at least in part, by the supplemental benefits an MA plan offers. One purpose of the Mid-Year Notice is to address concerns that some MA plans may be using supplemental benefits primarily as marketing tools to steer enrollment; our policy as described here will help to ensure that covered benefits are accessed and used by plan enrollees during the plan year by ensuring that enrollees are aware about supplemental benefits that they have not yet used by June 30 of the applicable year. Any potential underutilization of benefits could be due to a lack of effort by the plan to help the beneficiary access the benefits, or a lack of easy ability to know what benefits have not been accessed and are still available to the enrollee throughout the year. This new notice is intended to address both.

Another purpose of the Mid-Year Notice is to address disparities in health care utilization, aligning with our goal to advance health equity in the MA program and pursue a comprehensive approach to advancing health equity for all by encouraging more equitable utilization of these benefits.

Finally, the Mid-Year Notice will further ensure that MA organizations fulfill their obligation to adequately disclose details and notice of supplemental benefit coverage.

Comment: Some commenters expressed concern about the ability to offer ''real-time'' information on the Mid-Year Notice. For example, one commenter mentioned that MA organizations use a wide variety of providers to furnish supplemental benefits, and that these providers have varying degrees of capability; some are community-based organizations with limited resources, and such providers may not be able to transmit utilization and claim information with the speed of more conventional provider types.

Response: We understand that supplemental benefits are often available through community-based providers that often do not have the budget for sophisticated software systems that transmit information in ''real-time.'' With respect to timeliness, we consider information that is up to date as of June 30 of the plan year to satisfy the requirement for accuracy.

Comment: Many commenters were satisfied with a provision start date of January 2026, but some asked for an extension to January 2027.

Response: We believe a start date of January 2026 gives MA organizations sufficient time to plan and implement processes for the Mid-Year Notice. After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments, we are finalizing §§ 422.111(l) as proposed and 422.2267(e)(42) with a modification to clarify that supplemental benefits in the form of cost-sharing reductions are excluded from the notice.

E. Annual Health Equity Analysis of Utilization Management Policies and Procedures

In recent years, CMS has received feedback from interested parties, including people with Medicare, patient groups, consumer advocates, and providers that utilization management (UM) practices in Medicare Advantage (MA), especially the use of prior authorization, can sometimes create a barrier for patients in accessing medically necessary care. Further, some research has indicated that the use of

[95] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hpms%2520memo%2520primarily%2520health%2520related%25204-27-18_194.pdf.*

prior authorization may disproportionately impact individuals who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality,[96] due to several factors, including; the administrative burden associated with processing prior authorization requests (for example, providers and administrative staff serving historically underserved populations, in particular, may not have the time or resources to complete the prior authorization process, including navigating the appeals process [97]), a reduction in medication adherence, and overall worse medical outcomes due to delayed or denied care. Research has also shown that dual eligibility for Medicare and Medicaid is one of the most influential predictors of poor health outcomes, and that disability is also an important risk factor linked to health outcomes.[98]

On January 20, 2021, President Biden issued Executive Order 13985: ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' (E.O. 13985).[99] E.O. 13985 describes the Administration's policy goals to advance equity across Federal programs and directs Federal agencies to pursue a comprehensive approach to advancing equity for all, including those who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Consistent with this Executive Order, CMS announced ''Advance Equity'' as the first pillar of its 2022 Strategic Plan.[100] This pillar emphasizes the importance of advancing health equity by addressing the health disparities that impact our health care system. CMS defines health equity as ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [101]

The April 2023 final rule [102] included several policy changes to advance health equity, as well as changes to address concerns from interested parties about the use of utilization management policies and procedures, including prior authorization, by MA plans. CMS understands that utilization management is an important means to coordinate care, reduce inappropriate utilization, and promote cost-efficient care. The April 2023 final rule adopted several important guardrails to ensure that utilization management policies and procedures are used, and associated coverage decisions are made, in ways that ensure timely and appropriate access to covered items and services for people enrolled in MA plans. CMS also continues to work to identify regulatory actions that can help support CMS's goal to advance health equity and improve access to covered benefits for enrollees.

Authority for MA organizations to use utilization management policies and procedures regarding basic benefits is subject to the mandate in section 1852(a)(1) of the Act that MA plans cover Medicare Part A and Part B benefits (subject to specific, limited statutory exclusions) and, thus, to CMS's authority under section 1856(b) of the Act to adopt standards to carry out the MA statutory provisions. In addition, the MA statute and MA contracts cover both the basic and supplemental benefits covered under MA plans, so additional contract terms added by CMS pursuant to section 1857(e)(1) of the Act may also address supplemental benefits. Additionally, per section 1852(b) of the Act and § 422.100(f)(2), plan designs and benefits may not discriminate against beneficiaries, promote discrimination, discourage enrollment, encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. These requirements apply to both basic and supplemental benefits. We consider utilization management policies and procedures to be part of the plan benefit design, and therefore they cannot be used to discriminate or direct enrollees away from certain types of services.

In the April 2023 final rule, CMS finalized a new regulation at § 422.137, which requires all MA organizations that use UM policies and procedures to establish a Utilization Management Committee to review and approve all UM policies and procedures at least annually and ensure consistency with Traditional Medicare's national and local coverage decisions and relevant Medicare statutes and regulations. Per § 422.137, an MA plan may not use any UM policies and procedures for basic or supplemental benefits on or after January 1, 2024, unless those policies and procedures have been reviewed and approved by the UM committee. While this requirement will ensure that all UM policies and procedures are kept up to date, we believe that reviewing and analyzing these policies from a health equity perspective is an important beneficiary protection. In addition, such an analysis may assist in ensuring that MA plan designs do not deny, limit, or condition the coverage or provision of benefits on a prohibited basis (such as a disability) and are not likely to substantially discourage enrollment by certain MA eligible individuals with the organization. For these reasons, we proposed to add health equity-related requirements to § 422.137. First, we proposed at § 422.137(c)(5) to require that beginning January 1, 2025, the UM committee must include at least one member with expertise in health equity. We proposed that health equity expertise includes, but is not limited to, educational degrees or credentials with an emphasis on health equity, experience conducting studies identifying disparities amongst different population groups, experience leading organization-wide policies, programs, or services to achieve health equity, or experience leading advocacy efforts to achieve health equity. Since there is no universally accepted definition of expertise in health equity, we referred to materials from the Council on Linkages Between Academia and Public Health Practice [103] and the National Board of Public Health Examiners,[104] to describe ''expertise in health equity'' in the context of MA and prior authorization.

We also proposed to add a requirement at § 422.137(d)(6) that the UM committee must conduct an annual health equity analysis of the use of prior authorization. We proposed that the member of the UM committee, who has health equity expertise, as required at proposed § 422.137(c)(5), must approve the final report of the analysis before it is posted on the plan's publicly available website. The proposed analysis will examine the impact of prior authorization at the plan level, on

[96] *https://www.hmpgloballearningnetwork.com/site/frmc/commentary/addressing-health-inequities-prior-authorization;* and *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10024078/*

[97] *http://abcardio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf,*

[98] *https://www.aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf?_ga=2.49530854.1703779054.1662938643-470268562.1638986031*

[99] *https://www.federalregister.gov/d/2022-26956/p-227.*

[100] *https://www.federalregister.gov/d/2022-26956/p-228.*

[101] *https://www.cms.gov/pillar/health-equity.*

[102] ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' final rule, which appeared in the **Federal Register** on April 12, 2023 (88 FR 22120).

[103] *https://www.phf.org/resourcestools/Documents/Core_Competencies_for_Public_Health_Professionals_2021October.pdf*

[104] *https://www.nbphe.org/cph-content-outline/*

enrollees with one or more of the following social risk factors (SRF): (1) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or (2) having a disability. Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems. CMS chose these SRFs because they mirror the SRFs that will be used to measure the Heath Equity Index reward for the 2027 Star Ratings (see § 422.166(f)(3)), and we believe it is important to align expectations and metrics across the program. Moreover, CMS is requiring this analysis to take place at the MA plan level because the relevant information regarding enrollees with the specified SRFs is available at the plan level, and we believe this level of analysis is important to discern the actual impact of the use of utilization management on enrollees that may be particularly subject to health disparities.

To gain a deeper understanding of the impact of prior authorization practices on enrollees with the specified SRFs, the analysis, as proposed, must compare metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. Doing so, allows the MA plan and CMS to begin to identify whether the use of prior authorization causes any persistent disparities among enrollees with the specified SRFs. We proposed that the analysis must use the following metrics, calculated for enrollees with the specified SRFS, and for enrollees without the specified SRFs, from the prior contract year, to conduct the analysis:

- The percentage of standard prior authorization requests that were approved, aggregated for all items and services.
- The percentage of standard prior authorization requests that were denied, aggregated for all items and services.
- The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services.

Next, we proposed to add at § 422.137(d)(7) that by July 1, 2025, and annually thereafter, the health equity analysis be posted on the plan's publicly available website in a prominent manner and clearly identified in the footer of the website. We proposed that the health equity analysis must be easily accessible to the general public, without barriers, including but not limited to ensuring the information is available: free of charge; without having to establish a user account or password; without having to submit personal identifying information (PII); in a machine-readable format with the data contained within that file being digitally searchable and downloadable from a link in the footer of the plan's publicly available website, and include a .txt file in the root directory of the website domain that includes a direct link to the machine-readable file, in a format described by CMS (which CMS will provide in guidance), to establish and maintain automated access. We believe that by making this information more easily accessible to automated searches and data pulls, it will help third parties develop tools and researchers conduct studies that further aid the public in understanding the information and capturing it in a meaningful way across MA plans.

Finally, we welcomed comment on the proposal and sought comment on the following:

- Additional populations CMS should consider including in the health equity analysis, including but not limited to: Members of racial and ethnic communities, members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; members of rural communities; and persons otherwise adversely affected by persistent poverty or inequality.
- If there should be further definition for what constitutes ''expertise in health equity,'' and if so, what other qualifications to include in a definition of ''expertise in health equity.''
- The proposed requirements for publicly posting the results on the plan's website under § 422.137(d)(7) to ensure the data will be easily accessible to both the public and researchers.
- Alternatives to the July 1, 2025, deadline for the initial analysis to be posted to the plan's publicly available website.
- Whether to add an additional requirement that the UM committee submit to CMS the link to the analysis report. This would allow CMS to post every link in one centralized location, which would increase accessibility and transparency.

In addition, we requested comment on any specific items or services, or groups of items or services, subject to prior authorization that CMS should consider also disaggregating in the analysis to consider for future rulemaking. If further disaggregation of a group of items or services is requested, CMS solicited comment on what specific items or services would be included within the group. For example, if CMS should consider disaggregating a group of items or services related to behavioral health treatment in the health equity analysis, what items or services should CMS consider a part of behavioral health treatment.

We invited public comment on this proposal and received over 140 comments. A summary of the comments received, and CMS's responses are below.

Comment: Nearly all commenters supported the proposal to add a member to the utilization management committee with expertise in health equity. A majority of commenters also supported the proposed definition of expertise in health equity. Commenters expressed gratitude for CMS's recognition that there is not currently a widely accepted definition of what qualifies as ''expertise in health equity,'' and that the proposed non-exhaustive list provides adequate flexibility and acknowledges the varied experiences and qualifications that could comprise health equity expertise.

Response: CMS appreciates the suggestions and support for this proposal. As outlined in the November 2023 rule, we do not believe there is a universally accepted definition of expertise in health equity. Therefore, CMS believes there is value at this stage in providing a non-exhaustive list of examples of what constitutes such expertise to avoid inadvertently excluding qualified individuals by being overly restrictive. The proposed and finalized regulation text lists examples to illustrate what constitutes expertise in health equity includes to guide MA organizations in identifying individuals with the necessary expertise and experience to fulfill this new role on the UM committee. We are finalizing that list without the phrase ''but is not

limited to'' because that phrase is repetitive; the term ''includes'' means that the list that follows is a non-exhaustive list of examples.

Comment: Some commenters suggested that CMS include additional specificity in the definition of expertise in health expertise, such as clinical experience practicing in underserved and marginalized communities, as well as lived, community, and professional experience in addition to academic training. Other commenters suggested that the individual be a physician. A commenter suggested CMS include in expertise in health equity include, ''experience serving on Health Equity Technical Expert Panels convened by CMS contractors.'' A commenter proposed that CMS require two members with expertise in health equity. A commenter suggested the health equity expert be required to undergo bias training. A commenter suggested that CMS clarify that the individual with expertise in health equity can be a nonphysician clinician, data analyst, or researcher. A commenter suggested CMS define expertise in terms of time, *i.e.,* five years of experience.

Response: CMS appreciates the suggestions for additional credentials and qualifications for the member of the UM committee with expertise in health equity. At this time, we do not believe adding the additional examples suggested by commenters of expertise in health equity to the non-exhaustive list in the regulation would necessarily add clarity, and we believe there is value in leaving some flexibility for MA organizations to determine what qualifies as expertise in health equity. Furthermore, CMS clarifies that the individual with expertise in health equity may include but not be limited to a nonphysician clinician, data analyst, or researcher. We are not adopting the recommendation to require bias training for the committee member with expertise in health equity because we did not propose additional requirements for specific committee members and do not feel it is necessary at this time. We also decline to adopt the recommendation to require the UM committee to have two members with expertise in health equity at this time because we believe that one member is sufficient to ensure utilization management policies and procedures are reviewed from a health equity perspective. However, we will continue to monitor implementation and compliance to determine if additional requirements, including adding additional members to the committee or specific training requirements, are necessary for future rulemaking.

Comment: Some commenters requested that MA organizations be permitted to use existing committee members, or employees of the MA organization, who have relevant qualifications to fulfil the role or leverage existing committees, if appropriate. A commenter asked CMS to clarify that plans can meet the requirement by recruiting a new member.

Response: As finalized, § 422.137(c)(5) requires MA organizations to include at least one member on the UM committee with expertise in health equity. The regulation does not set a minimum or maximum number of UM committee members so long as the composition requirements in § 422.137(c) are met; therefore, an MA organization leverage existing committee members or recruit a new member for the UM committee, as long as all regulatory requirements are met for the UM committee to include at least one member with expertise in health equity beginning January 1, 2025.

Comment: A few commenters recommended the member with expertise in health equity not be affiliated with the MA plan.

Response: At this time, CMS declines to require that the UM committee member with expertise in health equity not be affiliated with the MA organization (or the various MA plans offered by the MA organization). The regulation at § 422.137(c)(2) already requires that the UM committee include at least one practicing physician who is independent and free of conflict relative to the MA organization and MA plan. CMS believes there is value in allowing flexibility at this stage and will monitor how this requirement is implemented to determine if additional requirements may be necessary in the future.

Comment: A commenter requested CMS delay the addition of a member with expertise in health equity.

Response: Given the flexibilities afforded plans regarding the ability to recruit a member with expertise in health equity, CMS does not believe an adjustment in the timeline is needed. We continue to believe that reviewing and analyzing UM policies from a health equity perspective serves as an important beneficiary protection and will evaluate the impact of this rule and consider all suggestions for future rulemaking. At the time that this final rule is issued, there are at least 6 months for an MA organization to ensure that its UM committee(s) include at least one member with health equity expertise to meet the January 1, 2025, deadline.

Comment: A commenter questioned whether there is sufficient evidence that adding such a role to this process will indeed improve health equity.

Response: CMS does not believe that a body of research or other formal evidence is necessary to justify the requirement that at least one UM committee member have expertise in health equity. The purpose of this requirement is to help ensure that all utilization management policies and procedures are reviewed from a health equity lens, and that the member of the committee with expertise in health equity provides final approval of the health equity analysis.

Comment: A commenter urged CMS to issue clear explanatory guidelines to ensure plan compliance.

Response: CMS believes that the requirements laid out in the regulation are sufficiently clear regarding what is necessary for compliance with this rule, including what constitutes expertise in health equity. However, CMS will monitor compliance and may issue additional guidance as necessary.

Comment: A commenter expressed that the entire UM committee, not just the member with health equity expertise, should be responsible for ensuring the analysis is comprehensive and complete.

Response: CMS expects that every member of the UM committee will participate in the production, review, and analysis of the health equity analysis, just as every member of the UM committee is responsible for reviewing all UM policies and procedures to ensure that they are kept up to date. However, just as the medical director is responsible for the overall actions of the UM committee itself, CMS believes it is important that the member of the UM committee with expertise in health equity will provide the final approval of the report in order to ensure the report is specifically reviewed from a health equity perspective.

Comment: Regarding the proposal to require the UM committee to conduct an annual health equity analysis of the use of prior authorization, commenters generally expressed support for the goal to advance health equity, increase transparency around the use of prior authorization, and ensure enrollees have timely access to medically necessary and clinically appropriate care. Some commenters did not support the proposal but did not elaborate as to their specific reasons for not supporting it. Some commenters encouraged CMS to continue advancing broader policy efforts to advance health equity goals

and expressed concern that the proposed analysis will not actually advance health equity or help identify gaps in health equity. A few commenters indicated the analysis could be helpful in assisting researchers to develop tools and conduct studies to further inform the public. Some commenters indicated that the UM committee may not be the best entity to conduct this analysis.

Response: CMS appreciates the feedback provided, as well as the support for the intent of the proposal. We also understand and agree with the sentiment that CMS should continue broader efforts to advance health equity. The goal of this proposal is to ensure that all utilization management policies and procedures are reviewed from a health equity perspective, and to establish baseline data by beginning to identify whether the use of prior authorization causes any persistent disparities among enrollees with the specified social risk factors. Because § 422.137 requires the UM committee to review any UM policies and procedures (including prior authorization) before an MA organization may use them beginning January 1, 2024, the UM committee is uniquely positioned to have access to data about when and how prior authorization policies and procedures are used by each MA plan offered by the MA organization in order to perform the health equity analysis and to use and report on the metrics we proposed and are finalizing at § 422.137(d)(iii).

This policy for the UM committee to perform and publicly post a health equity analysis with the information on specific prior authorization metrics, calculated using specific social risk factors, is just one piece of a much larger comprehensive approach to advancing equity for all, and we will continue to work to advance health equity. We will also consider all feedback received while working to develop future policy.

Comment: Some commenters indicated that prior authorization denial rates are not necessarily attributable to or correlated with an enrollee's social risk factor status. Commenters expressed concern about the proposed methodology and the practical utility of the data in its proposed form, and concerns about the potential for this information to mischaracterize plan activities or inadvertently mislead enrollees. Other commenters stated that comparing prior authorization metrics across MA plans cannot be done accurately given variation in how plans code and track prior authorizations. Therefore, the analysis should include explanatory info or methodological adjustments to account for varying conditions across populations.

A commenter requested that plans should automatically be required to explain their rates of denials for services that meet coverage rules. Some commenters requested general prior authorization utilization management reforms. Some commenters suggested that rather than create new data flows, CMS expand current part C data reporting requirements to include data elements specific to enrollees with the specified SRFs. Some commenters expressed concern that the number of enrollees with the SRFs enrolled in an MA plan (either too high or too low) could cause a comparison to be inaccurate. Several commenters expressed concern over ensuring that appropriate context for results of the analysis is available and not confusing or misleading for the public. Commenters also expressed concern that while making these results publicly available could increase accountability of MA organizations, CMS should also recognize that the amount of information enrollees must process, and that this data may not be useful or easy for a layperson to understand; therefore, commenters suggested that MA plans be required to include an executive summary posted with the report. A few commenters pointed out that for MA organizations that serve 100 percent limited-income subsidy/dual-eligible populations, these MA plans could be asked to publicly report the same metrics twice, since the ''Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program'' (CMS–0057–F) rule has been finalized to require reporting of certain information about prior authorization metrics.

Response: CMS understands the concern about appropriate interpretation of the data. The regulation we are finalizing in this rule requires the health equity analysis for informational purposes only, to help gain a deeper understanding of the impact of prior authorization practices on enrollees with the specified SRFs and allow MA plans and CMS to begin to identify whether the use of prior authorization causes any persistent disparities among enrollees with the specified SRFs. CMS believes this required analysis may assist in ensuring that MA plan designs do not deny, limit, or condition the coverage or provision of benefits on a prohibited basis (such as a disability) and are not likely to substantially discourage enrollment by certain MA eligible individuals with the organization. Since we currently do not have any information that compares data for enrollees with the specified SRFs to those without the specified SRFs, CMS continues to believe that this analysis is an important first step in looking deeper into the use of prior authorization and its potential effects on enrollees.

CMS appreciates the concern that enrollees already must process ample information when making plan decisions and that, as proposed, the information may not be easily comprehended or put into full context by a layperson, and will take these suggestions into account when issuing operational guidance for the format of the report. Further, we believe that by making this information easily accessible to automated searches and data pulls, it will help third parties develop tools and researchers conduct studies that further aid the public in understanding the information and capturing it in a meaningful way across MA plans. We also believe that since the required data must be aggregated for all items and services at the plan level, the resulting analysis, while comprehensive, will not be overwhelming to the public. While CMS is not requiring the health equity report for each MA plan to include an explanatory statement or executive summary with the analysis at this time, if MA organizations wish to provide additional context for the results of the analysis of their MA plans, they may provide clarifying information in the report, provided that any such accompanying language is not misleading.

Regarding concerns that comparing prior authorization metrics across MA plans cannot be done accurately given variation in how plans code and track prior authorizations, CMS does not believe this presents a significant issue, since there is not a requirement in this rule for comparison across plans. The ''Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health

Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program'' (CMS–0057–F) final rule (hereinafter referred to as the ''2024 Interoperability Final Rule''), which appeared in the **Federal Register** on February 8, 2024 (89 FR 8758), adopted, among other provisions related to exchanges of certain health information and prior authorization processes, requirements for MA organizations and certain other payers (State Medicaid agencies, State CHIP agencies, Medicaid managed care plans, CHIP managed care plans, and QHPs on Federally facilitated Exchanges) to report certain metrics about prior authorization beginning in 2026.[105] The 2024 Interoperability Final Rule requires reporting of this information:

- A list of all items and services that require prior authorization.
- The percentage of standard prior authorization requests that were approved, aggregated for all items and services.
- The percentage of standard prior authorization requests that were denied, aggregated for all items and services.
- The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a determination by the payer, plan, or issuer, for standard prior authorizations, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a decision by the payer, plan, or issuer, for expedited prior authorizations, aggregated for all items and services.

[105] The 2024 Interoperability Final Rule is available online here: *govinfo.gov/content/pkg/FR-2024-02-08/pdf/2024-00895.pdf*. The regulations requiring reports of prior authorization performance metrics are 42 CFR 422.122(c), 440.230(e)(3), 438.210(f), 457.732(c), and 457.1230(d) and 45 CFR 156.223(c).

The performance metrics for the reporting under § 422.122(c), as adopted in the 2024 Interoperability Final Rule, and the reporting metrics adopted in this final rule at § 422.137(d)(6) use the same general categories, except that the 2024 Interoperability Final Rule requires that the information be aggregated for all enrollees, reported at the contract level, and excluding any drug coverage, while this final rule requires the reported information to be by groups with and without the specified social risk factors, reported at the plan level, and for all covered benefits (also excluding Part B drugs and OTC drugs covered by the MA plan and Part D drugs covered under the Part D benefit). The specified social risk factors are (i) receipt of the Part D low-income subsidy or being dually eligible for Medicare and Medicaid and (ii) having a disability, determined using information specified in § 422.137(d)(6)(ii)(B). Because the reporting is not for identical populations, these two separate regulatory reports will not be duplicative, and we believe that they will be complementary by providing information about the same prior authorization metrics for different populations. In addition, excluding drugs—Part B drugs, OTC drugs covered by the MA plan, and Part D drugs—for both lists should help address concerns about burden. To clarify this aspect of the scope of § 422.137(d)(6), we are finalizing additional language to exclude drugs from the scope of the new reporting and health equity analysis metrics; as finalized, § 422.137(d)(6)(iii) provides that the data used for this analysis and reporting excludes data on drugs as defined in § 422.119(b)(1)(v). Further, because MA organizations should already be collecting the data at the plan level, they should be able to report it with the stratification by SRFs for the requirements of § 422.137(d)(6), and then can aggregate that data up to the contract level for the reporting required by the 2024 Interoperability Final Rule. Therefore, having the specific metrics be the same (but reported for different populations) should ease the burden on MA organizations in gathering, validating, and formatting the data.

Comment: CMS solicited comment on additional populations to consider including in the health equity analysis. Several commenters indicated that the populations proposed in the analysis should be expanded, and many commenters suggested additional populations for CMS to consider, including: Members of economically marginalized communities; Original Reason for Entitlement Code for ESRD; individuals who receive SSBCI; individuals who have visited the ER in the past year; individuals who were hospitalized and sought post-acute care; individuals with limited English proficiency; individuals with mental health conditions, including depression, anxiety, and substance use disorder; individuals with chronic diseases such as asthma, COPD, cancer, obesity, cardiovascular disease, and diabetes; individuals with a combination of chronic conditions/diseases; individuals with a rare disease; members of racial and ethnic communities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; members of rural communities; persons otherwise adversely affected by persistent poverty or inequality; formerly incarcerated individuals; veterans; and individuals experiencing homelessness. A commenter suggested CMS take an intersectional approach—considering how multiple identities intersect and manifest experiences. A commenter asked CMS to consider using the publicly available Vizient Vulnerability Index™, which identifies social needs and obstacles to care that may influence a person's overall health. A few commenters suggested the enrollee data should be separated into full/partial dually eligible for Medicare and Medicaid. A commenter suggested that CMS align its approach with the NCQA from a population health management approach.

Some commenters acknowledged that adding populations to the analysis is not feasible at this time, because neither MA plans nor CMS has access to this data. Further, several commenters pointed out that reporting on many of the additional populations suggested would present issues because this type of demographic information would have to be self-reported, which could lead to incomplete and skewed data collection. Some commenters suggested that plans could collect this data upon enrollment. Generally, plans indicated that CMS should not add populations to the annual health equity analysis until data collection and methods for collecting demographic information have been piloted, tested, and found to be reliable in the context of the MA population. A commenter requested that CMS assist plans in gathering this information.

Response: CMS appreciates the feedback and input regarding additional populations to consider including in the health equity analysis. We acknowledge that there are challenges associated with collecting data in a consistent manner, and that not all populations can be

reliably identified using available data elements due to a lack of standardization in collection methods. Since much of this information would have to be self-reported, we agree this could lead to a potentially inconsistent or misleading analysis. For that reason, we are not adding additional populations at this time. We will take all suggestions into consideration for future rulemaking and continue to explore ways to expand the populations included in the health equity analysis. We also urge MA plans to consider how data on some of the proposed populations could be collected and analyzed.

Comment: Some commenters pointed out that CMS's proposed method of determining disability status could leave out enrollees who are over the age of 65 and have a disability but did not originally qualify for Medicare on that basis.

Response: The variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems is the method used to determine disability status for the Health Equity Index and Categorical Adjustment Index. At this time, CMS believes that it is necessary to maintain consistency in identifying MA enrollment populations by this social risk factor for the Star Ratings and the UM committee's health equity analysis. However, we also understand the concern raised by commenters and will continue to evaluate how we could expand the ways we identify individuals who have a disability.

Comment: CMS requested comment on any specific items or services, or groups of items or services, subject to prior authorization that we should consider disaggregating in future rulemaking. Many commenters provided suggestions and feedback. Several commenters asserted that because the proposed analysis would consist of prior authorization metrics aggregated for all items and services, it will not provide enough detail for true accountability and could allow plans to hide disparities. Commenters recommended that CMS require a further level of granularity to ensure that potential disparities could be identified. Specifically, commenters suggested that CMS require disaggregation by item and service to ensure that CMS can identify specific services that may be disproportionately denied.

Commenters also provided suggestions for specific items and services for CMS to consider for disaggregation, including: Additional modalities beyond drugs/services that require prior authorization such as diagnostic tests, durable medical equipment, and skilled nursing facility care; substance use disorder and mental health services so these can be compared to medical services; prescription drugs; service category for rehabilitative services; physical therapist services; kidney care services, including dialysis treatments and transplant; prosthetics, orthotics and supplies; cellular and/or tissue-based products (CTPs, or skin substitute) services, in-office injections, in-office medically necessary imaging, ankle-foot orthoses (AFOs) for traumatic conditions, surgical dressings, and biopsy of suspicious lesions; disaggregated data on access to medically necessary post-acute care which should include LTCHs, IRFs, SNFs, and HHAs. A commenter suggested that CMS require MA plans to submit the data underlying the report, disaggregated with demographic and other health equity indicators that would allow CMS to conduct more flexible analysis and compare subpopulations within plans. CMS could then aggregate and provide searchable results across MA plans, including by original reason for entitlement code and by age group. A commenter requested that MA plans should have discretion to determine when disaggregating will provide meaningful information and not compromise the privacy of its members.

Response: CMS thanks commenters for their suggestions and feedback. We agree that disaggregation of the reported metrics by specific benefit could assist in increasing transparency and ensuring the most accurate data regarding prior authorization is available. As of now, it is our intent to require some level of disaggregation in the coming years, and we will consider all suggestions for any future rulemaking. We also believe there is significant value in establishing baseline data, since there is currently very little publicly available information regarding the use of prior authorization and its potential impact on specific populations. We believe that at least during the initial year, the analysis as proposed strikes a balance between providing information that may be useful to CMS, MA plans, and the public, and not providing an overwhelming amount of information.

Comment: Some commenters suggested that disenrollment data be included among the required metrics for the health equity analysis. Commenters relayed that this is important since prior authorization can lead individuals with complex health conditions and disabilities to disenroll from a plan after receiving a prior authorization decision. A commenter suggested that, in an effort to further identify disparities and advance health equity through conducting this analysis, CMS also include one or more of the following four criteria recognized by the National Committee for Quality Assurance as baseline to begin accounting for equitable outcomes: Select indicators of social determinants of health; Select a reference group (a ''standard'' comparison group independent of the data vs. the data informing the comparison group); Select health care quality metrics. These could include composites (*e.g.,* vaccination rates, quality measures, infant mortality rates); Use benchmarks (*e.g.,* compare results to national estimates). Another commenter suggested that CMS analyze if and how often providers decline to prescribe a treatment because they do not have the resources to engage in a prior authorization process. Several commenters suggested the analysis include the reason for which a prior authorization request was denied. A commenter suggested that MA plans report prior authorizations as a part of encounter data so that CMS and independent researchers can conduct unbiased analyses of the equity impacts of utilization management. Another commenter suggested MA plans target specific service types that are frequently subjected to inappropriate utilization review practices. A commenter proposed requiring plans to report whenever end-of-life status is the reason for denying a prior authorization. A commenter recommended comparing sub-populations enrolled in D–SNPs versus those enrolled in non-SNP MA plans. Another commenter recommended comparing appeal rates and outcomes on denied PA requests between populations. A commenter suggested that such analytics should include a side-by-side comparison of all data points by MA plan and compare them to traditional Medicare and Medicaid coverage; and that the MA plan should be required to provide criteria used to determine medical necessity and authorizations and include post-payment audit data in addition to prepayment authorization outcomes in the posted information and health equity analysis.

Response: CMS appreciates the feedback, and while we are not adding additional metrics to the analysis at this time, we will consider doing so in future rulemaking. We would also direct commenters to the 2024 Interoperability

Final Rule, which adopts certain procedural and timing requirements for prior authorizations and several API requirements for MA organizations and other impacted payers, including implementation of a Prior Authorization API, new reporting to CMS, and new requirements to provide to the applicable provider a specific reason for the denial of a request for prior authorization.

Comment: CMS requested comment on requiring MA plans to submit a link to their health equity analysis directly to CMS. Many commenters supported the addition of this requirement. Commenters further suggested that CMS make the specified metrics to be used in the analysis publicly available on the CMS website and to require MA plans to publish the results of the analysis in plain, easy to understand language that can be understood by the average enrollee. A commenter requested the results of the analysis be accessible on the Medicare Plan Finder on *www.medicare.gov* so that beneficiaries can evaluate the ease with which they may access services when determining which health plan to choose.

Additionally, several commenters also suggested that plans only submit a link to CMS, and not post the report publicly. These commenters generally stated that proposed requirement to post the report publicly on plan sponsors' websites could cause unnecessary confusion to providers and beneficiaries who can easily misinterpret publicly available prior authorization metrics. Further, because providers and enrollees are not consistent across MA plans, commenters pointed out that it may be challenging to compare metrics across plans. Some commenters suggested using Part C reporting requirements instead of the proposed analysis to collect the data.

Some commenters suggested that CMS should establish a unified portal where stakeholders can view all MA plans' health equity analyses and require certain standardized reporting to improve stakeholders' ability to compare health equity impacts across MA plans.

Several commenters requested that CMS first create a standard system of reporting before requiring a publicly reported analysis.

Response: At this time, we will not require plans to submit a weblink to their health equity analysis to CMS. However, we will continue to evaluate whether this is necessary, and may add such a requirement in future rulemaking. We disagree that requiring the health equity analysis be published directly on the MA plan's website could be confusing for enrollees. We believe that many individuals use the MA plan's website as a primary resource for information on that specific plan and would therefore be more inclined to visit the MA plan's website to learn about that plan. We are finalizing as proposed the requirements in § 422.137(d)(7) that the MA organization must publish the results of the health equity analysis (which must use the metrics specified in § 422.137(d)(6)) on the plan's website meeting requirements for public access listed in paragraphs (d)(7)(i) through (iv). Regarding the concern that metrics cannot be compared across MA plans, we are not requiring a comparison of metrics across MA plans at this time. Rather, the goal of the analysis and public reporting is to begin to identify whether the use of prior authorization causes any persistent disparities among enrollees with the specified SRFs within individual MA plans. However, the accessibility of these reports in .txt file in the root directory of the website domain that includes a direct link to the machine-readable file and with the data contained within that file being digitally searchable and downloadable are intended to ensure automated access to the data. This may facilitate comparisons of the data across plans.

Comment: Several commenters requested CMS clarify that the data elements reporting the average and median time elapsed should be calculated beginning with the time the MA plan has received all the necessary information to complete the prior authorization request. Commenters indicated that, often, prior authorization requests are initially denied, or may be delayed, because information necessary to complete the request is missing. Some commenters also expressed concern over whether and how to count enrollees who have not been enrolled in the MA plan for a full year, and one commenter asked how to account for enrollees whose social risk factors may change over time.

Response: The average and median time that elapsed between the submission of a request and a determination by the MA plan should be calculated based on when the initial request is made. Since the goal of this analysis is to collect baseline data and gain a clearer picture of the impact of prior authorization on enrollees with the specified social risk factors, it is pertinent for CMS and the public to understand how long the entire process takes. This includes when MA plans need additional information from providers to make decisions. Regarding counting enrollees who have been enrolled for less than a full year, MA plans must count these enrollees—the point of the analysis is to analyze the use of prior authorization, therefore an enrollee's time in the plan when the prior authorization request is processed is not relevant. Further, CMS does not believe that enrollees whose SRF status may change over time is an issue since again, the point of the analysis is to analyze the use of prior authorization and begin to understand any correlation between the use of prior authorization and the presence of the social risk factors. If an enrollee's SRF status changes throughout the plan year, that should not have an impact on how the analysis is conducted, because CMS expects the plan to use the enrollee's status at the time the prior authorization is processed for calculating the specified metrics.

Comment: Several commenters asked that CMS explain how it plans to use the information included in these health equity analyses, including how it may be used to help inform future policies and whether CMS will take enforcement action based on the results of the analysis. Some commenters expressed concern that the health equity analysis would be used as a mechanism to penalize MA plans. A commenter requested that plans be permitted to create solutions should inequalities be identified. A few commenters suggested that CMS factor the data produced by the analysis into determinations for 2027 Star Rating Health Equity Index rewards.

Response: At this time, CMS plans to use the health equity analysis for informational purposes, to allow MA plans and CMS to begin to identify whether the use of prior authorization correlates to any persistent disparities among enrollees with the specified SRFs. CMS is not imposing additional requirements currently, and will take all comments received, as well as the results of the initial health equity analysis, into account when considering future policymaking and guidance. This analysis is just one step in continued and ongoing efforts to ensure all enrollees have safe and equitable access to medically necessary services.

Comment: CMS solicited comment on alternatives to the July 1, 2025, deadline for the initial health equity analysis to be posted to an MA plan's publicly available website. Several commenters suggested that CMS adopt an alternative timeline for publication of the initial report. Some commenters suggested that CMS first work with MA plans to standardize data collection and reporting, or that CMS develop a standard template for MA plans to use.

Other commenters indicated that issuing the initial report in July 2025 could present challenges for plans' IT resources, especially for smaller plans. Some commenters requested that MA plans submit their reports to CMS in 2025, and that CMS provide confidential feedback during the initial year and use that time to determine whether the results of the report are useful. Then in 2026, MA plans report results publicly. Further, commenters indicated that a 2026 date for publication of the initial report would allow plans to collect a full year of data. A commenter suggested CMS extend data back over several contract years. A commenter expressed that for plans to publish a health equity analysis that is in a machine-readable format (MRF) with the data contained within that file being digitally searchable and downloadable, it will require CMS to develop an industry wide MRF schema, which will likely take longer than is provided for in the proposed rule.

Response: CMS understands the processes and resources required to produce a new reporting requirement, however since MA plans should already have the relevant data available, as they are currently conducting the prior authorization process. Therefore, CMS declines to adapt an alternative timeline for the report. Since the goal of this analysis is to begin to understand the potential impact of prior authorization on enrollees with the specified social risk factors, any level of information that is made publicly available will be useful at this stage. Regarding CMS's production of an MRF schema, CMS does not believe that this will require extending the timeline for the initial report due date, since as outlined in the preamble, CMS plans to issue guidance describing the format to be used by MA plans. CMS declines to extend the data collection back over several contract years.

Comment: Several commenters suggested that the health equity analysis be extended to cover step therapy and Part B drugs.

Response: CMS thanks commenters for this suggestion and will consider it for future policymaking.

Comment: Some commenters suggested that CMS extend the analysis to include all types of utilization management, not just prior authorization.

Response: CMS thanks commenters for this suggestion and will consider for future rulemaking.

Comment: Several commenters suggested the CMS establish a parallel health equity structure for Part D plans, including similar health equity related requirements for the composition and consideration of Pharmacy & Therapeutic (P&T) Committee, and make regulatory changes to the part D provisions.

Response: While this comment is out of scope for the current rulemaking, CMS thanks commenters for their feedback and will take it under consideration for future rulemaking.

Comment: A commenter requested that CMS provide a uniform definition for the specified social risk factors.

Response: As outlined in the preamble and provided in § 422.137(d)(6)(ii) (as proposed and finalized), the specified social risk factors are defined as follows: (1) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or (2) having a disability. Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems. CMS chose these SRFs because they mirror the SRFs that will be used to measure the Heath Equity Index reward for the 2027 Star Ratings (see § 422.166(f)(3)), and we believe it is important to align expectations and metrics across the program.

MA plans can access the relevant information through the Beneficiary Eligibility Query (BEQ), which is a pre-enrollment query MA plans use to check eligibility prior to enrolling an individual. The BEQ provides enrollee information including demographics, entitlement/eligibility, Part D employer subsidy, and Low-Income Subsidy. MA plans can submit a BEQ query by submitting their requests in a batch file via CMS Enterprise File Transfer (EFT). MA plans can also perform the query online using the MARx, which provides real time information regarding eligibility. MARx provides MA plans with data related to enrollees and their subsidies.

Comment: A commenter cautioned that some of the information gathered as part of a health equity analysis may be confidential or proprietary to the MA plan and, therefore encouraged CMS to permit the plan to withhold confidential and proprietary information included in these analyses from publication.

Response: CMS declines this suggestion. Given the nature of the report, and that all information must be aggregated, CMS does not believe there is a risk for proprietary information to be disclosed. However, CMS will permit MA organizations to suppress information for small cell sizes in instances where the MA plan's service area is so small, that even in the aggregate, the presentation of the data in the analysis could disclose confidential data about covered individuals.

Comment: A commenter requested clarification that the intent is for the link in the footer of the website to go directly to the analysis file, or, if would it be acceptable for the link to direct to a landing page that may contain multiple health equity related reports so long as the analysis remains easily accessible.

Response: It would be acceptable for the link in the footer of the website to direct to a landing page, so long as the analysis remains easily accessible. This means that the report for each MA plan must be clearly labeled, and readily accessible to interested parties and other members of the public.

Comment: A commenter recommended regulatory language to include requirements for the standard exchange of the data among payers, providers or healthcare community such as USCDI version 3.

Response: CMS thanks the commenter for the suggestion but declines to incorporate such a standard at this time.

We thank all commenters for their comments. After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments, as previously summarized, we are finalizing the modifications to § 422.137 substantively as proposed but with two revisions. First, we are not finalizing use of the repetitive phrase ''but is not limited to'' in the sentence that provides the non-exhaustive list of examples of expertise in health equity. Second, we are finalizing a clarification in § 422.137(d)(6)(iii) that the data used for the health equity analysis and reporting excludes data on drugs as defined in § 422.119(b)(1)(v).

V. Enrollment and Appeals

A. Required Notices for Involuntary Disenrollment for Loss of Special Needs Status (§ 422.74)

Section 231 of the Medicare Modernization Act of 2003 (MMA) amended section 1851(a)(2)(A)(ii) of the Act to establish specialized MA plans for special needs individuals. Special needs plans (SNPs), defined at section 1859(b)(6)(A) of the Act, are plans with limited enrollment, specifically designed to provide targeted care to ''special needs individuals,'' as defined at section 1859(b)(6)(B) of the Act, and which includes institutionalized individuals, dually eligible individuals, and individuals with severe or disabling chronic conditions. Only those

individuals who qualify as special needs individuals may enroll, and remain enrolled, in an SNP. In the January 2005 MA final rule, we established at § 422.52 that individuals were eligible to enroll in an SNP if they: (1) met the definition of a special needs individual, (2) met the eligibility requirements for that specific SNP, and (3) were eligible to elect an MA plan. Sections 1859(b)(6)(B) and 1894(c)(4) of the Act, and CMS's implementing regulation at § 422.52(d), allow individuals who lose special needs status, if, for example, they were to no longer have the level of Medicaid eligibility or other qualifying condition necessary to be eligible for the SNP, to have a period of deemed continued eligibility if they are reasonably expected to regain special needs status within, at most, the succeeding 6-month period. The period of deemed eligibility must be at least 30 days but may not be longer than 6 months. In implementing regulations, we also established loss of special needs status (and of deemed continued eligibility, if applicable) as a basis for required disenrollment at § 422.74(b)(2)(iv).

The January 2005 MA final rule served as the basis for our current sub-regulatory guidance in Chapter 2 of the Medicare Managed Care Manual, Section 50.2.5, which specifically provides that plans send certain notices prior to and following the effective date of involuntary disenrollment based on loss of special needs status. These policies are intended to ensure that enrollees are given adequate notice prior to being disenrolled from an SNP and provided an opportunity to prove that they are eligible to remain enrolled in the plan, if applicable. Providing these enrollees at least 30 days' advance notice of disenrollment, along with information about deemed continued eligibility and eligibility for an SEP to elect other coverage, gives enrollees ample time to prove they are still eligible for their SNP or to evaluate other coverage options.

To provide stability and assurance about the requirements for MA organizations in these situations as well as transparency to interested parties, we proposed to codify current policy for MA plan notices prior to disenrollment for loss of special needs status, as well as a final disenrollment notice. We intend that interested parties will be able to rely on these regulations, establishing the procedures that an MA organization must follow in the event that an SNP enrollee loses special needs status and is disenrolled from the SNP on that basis. Specifically, we proposed to revise § 422.74(d) by redesignating paragraph (d)(8) as paragraph (d)(9) and adding a new paragraph (d)(8), to state that the plan would be required to provide the enrollee a minimum of 30 days' advance notice of disenrollment, regardless of the date of the loss of special needs status. As proposed in new paragraphs (8)(i) and (ii), an advance notice would be provided to the enrollee within 10 calendar days of learning of the loss of special needs status, affording the enrollee an opportunity to prove that such enrollee is still eligible to remain in the plan. The advance notice would also include the disenrollment effective date, a description of SEP eligibility, as described in § 422.62(b)(11), and, if applicable, information regarding the period of deemed continued eligibility, the duration of the period of deemed continued eligibility, and the consequences of not regaining special needs status within the period of deemed continued eligibility. Additionally, as proposed in new paragraph (8)(iii), the plan would be required to provide the enrollee a final notice of involuntary disenrollment within 3 business days following the disenrollment effective date. Such disenrollment effective date is either the last day of the period of deemed continued eligibility, if applicable, or a minimum of 30 days after providing the advance notice of disenrollment. Additionally, the final notice of involuntary disenrollment must be sent before submission of the disenrollment to CMS. Lastly, we proposed in new paragraph (8)(iv), that the final notice of involuntary disenrollment must include an explanation of the individual's right to file a grievance under the MA organization's grievance procedures, which are required by § 422.564.

These proposed changes would codify longstanding guidance. Based on infrequent questions or complaints from MA organizations and enrollees on these notices, we believe that these notice requirements have been previously implemented and are currently being followed by plans. We do not believe the proposed changes to the regulatory text will adversely impact MA organizations or individuals enrolled in MA special needs plans who lose special needs status, other than the appropriate disenrollment from the plan due to the individual's loss of eligibility for the plan. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Fund.

We received the following comments, and our responses follow.

Comment: A commenter expressed support for this provision.

Response: We thank the commenter for their support of our proposal.

After consideration of all public comments and for the reasons outlined in the proposed rule and here, we are finalizing our proposal without substantive changes, but with minor changes for clarity.

B. Involuntary Disenrollment for Individuals Enrolled in an MA Medical Savings Account (MSA) Plan (§ 422.74)

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1851(a)(2) of the Act establishing private health plan options available through Part C of the Medicare program known originally as ''Medicare + Choice'' and later as ''Medicare Advantage (MA).'' Under this program, eligible individuals may elect to receive Medicare benefits through enrollment in one of an array of private health plan choices beyond the original Medicare program. As enacted, section 1851(a)(2)(B) of the Act established the authority for an MA organization to offer an MA medical savings account (MSA) option which is a combination of a high-deductible MA plan, as defined in section 1859(b)(3) of the Act, with a contribution into a Medical Savings Account (MSA).

In the interim final rule titled Medicare Program; Establishment of the Medicare+Choice Program'' which appeared in the **Federal Register** on June 26, 1998 (63 FR 34968), we established the conditions for MA organizations to enroll individuals in an MA MSA plan. The restrictions on enrollment in MA MSA plans were set forth under section 1851(b)(2) and (b)(3) of the Act and in implementing regulations at § 422.56. Specifically, consistent with section 1851(b)(2) of the Act, § 422.56(b) provides that an individual who is enrolled in a Federal Employee Health Benefits Program (FEHB) plan, or is eligible for health care benefits through the Veterans Administration (VA) or the Department of Defense (DoD), may not enroll in an MA MSA plan. In addition, § 422.56(c) incorporates the statutory prohibition under section 1851(b)(3) of the Act on enrollment in MA MSA plans by individuals who are eligible for Medicare cost-sharing under Medicaid State plans. Additional restrictions were set forth under section 1852(a)(3)(B) of the Act and in implementing regulations at § 422.56(d) based on supplemental benefits under an MA MSA plan.

The January 2005 MA final rule implemented section 233 of the MMA, which lifted the time and enrollment limits on MSA plans imposed by the BBA of 1997. However, section 233 of

the MMA did not alter the prohibitions in sections 1851(b)(2) and (b)(3) of the Act on enrollment into an MA MSA plan for individuals covered under other health programs, and likewise the January 2005 MA final rule did not alter the implementing regulations regarding these policies at § 422.56.

The current regulations do not specify whether the eligibility criteria described in § 422.56, which preclude an individual with certain health care coverage from electing an MA MSA plan, are applicable to individuals who gain or become eligible for other coverage *while enrolled in* an MSA plan. In other words, the current regulations do not specify that an individual who ceases to satisfy the eligibility criteria described in § 422.56 while already enrolled in an MA MSA plan must be involuntarily disenrolled from the MSA, regardless of the time of year. CMS has historically understood the eligibility criteria for an individual to be enrolled in an MSA plan in § 422.56, coupled with the statutory prohibitions on enrolling in an MA MSA by individuals with Medicaid or coverage under other health benefits, to mean that an enrollee in an MSA plan is not able to remain a member of the MSA plan and must be disenrolled by the plan when the individual ceases to meet the statutory and regulatory criteria for eligibility. We also note that this policy is consistent with our general approach in section 50.2, Chapter 2 of the Medicare Managed Care Manual, in which an enrollee becomes ineligible due to a status change, such as the loss of entitlement to Medicare Part A or Part B or the inability to regain special needs status during the period of deemed continued eligibility and outlined in § 422.74.

To address more clearly the consequences of the general loss of eligibility in an MSA plan, we proposed to amend § 422.74 to add new paragraph (b)(2)(vi) to include the requirement that an MA MSA enrollee must be disenrolled, prospectively, due to the loss of eligibility. If an MA MSA enrollee does not provide assurances that such enrollee will reside in the United States for at least 183 days during the year the election is effective, is eligible for or begins receiving health benefits through Medicaid, FEHBP, DoD, or the VA or obtains other health coverage that covers all or part of the annual Medicare MSA deductible, that enrollee must be involuntarily disenrolled by the MSA plan effective the first day of the calendar month after the month in which notice by the MA organization is issued that the individual no longer meets the MA MSA's eligibility criteria, as proposed in § 422.74(d)(10). We also proposed to revise § 422.74(c) to require MA MSA plans to provide a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual before the disenrollment transaction is submitted to CMS.

Should an individual's coverage under an MA MSA plan end before the end of a calendar year, CMS recovers from the plan the amount of the lump-sum deposit attributable to the remaining months of that year. This requirement is codified at § 422.314(c)(3). In addition, the disenrolled beneficiary will owe a prorated portion of the current year's deposit amount back to the MA MSA plan. Plans will be able to reconcile and identify MSA deposit amounts for the Current Payment Month (CPM) at the beneficiary level from the monthly generated MSA Deposit-Recovery Data file. We proposed at § 422.74(e)(1) that involuntarily disenrolled individuals will be defaulted to enrollment in Original Medicare, which will now pay claims incurred by the former MSA enrollees. Conversely, the former MSA enrollee also has the option to elect to join another MA plan during a valid enrollment period.

We did not receive comments related to this proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal without modification.

C. Required Notice for Reinstatements Based on Beneficiary Cancellation of New Enrollment (§§ 422.60 and 423.32)

Sections 1851(c)(1) and 1860D–1(b)(1) of the Act establish the enrollment, disenrollment, termination, and change in coverage processes for MA and PDP plans. In the June 1998 interim final rule, we established the M+C (now MA) enrollment process (63 FR 34968). These requirements are codified in regulation at § 422.60. In the January 2005 Part D final rule, we established the PDP enrollment process (70 FR 4193). These requirements are codified in regulation at § 423.32.

Section 1851(g)(3)(B)(i) of the Act provides that MA plans may terminate the enrollment of individuals who fail to pay basic and supplemental premiums on a timely basis; likewise, section 1860D–1(b)(1)(B)(v) of the Act directs the Secretary to use rules similar to (and coordinated with) the rules for a Medicare Advantage plan established under section 1851(g) of the Act. CMS has previously codified this process of optional disenrollment from an MA plan or PDP for failure to pay monthly premiums at §§ 422.74(d) and 423.44(d), as well as requirements for mandatory disenrollment for individuals who fail to pay the Part D Income Related Monthly Adjustment Amount (Part D–IRMAA), where applicable, at § 423.44(e). In addition, CMS has previously codified the ability for MAOs and PDP sponsors to reinstate for good cause an individual who is disenrolled for failure to pay plan premiums (at §§ 422.74(d)(1)(v) and 423.44(d)(1)(vi)) or the Part D–IRMAA (at § 423.44(e)(3)).

However, an individual's enrollment can also be reinstated if their enrollment in another plan is subsequently canceled within timeframes established by CMS.[106] We established at § 422.66(b)(1) that an individual is disenrolled from their MA plan when they elect a different MA plan; likewise, at § 423.36(a), an individual is disenrolled from their PDP plan when they enroll in a different PDP plan. Sub-regulatory guidance sets forth that MA and PDP plans are to provide notification of enrollment reinstatement based on a beneficiary's cancellation of a new enrollment in a different plan. This guidance is currently outlined in the Part C and Part D sub-regulatory guidance found in section 60.3.2 of Chapter 2 of the Medicare Managed Care Manual and section 60.2.2 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, respectively.

To provide transparency and stability for interested parties, we proposed at new §§ 422.60(h) and 423.32(h) to require that MA and PDP plans must notify an individual when the individual's enrollment is reinstated due to the individual's cancellation of enrollment in a different plan. A reinstatement is generally not allowed if the individual intentionally initiated a disenrollment and did not cancel the disenrollment prior to the disenrollment effective date. However, when a beneficiary is automatically disenrolled from their plan because of enrollment in a new plan but then cancels the request to enroll in the new plan within established timeframes, the associated automatic disenrollment from the previous plan becomes invalid. Therefore, the beneficiary's enrollment in the previous plan needs to be reinstated and CMS systems will attempt to automatically reinstate enrollment in the previous plan. Consistent with notification requirements in similar enrollment scenarios, we proposed that the

[106] This guidance can be found in section 60.3.2 of Chapter 2 of the Medicare Managed Care Manual and section 60.2.2 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

organization from which the individual was disenrolled send the member notification of the enrollment reinstatement within 10 days of receipt of Daily Transaction Reply Report (DTRR) confirmation of the individual's reinstatement. The reinstatement notice would include confirmation of the individual's enrollment in the previous plan with no break in coverage, plan-specific information as needed, and plan contact information.

These proposed changes represent the codification of longstanding guidance. Based on infrequent complaints and questions from plans and beneficiaries related to current requirements, we concluded that the requirements have been previously implemented and are currently being followed by plans. There is also no impact to the Medicare Trust Fund.

We received the following comments, and our responses follow.

Comment: A commenter requested that CMS provide a model letter for this required notice.

Response: We thank the commenter for the suggestion. We have longstanding model reinstatement notices that have been displayed in Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Comment: A commenter expressed that they currently send reinstatement letters and recommended this process continues. The commenter also noted that beneficiary history in MARx is typically removed when reinstatement situations occur and is concerned about how plans will know when the enrollment issue has happened.

Response: We appreciate the commenter's feedback. This proposal does not change the existing sub-regulatory guidance for plans to provide notification of enrollment reinstatement based on a beneficiary's cancellation of a new enrollment in a different plan. The plan can continue to send reinstatement letters to beneficiaries. We also note that the new plan receives a transaction reply code (TRC) 15 in MARx—which describes CMS's response to the enrollment transaction—when the enrollment is removed from a beneficiary's record. The plan in which the beneficiary's enrollment is being reinstated receives a TRC 287 if there are no changes to the beneficiary's profile from the time of the disenrollment to the time of the cancellation.

Comment: A commenter expressed support for this proposal.

Response: We thank the commenter for their support of this proposal.

After consideration of all public comments, and for the reasons outlined here and in the proposed rule, we are finalizing our proposal with minor modifications to clarify the regulation text proposed at § 423.32(h).

D. Part D Plan Failure To Submit Disenrollment Timely (§ 423.36)

Section 1860D–1(b) of the Act establishes the disenrollment process for Part D eligible individuals in prescription drug plans. This section of the Act grants the Secretary the authority to establish a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans. In 2005, the implementing regulations set forth at 70 FR 4525 established the voluntary disenrollment process for Part D prescription drug plans. These requirements are codified in regulation at § 423.36 and require the Part D sponsor to ''submit a disenrollment notice to CMS within timeframes CMS specifies.''

As previously noted, section 1860D–1(b)(1)(B) of the Act directs the Secretary to adopt enrollment rules ''similar to (and coordinated with)'' the rules established under Part C. In 1998 implementing regulations for Part C, CMS provided that if a ''Medicare + Choice'' (M+C) organization, later known as an MA organization, fails to submit the correct and complete notice of disenrollment, the M+C organization must reimburse the Health Care Finance Administration (the predecessor to CMS), for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely (63 FR 35074). This requirement was codified at § 422.66(b)(4) and has remained in place for MA organizations.

Current Part D regulations, however, do not impose requirements for Part D sponsors that fail to submit the transaction notice to CMS in a timely manner. However, longstanding CMS policy has provided that the PDP sponsor must submit disenrollment transactions to CMS in a timely manner, as described in section 50.4.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. When a valid request for disenrollment has not been communicated to CMS successfully within the required timeframes, a retroactive disenrollment can be submitted to CMS. If the retroactive disenrollment request is approved, the PDP sponsor must return any premium paid by the member for any month for which CMS processed a retroactive disenrollment, and CMS will retrieve any capitation payment for the retroactive period for an approved request for retroactive disenrollment, as described in section 60.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

To provide transparency and consistency for interested parties, and to align the Part D regulation with the requirements for MA organizations, we proposed to codify CMS's longstanding sub-regulatory guidance by amending § 423.36 to add a new paragraph (f) to reflect that if the Part D sponsor fails to submit a disenrollment notice to CMS timely as required by § 423.36(b)(1), such that the Part D sponsor receives additional capitation payments from CMS, the Part D sponsor must reimburse CMS for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely.

This proposal is a codification of longstanding Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. As these policies have been previously implemented and are currently being followed by plans, we concluded that there is no additional paperwork burden. All information impacts related to our collection of disenrollment requests have already been accounted for under OMB control number 0938–0964 (CMS–10141).

We did not receive comments related to this proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal with one minor modification. We are making a technical correction to the regulation text proposed at § 423.36(f) to update a cross-reference that is inaccurate, changing ''paragraph (c)(1)'' to ''paragraph (b)(1)''.

E. Codify Existing Policy ''Incomplete Disenrollment Requests'' (§§ 422.66 and 423.36)

Section 1851(c)(2)(B) of the Act provides that an individual who elects an MA plan and then chooses to terminate such election can do so by submitting a request to the MA organization. In addition, section 1860D–1(b)(1)(B)(ii) of the Act specifies that in establishing a process for Part D enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans, the Secretary shall use rules similar to (and coordinated with) the rules for an MA—formerly M+C—plan established under section 1851(c) of the Act.

The June 1998 final regulation established the process for individuals to voluntarily disenroll from an MA plan. This process is codified at § 422.66(b). Specifically, at

§ 422.66(b)(2), the regulations provide that a disenrollment request is considered to have been made on the date the disenrollment request is received by the MA organization. Once received, the MA organization is required to send the disenrollment notice to CMS, as well as send a copy to the enrollee which informs the enrollee of any lock-in requirements of the plan that apply until the effective date of disenrollment. This process is codified at § 422.66(b)(3), including the requirement that the MA plan must file and retain the disenrollment request for the period specified in CMS instructions.

In 2005, CMS issued implementing regulations establishing disenrollment procedures for Part D plans, whereby an individual elects to voluntarily disenroll from the Part D plan, and also established the requirements imposed upon the Part D sponsor as a result of that disenrollment request (70 FR 4211). These requirements were codified at § 423.36.

However, §§ 422.66(b) and 423.36 do not address what plans should do in the event that they receive incomplete disenrollment requests. CMS has historically provided, at section 50.4.2, Chapter 2 of the Medicare Managed Care Manual and section 50.4.2, Chapter 3 of the Medicare Prescription Drug Benefit Manual, the procedural steps for plans to address incomplete disenrollment requests. These steps include providing that when the disenrollment request is incomplete, plans must document efforts to obtain information to complete the request, and if any additional information needed to make the disenrollment request ''complete'' is not received within prescribed timeframes, the plan must deny the disenrollment request.

To provide transparency and stability for interested parties about the MA and Part D programs and about the requirements applicable to requests for voluntary disenrollment from MA and Part D plans, we proposed to codify CMS's longstanding policies that a disenrollment request is considered to be incomplete if the required but missing information is not received by the MA plan or Part D sponsor within the specified timeframes at new paragraphs §§ 422.66(b)(6) and 423.36(d). The specified timeframes are described at proposed §§ 422.66(b)(3)(v)(C) and 423.36(b)(4)(iii). We also proposed, at new paragraphs §§ 422.66(b)(3)(v) and 423.36(b)(4), that if the disenrollment request is incomplete, the plan must document its efforts to obtain information to complete the election. Plans would be required to notify the individual (in writing or verbally) within 10 calendar days of receipt of the disenrollment request. For incomplete disenrollment requests received by plan sponsors during the annual election period (AEP), we proposed that information to complete the request must be received by December 7, or within 21 calendar days of the plan sponsor's request for additional information, whichever is later. For all other election periods, we proposed that required information must be received by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information, whichever is later. Finally, we proposed that if any additional information needed to make the disenrollment request complete is not received within these timeframes, the disenrollment request must be denied.

This proposal codifies longstanding guidance. All information impacts related to the procedural steps plans must take to address incomplete disenrollment requests have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D. Based on infrequent questions from MA organizations and Part D plan sponsors, as these requirements have been previously implemented and are currently being followed by plans, we concluded that these updates do not add to the existing disenrollment process and we do not believe there is any additional paperwork burden.

We received the following comment, and our response follows.

Comment: A commenter expressed support for this provision.

Response: We thank the commenter for their support of our proposal.

After consideration of all public comments, and for the reasons outlined here and in the proposed rule, we are finalizing our proposal without modification.

F. Reinstatement of Enrollment for Good Cause (§§ 417.460, 422.74 and 423.44)

Sections 1851(g)(3)(B)(i) and 1860D–1(b)(1)(B)(v) of the Act provide that MA and Part D plans may terminate the enrollment of individuals who fail to pay basic and supplemental premiums on a timely basis. In addition, section 1860D–13(a)(7) of the Act mandates that individuals with higher incomes pay an additional premium, the Part D IRMAA, for the months in which they are enrolled in Part D coverage.

Consistent with these sections of the Act, the MA and Part D subpart B regulations set forth our requirements with respect to involuntary disenrollment procedures under §§ 422.74 and 423.44, respectively. Pursuant to §§ 422.74(d)(1)(i) and 423.44(d)(1), an MA or Part D plan that chooses to disenroll beneficiaries for failure to pay premiums must be able to demonstrate to CMS that it made a reasonable effort to collect the unpaid amounts by notifying the beneficiary of the delinquency, providing the beneficiary a grace period of no less than two months in which to resolve the delinquency, and advising the beneficiary of the termination of coverage if the amounts owed are not paid by the end of the grace period. Further, as outlined in § 423.44(e), CMS involuntarily disenrolls individuals from their Part D coverage for failure to pay Part D–IRMAA following an initial grace period of 3 months.

Current regulations at § 417.460(c) specify that an HMO or competitive medical plan (cost plan) may disenroll a member who fails to pay premiums or other charges imposed by the plan for deductible and coinsurance amounts. While there is not a grace period parallel to the grace period required by the MA and Part D regulations, the requirements for cost plans are otherwise similar. The cost plan must demonstrate that it made reasonable efforts to collect the unpaid amount and send the enrollee written notice of the disenrollment prior to transmitting the disenrollment to CMS.

The final rule, titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes'' which appeared in the **Federal Register** on April 15, 2011 (76 FR 21432) amended both the Parts C and D regulations at §§ 422.74(d)(1)(v), 423.44(d)(1), and 423.44(e)(3) regarding involuntary disenrollment for non-payment of premiums or Part D–IRMAA to allow for reinstatement of the beneficiary's enrollment into the plan for good cause. The good cause provision established that CMS can reinstate enrollment of a disenrolled individual's coverage in certain circumstances where the non-payment of premiums was due to a circumstance that the individual could not reasonably foresee and could not control, such as an extended period of hospitalization. In the final rule titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes'' which appeared in the **Federal Register** on April 12, 2012 (77 FR 22072), we extended the policy of reinstatement for

good cause to include beneficiaries enrolled in cost plans in § 417.460(c)(3), thus aligning the cost plan reinstatement provision with the MA and Part D plan provisions. In the final rule titled ''Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' which appeared in the **Federal Register** on February 12, 2015 (80 FR 7911), we amended §§ 417.460(c)(3), 422.74(d)(1)(v), and 423.44(d)(1)(vi) to permit an entity acting on behalf of CMS, such as an MA organization, Part D sponsor, or entity offering a cost plan, to effectuate reinstatements for beneficiaries disenrolled for nonpayment of plan premium when good cause criteria are met.

To provide transparency to interested parties, we proposed to codify our current policy for MA organizations, Part D sponsors, or entities offering cost plans, as set out in sub-regulatory guidance in section 60.3.4 of Chapter 2, Medicare Managed Care Manual, section 60.2.4 of Chapter 3, Medicare Prescription Drug Benefit Manual and section 60.6.3 of Chapter 17–D, Medicare Managed Care Manual, that reinstatement for good cause, pursuant to §§ 417.460(c)(3), 422.74(d)(1)(v), and 423.44(d)(1)(vi), will occur only when the individual requests reinstatement within 60 calendar days of the disenrollment effective date and that an individual may make only one reinstatement request for good cause in this 60-day period. Specifically, CMS proposed to amend §§ 417.460(c)(3), 422.74(d)(1)(v), and 423.44(d)(1)(vi) to provide that the disenrolled individual must request reinstatement within 60 calendar days of the disenrollment effective date and has not previously requested reinstatement for good cause during the same 60-day period following the involuntary disenrollment. These proposed changes represent the codification of longstanding guidance. Based on infrequent questions or complaints from plan sponsors and beneficiaries, and a lack of reported instances of noncompliance regarding the 60-day timeframe, as these requirements have been previously implemented and are currently being followed by plan sponsors, we concluded that the proposed changes to the regulatory text will not adversely impact plan sponsors or individuals disenrolled for nonpayment of plan premium who choose to request reinstatement for good cause, nor would the proposed changes have any impact to the Medicare Trust Funds or result in a paperwork burden.

We received the following comment, and our response follows.

Comment: A commenter expressed concern about requiring disenrolled individuals to request reinstatement within the 60-calendar day period following the date they are disenrolled from the plan. The commenter states that contacting the plan within the 60-day period to request reinstatement will be challenging for people with a mental health or substance use disorder (MH/SUD), adding that people with a MH/SUD often do not complain when they face administrative difficulties.

Response: While we agree that taking action to request reinstatement following disenrollment may be more challenging for some than it is for others, we believe that 60 days is a sufficient amount of time and that it is not unreasonable to ask someone who has been disenrolled from their plan and, as such, is no longer being covered, to reach out to the plan and request reinstatement within the 60-day period following disenrollment. We require that all MA and Part D plans offer a minimum two-month grace period prior to disenrolling someone who has not paid their plan premium; many plans offer a longer grace period. This minimum two-month period prior to disenrollment, combined with the 60-day period following disenrollment to request reinstatement for good cause, provides a reasonable amount of time for someone who wishes to continue their enrollment in the plan to take action to resolve the premium delinquency and, if disenrolled, make a reinstatement request.

After consideration of all public comments, and for the reasons outlined here and in the proposed rule, we are finalizing our proposal with minor modifications to reorganize and clarify the regulation text proposed at §§ 417.460(c)(3), 422.74(d)(1)(v), and 423.44(d)(1)(vi).

G. Required Notices for Involuntary Disenrollment for Disruptive Behavior (§§ 417.460, 422.74 and 423.44)

Section 1851(g)(3)(B)(ii) of the Act authorizes an MA organization to disenroll individuals who engage in disruptive behavior. Section 1860D–1(b)(1)(B)(v) of the Act generally directs us to establish rules related to enrollment, disenrollment, and termination for Part D plan sponsors that are similar to those established for MA organizations under section 1851(g) of the Act. Section 1876 of the Act sets forth the rules for Medicare cost plan contracts with HMOs and competitive medical plans (CMPs). (For this section and throughout 42 CFR 417, CMP is used to mean competitive medical plan, not civil monetary penalties.) In implementing regulations which appeared in the **Federal Register** on September 1, 1995 (60 FR 45679), we established at § 417.460(e) the basis for HMOs and CMPs to disenroll individuals for disruptive, unruly, abusive, or uncooperative behavior. In implementing regulations which appeared in the **Federal Register** on June 26, 1998 (63 FR 34968), we established at § 422.74 the conditions for MA organizations (referred to M+C organizations at the time) to disenroll individuals for disruptive behavior. Additionally, the regulations established the requirement for a final notice to the enrollee of the submission of the disenrollment, which applies to disruptive behavior disenrollments, at § 422.74(c). The optional basis for disenrollment for disruptive behavior was established at § 422.74(b)(1)(ii). The general standards defining disruptiveness were established at § 422.74(d)(2).

In January 2005, we published a final rule that revised the definition for disruptive behavior at § 422.74(d)(2) (70 FR 4718), with the purpose of creating an objective definition that did not use the previously subjective terms such as ''unruly'' or ''abusive.'' The current, objective definition from the January 2005 MA final rule both defines disruptive behavior and establishes the required process for an MA plan to request disenrollment of a disruptive individual. In January 2005 we also published the Part D implementing regulation (70 FR 4525), where we established the conditions for a PDP sponsor to disenroll an individual for disruptive behavior. We established the basis for optional disenrollment for disruptive behavior at § 423.44(b)(1)(ii). We also established the definition of disruptive behavior and disenrollment process as it exists currently at § 423.44(d)(2). In the January 2005 Part D final rule, we also established the requirement for a final notice of the submission of the disenrollment transaction, which applies to disruptive behavior disenrollments, at § 423.44(c).

Under CMS's current MA and Part D regulations, disruptive behavior is defined as behavior by the plan enrollee that substantially impairs the plan's ability to arrange for or provide services for the individual or other plan members (§§ 417.460(e)(1); 422.74(d)(2)(i); 423.44(d)(2)(i)). The process for disenrolling an enrollee for disruptive behavior requires approval by CMS before the disenrollment may

be submitted (§§ 417.460(e)(5); 422.74(d)(2)(v); 423.44(d)(2)(v)). MA organizations, Part D sponsors, and cost plans must make serious efforts to resolve the problem considering any extenuating circumstances; for MA organizations, cost plans, and Part D sponsors, this includes providing reasonable accommodations for those enrollees with mental or cognitive conditions (§§ 417.460(e)(2) and (3); 422.74(d)(2)(iii); 423.44(d)(2)(iii)). MA organizations, Part D sponsors, and cost plans must also document the enrollee's behavior and the plan's own efforts to resolve the issue, and this record must be submitted to CMS before disenrollment can be approved (§§ 417.460(e)(4) and (5); 422.74(d)(2)(iv) and (v); 423.44(d)(2)(iv) and (v)). The current definition of disruptive behavior in §§ 417.460(e)(1), 422.74(d)(2), and 423.44(d)(2) served as the basis for CMS's current sub-regulatory guidance found in Chapter 2, section 50.3.2, of the Medicare Managed Care Manual and Chapter 3, section 50.3.2, of the Medicare Prescription Drug Benefit Manual and Chapter 17D, section 50.3.3, of the Medicare Managed Care Manual. In guidance, we outline notices that an MA organization, Part D sponsor, and cost plans must send before requesting permission from CMS to involuntarily disenroll the individual.

To provide transparency to interested parties and stability as to the operation of the program, we proposed to codify current policy for MA, Part D, and cost plan notices during the disenrollment for disruptive behavior process. These notices provide the enrollee with a warning of the potential consequences of continued disruptive behavior. In a new proposed paragraph at § 422.74(d)(2)(vii), we proposed to codify existing policy currently set out in sub-regulatory guidance regarding MA plan notices prior to disenrollment for disruptive behavior. To request approval of a disenrollment for disruptive behavior, an MA organization would be required to provide two notices: (1) an advance notice, informing the plan enrollee that continued disruptive behavior could lead to involuntary disenrollment; and (2) a notice of the plan's intent to request CMS permission to disenroll the individual, sent at least 30 days after the advance notice to give the enrollee an opportunity to cease the behavior. These notices are in addition to the disenrollment submission notice currently required under § 422.74(c). We also proposed to revise the existing requirement at § 422.74(d)(2)(iii) that plans inform the individual of the right to use the plan's grievance procedures to clarify that this information should be conveyed as part of the notices described in new paragraph (d)(2)(vii). Additionally, as proposed in addition to § 422.74(d)(2)(iv), the plan would be required to submit dated copies of these required notices to CMS along with the other documentation regarding enrollee behavior and the plan's efforts to resolve the issues.

At new paragraph § 423.44(d)(2)(viii), we proposed to codify existing policy currently set out in sub-regulatory guidance regarding PDP sponsor notices prior to disenrollment for disruptive behavior. To request approval of a disenrollment for disruptive behavior, a PDP sponsor would be required to provide two notices: (1) an advance notice, informing the plan enrollee that continued disruptive behavior could lead to involuntary disenrollment; (2) a notice of intent to request CMS permission to disenroll the individual, sent at least 30 days after the advance notice to give the enrollee an opportunity to cease the behavior. These notices are in addition to the disenrollment submission notice currently required under § 423.44(c). We also proposed to revise the existing requirement at § 423.44(d)(2)(iii) that plans inform the individual of the right to use the plan's grievance procedures, to clarify that this information should be conveyed as part of the notices described in new paragraph (d)(2)(viii). Additionally, as proposed in additions to § 423.44(d)(2)(iv), the plan would be required to submit dated copies of these required notices to CMS along with the other documentation regarding enrollee behavior and the plan's efforts to resolve the issues.

At § 417.460(e)(7) we proposed to codify existing policy guidance currently set out in sub-regulatory guidance regarding cost plan notices prior to an enrollee disenrollment for cause (disruptive behavior). Current guidance is found in Chapter 17D of the Medicare Managed Care Manual, section 50.3.3. To request approval of a disenrollment for disruptive behavior, an HMO or CMP would be required to provide two notices: (1) an advance notice, informing the enrollee that continued disruptive behavior could lead to involuntary disenrollment; (2) a notice of intent to request CMS permission to disenroll the enrollee, sent at least 30 days after the advance notice to give the enrollee an opportunity to cease the behavior. These notices are in addition to the disenrollment submission notice currently required under § 417.460(e)(6). We also proposed to revise the existing requirement at § 417.460(e)(2) that plans inform the individual of the right to use the plan's grievance procedures, to clarify that this information should be conveyed as part of the notices described in new paragraph (e)(7). Additionally, we proposed in § 417.460(e)(2) that, as part of its efforts to resolve the problem presented by the enrollee, an HMO or CMP must provide reasonable accommodations for individuals with mental or cognitive conditions, including mental illness and developmental disabilities, similar to the existing requirement in the MA and Part D regulations at §§ 422.74(d)(2)(iii); 423.44(d)(2)(iii)). As proposed in § 417.460(e)(4), cost plans would be required to submit dated copies of these required notices to CMS along with other documentation regarding enrollee behavior and the plan's efforts to resolve the issues.

This proposal codifies longstanding guidance. All information impacts related to the involuntary disenrollment by the plan for disruptive behavior have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D. Based on infrequent questions from MA organizations, Part D, and cost plan sponsors on these notices, as these notice requirements have been previously implemented and are currently being followed by plans, we concluded that these updates do not add to the existing disenrollment process and we do not believe there is any additional paperwork burden.

We did not receive comments related to this proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal with slight modifications to reorganize the regulation text for additional clarity.

H. Codification of the Part D Optional Disenrollment for Fraud and Abuse Policy (§ 423.44)

As noted previously, section 1851(g)(3)(B)(ii) of the Act provides that an MA organization may disenroll individuals who engage in disruptive behavior. In 1998, the Part C implementing regulations at 63 FR 35075 separately referred to a different kind of ''disruption'' or failure to ''cooperate,'' namely, fraud or abuse on the part of the individual on the enrollment form, or by misuse of the individual's enrollment card. This ground for termination is if the individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card, which was also based on section 1851(g)(3)(B)(ii) of the Act

was codified as a separate paragraph at § 422.74(b)(1)(iii) (63 FR 35075). Regulations also provided a process for disenrollment on this basis, whereby an M+C organization may disenroll an individual who knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the M+C plan, or intentionally permits others to use his or her enrollment card to obtain services under the M+C plan, as long as a notice of disenrollment is provided as outlined in federal law. The M+C organization was also required to report the disenrollment to Medicare. This process for disenrollment based on fraud or abuse on the part of the individual was codified at § 422.74(d)(3) (63 FR 35075). Fraud and abuse by the enrollee are treated in the same manner as other forms of disruptive behavior, with the individual being disenrolled into the original Medicare program.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) enacted the Medicare Advantage program, which replaced the M+C program established under title XVIII of the Act, and amended title XVIII of the Act to add a new part D (Voluntary Prescription Drug Benefit Program). Section 1860D–1(b)(1)(B)(v) of the Act specifies that in establishing a process for Part D enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans, the Secretary shall use rules similar to (and coordinated with) the rules for an MA–PD plan established under section 1851(g) of the Act. In 2005, CMS finalized implementing regulations at §§ 423.44(b)(1)(ii) and (d)(2), providing that PDP sponsors may disenroll an individual who engages in disruptive behavior and defining the process for disenrollment on this basis (70 FR 4530). However, CMS's 2005 implementing regulations did not include provisions allowing PDP sponsors the ability to disenroll individuals on the basis of fraud or abuse on the part of the individual on the enrollment form, or by misuse of the individual's enrollment card, equivalent to the MA regulations at §§ 422.74(b)(1)(iii) and (d)(3). Although CMS has adopted and implemented this same basis for optional disenrollment from a Part D plan in sub-regulatory guidance, we proposed to codify the policy for optional disenrollment from a Part D plan based on an individual providing fraudulent information on his or her election form or permitting abuse of his or her enrollment card. Our intent was to codify the current policy, as reflected in section 50.3.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

We proposed to add a new § 423.44(b)(1)(iii) to codify that if an individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in new paragraph § 423.44(d)(9), the Part D plan has the option to involuntarily disenroll the individual. Further, we proposed to establish at such new paragraph § 423.44(d)(9) the process for optional disenrollment for an individual who commits fraud or permits abuse of their enrollment card. We proposed to add a new § 423.44(d)(9)(i) to establish a basis for disenrollment for an individual who commits fraud or permits abuse of their enrollment card, to be provided at §§ 423.44(d)(9)(i)(A) and 423.44(d)(9)(i)(B), respectively. We proposed to establish at § 423.44(d)(9)(i)(A) that a Part D plan may disenroll an individual who knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the Part D plan. We proposed to establish in § 423.44(d)(9)(i)(B) that a Part D plan may disenroll an individual who intentionally permits others to use his or her enrollment card to obtain drugs under the Part D plan.

We further proposed to add a new § 423.44(d)(9)(ii) to establish that a Part D plan that opts to disenroll an individual who commits fraud or permits abuse of their enrollment card must provide the individual a written notice of the disenrollment that meets the notice requirements set forth in § 423.44(c) of this section. We also proposed to add a new § 423.44(d)(9)(iii) to establish that a Part D plan must report to CMS any disenrollment based on fraud or abuse by the individual.

With regard to the Part D optional involuntary disenrollment for fraud and abuse regulations at § 423.44(d)(9)(i), the following change will be submitted to OMB for review under control number OMB 0938–0964 (CMS–10141). We estimate that it will take a Part D plan three hours to capture and retain the required documentation for each occurrence of disenrollment for fraud and abuse. In part, the burden associated with this requirement is the time and effort necessary for a Part D plan to document and retain the documentation that meets the requirements set forth in this section. Since 2012, there have been only five disenrollments for fraud and abuse. Three of those disenrollments were from MA/MA–PD plans, one was from the Limited Income Newly Eligible Transition (LI NET) plan, and one was from a standalone Part D plan. Thus, the burden to Part D plans is negligible and, per 5 CFR 1320.3(c), not subject to PRA because it involves less than 10 entities per year. Nonetheless, we will still add this information to the information collection currently approved under OMB control number 0938–0964. In addition, based on these data, we do not expect any future impact to the Medicare Trust Fund.

We further proposed in § 423.44(d)(9)(ii) that the Part D plan must provide a written notice of disenrollment to the member to advise them of the plan's intent to disenroll, as required under § 423.44(c) of this subpart. Lastly, we proposed in § 423.44(d)(9)(iii) that the Part D plan must report to CMS any disenrollment based on fraud or abuse by the member. All information impacts related to providing written notice to the member and notifying CMS of the disenrollment have already been accounted for under OMB control numbers 0938–0964 (CMS–10141).

We received no comments on our proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal without modification.

I. SPAP or Other Payer Exception for Disenrollment for Failure To Pay (§ 423.44)

Section 1851(g)(3)(B)(i) of the Act allows MA plans to disenroll members who fail to pay premiums on a timely basis. Section 1860D–1(b)(1)(B)(v) of the Act directs us to adopt Part D disenrollment rules similar to the MA provisions in section 1851(g) of the Act. Additionally, section 1860D–1(b)(3)(A)(iii) of the Act states that disenrollment in a plan for failure to pay premiums will be considered a voluntary disenrollment action. In Part D implementing regulations (70 FR 4525), we established the basis for an optional involuntary disenrollment for failure to pay premiums as well as the disenrollment process. The basis for disenrollment for failure to pay premiums was established at § 423.44(b)(1)(i). The disenrollment process for failure to pay premiums was established at § 423.44(d)(1). In 2009, we added an exception to this disenrollment provision which prohibited plans from disenrolling individuals who are in premium withhold status (74 FR 1543). The premium withhold status exception was established at § 423.44(d)(1)(iv) and later renumbered to paragraph (v) in

2010 when we added the grace period requirement at § 423.44(d)(1)(iii) (75 FR 19816).

Section 1860D–23 of the Act directed the Secretary to establish coordination rules between State Pharmaceutical Assistance Programs (SPAPs) and Part D plan sponsors regarding the payment of premiums for Part D eligible individuals. SPAPs, and other third-party payer assistance programs, have the option to cover Part D premiums for individuals. Implementing regulations (70 FR 4525) established the requirement that Part D plan sponsors must permit SPAPs, and other entities, to coordinate benefits with the plan, including paying for premiums, at § 423.464(a).

To protect beneficiaries who have SPAPs, or other payers, cover their premiums, we proposed to codify current policy that excepts certain prescription drug plan (PDP) members from being disenrolled for failure to pay plan premiums, at § 423.44(d)(1)(v). This policy is currently set out in sub-regulatory guidance at section 50.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, and Part D plan sponsors have previously implemented and are currently following such policy. We proposed, at revised § 423.44(d)(1)(v), a disenrollment exception if the sponsor has been notified that an SPAP, or other payer, is paying the Part D portion of the premium, and the sponsor has not yet coordinated receipt of the premium payments with the SPAP or other payer. Sponsors would not be able to initiate the disenrollment process or disenroll members who qualify for this exception.

In addition, we proposed a technical correction to revise an erroneous cross reference in § 423.44(d)(1). Instead of referring to paragraph (d)(1)(iv), the language should refer to paragraph (d)(1)(v).

We are codifying longstanding guidance with these changes. All information impacts related to the involuntary disenrollment by the plan for failure to pay Part D plan premiums have already been accounted for under OMB control 0938–0964 (CMS–10141). Based on infrequent questions or complaints from Part D sponsors on these notices, we believe that these disenrollment requirements have been previously implemented and are currently being followed by sponsors. This proposal is a codification of longstanding Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. These updates do not add to the existing disenrollment process, so we do not believe there is any additional paperwork burden.

We did not receive comments related to this proposal. For the reasons outlined here and in the proposed rule, we are finalizing our proposal without substantive changes but with minor organizational and editorial changes in § 423.44(d)(1) for clarity.

J. Possible End Dates for the SEP for Government Entity-Declared Disaster or Other Emergency (§§ 422.62 and 423.38)

Section 1851(e)(4)(D) of the Act authorizes the Secretary to establish MA special enrollment periods (SEP) for Medicare-eligible individuals to elect a plan or change the individual's plan election when the individual meets an exceptional condition, as determined by the Secretary. Section 1860D–1(b)(3)(C) of the Act authorizes the Secretary to establish SEPs for exceptional circumstances for Medicare-eligible individuals to make Part D elections.

The SEPs for exceptional circumstances were historically included in our sub-regulatory guidance rather than in regulation. In 2020, we codified and amended a number of SEPs that had been adopted and implemented through sub-regulatory guidance as exceptional circumstances SEPs, including the SEP for Government Entity-Declared Disaster or Other Emergency (85 FR 33901, 85 FR 33909). This SEP, as codified at § 422.62(b)(18) for enrollment in an MA or MA–PD plan and § 423.38(c)(23) for enrollment in a Part D-only plan, allows individuals who are or have been affected by an emergency or major disaster declared by a Federal, state, or local government entity, and did not make an election during another period of eligibility as a result of the disaster/emergency, to make an MA and/or Part D enrollment or disenrollment action. Although CMS originally proposed that this SEP would only apply to FEMA-declared disasters or emergencies, as finalized in 2020, the regulations also include state and local emergency or major disaster declarations (85 FR 33868). This SEP begins the date the disaster/emergency declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier. This SEP ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later.

In order to clarify the length of this SEP, we proposed to revise the end date(s) for the SEP for Government Entity-Declared Disaster or Other Emergency specified within §§ 422.62(b)(18) and 423.38(c)(23). As part of this proposal, we proposed to create a new § 422.62(b)(18)(i), and redesignate what is currently in § 422.62(b)(18)(i)–(iii) as (b)(18)(ii)–(iv); likewise, we proposed to create a new § 423.38(c)(23)(i) and redesignate what is currently in § 423.38(c)(23)(i)–(iii) as (c)(23)(ii)–(iv).

First, we proposed that for state or local emergencies/disasters, the end date for the SEP may also be based on an emergency/disaster order automatically expiring pursuant to a state or local law, if such a law exists. Applicable state or local law could be statutes, regulations, local or municipal ordinances or codes regarding the automatic expiration date of state or local emergency/disaster orders. If the announced incident period end date is different than the expiration date specified in state or local law, the announced incident end date controls the SEP end date. Under this proposal, the SEP ends based on the end of the emergency/disaster period, regardless of whether that period ends based on an announcement by the applicable authority or expires based on applicable state or local law.

Second, we proposed an automatic incident end date which will apply if no end date for the period of disaster/emergency is otherwise identified within 1 year of the start of the SEP. This automatic incident end date will fall 1 year after the SEP start date, meaning that if no end date is otherwise identified, the SEP will be 14 full calendar months in length. For example, under our proposed changes, if no incident end date was identified in the declaration, or announced later, and there is no applicable expiration date provided by state or local law, CMS would consider the incident end date to be 1 year after the SEP start date and the SEP would end 2 full calendar months after that incident end date, which would result in a 14-month maximum SEP. We sought public comment on this automatic 1-year incident end date to determine if the 14-month maximum eligibility period for this SEP is sufficient. We proposed that if the emergency/disaster declaration is extended, then the automatic 1-year incident end date would be from the date of the extension. This would address situations where a declaration of emergency or major disaster is renewed or extended (perhaps multiple times) so that the state of emergency or major disaster lasts for a year or more. These proposed changes will provide clear end dates for this SEP and should allow interested parties to more easily calculate SEP length and determine beneficiary eligibility for the SEP.

Because an individual may elect a Medicare Advantage or Part D plan only during an election period, Medicare Advantage organizations and Part D sponsors already have procedures in place to determine the election period(s) for which an applicant is eligible. Our proposal would not add to existing enrollment processes, so we believe any burden associated with this aspect of enrollment processing would remain unchanged from the current practice and would not impose any new requirements or burden. All information impacts of this provision have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267), 0938–1378 (CMS–10718), and 0938–0964 (CMS–10141). In addition, Medicare Advantage organizations and Part D sponsors have previously implemented and are currently following the process to determine applicant eligibility for this SEP. We believe that changing the possible end date for this SEP will make a negligible impact, if any. We do not believe the proposed changes will adversely impact individuals requesting enrollment in Medicare plans, the plans themselves, or their current enrollees. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Fund.

We received the following comments, and our responses follow.

Comment: Multiple commenters expressed support for this provision.

Response: We thank the commenters for their support of our proposal.

Comment: Multiple commenters suggested that we extend this SEP eligibility period to six months after the end of the incident period, to align with the timeframe of the Parts A and B SEP for disasters or emergencies, instead of the two months currently codified in regulations.

Response: We thank the commenters for their suggestion; however, these proposed changes were aimed to provide clarity on incident end dates in cases where automatic expirations were relied upon, or when no end date was identified. We believe that the two full calendar months after the end of the incident period, as currently codified, provides ample opportunity for beneficiaries to select and enroll in a new plan. Though the timeframe for the Parts A and B SEP for disasters or emergencies is six months, two months is appropriate for making a Parts C/D election, given the procedural differences in enrolling in Medicare for the first time and making a new C/D plan election. The two-month period is also consistent with our other Parts C/D SEPs. We also note that beneficiaries who are unable to make an election during this SEP because of continued impacts of the disaster or emergency may be eligible for the SEP for Other Exceptional Circumstances and should contact 1–800–MEDICARE to explain their unique situation.

Comment: A commenter expressed concern that individuals who use the Medicare Parts A and B Disaster/Emergency SEP to enroll in Premium Part A or Part B may not be able to use the MA or Part D Disaster/Emergency SEP given the different eligibility timelines between the A/B SEP and C/D SEP.

Response: In order to use the MA and Part D SEP for Government Entity-Declared Disaster or Other Emergency, the individual must have been eligible for another valid election period but was unable to utilize it because they were affected by a disaster or other emergency. Newly MA-eligible individuals, because of their A/B SEP election, do not meet this eligibility criteria and are thus not impacted by the different eligibility timelines between the A/B and C/D SEPs. Because their MA eligibility is as a result of using the A/B SEP, these individuals would not be eligible to use the MA and Part D SEP for Government Entity-Declared Disaster or Other Emergency because they were not eligible for another MA or Part D election period that they were unable to use due to the disaster or other emergency. We also note that individuals who do utilize the A/B Emergency SEP are eligible to use the SEPs newly codified at 42 CFR 422.62(b)(26) and 423.38(c)(34), and thus would have the ability to make a Part C/D election after taking advantage of their A/B SEP.

After consideration of all public comments, and for the reasons outlined here and in the proposed rule, we are finalizing our proposal with minor edits at §§ 422.62(b)(18) and 423.38(c)(23) for grammar and clarity, as well as modifications to correctly redesignate existing paragraphs.

K. Updating MA and Part D SEPs for Changes in Residence and Codifying Procedures for Developing Addresses for Members Whose Mail Is Returned as Undeliverable (§§ 422.62, 422.74, 423.38 and 423.44)

Section 1851(b)(1)(A) of the Act provides that an individual is eligible to elect an M+C, later known as MA, plan only if the plan serves the geographic area in which the individual resides. Section 1851(b)(1)(B) of the Act provides for a continuation of enrollment option under which an MA organization offering an MA local plan may offer its enrollees the option to continue enrollment in the plan when they move out of the plan service area and into a continuation area, so long as the organization provides that in the continuation area enrollees have access to the full range of basic benefits under the original Medicare fee-for-service program option. In addition, section 1860D–1(b)(1)(B)(i) of the Act generally directs CMS to use rules for enrollment, disenrollment, and termination relating to residence requirements for Part D sponsors that are similar to those established for MA organizations under section 1851(b)(1)(A) of the Act.

In the June 1998 Interim Final Rule with Comment Period (IFC), we adopted regulations to address the residency and continuation area requirements, at §§ 422.50(a)(3) and 422.54, respectively, as well as a regulation, at § 422.74(b)(2)(i), requiring that an MA organization must disenroll an individual who no longer resides in the plan service area.

In January 2005, we published a final rule (70 FR 4194) to establish at § 423.30(a)(2)(ii) that an individual must reside in a Part D plan service area in order to be eligible to enroll in the plan and at § 423.44(b)(2)(i) that a Part D plan sponsor is required to disenroll an individual who no longer resides in the plan service area.

Section 1851(e)(4)(B) of the Act establishes that an individual who is no longer eligible to elect an MA plan because of a change in the individual's place of residence is eligible for a special election period (SEP) during which the individual may disenroll from the current plan or elect another plan. Further, section 1860D–1(b)(1)(B)(iii) of the Act directs CMS to generally use rules related to coverage election periods that are similar to those established for MA organizations under section 1851(e) of the Act. In the June 1998 IFC (63 FR 35073), we established at § 422.62(b)(2) an SEP for an individual who is not eligible to remain enrolled in an MA plan because of a change in his or her place of residence to a location out of the service area or continuation area. Likewise, in the January 2005 Part D final rule (70 FR 4194), we established at § 423.38(c)(7) an SEP for an individual who is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) where the PDP is offered are eligible for an SEP.

Current sub-regulatory guidance for these SEPs that are codified at §§ 422.62(b)(2) and 423.38(c)(7) are reflected in section 30.4.1 of Chapter 2 of the Medicare Managed Care Manual

for MA and in section 30.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. This guidance provides that these SEPs are available not only to individuals who become ineligible for their current plan due to a move out of the service area of their current plan, but also to those who move within the service area of their current plan and have new plan options available to them, as well as to those who are not currently enrolled in a Medicare health or drug plan who move and have new plan options available to them. We proposed to address the wider scope of these SEPs, as they are currently set out in sub-regulatory guidance, by amending §§ 422.62(b)(2) and 423.38(c)(7) to include individuals who move within the service area of their current plan and have new Medicare health or drug plan options available to them, as well as to those who are not currently enrolled in a Medicare health or drug plan who move and have new plan options available to them.

The intent of our proposal was to codify current policy as reflected in CMS's existing sub-regulatory guidance and that is being carried out currently by MA organizations and Part D plan sponsors. Codifying our current policy for these SEPs will provide transparency and stability for interested parties about the MA and Part D programs and about the nature and scope of these SEPs.

Separate from, but related to, the aforementioned policy for disenrolling individuals who report that they no longer reside in the plan service area are the current regulations at § 422.74(d)(4)(ii) that require that MA organizations disenroll individuals who are absent from the service area for more than six months. However, § 422.74(d)(4)(iii) provides an exception for individuals enrolled in MA plans that offer a visitor/traveler benefit are permitted an absence from the service area for up to 12 months; such individuals are disenrolled if their absence from the service area exceeds 12 months (or the length of the visitor/traveler program if less than 12 months). As outlined at § 423.44(d)(5)(ii), PDP sponsors must disenroll PDP enrollees who are absent from the plan service area for more than 12 consecutive months.

If member materials are returned to plan sponsors as undeliverable and a forwarding address is not specified, current sub-regulatory guidance directs the plan sponsor to document the return, retain the returned material and continue to send future correspondence to that same address, as a forwarding address may become available at a later date. See § 50.2.1.4 of Chapter 2 of the Medicare Managed Care Manual for MA and § 50.2.1.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual for Part D. In sub-regulatory guidance, we state that plan sponsors are to consider returned mail as an indication of a possible change in residence that warrants further investigation. As such, we encourage the plan sponsor to attempt to locate the member using any available resources, including CMS systems, to identify new address information for the member. We describe how plans should attempt to research a member's change of address at § 50.2.1.4 of Chapter 2 of the Medicare Managed Care Manual for MA and § 50.2.1.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual for Part D. Plan sponsors that are unable to contact the member or obtain current address information will disenroll the member upon expiration of the 6- or 12-month period of permitted temporary absence from the plan service area, as previously discussed.

Current MA guidance in § 50.2.1.4 of Chapter 2 of the Medicare Managed Care Manual regarding research of potential changes in address is consistent with the MA regulation at § 422.74(d)(4)(i) providing that ''the MA organization must disenroll an individual if the MA organization establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved . . .'' The analogous Part D regulation at § 423.44(d)(5)(i) requires that the ''PDP must disenroll an individual if the individual notifies the PDP that he or she has permanently moved out of the PDP service area,'' but the Part D regulation does not provide a basis similar to the MA regulation for when PDPs may start the process of researching and acting on a change of address that the plan learns about from a source other than the member. Although current Part D guidance in § 50.2.1.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual allows PDPs to use information they receive from sources other than the member, specifically from either CMS or the U.S. Postal Service, as an indicator that a beneficiary may no longer reside in the service area, this is not codified in the Part D regulation. Therefore, we proposed to align the Part D regulation with the MA regulation by amending § 423.44(d)(5)(i) to state that a PDP must disenroll an individual if the PDP establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved out of the PDP service area.

Current sub-regulatory guidance does not identify returned mail as a basis for involuntary disenrollment. Materials plans send to members that include protected health information (PHI) and/or personal identifying information (PII), as well as materials intended to inform members of plan-specific information, such as premiums, benefits, cost-sharing, network and network changes and plan rules, have the potential for greater adverse impact on individual members, if returned as undeliverable, than materials such as newsletters, flyers and other items covering general health and wellness.

To provide additional clarity to plan sponsors in their efforts to ascertain the residency status of members when there is an indication of a possible temporary or permanent absence from the service area, we proposed to amend § 422.74 by adding paragraphs (d)(4)(ii)(A) and (d)(4)(iii)(F) for MA and to amend § 423.44 by revising paragraph (d)(5)(ii) for Part D to state that an individual is considered to be temporarily absent from the plan service area when any one or more of the required materials and content referenced in §§ 422.2267(e) and 423.2267(e), respectively, if provided by mail, is returned to the plan sponsor by the U.S. Postal Service as undeliverable and a forwarding address is not provided. Codifying current sub-regulatory guidance regarding the use of returned mail as a basis for considering a member potentially out of area would provide a regulatory basis for plan sponsors to apply the 6- and 12-month timeframes as previously described, as well as the current practice of disenrolling individuals when the plan sponsor is unable to communicate with them using the residence address provided by the individual to the plan sponsor. Since plan sponsors are required by regulation to continue to mail certain materials to enrollees until the point at which the individual is no longer enrolled in the plan, we believe that it is important to codify the basis on which plan sponsors are to consider an individual to be temporarily out of the plan service area and able to be disenrolled, after an appropriate period of time, thus bringing about the cessation of any additional member material mailings.

Codifying our current policy for temporary absences from the plan service area, the sources of information on which plan sponsors may make related eligibility determinations, and the implications for disenrollment will provide transparency and stability for interested parties about the MA and Part D programs and about plan service area

requirements for the MA and Part D programs.

These proposals are a codification of longstanding MA and Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. Because an individual may elect an MA or Part D plan only during an election period and may continue enrollment in an MA or Part D plan only if the individual resides in the plan service area, or for some MA plans, the plan continuation area, MA organizations and Part D plan sponsors already have procedures in place to determine the election period(s) for which an applicant is eligible and to determine the point at which an enrollee is no longer eligible for the plan and must be disenrolled. Our proposal would not add to existing enrollment and disenrollment processes, so we believe any burden associated with these aspects of enrollment and disenrollment processing would remain unchanged from the current practices and would not impose any new requirements or burden. All information impacts related to the determination of eligibility for an election period and to the disenrollment of individuals who become ineligible for an MA or Part D plan based on the residency requirements have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D.

We received no comments on our proposal. Except for a minor change to the organization of the regulation text for 423.38(c)(7), we are finalizing the proposal without modification for the reasons outlined here and in the proposed rule.

L. Codify the Term ''Whole Calendar Months'' (§§ 422.74 and 423.44)

Section 1851(g)(3)(B)(i) of the Act provides that an MA organization may involuntarily terminate an individual's election in an MA plan if monthly basic and supplemental beneficiary premiums are not paid timely and provides for a grace period for payment of such premiums. Consistent with this section of the Act, the Part C regulations set forth our requirements with respect to optional involuntary disenrollment procedures under § 422.74.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) enacted the Medicare Advantage (MA) program, which replaced the M+C program established under title XVIII of the Act and amended title XVIII of the Act to add a new Part D (Voluntary Prescription Drug Benefit Program). Section 1860D–1(b)(1)(B)(v) of the Act specifies that in establishing a process for Part D enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans, the Secretary shall use rules similar to (and coordinated with) the rules for an MA plan established under section 1851(g) (other than paragraph (2) of such section and clause (i) and the second sentence of clause (ii) of paragraph (3)(C) of such section) of the Act. Consistent with these sections of the Act, the Part D regulations set forth our requirements with respect to optional involuntary disenrollment procedures under § 423.44.

In 2010, CMS amended the Part C and Part D regulations regarding optional involuntary disenrollment for nonpayment of premiums to require a minimum grace period of 2 months before any disenrollment occurs. These requirements were codified at § 422.74(d)(1)(i)(B)(1) (75 FR 19804) and § 423.44(d)(1)(iii)(A) (75 FR 19816). CMS also revised these regulations to include the requirement that the grace period begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later. These regulations were codified at § 422.74(d)(1)(i)(B)(2) (75 FR 19804) and § 423.44(d)(1)(iii)(B) (75 FR 19816).

In subsequent sub-regulatory guidance in section 50.3.1, Chapter 2 of the Medicare Managed Care Manual and section 50.3.1, Chapter 3 of the Medicare Prescription Drug Benefit Manual, we defined the grace period for nonpayment of plan premium as a *whole* number of calendar months, not fractions of months. As the term ''whole calendar months'' is not specifically mentioned in the Part C and Part D regulations, we proposed to revise §§ 422.74(d)(1)(i)(B)(1) and 423.44(d)(1)(iii)(A) to include the requirement that the grace period be at least 2 whole calendar months, to begin on the first day of the month for which the premium is unpaid or the first day of the month following the date on which premium payment is requested, whichever is later.

Plan sponsors that have chosen to disenroll individuals based on unpaid premiums already have procedures in place to implement a grace period that is a minimum of 2 months in length. Based on infrequent complaints or questions from MA organizations and Part D sponsors, we believe that plans are complying with this guidance, and we did not propose any changes to the requirements or process for involuntary disenrollment that plan sponsors have previously implemented and are currently following. All burden impacts of these provisions have already been accounted for under OMB control number 0938–0753 (CMS–R–267) for Part C and OMB control number 0938–0964 (CMS–10141). There is also no impact to the Medicare Trust Fund.

We received no comments on our proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal without modification.

M. Researching and Acting on a Change of Address (§§ 422.74 and 423.44)

As discussed in our proposal for Developing Addresses for Members Whose Mail is Returned as Undeliverable and SEP for Changes in Residence (§§ 422.62, 422.74, 423.38, 423.44), section 1851(b)(1)(A) of the Act provides that an individual is eligible to elect an MA plan only if the plan serves the geographic area in which the individual resides, and section 1860D–1(b)(1)(B) of the Act generally directs CMS to use rules related to enrollment, disenrollment, and termination for Part D sponsors that are similar to those established for MA organizations under section 1851(b)(1)(A) of the Act.

Pursuant to regulations at § 422.74(c) for MA and § 423.44(c) for Part D, MA organizations and Part D plan sponsors are currently required to issue a disenrollment notice when an enrollee is disenrolled for not residing in the plan service area. Existing sub-regulatory guidance includes a requirement that MA organizations and Part D plan sponsors issue the disenrollment notice within 10 days of the plan learning of the permanent move. See § 50.2.1.5 of Chapter 2 of the Medicare Managed Care Manual for MA and § 50.2.1.6 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, respectively. In the case of MA plan enrollees who are disenrolled because they are absent from the service area for more than six months, the disenrollment notice must be provided within the first ten calendar days of the sixth month of such absence. Individuals enrolled in MA plans that offer a visitor/traveler benefit are permitted an absence from the service area for up to 12 months; such individuals are disenrolled if their absence from the service area exceeds 12 months (or the length of the visitor/traveler program if less than 12 months). In this scenario, the MA organization must provide notification of the upcoming disenrollment to the enrollee during the first ten calendar days of the 12th month (or the last month of the allowable absence, per the visitor/

traveler program). PDP enrollees are disenrolled if they are absent from the plan service area for more than 12 months. For these cases, the disenrollment notice must be provided within the first 10 calendar days of the 12th month of such absence. For instances in which a plan learns of an individual's absence from the service area after the expiration of the period of time allowed under the applicable regulation, the plan would provide the disenrollment notice within 10 calendar days of learning of the absence.

Although we have previously codified the requirement to issue a disenrollment notice when an individual is disenrolled due to an extended absence from the plan service area, or a change in residence to a location outside the service area, the 10-day timeframe for issuing that notice is reflected only in sub-regulatory guidance. We proposed to amend the MA and Part D plan disenrollment notification requirements to include the 10-day timeframe that is currently reflected in sub-regulatory guidance. Specifically, we proposed to codify at § 422.74(d)(4)(iv) and at § 423.44(d)(5)(i) and (d)(5)(ii) a timeliness requirement of 10 calendar days for issuing notices for disenrollments based on the residency requirements. Separate from the disenrollment notification requirements described in the preceding paragraphs is a documentation retention requirement currently reflected in § 50.2.1.3 of Chapter 2 of the Medicare Managed Care Manual for MA and in § 50.2.1.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. It has been CMS policy that MA organizations and Part D plan sponsors document their efforts to determine whether an enrollee has relocated out of the plan service area or has been absent from the service for a period of time in excess of what is allowed; however, our expectation that plans document their research efforts, although outlined in sub-regulatory guidance, is not codified. As such, we proposed to amend the MA and Part D regulations to include the requirement that plans document their efforts to determine an enrollee's residency status.

We proposed to codify at § 422.74(d)(4)(i) and at § 423.44(d)(5)(i) and (d)(5)(ii) that MA organizations and Part D plan sponsors, respectively, must document the basis for involuntary disenrollment actions that are based on the residency requirements.

The intent of our proposal was to codify current disenrollment notice policy, as reflected in § 50.2.1.5 of Chapter 2 of the Medicare Managed Care Manual for MA and in § 50.2.1.6 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, and also codify the documentation policy that is reflected in § 50.2.1.3 of Chapter 2 of the Medicare Managed Care Manual for MA and in § 50.2.1.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, all of which are policies that are already being carried out by MA organizations and Part D plan sponsors. Codifying these policies regarding notification of disenrollment and document retention will provide transparency and stability for interested parties about the MA and Part D programs and about the nature and scope of these notification and retention policies.

These proposals are a codification of longstanding MA and Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. MA organizations and Part D plan sponsors already have procedures in place to provide disenrollment notifications and to retain documentation related to such disenrollments. Our proposal would not add to existing processes, so any burden associated with this aspect of disenrollment processing and document retention would remain unchanged from current practices and would not impose any new requirements or burden. All information impacts related to these existing practices have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D.

We received no comments on our proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal without modification.

N. Part D Retroactive Transactions for Employer/Union Group Health Plan (EGHP) Members (§§ 423.32 and 423.36)

Section 1860D–1(b) of the Act establishes the enrollment and disenrollment process for Part D-eligible individuals in prescription drug plans. This section of the Act grants the Secretary the authority to establish a process for the enrollment, disenrollment, termination, and change of enrollment of Part D eligible individuals in prescription drug plans. In January 2005, the Part D implementing regulations established the enrollment and disenrollment processes for Part D prescription drug plans. The enrollment and disenrollment processes for prescription drug plans are codified in regulation at §§ 423.32 and 423.36, respectively (70 FR 4525).

Section 1860D–1(b)(1)(B) of the Act directs the Secretary to adopt Part D enrollment rules ''similar to,'' and coordinated with, those under Part C. In 1998, Part C implementing regulations (and subsequent correcting regulations) added the requirement that allowed an exception for employer/union group health plan (EGHP) sponsors to process election forms for Medicare-entitled group members (63 FR 52612, 63 FR 35071). These requirements were codified in the Part C regulations but were not codified in the Part D regulations.

We proposed to codify this existing policy to provide transparency and ensure consistency between the Part C and Part D programs. Specifically, we proposed at new §§ 423.32(i) and 423.36(e) to permit a Part D plan sponsor that has a contract with an employer or union group to arrange for the employer or union to process enrollment and disenrollment elections for Medicare-entitled group members who wish to enroll in or disenroll from an employer or union sponsored Part D plan. As outlined in sections 60.5.1 and 60.5.2 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, retroactive enrollments and disenrollments are permitted for up to 90 days to conform to the payment adjustments described under §§ 422.308(f)(2) and 423.343(a). In addition, to obtain the retroactive effective date of the election, the individual must certify receipt of the group enrollment notice materials that include the summary of benefits offered under the PDP, as provided in sections 40.1.6 and 60.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual. Once the enrollment or disenrollment election is received from the employer, the Part D plan sponsor must submit the disenrollment to CMS within the specified timeframes described in section 60.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Our intent is to align the Part D regulation with the requirements that MA organizations follow in existing Part C regulations at §§ 422.60(f) and 422.66(f) and codify existing policies in the sub-regulatory guidance in Chapter 3 of the Medicare Prescription Drug Benefit Manual. Under section 60.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual, retroactive transactions may be necessary and are permitted if a delay exists between the time the individual completes the enrollment or disenrollment request through the employer's election process and when the request is received by the Part D plan sponsor. Further, we state in current sub-regulatory guidance at section 60.5.1 of Chapter 3 of the

Medicare Prescription Drug Benefit Manual that the option to submit limited EGHP retroactive enrollment and disenrollment transactions is to be used only for the purpose of submitting a retroactive enrollment into an EGHP made necessary due to the employer's delay in forwarding the completed enrollment request to the Part D plan sponsor.

This is a codification of existing Part D sub-regulatory guidance and there is no impact to the Medicare Trust Fund. Based on infrequent complaints and questions from plans and beneficiaries related to current policies, which have been previously implemented and are currently being followed by plans, we concluded that there is no additional paperwork burden. All information impacts related to this provision have already been accounted for under OMB control numbers 0938–1378 (CMS–10718) for Part D enrollment requests and 0938–0964 (CMS–10141) for Part D disenrollment requests.

We did not receive comments related to this proposal. For the reasons outlined here and in the proposed rule, we are finalizing this proposal without modification.

O. Drug Management Program (DMP) Appeal Procedures (§ 423.562)

We proposed a technical change at § 423.562(a)(1)(v) to remove discretionary language as it relates to a Part D plan sponsor's responsibility to establish a DMP under § 423.153(f) with appeal procedures that meet the requirements of subpart M for issues that involve at-risk determinations. This eliminates discretionary language and improves consistency with § 423.153(f), which requires each Part D plan sponsor to establish and maintain a DMP and include appeal procedures that meet the requirements of subpart M for issues involving at-risk determinations. This is strictly a technical change to the wording at § 423.562(a)(1)(v) and does not impact the underlying burden related to processing appeals of at-risk beneficiaries. This change is not expected to have an economic impact beyond current operating expenses, and there is no paperwork burden or associated impact on the Medicare Trust Fund.

We did not receive comments on this proposal. For the reasons outlined here and in the proposed rule, we are finalizing the proposal as proposed.

P. Revise Initial Coverage Election Period Timeframe To Coordinate With A/B Enrollment (§ 422.62)

Section 4001 of the Balanced Budget Act of 1997 (Pub. L. 105–33) added sections 1851 through 1859 to the Social Security Act (the Act), establishing Part C of the Medicare program known originally as M+C and later as Medicare Advantage (MA). As enacted, section 1851(e) of the Act establishes specific parameters in which elections can be made and/or changed during enrollment and disenrollment periods under the MA program. Specifically, section 1851(e)(1) of the Act requires that the Secretary specify an initial coverage election period (ICEP) during which an individual who first becomes entitled to Part A benefits and enrolled in Part B may elect an MA plan. The statute further stipulates that if an individual elects an MA plan during that period, coverage under the plan will become effective as of the first day on which the individual may receive that coverage. Consistent with this section of the Act, in the ''Medicare Program; Establishment of the Medicare+Choice Program'' interim final rule with comment period which appeared in the **Federal Register** on June 26, 1998, (herein referred to as the June 1998 interim final rule), CMS codified this policy at § 422.62(a)(1) (63 FR 35072).

In order for an individual to have coverage under an MA plan, effective as of the first day on which the individual may receive such coverage, the individual must elect an MA plan before he or she is actually entitled to Part A and enrolled in Part B coverage. Therefore, in the June 1998 interim final rule CMS codified the ICEP to begin 3 months prior to the month the individual is first entitled to both Part A and enrolled in Part B and ends the last day of the month preceding the month of entitlement (63 FR 35072).

Section 102 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) revised section 1851(e)(1) of the Act to provide for an ICEP for MA that ends on the later of, the day it would end under pre-MMA rules as described above, or the last day of an individual's Medicare Part B Initial Enrollment Period (IEP). This approach extended an individual's ICEP which helped to ensure that an individual who uses their IEP to enroll in Medicare Part A and B has the opportunity to elect an MA or MA prescription drug (MA–PD) plan following their first entitlement to Part A and enrollment in Part B. Consistent with the revised provisions of section 1851(e)(1) of the Act, CMS codified this policy at § 422.62(a)(1) in the Medicare Program; Establishment of the Medicare Advantage Program final rule which appeared in the **Federal Register** on January 28, 2005 (70 FR 4717).

As described in § 422.50(a)(1), eligibility for MA or MA–PD enrollment generally requires that an individual first have Medicare Parts A and B and meet all other eligibility requirements to do so. The ICEP is the period during which an individual newly eligible for MA may make an initial enrollment request to enroll in an MA or MA–PD plan. Currently, once an individual first has both Parts A and B, their ICEP begins 3 months immediately before the individual's first entitlement to Medicare Part A and enrollment in Part B and ends on the later of:

1. The last day of the month preceding entitlement to Part A and enrollment in Part B; or

2. The last day of the individual's Part B IEP.

Individuals who want to enroll in premium-Part A, Part B, or both, must submit a timely enrollment request during their IEP, the General Enrollment Period (GEP), or an existing special enrollment period (SEP) for which they are eligible. Eligible individuals may choose to enroll in both Part A and B during their first opportunity, that is, during their IEP. These individuals have an ICEP as described in § 422.62(a)(1)(ii), that is, they can choose to enroll in an MA plan (with or without drug coverage) at the time of, or after, they have both Part A and B, up until the last day of their IEP. However, not all individuals enroll in both Part A and B during their IEP. Other individuals, such as those who are working past age 65, may not have both Part A and B for the first time until after their IEP. These individuals may only have Part A and/or B for the first time when they use an SEP or a future GEP to enroll. To note, prior to January 1, 2023, individuals who enrolled in Part A and/or Part B during the GEP had a universal effective date of July 1st. These individuals had an ICEP as described in § 462.22(a)(1)(i), that is, the ICEP started April 1st and ended June 30th. Although these individuals had to decide whether to enroll in an MA or MA–PD plan prior to their July 1st effective date, they did have time to consider their options, as the GEP is January 1st–March 31st annually, and their enrollment in Part B, (and Part A if applicable), was not effective until July 1st. However, the Consolidated Appropriations Act, 2021, (CAA) (*Pub. L. 116–260*), revised sections 1838(a)(2)(D)(ii) and 1838(a)(3)(B)(ii) of the Act to provide that for individuals who enroll during the GEP in a month beginning on or after January 1, 2023, their entitlement would begin with the first day of the month following the month in which they enroll. For

example, if an individual has Part A, but enrolls in Part B in March, during the GEP, they would first have both Part A and Part B effective April 1st. Although this provides for an earlier Medicare effective date, the individual's ICEP would occur prior to that Medicare effective date, that is, as described in § 422.62(a)(1)(i) above, and they no longer have that additional time to consider their options.

Currently, the individuals described above have an ICEP as described in § 422.62(a)(1)(i) and can only enroll in an MA plan (with or without drug coverage) *prior* to the effective date of their Part A and B coverage. For example, an individual's 65th birthday is April 20, 2022, and they are eligible for Medicare Part A and Part B beginning April 1, 2022. They have premium-free Part A; however, the individual is still working, and has employer health insurance, so they decide not to enroll in Part B during their IEP. The individual retires in April 2023, and enrolls in Part B effective May 1, 2023 (using a Part B SEP). The individual's ICEP would be February 1st through April 30, 2023. These individuals need to decide if they want to receive their Medicare coverage through an MA plan prior to the effective date of their enrollment in both Part A and B. In this example, the individual would have to enroll in an MA plan using the ICEP by April 30, 2023.

Section 422.62(a)(1) was intended to provide beneficiaries who enroll in both Part A and Part B for the first time with the opportunity to elect an MA plan *at the time* that both their Part A and B coverage were effective. However, in practice, individuals described above, who do not enroll in Part B during their IEP, do not have an opportunity to elect to receive their coverage through an MA plan *after* their Part A and B coverage goes into effect. When an individual enrolls in both Part A and B for the first time using an SEP or the GEP, they have to determine, prior to the start of their coverage, if they want to receive their coverage through Original Medicare or an MA plan prior to the effective date of their Part A and B coverage. If they do not use their ICEP to enroll in an MA plan prior to when their Part A and B coverage becomes effective, they lose the opportunity to enroll in an MA plan to receive their Medicare coverage and will generally have to wait until the next enrollment period that is available to them to choose an MA plan.

To provide more flexibility, we proposed to revise the end date for the ICEP for those who cannot use their ICEP during their IEP. That is, we proposed in § 422.62(a)(1)(i) that an individual would have an opportunity to enroll in an MA plan (with or without drug coverage) using their ICEP until the last day of the second month after the month in which they are first entitled to Part A and enrolled in Part B. Under proposed § 422.62(a)(1)(i), the individual's ICEP would begin 3 months prior to the month the individual is first entitled to Part A and enrolled in Part B and would end on the last day of the second month after the month in which the individual is first entitled to Part A and enrolled in Part B. Using the example above, we are proposing that the individual's ICEP would be February 1st through June 30, 2023, instead of February 1st to April 30th. As described in § 422.68(a)(1), if an election is made prior to the month of entitlement in both Part A and Part B, the MA election would be effective as of the first date of the month that the individual is entitled to both Part A and Part B.

We believed that extending the timeframe for the ICEP under § 422.62(a)(1)(i) would provide beneficiaries that are new to Medicare additional time to decide if they want to receive their coverage through an MA plan. We believed that extending this timeframe would help those new to Medicare to explore their options and select coverage that best suits their needs and reduce the number of instances where an individual inadvertently missed their ICEP and has to wait until the next open enrollment period to enroll in MA or MA–PD plan. This also supports President Biden's April 5, 2022 *Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage,*[107] which, among other things, requires agencies to examine policies or practices that make it easier for all consumers to enroll in and retain coverage, understand their coverage options and select appropriate coverage, and also examine policies or practices that strengthen benefits and improve access to health care providers.

This proposed change in the ICEP timeframe aligned with the SEP timeframe that we have established in § 422.62(b)(10), for individuals to enroll in an MA or MA–PD plan when their Medicare entitlement determination is made for a retroactive effective date, and the individual has not been provided the opportunity to elect an MA or MA–PD plan during their ICEP. It also aligned with the timeframe we have established in § 422.62(b)(26), effective January 1, 2024, for an individual to enroll in an MA plan when they enroll in Part A and/or Part B using an exceptional condition SEP, as described in §§ 406.27 and 407.23.

This final rule would extend the timeframe of an existing enrollment period, but we noted it would not result in a new or additional paperwork burden since MA organizations are currently assessing applicants' eligibility for election periods as part of existing enrollment processes. All burden impacts of these provisions have already been accounted for under OMB control number 0938–1378 (CMS–10718). Similarly, we did not believe the proposed changes would have any impact to the Medicare Trust Fund.

We received the following comments, and our responses follow.

Comment: All commenters supported our proposed policy to extend the ICEP for those individuals who are first entitled to Part A and enrolled in Part B and did not enroll in Part A and B during their IEP. Many commenters stated this extended timeframe would provide beneficiaries more time to evaluate their options for coverage. Another commenter said this additional enrollment allowance will be welcome by many beneficiaries who are still learning and adjusting to the Medicare program. A commenter added that this additional time would allow beneficiaries to consider the benefits of MA enrollment, including care coordination services and the availability of supplemental benefits. A commenter added that expanding the opportunity for beneficiaries to choose the appropriate plan ensures that they will more likely be satisfied with their plan choice and coverage options. Another commenter added that this additional time will also provide Medicare Advantage Organizations (MAOs) with additional opportunity to further educate individuals on what options are available to them.

Response: We agree and thank the commenters for their support.

Comment: A commenter asked CMS to explain how the new proposed ICEP timeframe is different from the SEP that provides individuals with 2 months to elect a stand-alone Part D Plan or MA plan once their retiree or current employer group health plan ends.

Response: An SEP exists for individuals disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan (with or without drug coverage) or a Part D plan (§§ 422.62(b)(4) and 423.38(c)(11)). This SEP is only for use in accordance with

[107] *https://www.whitehouse.gov/briefing-room/presidential-actions/2022/04/05/executive-order-on-continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage/.*

an individual's change in employer coverage and ends 2 months after the month the employer or union coverage ends. The ICEP is not limited for use based on the gain or loss of employer or union sponsored coverage. It is a universal election period available to all individuals to elect an MA plan (with or without prescription drug coverage) starting 3 months immediately before the individual's first entitlement to both Medicare Part A and Part B and will end, as proposed, the last day of the second month after the month in which the individual is first entitled to Part A and enrolled in Part B or the last day of the individual's Part B IEP, whichever is later.

Comment: Although they support our proposal to extend the timeframe for the ICEP, several commenters recommended alternate timeframes for the end of the ICEP. The commenters encouraged CMS to consider extending the proposed ICEP timeframe to end 3 full months after the month the individual is first entitled to Part A and enrolled in Part B. This timeframe would mirror the current IEP, wherein an individual would have a total of 7 months (prior to, at the time of, and after their first entitlement to Part A and enrollment in Part B) to consider their enrollment choice. The commenters stated that, due to the complex decision-making that must take place during these initial coverage situations, individuals newly eligible for Medicare would benefit greatly from additional time and that this timeframe would simplify policy since it would mirror the current IEP. A commenter suggested that CMS consider extending the ICEP timeframe to mirror the Medicare Advantage Open Enrollment Period (MA OEP), that is, to end on the last day of the third month that the individual is first entitled to Part A and enrolled in Part B, which would be a total of 6 months.

Response: We thank the commenters for their suggestions. We considered various ending dates when we proposed to extend the ICEP timeframe. As stated in the proposed rule, the proposed change in the ICEP timeframe aligns with the SEP timeframe that we established in § 422.62(b)(10) for individuals to enroll in an MA or MA–PD plan when their Medicare entitlement determination is made for a retroactive effective date and the individual has not been provided the opportunity to elect an MA or MA–PD plan during their ICEP. It also aligns with the timeframe we established in § 422.62(b)(26) for an individual to enroll in an MA or MA–PD plan when they enroll in Part A and/or Part B using an exceptional condition SEP which was recently codified in the April 2023 final rule (88 FR 22328).

The proposed timeframe to extend the ICEP will provide individuals a total of 5 months to consider how they want to receive their Medicare coverage. We believe this timeframe is adequate for beneficiaries to decide if they want to receive their coverage through Original Medicare or an MA plan and to select a plan that meets their needs. To note, individuals also have ample opportunities to change plans outside of the ICEP, including the MA OEP, the Annual Coordinated Election Period, or any SEP for which they are eligible.

Comment: Several commenters expressed support for the proposed changes to the ICEP timeframe, but provided feedback on areas that were not addressed in the proposed rule. A commenter stated that beneficiaries in traditional Medicare should have an opportunity to change stand-alone Part D plans during the first 3 months of the year—an option that is available to people who wish to change MA plans through the MA OEP. The commenter also stated that federal Medigap rights should be expanded to allow individuals to purchase such plans on at least an annual basis. Another commenter asked CMS to simplify the enrollment and plan selection processes—including by modernizing consumer tools, notifying people approaching Medicare eligibility about enrollment rules and timelines, and ensuring agency communications clearly explain the trade-offs between Original Medicare and MA.

Response: We thank the commenters for their support of the change to the ICEP timeframe, but we note that these recommendations are outside of the scope of this rulemaking.

After consideration of all public comments, we are finalizing our proposal to revise § 422.62(a)(1)(i) without modification.

Q. Enhance Enrollees' Right To Appeal an MA Plan's Decision To Terminate Coverage for Non-Hospital Provider Services (§ 422.626)

Medicare Advantage (MA) enrollees have the right to a fast-track appeal by an Independent Review Entity (IRE) when their covered skilled nursing facility (SNF), home health, or comprehensive outpatient rehabilitation facility (CORF) services are being terminated. The regulations for these reviews at the request of an MA enrollee are located at 42 CFR 422.624 and 422.626. Section 422.624 requires these providers of services to deliver a standardized written notice to the enrollee of the MA organization's decision to terminate the provider's services for the enrollee. This notice, called the Notice of Medicare Non-Coverage (NOMNC), must be furnished to the enrollee before services from the providers are terminated. The NOMNC informs enrollees of their right to a fast-track appeal of the termination of these provider services and how to appeal to the IRE. CMS currently contracts with certain Quality Improvement Organizations (QIOs) that have contracts under Title XI, Part B and section 1862(g) of the Act to perform as the IRE for these specific reviews. Specifically, the Beneficiary and Family Centered Care QIOs (BFCC QIOs) are the type of QIO that currently performs these reviews. There is a parallel appeal process in effect for Medicare beneficiaries in Original Medicare (42 CFR Part §§ 405.1200 and 405.1202).

Presently, if an MA enrollee misses the deadline to appeal as stated on the NOMNC, the appeal is considered untimely, and the enrollee loses their right to a fast-track appeal to the QIO. Enrollees may, instead, request an expedited reconsideration by their MA plan, as described in § 422.584. The QIO is unable to accept untimely requests from MA enrollees but does perform appeals for untimely requests from Medicare beneficiaries in Original Medicare as described at § 405.1202(b)(4).

Further, MA enrollees forfeit their right to appeal to the QIO if they leave a facility or otherwise end services from one of these providers before the termination date listed on the NOMNC, even if their appeal requests to the QIO are timely. (The MA enrollee retains the right to appeal to their MA plan in such cases because the decision to terminate the services is an appealable organization determination per § 422.566(b)(3).) Beneficiaries in Original Medicare retain their right to appeal to the QIO, regardless of whether they end services before the termination date on the NOMNC.

We proposed to modify the existing regulations regarding fast-track appeals for enrollees when they untimely request an appeal to the QIO, or still wish to appeal after they end services on or before the planned termination date. As noted in the proposed rule, these changes would bring the MA program further into alignment with Original Medicare regulations and procedures for the parallel appeals process. Finally, these changes were recommended by interested parties in comments to a previous rulemaking (CMS–4201–P, February 27, 2022).

Specifically, the changes would (1) require the QIO, instead of the MA plan, to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF; and (2) allow enrollees the right to appeal the decision to terminate services after leaving a SNF or otherwise ending covered care before the planned termination date. The proposed changes are modeled after the parallel process in effect for Original Medicare at 42 CFR 405.1200 through 405.1202.

To implement these changes, we proposed to revise § 422.626(a)(2) to specify that if an enrollee makes an untimely request for a fast-track appeal, the QIO will accept the request and perform the appeal. We also specified that the IRE decision timeframe in § 422.626(d)(5) and the financial liability provision in § 422.626(b) would not apply.

Secondly, we proposed removing the provision at § 422.626(a)(3) that prevents enrollees from appealing to the QIO if they end their covered services on or before the date on their termination notice, even in instances of timely requests for fast-track appeals. Removal of this provision preserves the appeal rights of MA enrollees who receive a termination notice, regardless of whether they decide to leave a provider or stop receiving their services.

This proposed expedited coverage appeals process would afford enrollees in MA plans access to similar procedures for fast-track appeals as for beneficiaries in Original Medicare in the parallel process. Untimely enrollee fast-track appeals would be absorbed into the existing process for timely appeals at § 422.626, and thus, would not necessitate additional changes to the existing fast-track process. The burden on MA plans would be minimal and would only require that MA plans provide notices as required at § 422.626(d)(1) for these appeals. Further, MA plans would no longer have to perform the untimely appeals as currently required at § 422.626(a)(2). Beneficiary advocacy organizations, in comments to previous rulemakings on this topic, supported changes that would afford enrollees more time to appeal and afford access to IRE appeals even for untimely requests.

We noted that the burden of conducting these reviews is currently approved under OMB collection 0938–0953. The proposed changes would require that untimely fast-track appeals would be performed by the QIO, rather than the enrollee's health plan; thus, any burden related to this proposal would result in a shift in fast-track appeals from health plans to QIOs.

We received the following comments, and our responses follow.

Comment: We received numerous comments on our proposal to require the BFCC–QIO, instead of the plan, to review untimely fast-track appeals of a plan's decision to terminate services in an HHA, CORF, or SNF and to fully eliminate the provision requiring the forfeiture of an enrollee's right to appeal a termination of services decision when they leave a SNF or CORF. Nearly all interested parties commenting on this provision supported these policies. A commenter stated that permitting enrollees to maintain access to a BFCC–QIO review beyond this timeframe is important and, as noted in the proposed rule, provides parity with Original Medicare. Another commenter commended CMS for seeking uniform appeal rights between MA and Original Medicare and addressing access disparities, particularly in post-acute care.

Response: We appreciate the widespread support we received for this proposal and share the commenters' goal of parallel QIO appeals processes, whenever possible, for MA and Original Medicare. We intend to continue the current policy of having the BFCC–QIOs perform these appeals.

Comment: Several commenters suggested that CMS make parallel changes to § 422.622(a)(5), which pertains to late appeal requests for expedited appeals for inpatient hospital discharges. Additionally, a commenter wanted to extend the scope of the fast-track appeals process to include outpatient services.

Response: We appreciate these suggestions from the commenters and will take them into consideration for future rulemaking. We believe that such a change should be adopted only after notice and an opportunity for the public to comment on such a revision to the hospital discharge process.

Comment: A few commenters asked that we reflect these new policies in related beneficiary appeals notices as well as plan materials such as EOCs, manuals, and other guidance. Another commenter suggested that CMS engage in efforts to educate enrollees of their appeal rights.

Response: We thank the commenters for their suggestions related to necessary changes to notices and plan materials resulting from this provision. We will update manuals and other guidance as well as beneficiary materials pertaining to appeal rights, as appropriate. In addition, we will make necessary revisions to the standardized notice, required under § 422.624, which informs beneficiaries of their right to a fast-track appeal by an BFCC–QIO. This standardized notice, the NOMNC, is subject to the Paperwork Reduction Act (PRA) process and approval by the Office of Management and Budget (OMB), and as such, any changes made to the NOMNC will be subject to public notice and comment.

Comment: A few commenters asked for clarification on the deadline to request an untimely appeal and whether the intent is for these MA provisions to precisely mirror procedures for Original Medicare. Another commenter recommended that CMS adopt a 60-day deadline for untimely enrollee appeals to plans.

Response: As finalized in this rule, per § 422.626(a)(2), a QIO will accept untimely requests for review of the termination of CORF, HHA or SNF services from enrollees. There is no deadline in this provision, and this is consistent with the parallel provision for Original Medicare at § 405.1204(b)(4). Our intent is to conform the QIO appeal processes for terminations of these provider services for Original Medicare and MA and to bring the MA appeals process in line with the parallel reviews for beneficiaries in Original Medicare. To that end, this provision, by design, mirrors the process for Original Medicare appeals of this type, set forth at § 405.1204(b)(4), rather than the process for enrollees set forth at § 422.584, which has a 60-day deadline to for an enrollee to file an appeal with the MA plan of an organization determination.

Comment: A commenter requested clarification on BFCC–QIO processing time for untimely requests. This commenter also asked if an enrollee could appeal to the plan if the BFCC–QIO decision is unfavorable. If so, the commenter requested clarification on the applicable processing timeframes.

Response: We appreciate the request for clarification on QIO processing timeframes and the interrelationship between QIO and plan appeals. Under the provisions we are finalizing at § 422.626(a)(2), a QIO will accept untimely requests from enrollees but the timeframes under (d)(5) of this section will not apply, as those timeframes pertain to timely requests. Consistent with the parallel regulations at § 405.1202(b)(4) for untimely Original Medicare appeals, the QIO will make its determination as soon as possible. We note that the provision we are finalizing in this rule has no effect on existing policy with respect to the MA plan appeals process set forth at §§ 422.582 and 422.584. As per current policy, an enrollee may appeal to the QIO and the

plan, but plan appeals deadlines continue as set forth at § 422.582(b).

Comment: A commenter was concerned about perceived implementation barriers health plans might encounter from these provisions. The commenter stated that there could be challenges with the availability of SNF beds and SNF readmissions for patients in rural areas should they request and receive a favorable BFCC–QIO appeal decision.

Response: We appreciate the commenter's concerns about perceived access issues particular to rural areas. However, as noted in the proposed rule, we expect only a very small increase in appeals to the overall existing appeals volume as a result of this provision. We also note that the acceptance of untimely appeals is a longstanding policy of the parallel appeals process for Original Medicare, with no known challenges regarding access particular to rural providers.

Comment: A commenter asked that we include language to state to which non-hospital providers these provisions would apply.

Response: As stated in the preamble, the relevant provisions for these reviews are found at §§ 422.624 and 422.626. Section 422.624(a)(1) specifies that providers included in this provision are skilled nursing facilities, home health agencies, and comprehensive outpatient rehabilitation facilities. The untimely appeals affected by the provisions in this final rule are the reviews of the terminations of services from the providers specified at § 422.624(a)(1). Section 422.626, which we are amending in this final rule, establishes the fast appeals for an MA plan's decision to terminate the services specified in § 422.624. As the non-hospital provider types applicable to these reviews are already specified, we do not believe further regulatory revisions are necessary to address this comment.

Comment: A commenter expressed concern that the proposal will interfere with value based contracting relationships. The commenter indicated MA plans are familiar with value-based arrangements, supplemental benefits, and graduated care programs, and thus expressed concern with removing appeals to the plans from the appeal processes for terminations of CORF, HHA and SNF services. The commenter also raised concerns that adding the BFCC–QIO into the process for untimely fast track appeals adds another party and additional complexity to conversations requiring high levels of scrutiny and understanding of the needs of an enrollee. The commenter also maintained there could be a significant administrative burden created if providers encourage or ''coach'' enrollees to take a default position of appealing termination decisions. Finally, the commenter indicated these provisions could expose the patients to longer lengths of inappropriate care and significant personal liability.

Response: We thank the commenter for their perspective. However, we do not believe this provision will interfere with value-based contracting relationships or result in inappropriate care, nor do we anticipate any changes with respect to the providers' role, including creation of any incentives to improperly influence an enrollee's decision on whether to request a fast-track appeal. As we have stated, this provision solely addresses the allowance for untimely appeals by enrollees in the current, longstanding process for MA fast-track appeals of terminations of CORF, HHA and SNF services. These additional, untimely appeals will be processed under current appeals procedures. This process, currently applicable to timely fast-track appeals, already includes QIOs as the entity conducting these independent reviews. Finally, as stated in the proposed rule, we estimate a minimal increase of less than 3 percent in the total appeals volume for this existing appeals process. Thus, we expect no significant change in the administrative burden in any aspect of the process or any significant change to overall lengths of stay in the provider types covered by this provision.

Comment: We received a few comments pertaining to the denial of care by plans. A commenter requested that we take measures to ensure that enrollees receive care equivalent to beneficiaries in Original Medicare with a particular interest in post-acute care. A few commenters expressed concerns with plans' use of utilization management guidelines rather than appropriate Medicare coverage criteria. Another commenter recommended not allowing care to be terminated at all, but acknowledged this may not be possible within existing statutory or regulatory frameworks, and supported the enhancement of enrollee's rights, in the meantime.

Response: We thank the commenters for their thoughts but note that these issues are outside the scope of this proposal. At the same time, we do wish to acknowledge that many of the recommendations related to patient care and prior authorization processes have been recently addressed in other regulation issued by CMS. See ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program,'' which appeared in the **Federal Register** on February 8, 2024 (89 FR 8758) that established new requirements for MA organizations that will enhance the electronic exchange of health care data and streamline processes related to prior authorization while reducing overall payer and provider burden and ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.'' which appeared in the **Federal Register** on April 12, 2023 (88 FR 22120) that finalized regulatory changes clarifying when MA organizations may utilize prior authorization processes, the effect and duration of prior authorization approvals, and the circumstances under which MA organizations may utilize internal or proprietary coverage criteria.

Comment: A commenter expressed concern regarding overutilization of services (specifically reaching or exceeding the 100 days benefit limit for SNF stays) if this provision is finalized.

Response: We appreciate the concern of the commenter, but do not agree that finalizing this provision will result in the overutilization of services. First, if an enrollee requests an untimely appeal of the termination of SNF coverage and receives a favorable decision by the QIO, any resulting additional benefits days would demonstrate that the services meet medical necessity as well as coverage requirements. Second, favorable QIO decisions do not override any existing Part A SNF benefit limitations.

Comment: Two commenters requested clarification on plan and provider responsibilities for appeals affected by this provision. Specifically, the commenters asked for more information regarding whether health plans or providers are responsible for producing medical records for untimely appeals. The commenter also asked whether a plan would be responsible for days of

coverage, should the BFCC–QIO rule in favor of the enrollee in the appeal, and if this would also be true if the enrollee appeals after leaving a skilled nursing home.

Response: We note that plan and provider responsibilities for these untimely QIO appeals of terminations of CORF, HHA and SNF services will be the same as for timely appeals in the current process as set forth at §§ 422.624 through 422.626. Specifically, § 422.626(e)(3) states a plan is responsible for supplying all necessary medical records to the QIO, once the plan is notified of the appeal. Should plans wish to delegate this responsibility to contracted providers, that would be a contracting arrangement and outside the purview of CMS. However, MA plans remain ultimately responsible for compliance with this requirement. Plans' financial responsibilities will continue to be as set forth at § 422.626(b). Among other requirements, this section requires that coverage of provider services continues until the date and time designated on the NOMNC, unless the enrollee appeals and the IRE reverses the plan's decision. If the IRE reverses the plan's termination decision, coverage of provider services shall resume or apply in accordance with the QIO's decision, and the provider must provide the enrollee with a new notice consistent with § 422.626(b) when the enrollee is still present in the facility.

Comment: A commenter suggested that instruction was needed for situations where an untimely fast-track appeal request was incorrectly submitted to the MA plan, rather than to the BFCC–QIO.

Response: We appreciate the commenter's suggestion to revise plan level guidance related to this provision. Currently, Section 50.2.2 of the Parts C & D Enrollee Grievances, Organization/ Coverage Determinations, and Appeals Guidance [108] instructs plans to maintain a process to distinguish between misdirected requests that should go to the QIO and valid requests to the plan. We will update the guidance in this manual section to reflect that untimely requests intended for the QIO must be included in those appeals that are to be redirected to the QIO.

Comment: A commenter recommended additional language to protect provider contracts and that guidance to require such language be posted in facilities and included in admission documentation.

Response: We thank the commenter for their comment. However, without further specifics on which contracts and language to which the commenter is referring, we are unable to address these recommendations. We note that we will update the related standardized appeals notice and Notice of Medicare Non-Coverage (NOMNC) required under § 422.624 as well as other materials, as appropriate to reflect the changes adopted in this final rule In addition, § 422.504(i)(4) provides that MA organizations must ensure that their agreements with related, first tier, downstream entities, which include providers under contract with the MA organization to furnish services, clearly identify any delegated responsibilities. We anticipate that MA organizations will comply with these requirements to the extent that the changes we are finalizing to § 422.626 affect the scope of provider duties under their contracts with MA plans.

Comment: A commenter expressed concerns about whether the BFCC–QIOs could absorb the potential increase in appeals that may result from this provision. The commenter suggested that we assess the capacity of BFCC–QIOs prior to implementation of this provision.

Response: We appreciate the commenter's concerns. We do not anticipate an appreciable increase in the appeals volume as a result of this provision. Additionally, we plan to further assess and mitigate as possible and appropriate any workload impacts of transitioning these appeals prior to the implementation date.

Comment: A commenter expressed their perception that BFCC–QIOs uphold nearly all fast-track appeals. The commenter recommended that we publish BFCC–QIO appeals data and use these metrics for evaluating BFCC–QIO contracts.

Response: We thank the commenter for sharing their concerns and recommendations but note that these issues are outside the scope of this rulemaking.

After consideration of all public comments and for the reasons outlined in the proposed rule and our response to public comments, we are finalizing without modification our proposals to amend § 422.626(a)(2) and to remove § 422.626(a)(3).

R. Amendments to Part C and Part D Reporting Requirements (§§ 422.516 and 423.514)

CMS has authority under sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act to require MA organizations and Part D plan sponsors to provide CMS ''with such information . . . as the Secretary may find necessary and appropriate.'' CMS also has authority, in section 1856(b) of the Act, to establish standards to carry out the MA program.

Likewise, existing CMS regulations cover a broad range of topics and data to be submitted to CMS. Under these authorities, CMS established reporting requirements at §§ 422.516(a) (Validation of Part C reporting requirements) and 423.514(a) (Validation of Part D reporting requirements), respectively. Pursuant to §§ 422.516(a) and 423.514(a), each MA organization and Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report information to CMS at the times and in the manner that CMS requires. In addition, §§ 422.504(f)(2) and 423.505(f)(2) require MA organizations and Part D plan sponsors, respectively, to submit to CMS all information that is necessary for CMS ''to administer and evaluate'' the MA and Part D programs and to facilitate informed enrollment decisions by beneficiaries. Part D plan sponsors are also required to report all data elements included in all its drug claims by § 423.505(f)(3). Sections 422.504(f)(2), 422.516(a), 423.505(f)(2), and 423.514(a) each list general topics of information and data to be provided to CMS, including benefits, enrollee costs, quality and performance, cost of operations, information demonstrating that the plan is fiscally sound, patterns of utilization, information about beneficiary appeals, and information regarding actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization.

For many years, CMS has used this authority to collect retrospective information from MA organizations and Part D plan sponsors according to the Parts C and D Reporting Requirements that we issue each year, which can be accessed on CMS's website.[109] In addition to the data elements, reporting frequency and timelines, and levels of reporting found in the Reporting Requirements information collection documents, CMS also issues Technical Specifications, which supplement the Reporting Requirements and serve to further clarify data elements and outline CMS's planned data analyses. The reporting timelines and required levels

[108] *https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.*

[109] Part C Reporting Requirements are at *https://www.cms.gov/medicare/health-plans/healthplansgeninfo/reportingrequirements* and Part D Reporting Requirements are at *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/rxcontracting_reportingoversight.*

of reporting may vary by reporting section. While many of the current data elements are collected in aggregate at the contract level, such as grievances, enrollment/disenrollment, rewards and incentives, and payments to providers, the collection of more granular data is also supported by the regulations. CMS has the ability to collect more granular data, per the Part C and D Reporting Requirements as set forth in §§ 422.516(a) and 423.514(a), or to collect more timely data with greater frequency or closer in real-time than we have historically done. We proposed revisions to update §§ 422.516(a) and 423.514(a). Section 422.516 currently provides, ''Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information.'' We proposed to strike the term ''statistics,'' as well as the words ''and other,'' with the understanding that the broader term ''information'' which is already at § 422.516(a), includes statistics, Part C data, and information on plan administration. In a conforming proposal to amend § 423.514(a), we proposed to strike the term ''statistics'' and add ''information.'' CMS does not interpret the current regulations to limit data collection to statistical or aggregated data and we used the notice of proposed rulemaking as an opportunity to discuss our interpretation of these rules and amend the regulations consistent with our interpretation.

Additionally, we proposed to amend §§ 422.516(a)(2) and 423.514(a)(2) to make an affirmative change regarding CMS's collection of information related to what occurs from beginning to end when beneficiaries seek to get coverage from their Medicare health and drug plans for specific services. Both §§ 422.516(a)(2) and 423.514(a)(2) currently require plans to report ''[t]he patterns of utilization of services.'' We proposed to amend both sections to read, ''The procedures related to and utilization of its services and items'' to clarify that these regulations authorize reporting and data collection about MA organizations and Part D plan sponsor procedures related to coverage, utilization in the aggregate, and beneficiary-level utilization, including the steps beneficiaries may need to take to access covered benefits. Such information will ensure that CMS may better understand under what circumstances plans choose whether to provide or pay for a service or item.

CMS did not propose to change specific current data collection efforts through this rulemaking. While §§ 422.516(a) and 423.514(a) provide CMS extensive flexibility in the time and manner in which we can collect data from MA organizations and Part D plan sponsors, we will continue to address future standardized information collection of the Parts C and D reporting requirements, as necessary, through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process, which would provide advance notice to interested parties and provides both a 60 and 30 day public comment period on drafts of the proposed collection.

We do not believe the proposed changes to §§ 422.516(a) and 423.514(a) have either paperwork burden or impact on the Medicare Trust Fund at this time. These proposed changes allow CMS, in the future, to add new burden to plans in collection efforts; however, any such new burden associated with a new data collection would be estimated through the PRA process, as applicable.

We received the following comments, and our responses follow.

Comment: We received several comments in support of the reassertion of our authority to engage in new or more frequent data collection, including collection of more granular data from MA organizations and Part D plan sponsors. The majority of commenters expressed general support for our proposal to affirm CMS's authority to collect detailed data from MA organizations and Part D plan sponsors under the Part C and D reporting requirements. We did not receive any comments objecting to the reassertion of authority to collect data that we included in the proposed rule.

Response: We appreciate the comments in support of our proposal.

Comment: In further support of the proposal, many commenters recommended CMS collect data elements for specific areas of interest, including data related to enrollee's cost-sharing for Part D medications, disease modification trends, multiple sclerosis diagnoses and enrollee demographics, plan referrals to specialists (*e.g.,* neurologists), End-Stage Renal Disease (ESRD) services, social determinants of health (*e.g.,* access to transportation, food insecurity, need for rental/utility assistance), plan use of prior authorization in specific settings, length of stays in post-acute care facilities, rehospitalization rates, qualifications of plan organization determination and appeal reviewers, plan use of algorithm and artificial intelligence when making coverage determinations, Medicaid coverage, pharmacy benefit managers, point-of-sale coverage decisions, service-level initial determinations, and initial determination denial rationale. Some commenters also requested we collect aggregate data elements that are already collected by CMS through the Parts C and D Reporting Requirements, including initial determination denials and appeal overturns made by the plan and Independent Review Entities.

Response: We thank the commenters for the data collection suggestions. We did not propose to implement changes to specific current data collection efforts in this rulemaking and would like to reiterate that any future information collection would be addressed through the OMB PRA process, as applicable, which would provide advance notice to interested parties and provides both a 60- and 30-day public comment period on drafts of the proposed collection.

Comment: Several commenters noted the positive benefit that robust data collection may generally have on strengthening CMS oversight of MA organizations and Part D plan sponsors, identifying and reducing potential gaps in health coverage policy, and ensuring enrollees have meaningful access to care. Some commenters suggested CMS incorporate collected data into plan audits and enforcement actions. A number of commentors also suggested CMS publish collected data on consumer-facing websites to improve transparency and plan accountability by allowing beneficiaries to compare plans' performance data.

Response: We appreciate the commenters' support and agree with the significance of CMS's role in overseeing MA organizations and Part D plan sponsors to ensure enrollees have continued access to care. We also agree the collection of more detailed standardized information from MA organizations and Part D plan sponsors is a necessary step in improving transparency and data in the MA and Part D programs. We will take these comments related to increasing oversight and transparency of the MA and Part D programs into consideration when developing future processes related to the public sharing of collected plan data.

Comment: A few commenters recommended that CMS consider a further revision to the proposed language in § 422.516(a), specifically the term ''doctor-patient relationship.'' A commenter noted that health care is increasingly delivered by a wider range of roles than just physicians and recommended that we replace the term

''doctor-patient'' with ''clinician-patient'' to better reflect the need for confidentiality between patients and their entire healthcare team.

Response: We appreciate the commenters' suggestion to modify the regulation text in § 422.516(a) to reflect the diverse team of health care professionals who provide care to MA enrollees. While we did not specifically propose to replace the term ''doctor'' with a more inclusive term in the introductory text at § 422.516(a), we agree with this suggestion. Accordingly, we are modifying § 422.516(a) in this final rule and replacing the term ''doctor-patient relationship'' with ''provider-patient relationship.'' Although commenters suggested the term ''doctor'' be replaced with ''clinician,'' the term ''provider'' is defined in § 422.2 and used throughout 42 CFR part 422 when describing health care professionals and entities that furnish health care services to MA enrollees. For example, the regulation text at § 422.200 explains, in part, that the provisions in Subpart E govern MA organizations' relationships with providers by setting forth ''requirements and standards for the MA organization's relationships with providers including physicians, other health care professionals, institutional providers and suppliers, under contracts or arrangements or deemed contracts under MA private fee-for-service plans.'' Therefore, replacing ''doctor-patient'' with ''provider-patient'' in § 422.516(a) will enhance clarity and consistency across regulation text in Part 422.

Comment: One commenter suggested that for future data collection efforts CMS utilize notice-and-comment rulemaking instead of the PRA process to provide stakeholders a greater opportunity to comment on the future proposal.

Response: We appreciate the commenter's concern that stakeholders should have opportunity to comment on changes to the MA and Part D reporting requirements. When applicable, CMS uses notice-and-comment rulemaking to solicit public comments on proposed information collection requirements. CMS must also comply with the implementing regulations of the PRA at 5 CFR 1320.10 (clearance of collections of information, other than those contained in proposed rules or in current rules), 1320.11 (clearance of collections of information in proposed rules), and 1320.12 (clearance of collections of information in current rules). CMS's compliance with the PRA, when required, allows interested parties to review and comment on future information collection request changes via two required public notice and comment periods; that is, the 60-day and 30-day notice and comment periods.

While 42 CFR 422.516(a) and 423.514(a) [110] provide CMS extensive flexibility in the time and manner in which we can require reporting by (and/or collect data from) MA organizations and Part D plan sponsors, as explained above, CMS must adhere to the implementing regulations of the OMB PRA process, when required, including circumstances when CMS collects data in a standardized format from 10 or more respondents. For any future information collection applicable to all MA organizations and Part D plan sponsors or groups larger than 9, we will, as necessary, use the OMB PRA process when proposing future Parts C and D reporting requirement changes. The PRA process provides the opportunity for interested parties to have notice of and comment on future data collection changes. As we stated in our proposal, the OMB PRA process provides advance notice to interested parties and provides both a 60- and 30-day public comment period on drafts of the proposed collection. Therefore, we believe the PRA process is appropriate and sufficient to use when establishing any future data collection subject to its terms.

Comment: While indicating overall support for CMS's position, a commenter requested more clarification on the purpose of increasing CMS's data collection from MA organizations and Part D plan sponsors and requested CMS work with the industry to minimize and reduce reporting burdens. Specifically, the commenter suggested CMS establish guidelines for its proposal and implement the Part C and D plan reporting requirements before proposing new collections.

Response: As we explained in the proposed rule, an increase in detailed data collection would increase transparency as well as CMS's access to data in the MA and Part D programs. The data currently acquired through the Parts C and D reporting requirements are often used for monitoring an MA organization's or Part D plan sponsor's continued compliance with MA and Part D requirements as well as evaluating the success of these programs. At times, we may use an outlier analysis to determine a plan or sponsor's performance relative to industry standards established by the performance of all other organizations and sponsors. *See* §§ 422.504(m) and 423.505(n). Increasing the quality of the data CMS has to support these practices would enhance our ongoing monitoring and enforcement responsibility for the MA and Part D programs. Additionally, a comprehensive, high-quality database of MA and Part D programmatic data will promote more program transparency and assist our efforts to identify and close potential gaps in access to care for Medicare beneficiaries enrolled in these programs.

When creating any new data collection initiative, we will consider and account for the impact the initiative would have on plans and sponsoring organizations and will make an effort to avoid creating excessive burdens, both when necessary to comply with the PRA and as part of our administration of the programs even if the PRA is not applicable. Further, in developing additional meaningful future data collection changes, we are committed to obtaining input from all interested parties as necessary. As we stated in our proposal, the OMB PRA process provides advance notice to interested parties and provides both a 60- and 30-day public comment period on drafts of the proposed collection. Interested parties will have an opportunity to comment on specific guidelines for reporting requirements under consideration.

After consideration of all public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing this provision as proposed, with a minor modification at § 422.516(a) to replace the term ''doctor-patient relationship'' with ''provider-patient relationship''.

S. Amendments To Establish Consistency in Part C and Part D Timeframes for Filing an Appeal Based on Receipt of the Written Decision (§§ 422.582, 422.584, 422.633, 423.582, 423.584, and 423.600)

We proposed to amend the Parts C and D regulations at §§ 422.582(b), 422.584(b), 422.633(d)(1), 423.582(b), 423.584(b) and 423.600(a) with respect to how long an enrollee has to file an appeal with a plan or the Part D Independent Review Entity (IRE). These amendments were proposed to ensure consistency with the regulations at §§ 422.602(b)(2), 423.2002(d), 422.608, and 423.2102(a)(3), applicable to Administrative Law Judge (ALJ) and Medicare Appeals Council (Council) reviews. These ALJ and Council regulations state or cross-reference the Medicare FFS regulations at 42 CFR part 405 that prescribe that the date of

[110] CMS also possesses considerable authority to collect data and other specific information from MA organizations and Part D plan sponsors through §§ 422.504(f) and 423.505(f).

receipt of the notice of decision or dismissal is presumed to be 5 calendar days after the date of the notice unless there is evidence to the contrary. We also proposed that these changes apply to integrated organization determinations and reconsiderations. In addition, because cost plans are required to comply with the MA appeal regulations pursuant to §§ 417.600 and 417.840, these proposed changes will also apply to cost plan appeals.

Pursuant to our authority under section 1856(b) and 1860D–12 of the Act to adopt standards to carry out the Part C and Part D programs, and in order to implement sections 1852(g)(2) and 1860D–4(g) and (h) of the Act regarding coverage decisions and appeals, CMS established procedures and minimum standards for an enrollee to file an appeal regarding benefits with an MA organization, Part D plan sponsor, and IREs. These requirements are codified in regulation at 42 CFR parts 422 and 423, subpart M. See also section 1876(c)(5) of the Act regarding cost plans' obligations to have appeal processes.

Specifically, section 1852(g)(2)(A) of the Act requires that an MA organization shall provide for reconsideration of a determination upon request by the enrollee involved. The reconsideration shall be made not later than 60 days after the date of the receipt of the request for reconsideration. Section 1860D–4(g)(1) of the Act requires that a Part D plan sponsor shall meet the requirements of paragraph (2)(A) of section 1852(g) with respect to providing for reconsideration of a determination upon request by the enrollee involved.

While section 1852 of the Act does not specify the timeframe in which an enrollee must request an appeal of an unfavorable organization determination, integrated organization determination or coverage determination, the timeframe for filing an appeal in the Part C and Part D programs is established in regulations. Sections 422.582(b), 422.633(d)(1), and 423.582(b) state that an appeal must be filed within 60 calendar days from the date of the notice issued as a result of the organization determination, integrated organization determination, coverage determination, or at-risk determination. Plans are permitted to extend this filing deadline for good cause.

As noted in the proposed rule, we continue to believe that a 60 calendar day filing timeframe strikes an appropriate balance between due process rights and the goal of administrative finality in the administrative appeals process. However, to establish consistency with the regulations applicable to ALJ and Council reviews with respect to receipt of the notice of decision or dismissal and how that relates to the timeframe for requesting an appeal, we proposed to account for a presumption that it will generally take 5 calendar days for a notice to be received by an enrollee or other appropriate party. Therefore, we proposed to revise §§ 422.582(b), 422.633(d)(1)(i), 423.582(b), and 423.600(a) to state that a request for a Part C reconsideration, Part D redetermination, Part D at-risk redeterminations and Part D IRE reconsiderations must be filed within 60 calendar days after receipt of the written determination notice. We also proposed to add new §§ 422.582(b)(1), 422.633(d)(1)(i), and 423.582(b)(1), to provide that the date of receipt of the organization determination, integrated organization determination, coverage determination, or at-risk determination is presumed to be 5 calendar days after the date of the written organization determination, integrated organization determination, coverage determination or at-risk determination, unless there is evidence to the contrary. Based on CMS's experience with audits and other similar review of plan documents, we realized that it was standard practice that the date of the written decision notice is the date the plan sends the notice. The presumption that the notice is received 5 calendar days after the date of the decision is a long-standing policy with respect to IRE appeals and has been codified in regulation at §§ 422.602(b)(2), 423.2002(d), and 423.2102(a)(3) regarding hearings before an ALJ and Council; further, § 422.608 regarding MA appeals to the Medicare Appeals Council provides that the regulations under part 405 regarding Council review apply to such MA appeals, which would include the provision at § 405.1102(a)(2) that applies the same 5 calendar day rule. To ensure consistency throughout the administrative appeals process, we proposed to adopt this approach for plan and Part D IRE appeals in §§ 422.582(b), 422.633(d)(1), 423.582(b), 423.584 and 423.600(a).

In addition to the aforementioned proposals related to when an organization determination, integrated organization determination, coverage determination, or at-risk determination is presumed to be received by an enrollee of other appropriate party, we also proposed adding language to §§ 422.582, 422.633, 423.582 and 423.600(a) that specifies when an appeal is considered filed with a plan and the Part D IRE. Specifically, we proposed to add new §§ 422.582(b)(2), 422.633(d)(1)(ii), 423.582(b)(2) and 423.600(a) to provide that for purposes of meeting the 60 calendar day filing deadline, the appeal request is considered filed on the date it is received by the plan, plan-delegated entity or Part D IRE specified in the written organization determination, integrated organization determination, coverage determination, at-risk determination, or redetermination. As stated in the proposed rule, inclusion of when a request is considered filed would codify what currently exists in CMS's sub-regulatory guidance and the Part D IRE procedures manual. CMS's sub-regulatory guidance indicates that a standard request is considered filed when any unit in the plan or delegated entity receives the request. An expedited request is considered filed when it is received by the department responsible for processing it. Pursuant to existing manual guidance, plan material should clearly state where requests should be sent, and plan policy and procedures should clearly indicate how to route requests that are received in an incorrect location to the correct location as expeditiously as possible.

These proposed revisions related to when a notice is presumed to have been received would ensure that the time to request an appeal is not truncated by the time it takes for a coverage decision notice to reach an enrollee by mail or other delivery method. We noted that if the proposals were finalized, corresponding changes would be made to the Part C and Part D standardized denial notices so that enrollees are accurately informed of the timeframe for requesting an appeal.

We also proposed clarifications to §§ 422.584(b) and 423.584(b) to explicitly state the timeframe in which an enrollee must file an expedited plan appeal for it to be timely. The current text of §§ 422.584 and 423.584 does not include the 60 calendar day timeframe for filing an expedited appeal request, but as noted in the proposed rule, CMS manual guidance for Part C and Part D appeals has long reflected this 60 calendar day timeframe. We also noted that this timeframe for filing an appeal is consistent with the current regulations at §§ 422.582(b) and 423.582(b) for filing a request for a standard appeal. Neither sections 1852 and 1860D–4 of the Act, nor §§ 422.584 and 423.584 specify the timeframe in which an enrollee must request an expedited appeal of an unfavorable organization determination, coverage determination or at-risk determination in the Part C and Part D programs. This provision would codify existing

guidance. We are certain that plans already comply as this long-standing policy is reflected in CMS's sub-regulatory guidance [111] and standardized denial notices [112] that explain an enrollee's right to appeal. Additionally, we had not received any complaints on this matter. In proposing new §§ 422.584(b)(3) and (4) and 423.584(b)(3) and (4), we also proposed to add the procedure and timeframe for filing expedited organization determinations and coverage determinations consistent with proposed requirements at §§ 422.582(b)(1) and (2) and 423.582(b)(1) and (2).

If finalized, we believe these proposals will enhance consistency in the administrative appeals process and provide greater clarity on the timeframe for requesting an appeal and when an appeal request is considered received by the plan. Theoretically, the proposed amendments may result in a small increase in the number of appeals from allowing 65 versus 60 days to appeal an organization determination, integrated organization determination, coverage determination or at-risk determination. However, based on the low level of dismissals at the plan level due to untimely filing, we believe most enrollees who wish to appeal a denial do so immediately, thereby mitigating the impact of 5 additional days for a plan to accept an appeal request if this proposal is finalized. Consequently, we do not believe there is an impact to the Medicare Trust Fund. We solicited interested party input on the accuracy of this assumption.

We received the following comments, and our responses follow.

Comment: We received several comments in support of extending the current 60-day timeframe to file an appeal with an MA or Part D plan to include 5 additional calendar days as proof of receipt of the written determination notice believing that it expanded beneficiary access to the appeals process. Commenters appreciated that the additional time period would also apply to expedited appeal requests, expedited organization determinations, and coverage determinations, while a few of the commenters noted that the proposal was consistent with appeals timeframes in Social Security, SSI, and Medicare more generally, and provides needed clarity for enrollees and their representatives. A few commenters also expressed support and stated the proposal reflected the reality of slower post office delivery times in recent years, as well extra time needed to forward mail for individuals who have changed their addresses.

Response: We appreciate the comments in support of our proposal.

Comment: A commenter stated agreement with establishing consistency in Part C and Part D appeals timeframes, but suggested that instead of specifying that an appeal request be filed within in 60 calendar days after receipt of the written determination notice, CMS should instead require that appeal requests be filed within in 65 calendar days of the letter date.

Response: We thank the commenter for this recommendation; however, we decline to revise our proposal because CMS proposed these amendments to ensure consistency with the regulations at §§ 422.602(b)(2), 423.2002(d), 422.608, and 423.2102(a)(3), applicable to Administrative Law Judge (ALJ) and Medicare Appeals Council (Council) reviews, that either state or cross-reference the Medicare FFS regulations at 42 CFR part 405 that prescribe that the date of receipt of the notice of decision or dismissal is presumed to be 5 calendar days after the date of the notice, unless there is evidence to the contrary. The commenters recommendation would not accomplish this consistency.

After consideration of the public comments, and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the revisions to §§ 422.582, 422.584, 422.633, 423.582, 423.584, and 423.600 as proposed.

T. Authorized Representatives for Parts C/D Elections (§§ 422.60 and 423.32)

Section 1851(c)(1) of the Act gives the Secretary the authority to establish a process through which MA elections, that is, enrollments and disenrollments, are made and changed. This authority includes establishing the form and manner in which elections are made. Section 1860D–1(b)(1)(A) of the Act gives the Secretary the authority to establish a process for enrollment, disenrollment, termination, and change of enrollments in Part D prescription drug plans. Likewise, section 1860D–1(b)(1)(B)(ii) of the Act directs CMS to use rules similar to those established in the MA context pursuant to 1851(c) for purposes of establishing rules for enrollment, disenrollment, termination, and change of enrollment with an MA–PD plan.

Consistent with these sections of the Act, Parts C and D regulations set forth our election processes under §§ 422.60 and 423.32. These enrollment processes require that Part C/D eligible individuals wishing to make an election must file an appropriate enrollment form, or other approved mechanism, with the plan. The regulations also provide information for plans on the process for accepting election requests, notice that must be provided, and other ways in which the plan may receive an election on behalf of the beneficiary.

Though the term ''authorized representative'' is not used in the context of the statutory provisions within the Act governing MA and Part D enrollment and eligibility (*e.g.,* sections 1851 and 1860D–1), ''authorized representative''—and other similar terms—are used in other contexts throughout the Act. Section 1866(f)(3) of the Act defines the term ''advance directive,'' deferring to applicable state law to recognize written instructions such as a living will or durable power of attorney for health care. Section 1862(b)(2)(B)(vii)(IV) of the Act recognizes that an individual may be represented by an ''authorized representative'' in secondary payer disputes. Section 1864(a) of the Act allows a patient's ''legal representative'' to stand in the place of the patient and give consent regarding use of the patient's medical records.

In the June 1998 interim final rule that first established the M+C program, now the MA program (63 FR 34985), we acknowledged in Part C enrollment regulations at § 422.60(c) that there are situations where an individual may assist a beneficiary in completing an enrollment request and required the individual to indicate their relationship to the beneficiary. In the Medicare Program; Medicare Prescription Drug Benefit final rule which appeared in the **Federal Register** on January 28, 2005, (70 FR 4193), we first recognized in § 423.32(b)(i) that an authorized representative may assist a beneficiary in completing an enrollment request, and required authorized representatives to indicate that they provided assistance. In response to public comments about the term ''authorized representative'' in that rule, we indicated that CMS would recognize and rely on State laws that authorize a person to effect an enrollment on behalf of a Medicare beneficiary for purposes of this provision (42 FR 4204). We also stated that the authorized representative would constitute the ''individual'' for purposes of making the enrollment or disenrollment request.

[111] *https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.*

[112] *https://www.cms.gov/medicare/medicare-general-information/bni/madenialnotices.*

Historically, we have provided the definition and policies related to authorized representatives in our sub-regulatory manuals.[113] We proposed in the November 2023 proposed rule to add new paragraphs §§ 422.60(h) and 423.32(h) to codify our longstanding guidance on authorized representatives making Parts C and D elections on behalf of beneficiaries.

Current regulation in § 423.32(b)(i) acknowledges that an ''authorized representative'' may assist a beneficiary in completing an enrollment form, but it does not define who an ''authorized representative'' is. A similar term, ''representative,'' is currently defined under §§ 422.561 and 423.560; however, that definition is used only in the appeals context and applies only to subpart M of the MA and Part D regulations. Therefore, we proposed to define the term ''authorized representative'' for subpart B (eligibility, election, and enrollment).

Our proposal deferred to the law of the state in which the beneficiary resides to determine who is a legal representative. Deference to state law on these matters is consistent with other similar practices within CMS, including in the MA appeals definition of ''representative'' (§ 422.561) and Medicaid's definition of ''authorized representative'' (§§ 435.923; 438.402), as well as in the HIPAA Privacy Rule description of ''personal representative'' (45 CFR 164.502(g)).

For those with state legal authority to act and make health care decisions on behalf of a beneficiary, we proposed to codify at paragraph (h)(1) of § 422.60 and (h)(1) of § 423.32 that authorized representatives will constitute the ''beneficiary'' or the ''enrollee'' for the purposes of making an election, meaning that CMS, MA organizations, and Part D sponsors will consider the authorized representative to be the beneficiary/enrollee during the election process. Any mention of beneficiary/enrollee in our enrollment and eligibility regulations would be considered to also include ''authorized representative,'' where applicable. Our proposal at paragraph (h)(2) of § 422.60 and (h)(2) of § 423.32 clarified that authorized representatives under state law may include court-appointed legal guardians, durable powers of attorney for health care decisions and state surrogate consent laws as examples of those state law concepts that allow the authorized representative to make health care decisions on behalf of the individual. This is not a complete list; we would defer to applicable state law granting authority to act and make health care decisions on behalf of the beneficiary.

Codifying this longstanding guidance provides plans, beneficiaries and their caregivers, and other interested parties clarity and transparency on the requirements when those purporting to be the representatives of the beneficiary attempt to make election decisions on their behalf. We have not received negative public feedback on this longstanding policy. However, we have recently answered questions on plan procedures when dealing with authorized representatives. We proposed to codify this longstanding guidance in order to clarify our policy regarding the role of authorized representatives in the MA and Part D enrollment process, including the applicability of state law in this context.

This proposal codifies longstanding MA and Part D sub-regulatory guidance. Based on questions from plans and beneficiaries related to current guidance, we concluded that the guidance had been previously implemented and is currently being followed by plans. Therefore, we concluded there was no additional paperwork burden associated with codifying this longstanding sub-regulatory policy, and there would also be no impact to the Medicare Trust Fund. All information impacts related to the current process for determining a beneficiary's eligibility for an election period and processing election requests have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267), 0938–1378 (CMS–10718), and 0938–0964 (CMS–10141).

We received the following comments, and our responses follow.

Comment: Several commenters expressed general support for this proposal, with one commenter noting that the term ''authorized representative'' can be ambiguous and, thus, it was good for CMS to codify the existing policy.

Response: We appreciate the comments in support of our proposal.

Comment: One commenter requested that CMS establish a form, outside of state law requirements, that individuals can use to appoint an authorized representative to act on their behalf for MA/Part D enrollment purposes.

Response: We thank the commenter for their proposal. We decline to revise our proposal because it is CMS's standard practice to defer to state law on similar matters of legally authorized representation. We believe that compliance with state law requirements for establishing authorized representation serves as an important form of beneficiary protection. We believe that states are better positioned to determine these requirements and resolve any disputes over representative appointment and scope.

Comment: One commenter suggested the removal of ''as the law of the State in which the beneficiary resides may allow,'' from our proposed regulatory text. The commenter was concerned that, as proposed, the regulatory text required state law to specifically address the appointment of a representative for Medicare enrollment purposes. The commenter also requested clarification on the difference between an authorized representative and those who provide information during, or otherwise assist the individual in, the enrollment process.

Response: We disagree with this interpretation. As stated above, we defer to applicable state law granting a representative the authority to act and make health care decisions on behalf of the beneficiary. States would not need to specifically address the power to make Medicare enrollment decisions on behalf of an individual. Authorized representatives may include court-appointed legal guardians, persons having durable powers of attorney, or individuals authorized to make health care decisions under state surrogate consent agreements, provided that the specific state law mechanism for establishing legal representation would allow the representative to make health care decisions on the individual's behalf.

We also clarify that assisting a beneficiary in the enrollment process is different from representing that beneficiary in a legal capacity. For example, a family member might help an individual read and fill out an enrollment application, but they are not completing the application on behalf of the individual. Assisting a family member is different from attesting that they are acting on their behalf as an authorized representative. If an individual is merely receiving assistance with the application, they would still complete and sign their own application. Whereas an authorized representative provides their signature and an attestation that they are authorized by law to act on the individual's behalf.

Comment: Several commenters requested that ''authorized representatives'' be excluded from the 48-hour waiting period between a Scope of Appointment and a personal

[113] This guidance can be found in Chapter 2, Sections 10 and 40.2.1 of the Medicare Managed Care Manual and Chapter 3, Sections 10 and 40.2.1 of the Prescription Drug Benefit Manual.

marketing appointment with an agent/broker.

Response: We thank the commenters for this recommendation, but these requests are related to existing marketing regulations and are, thus, outside the scope of the proposal.

After consideration of all public comments and for the reasons discussed here and in the proposed rule, we are finalizing our proposal with a technical change to add the language as new paragraphs §§ 422.60(i) and 423.32(j) instead of §§ 422.60(h) and 423.32(h).

U. Open Enrollment Period for Institutionalized Individuals (OEPI) End Date (§ 422.62(a)(4))

Section 1851(e) of the Act establishes the coverage election periods for making or changing elections in the M+C, later known as MA, program. Section 501(b) of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) amended Section 1851(e)(2) of the Act by adding a new subparagraph (D), which provides for continuous open enrollment for institutionalized individuals after 2001. CMS published a final rule with comment period (65 FR 40317) in June 2000 implementing section 1851(e)(2)(D) by establishing a new continuous open enrollment period for institutionalized individuals (OEPI) at then § 422.62(a)(6). In subsequent rulemaking (83 FR 16722), the OEPI regulations were further updated to reflect conforming changes related to implementation of Title II of The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) (70 FR 4717) and to redesignate this provision from § 422.62(a)(6) to (a)(4).

As noted above, the OEPI is continuous. Individuals may use the OEPI to enroll in, change, or disenroll from a plan. Individuals are eligible for the OEPI if they move into, reside in, or move out of an institution. Longstanding sub-regulatory guidance has stated that the OEPI ends 2 months after an individual moves out of an institution, but this has not been articulated in regulations.[114]

To provide transparency and stability for plans, beneficiaries and their caregivers, and other interested parties about this aspect of MA enrollment, we proposed in the November 2023 proposed rule to codify current sub-regulatory guidance that defines when the OEPI ends. Specifically, we proposed to codify at new subparagraph § 422.62(a)(4)(ii) that the OEPI ends on the last day of the second month after the month the individual ceases to reside in one of the long-term care facility settings described in the definition of ''institutionalized'' at § 422.2.

This proposal defined when the OEPI ends and would not result in a new or additional paperwork burden since MA organizations are currently implementing the policy related to the OEPI end date as part of existing enrollment processes. All burden impacts related to an applicant's eligibility for an election period have already been accounted for under OMB control number 0938–0753 (CMS–R–267). Similarly, we stated in the proposed rule that we did not believe the proposed changes would have any impact to the Medicare Trust Fund.

We received the following comments, and our responses follow.

Comment: A commenter supported the proposal to codify the definition of when the OEPI ends.

Response: We thank the commenter for the support.

Comment: A commenter supported the proposal and encouraged CMS to further clarify that the OEPI also permits institutionalized individuals to enroll in a special needs plan (SNP) or Program of All-Inclusive Care for the Elderly (PACE) plan, in addition to an MA plan or Original Medicare.

Response: We appreciate the feedback and acknowledge that the OEPI allows institutionalized individuals to enroll in an MA plan, an SNP (which is a type of MA plan), or discontinue enrollment in an MA plan and enroll in Original Medicare. PACE is addressed under separate regulations and we note that individuals enrolling in the PACE program do not require an election period.

Comment: A commenter suggested that we include institutionalized-equivalent for purposes of OEPI.

Response: We appreciate the feedback but note that the proposed change pertained to the period of time in which an individual is eligible for the OEPI and able to make an election, not to the election period eligibility criteria. As such, this recommendation is outside of the scope of the proposed rulemaking.

After consideration of all public comments and for the reasons described here and in the November 2023 proposed rule, we are finalizing our proposal to amend § 422.62(a)(4) without modification.

V. Beneficiary Choice of C/D Effective Date if Eligible for More Than One Election Period (§§ 422.68 and 423.40)

Section 1851(f) of the Act establishes the effective dates of elections and changes of elections for MA plans. In the June 1998 interim final rule, we specified the effective dates for elections and changes of elections of M+C (now MA) plan coverage made during various specified enrollment periods (63 FR 34968). The effective date requirements for the initial coverage election period (ICEP), annual election period (AEP), MA open enrollment period (MA–OEP), open enrollment period for institutionalized individuals (OEPI), and special election periods (SEP) are codified in regulation at § 422.68. For Part D plans, section 1860D–1(b)(1)(B)(iv) of the Act directs us to establish similar rules for effective dates of elections and changes of elections to those provided under the MA program statute at section 1851(f). In the January 2005 Part D final rule, we specified the effective dates for elections and changes of elections of Part D coverage made during various specified enrollment periods (70 FR 4193). The effective date requirements for the initial enrollment period (IEP) for Part D, AEP, and SEPs are codified in regulation at § 423.40.

Existing regulations at §§ 422.68 and 423.40 do not address what the MA organization or Part D plan sponsor should do when a beneficiary is eligible for more than one election period, thus resulting in more than one possible effective date for their election choice. For example, the beneficiary is eligible to make a change in their election choice during the MA–OEP, but they are also eligible for an SEP due to changes in the individual's circumstances. Current sub-regulatory guidance provides that the MA organization or Part D plan sponsor determine the proper effective date based on the election period for which the beneficiary is eligible before the enrollment or disenrollment may be transmitted to CMS.[115] Because the election period determines the effective date of the election in most instances, with the exception of some SEPs or when election periods overlap, beneficiaries may not request their election effective date. The MA organization or Part D plan sponsor determines the effective date once the election period is identified. If a beneficiary is eligible for more than one election period, which results in more than one possible effective date, CMS's sub-regulatory guidance[116] directs the

[114] This guidance can be found in Chapter 2, Section 30.3 of the Medicare Managed Care Manual.

[115] This guidance can be found in Chapter 2, Section 30.6 and 30.7 of the Medicare Managed Care Manual and Chapter 3, Section 30.4 and 30.5 of the Prescription Drug Benefit Manual.

[116] This guidance can be found in Chapter 2, Section 30.6 of the Medicare Managed Care Manual

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MA organization or Part D plan sponsor to allow the beneficiary to choose the election period that results in the desired effective date. To determine the beneficiary's choice of election period, MA organizations and Part D plan sponsors are instructed to attempt to contact the beneficiary, and to document their attempt(s). However, sub-regulatory guidance [117] states that this does not apply to beneficiary requests for enrollment into an employer or union group health plan (EGHP) using the group enrollment mechanism. Beneficiaries who make an election via the employer or union election process will be assigned an effective date according to the SEP EGHP, unless the beneficiary requests a different effective date that is allowed by one of the other election periods for which they are eligible.

Because a beneficiary must be entitled to Medicare Part A and enrolled in Medicare Part B in order to be eligible to receive coverage under an MA or MA–PD plan, CMS's sub-regulatory guidance [118] explains that if one of the election periods for which the beneficiary is eligible is the ICEP, the beneficiary may not choose an effective date any earlier than the month of entitlement to Part A and enrollment in Part B. Likewise, because a beneficiary must be entitled to Part A or enrolled in Part B in order to be eligible for coverage under a Part D plan, sub-regulatory guidance explains that if one of the election periods for which the beneficiary is eligible is the Part D IEP, the beneficiary may not choose an effective date any earlier than the month of entitlement to Part A and/or enrollment in Part B.[119]

Furthermore, sub-regulatory guidance [120] provides that if a beneficiary is eligible for more than one election period and does not choose which election period to use, and the MA organization or Part D plan sponsor is unable to contact the beneficiary, the MA organization or Part D plan sponsor assigns an election period for the beneficiary using the following ranking of election periods (1 = Highest, 5 = Lowest): (1) ICEP/Part D IEP, (2) MA–OEP, (3) SEP, (4) AEP, and (5) OEPI. The election period with the highest rank generally determines the effective date of enrollment. In addition, if an MA organization or Part D sponsor receives a disenrollment request when more than one election period applies, the plan is instructed to allow the beneficiary to choose which election period to use. If the beneficiary does not make a choice, then the plan is directed to assign the election period that results in the earliest disenrollment.

To provide transparency and stability about the MA and Part D program for plans, beneficiaries, and other interested parties, we proposed at new §§ 422.68(g) and 423.40(f) that if the MA organization or Part D plan sponsor receives an enrollment or disenrollment request, determines the beneficiary is eligible for more than one election period and the election periods allow for more than one effective date, the MA organization or Part D plan sponsor must allow the beneficiary to choose the election period that results in the desired effective date. We also proposed at §§ 422.68(g)(1) and 423.40(f)(1) that the MA organization or Part D plan sponsor must attempt to contact the beneficiary and must document its attempt(s) to determine the beneficiary's choice. The plan may contact the beneficiary by phone, in writing, or any other communication mechanism. Plans would annotate the outcome of the contact(s) and retain the record as part of the individual's enrollment or disenrollment request. In addition, we proposed at §§ 422.68(g)(2) and 423.40(f)(2) to require that the MA organization or Part D plan sponsor must use the proposed ranking of election periods to assign an election period if the beneficiary does not make a choice. With the exception of the SEP EGHP noted earlier, if a beneficiary is simultaneously eligible for more than one SEP and they do not make a choice, and the MA organization or PDP sponsor is unable to obtain the beneficiary's desired enrollment effective date, the MA organization or PDP sponsor should assign the SEP that results in an effective date of the first of the month after the enrollment request is received by the plan. Finally, we proposed at §§ 422.68(g)(3) and 423.40(f)(3) to require that if the MA organization or Part D plan sponsor is unable to obtain the beneficiary's desired disenrollment effective date, they must assign an election period that results in the earliest disenrollment.

This proposal represented the codification of longstanding MA and Part D sub-regulatory guidance. Based on infrequent complaints and questions from plans and beneficiaries related to current guidance, we concluded that the guidance has been previously implemented and is currently being followed by plans. We concluded that there was no additional paperwork burden associated with codifying this longstanding sub-regulatory policy, and there was also no impact to the Medicare Trust Fund. All information impacts related to the current process for determining a beneficiary's eligibility for an election period and processing election requests have already been accounted for under OMB control number 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D.

We received the following comments, and our responses follow.

Comment: Commenters were generally supportive of the proposal as written, with some commenters noting that it reflects current practices and prioritizes beneficiary preference.

Response: We thank the commenters for the support.

Comment: A commenter supported the proposal but suggested that CMS require plans to exhaust all available communication methods if the beneficiary does not respond to plan attempts to reach them.

Response: We appreciate the suggestion. However, we believe the parameters of the proposal to require the plan to attempt to contact the individual to indicate a desired effective date is sufficient. We encourage plans to attempt to contact individuals using all feasible communication methods including by phone, in writing, or another preferred method.

Comment: Several commenters suggested updating Medicare.gov to allow individuals to indicate their desired effective date during online enrollments, which would alleviate plan burden in needing to contact individuals who are eligible for more than one election period. One of the commenters added as an example that an individual may end up overlapping their EGHP coverage with Medicare coverage for a period of time if they do not understand the different enrollment timeframes or which SEP applies to their situation.

Response: We appreciate the commenters' feedback. We will consider future updates to Medicare.gov that would enable individuals to indicate their preferred effective date or provide explanations that help individuals better understand possible effective dates or which SEP timeframes apply to their situation.

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and Chapter 3, Section 30.4 of the Prescription Drug Benefit Manual.

[117] This guidance can be found in Chapter 2, Section 30.6 of the Medicare Managed Care Manual and Chapter 3, Section 30.4 of the Prescription Drug Benefit Manual.

[118] This guidance on effective dates of elections is currently outlined in section 30.6 of Chapter 2 of the Medicare Managed Care Manual.

[119] This guidance on effective dates of elections is currently outlined in section 30.4 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

[120] This guidance can be found in sections 30.6 and 30.7 of Chapter 2 of the Medicare Managed Care Manual and sections 30.4 and 30.5 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Comment: A commenter suggested that the individual should be asked by the plan at the time of their enrollment when they want their plan coverage to begin. The commenter added that if an individual does not select their desired effective date when they contact the plan to enroll, CMS should require the plan to space out the three-attempt contact requirement.

Response: We appreciate the feedback. If an individual is enrolling with the plan in person or by phone, we encourage the plan to ask the individual to indicate their preferred effective date. The proposal and sub-regulatory guidance do not specify that plans need to make three attempts to contact the individual if they do not indicate their preferred effective date. However, plans are strongly encouraged to make multiple contact attempts to request additional information from individuals before assigning an effective date.

Comment: A commenter requested additional information in the sub-regulatory guidance regarding the required timeframe to contact the individuals about selecting their enrollment effective date.

Response: Plans determine which election period applies to each individual to assign the proper election period and effective date before the enrollment may be transmitted to CMS. Plans should contact individuals eligible for more than one election period about selecting their enrollment effective date within the timeframes for processing enrollment requests. Sub-regulatory guidance for processing enrollment requests in sections 40.3 of Chapter 2 of the Medicare Managed Care Manual and 40.3 of the Chapter 3 of the Medicare Prescription Drug Benefit Manual explains the timeframe for processing and transmitting election requests to CMS. Plans are required to submit the information necessary for CMS to add the individual to its records as an enrollee of the MA organization or PDP sponsor within 7 calendar days of receipt of the completed enrollment request.

Comment: A commenter stated that allowing dually eligible beneficiaries to choose the election period that results in a desired effective date for MA or Part D could influence utilization patterns and impact associated costs for health care services. The commenter added that changes to enrollment periods and requirements could result in member disenrollment or churn, which may affect the financial stability of MA organizations.

Response: While we appreciate the feedback, we do not believe this change would have such an impact on utilization patterns and associated costs for health care services. This change allowing the beneficiary to choose the election period that results in the desired effective date codifies longstanding sub-regulatory guidance and has been previously implemented by plans. Therefore, we expect that codifying this proposal will have minimal impact on plans' current enrollments.

After consideration of all public comments, for the reasons described here and in the November 2023 proposed rule, we are finalizing our proposal at §§ 422.68(g) and 423.40(f) without modification.

VI. Medicare Advantage/Part C and Part D Prescription Drug Plan Marketing

A. Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (§§ 422.2274(g) and 423.2274(g))

In the December 2022 proposed rule, CMS proposed to add a new paragraph (4) at §§ 422.2274(g) and 423.2274(g) to address issues with third party marketing organizations (TPMOs) distributing beneficiary contact information to other TPMOs, in any manner, including selling this information.[121] In paragraph (4), we proposed that personal beneficiary data collected by a TPMO may not be distributed to other TPMOs. We explained that when a beneficiary calls a 1–800 number from a direct mail flyer, a television advertisement, or an internet advertisement, or other similar material, the beneficiary most likely believes they are only responding to or calling—and requesting contact with—the entity that advertised the 1–800 number and answers the call. However, some of these entities, in quickly read disclaimers or through web or printed material-based disclaimers in very small font, inform the beneficiary that their personal contact information may be sold or distributed to other entities. The contact information (name, address, phone number) obtained by these entities is then sold or distributed to one or more TPMOs, such as field marketing organizations and/or agents/brokers. As a result, these other entities then reach out or call the beneficiary, using the initial incoming call and the contact information obtained by the TPMO from that incoming call, as a form of permission to reach out and contact the beneficiary. We asserted that when a beneficiary calls an entity based on an advertisement, the beneficiary is only expecting to connect with that particular entity, not to have return calls made to their personal home or cell number from other entities.

As discussed in the December 2022 proposed rule, CMS has learned through environmental scanning efforts that the selling and reselling of beneficiary contact information is happening as described here and that beneficiaries are unaware that by placing the call or clicking on the web-link they are unwittingly agreeing for their contact information to be collected and sold to other entities and providing consent for future marketing activities. We did not believe that beneficiaries knowingly gave their permission to receive multiple calls from multiple different entities based on a single call made by a beneficiary and that beneficiaries intended in these scenarios that their information would be received only by one entity, that being the plan or agent or broker that will ultimately receive the beneficiary's enrollment request. As another example of this type of behavior, we noted in the December 2022 proposed rule that CMS was aware of situations where entities require the beneficiary to agree to allowing their contact information to be resold or shared prior to speaking with a representative or having access to any information. In these situations, a beneficiary initiates contact with one entity and then ends up receiving calls from multiple other unrelated entities. Additionally, we asserted that providing a quickly read disclaimer or providing a disclaimer in very small print or placing a disclaimer in an inconspicuous place when that disclaimer indicates that a beneficiary's contact information may be provided or sold to another entity or party, are considered misleading marketing tactics because these entities are using beneficiary contact information in a manner in which the beneficiary did not intend.

In order to address this type of activity, we proposed to add a new paragraph (4) to §§ 422.2274(g) and 423.2274(g) that would prohibit TPMOs from distributing any personal beneficiary data that they collect to other TPMOs. In the December 2022 proposed rule, we noted that this proposal was consistent with the statutory prohibition on unsolicited contact contained within sections 1851(j)(1)(A) and 1860D–04(l)(1) of the Act, as well as the corresponding CMS regulations at 42 CFR 422.2264(a)(3) and 423.2264(a)(3). In addition, we note that CMS's authority to promulgate rules related to TPMOs in this circumstance also derives from sections 1851(h)(4)(C)

[121] 87 FR 79535.

and 1860D–01(b)(1)(B)(vi) of the Act, which allow CMS to establish fair marketing standards that shall not permit MA organizations and Part D plans (and the agents, brokers, and *other third parties representing such organizations)* to conduct the prohibited activities described in subsection 1851(j)(1) of the Act. Likewise, we rely in this situation on sections 1856(b)(1), 1857(e)(1) and 1860D–12(b)(3)(D) of the Act, which grant the Secretary authority to establish by regulation other standards that are consistent with and carry out the statute and to include additional contract terms and conditions that are not inconsistent with the statute and that the Secretary finds necessary and appropriate.

As noted above, CMS proposed in the December 2022 proposed rule to modify §§ 422.2274(g) and 423.2274(g) to prohibit TPMOs from distributing personal beneficiary data to other TPMOs. However, in light of the comments received on our proposal, which we discuss further below, and for the reasons discussed in our responses, we are instead finalizing § 422.2274(g)(4) and 423.2274(g)(4) with revisions compared to our proposal in the December 2022 proposed rule, which will permit TPMOs to share personal beneficiary data with other TPMOs for marketing or enrollment purposes only if they first obtain express written consent from the relevant beneficiary. In our below responses to comments received regarding the proposed changes to §§ 422.2274(g)(4) and 423.2274(g)(4), we further articulate what TPMOs will be required to do to conform with this consent requirement, including what should be included in a disclosure to beneficiaries.

We acknowledge that other agencies regulate certain types of information collection and sharing of personal information, such as the Department of Health and Human Services' Office for Civil Rights (OCR), the Federal Trade Commission (FTC), and the Federal Communications Commission (FCC). OCR administers and enforces the HIPAA Privacy Rule (45 CFR parts 160 and 164 subparts A and E) which provides standards for the use and disclosure of protected health information by HIPAA covered entities and business associates. A covered entity is a health care provider that conducts certain health care transactions electronically, a health plan, or a health care clearinghouse, while a business associate is a person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to protected health information.[122] Generally, protected health information is individually identifiable health information maintained or transmitted by a covered entity or its business associate. The definitions of a covered entity, business associate, and protected health information can be found at 45 CFR 160.103. The HIPAA Privacy Rule requires that covered entities enter contracts or other arrangements with their business associates to ensure that the business associates will appropriately safeguard protected health information.[123] A covered entity or business associate can share protected health information with a telemarketer only if the covered entity or business associate has either obtained the individual's prior written authorization to do so or has entered into a business associate relationship with the telemarketer for the purpose of making a communication that is not marketing, such as to inform individuals about the covered entity's own goods or services.[124] If the telemarketer is a business associate under the HIPAA Privacy Rule, it must agree by contract to use the information only for communicating on behalf of the covered entity, and not to market its own goods or services (or those of another third party).[125]

As such, it becomes relevant for this final rule whether TPMOs are covered entities or business associates that must comply with the HIPAA Privacy Rule. TPMOs (as defined at § 422.2260) have varying degrees of business and contractual arrangements with MA organizations and Part D sponsors (who are covered entities under the HIPAA Privacy Rule) and may or may not be considered business associates under the HIPAA Privacy Rule. It is the responsibility of the TPMO to understand whether they are a covered entity or acting as a business associate when collecting personal beneficiary data that meets the definition of protected health information. If the TPMO is a covered entity or business associate, the TPMO must ensure they are compliant with the HIPAA Privacy, Security, and Breach Notification Rules when using or disclosing an individual's protected health information.

On December 13, 2023, in the Second Report and Order[126] (*FCC 23–107*), the FCC amended consent rules for robotexts and robocalls governed by the Telephone Consumer Protection Act (TCPA). In the order, FCC made it clear that texters and callers subject to the TCPA must obtain a consumer's prior express written consent when telemarketing via robocall or robotext and that the requirement applies a single seller at a time.[127] Furthermore, the rule made clear that ''the consumer's consent is not transferrable or subject to sale to another caller because it must be given by the consumer to the seller.'' [128] Sharing many concerns that CMS articulated in the December 2022 proposed rule[129] and this final rule, the FCC explained that ''lead generated communications are a large percentage of unwanted calls and texts and often rely on flimsy claims of consent and result in consent abuse by unscrupulous robotexters and robocallers.'' [130] The TCPA generally requires callers to get consumer consent before making certain calls or texts to consumers using an ''automatic telephone dialing system'' (also known as an ''autodialer'') or an artificial or prerecorded voice. 47 U.S.C. 227(b)(1)(A).[131] This new rule, once effective, will require lead generators and comparison-shopping websites to obtain one-to-one consent with a clear and conspicuous disclosure from the consumer for each seller that intends to

[122] 45 CFR 160.103.

[123] 45 CFR 164.502(a).

[124] United States Department of Health and Human Services, Office for Civil Rights: *Can telemarketers obtain my health information and use it to call me to sell good and services?, https://www.hhs.gov/hipaa/for-individuals/faq/277/can-telemarketers-obtain-my-health-information-and-use-it/index.html.* Last reviewed January 9, 2023.

[125] United States Department of Health and Human Services, Office for Civil Rights: *Can telemarketers obtain my health information and use it to call me to sell good and services?*

[126] *Federal Communications Commission, FC–23–107: Second Report and Order, Second Further Notice of Proposed Rulemaking in CG Docket NOS. 02–278 and 21–402, and Waiver Order in CG Docket no. 17–59, https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.* Released December 18, 2023.

[127] Federal Communications Commission, FC–23–107, Page 12 of FCC 23–107. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.* The content of the call or text determines whether the prior express consent from the called party must be in writing.

[128] Federal Communications Commission, FC–23–107, Page 21. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[129] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications.

[130] *Federal Communications Commission, FC–23–107,* Page 12. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[131] Federal Communications Commission, *Telephone Consumer Protection Act 47 U.S.C. 227,* RESTRICTIONS ON THE USE OF TELEPHONE EQUIPMENT. *https://www.fcc.gov/sites/default/files/tcpa-rules.pdf.*

make a call or send a text using an automatic telephone dialing system or make a call containing an artificial or prerecorded voice.[132] Therefore, even if a lead generator or comparison-shopping website lists multiple sellers on its web page, each seller is responsible for obtaining the prior express written consent from the called party through a ''clear and conspicuous'' disclosure on the lead generator or comparison-shopping website in order to robocall or robotext the consumer. The changes to the FCC consent rules also require that telemarketing texts and calls that result from consumer consent must be ''logically and topically associated with the interaction that prompted the consent.'' [133] The FCC explained that this requirement makes ''it clear that sharing lead information with a daisy-chain of ''partners'' is not permitted.'' [134] The FCC refers to these changes as ''closing the lead generator loophole'' [135] which will go into effect at a later date, either 12 months after publication in the **Federal Register**, or 30 days after notice that the Office of Management and Budget has completed review of any information collection requirements.[136] These new FCC rules will apply to TPMOs operating in the MA and Part D marketplace that seek to contact Medicare beneficiaries with advertisements or telemarketing messages using an automatic telephone dialing system or an artificial or prerecorded voice.

The FTC also enforces rules and regulations that apply to TPMOs, such as the Telemarketing Sales Rule (TSR) [137] (16 CFR 310) and Section 5 of the FTC Act (FTCA). The TSR is a set of regulations that apply to telemarketing and generally prohibits abusive and deceptive tactics in marketing. Section 5 of the FTCA provides that unfair or deceptive acts or practices in or affecting commerce are declared unlawful (15 U.S.C. 45(a)(1)).[138] We note that the regulations in this rule do not attempt to change or define what is unlawful under OCR, FCC, or FTC regulations; we are reiterating that TPMOs operating in the MA and Part D marketplace must comply with numerous laws and regulations that govern information sharing, disclosure, and consent to be contacted for marketing or enrollment purposes. The limitations being adopted under the MA and Part D statutes in these MA and Part D regulations are not replacements for other protections for individual information collected in the course of marketing or enrollment, but supplement those protections with specific limitations and restrictions to protect Medicare beneficiaries so that CMS can take steps within its authority under Title 18 [139] to protect Medicare beneficiaries (rather than deferring to other agencies to enforce other requirements that offer similar protections).

We received the following comments on this proposal and our responses follow:

Comment: We received several comments that the proposal disregards a beneficiary's choice on whether to opt in to having their personal contact information shared. While some commenters were largely supportive of the total prohibition, citing the protections to beneficiary privacy and autonomy, many commenters believed that beneficiaries should be able to consent to having their information shared. A few commenters stated that TPMOs should be able to share beneficiary contact information when the beneficiary knowingly consents and requests to have it shared, which would not be possible if the rule was finalized as proposed. Another commenter stated that the statute expressly gives beneficiaries the right to solicit direct contacts, and if CMS implemented this new requirement, without any ability for them to consent, that right to permit direct contacts would be taken away from the beneficiary. Some commenters suggested that rather than implementing a full prohibition on sharing information, CMS could introduce measures to clarify how to request consent for the sharing of beneficiary information to multiple entities. Commenters provided suggestions on how to ensure beneficiaries knowingly consent to having their data shared, which included adopting the FTC's clear and conspicuous standard, limitations on who may contact a beneficiary, and how often or for how long a beneficiary may be contacted. A few commenters believed that CMS incorrectly assumes a beneficiary never wants their information to be shared, or that they are unable to make that choice. A commenter agreed that stronger consent is needed, but disagreed with the CMS claim that beneficiaries are not aware that they are opting into their information being shared with multiple entities. Commenters also suggested including more effective disclosures or disclaimers that indicate the resale and/or the specific details of where and to whom this information will be shared. A commenter provided their standards as a resource, which listed the different standards they currently utilize.

Response: CMS thanks commenters that were supportive of our proposal to prohibit the sharing of beneficiaries' personal information and appreciates the various suggestions that commenters provided to allow beneficiaries to consent to the sharing of their personal information. We recognize that other statutory and regulatory frameworks, such as the TCPA, TSR, and HIPAA Privacy Rule, which deal with sharing personal information and contacting consumers, allow individuals to consent to the sharing of their information or the receipt of calls from product and service providers. Equally as important, we recognize the right of beneficiaries to share their personal information and that some may want to share their information with many TPMOs to solicit direct contact from a larger group of TPMOs to assist them in selecting a health plan that best meets their needs. Therefore, we agree with the commenters that beneficiaries should be able to consent to having their personal information shared in a clear and understandable way and have modified the proposed regulation text to provide for this option. In this final rule and based upon suggestions received in comments, we are codifying that personal beneficiary data collected by a TPMO for marketing or enrolling the beneficiary into an MA or Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Further, we are codifying that prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained separately for each TPMO that receives the data through a clear and conspicuous disclosure. We believe that beneficiaries have the right to share their personal data with whom they choose and should have the opportunity

[132] *Federal Communications Commission, FC–23–107,* Page 12. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[133] *Federal Communications Commission, FC–23–107,* Page 51. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[134] *Federal Communications Commission, FC–23–107,* Page 14. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[135] *Federal Communications Commission, FC–23–107,* Page 12. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[136] *Federal Communications Commission, FC–23–107, VII. ORDERING CLAUSES,* Page 39. *https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[137] *https://www.ecfr.gov/current/title-16/part-310.*

[138] *https://uscode.house.gov/view.xhtml?req=(title:15%20section:45%20edition:prelim)%20OR%20(granuleid:U.S.C.-prelim-title15-section45)&f=treesort&num=0&edition=prelim.*

[139] *https://www.ssa.gov/OP_Home/ssact/title18/1800.htm.*

to fully understand with whom their personal data may be shared. By finalizing the rule in this way, we are not codifying an outright prohibition of sharing personal beneficiary data. CMS sought technical studies on the results of limiting beneficiary data sharing and its effectiveness. For example, in a 2023 Pew Survey, CMS learned from Pew's findings that ''overall, 72% [of Americans] say there should be more government regulation of what companies can do with their customers' personal information.'' [140] The survey also revealed that ''a majority of Americans say they are concerned, lack control and have a limited understanding about how the data collected about them is used.'' [141] No studies that we can find exist on whether completely limiting the distribution improves the beneficiary experience. We have, however, numerous complaints, both through 1–800-Medicare, the new FCC Second Report and Order [142] cited earlier, as well as State Health Insurance Programs, testimony from health insurance administrators and executives,[143] and advocacy groups noting that the overwhelming number of marketing calls beneficiaries receive from TPMOs are unwanted, confusing, and inhibit the beneficiary's ability to make an informed choice. Our final rule aims to limit when a beneficiary's personal data can be shared and ensures that they know who will be contacting them, which we believe will lower the number of complaints, be less overwhelming, and will result in beneficiaries having a more meaningful discussion with fewer agents, and ultimately enrolling in a health plan that best meets their needs.

We are codifying the regulation text in a way that is generally consistent with the one-to-one consent structure announced by the FCC in the Second Report and Order [144] (*FCC 23–107*) in order to make it simple and less arduous for a TPMO to comply with both rules, when applicable. The FCC's Order amends the definition of prior express written consent at 47 CFR 64.1200 for a person to be called or texted advertisements or telemarketing messages using an automatic telephone dialing system or an artificial or prerecorded voice by requiring an agreement, in writing, that bears the signature of the person called or texted that clearly and conspicuously authorizes no more than one identified seller. The FCC explained that if a lead generator or comparison-shopping website seeks to obtain prior express written consent for multiple sellers, they must obtain prior express written consent separately for each seller. Secondly, the FCC Order requires a written agreement that includes a clear and conspicuous disclosure informing the person signing that they are authorizing the seller to deliver or cause to be delivered to the signatory telemarketing calls or texts using an automatic telephone dialing system or an artificial or prerecorded voice. The FCC defined clear and conspicuous as ''notice that would be apparent to a reasonable consumer.'' [145]

We believe that prior express written consent, one-to-one from person to seller, through a clear and conspicuous disclosure to share personal beneficiary data with another TPMO, is a reasonable and less restrictive standard than a ''complete prohibition'' on the sharing of personal beneficiary data with other TPMOs. This consent and disclosure are necessary to provide beneficiaries with the information they need to understand where their personal data is going, what they are consenting to being contacted about, and who will be contacting them for health care options. Prior express *written* consent will ensure that there is a record of the beneficiary consenting to the sharing of their data, which can easily be obtained through a website interface, but can also be provided through email or text message when a beneficiary calls a toll-free number. By adopting the one-to-one consent requirement, we will prevent TPMOs from having to build a different consent and disclosure structure on their websites and systems because it aligns with the one-to-one consent structure in the FCC rules on consenting to telemarketing calls or texts using an automatic telephone dialing system or an artificial or prerecorded voice. Under the FCC's new rules, if a TPMO marketing MA or Part D plan options wants to robotext or robocall a beneficiary, they must obtain consent from the beneficiary that they agree for that specific entity to contact them via robotext or robocall. Similarly, under our amended rule, if a TPMO wants to share a beneficiary's personal data with another TPMO, the TPMO must obtain consent from the beneficiary for each entity that it intends to share the data with. Thus, the shared one-to-one consent structure will make it easier for TPMOs to collect both consents at the same time; a consent to share the beneficiary's personal data with a specific entity and the consent for that entity to robotext, robocall, or call the beneficiary, as applicable.

In addition, this rule will prevent the sharing of personal beneficiary data with another TPMO unless expressly authorized by the beneficiary, which means beneficiaries will not be called by TPMOs with whom they have not given permission to be called, even when the new FCC rule does not apply (*i.e.,* a manually dialed phone call). Finally, the regulation requires a ''clear and conspicuous'' disclosure to the beneficiary, which is a standard used in the FCC Order as well as by the FTC as defined at 16 CFR 255.0(f). Under 16 CFR part 255—Guides Concerning Use of Endorsements and Testimonials in Advertising, the FTC defines clear and conspicuous to mean ''that a disclosure is difficult to miss (*i.e.,* easily noticeable) and easily understandable by ordinary consumers.'' [146] The FTC also provides numerous examples to illustrate how the definition of clear and conspicuous is applied in real life examples in Part 255.[147] We find the FCC and FTC definition of clear and conspicuous to be similar but point to the FTC's definition as guiding for our rule because the definition has been recently updated [148] and there are numerous examples that can help guide TPMOs in how to apply it.

We understand that sometimes a beneficiary can be connected to another TPMO in real time. For example, a beneficiary may call a TPMO seeking to get information about Medicare plan options and that TPMO, in order to assist the beneficiary, may be able to

[140] Pew Research Center, *How Americans View Data Privacy: Views of data privacy risks, personal data and digital privacy laws. https://www.pewresearch.org/internet/2023/10/18/views-of-data-privacy-risks-personal-data-and-digital-privacy-laws/.*

[141] Pew Research Center, *How Americans View Data Privacy: Views of data privacy risks, personal data and digital privacy laws. https://www.pewresearch.org/internet/2023/10/18/views-of-data-privacy-risks-personal-data-and-digital-privacy-laws/.*

[142] Federal Communications Commission, *FC–23–107. https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[143] United States Senate Committee on Finance, *Medicare Advantage Annual Enrollment: Cracking Down on Deceptive Practices and Improving Senior Experiences. https://www.finance.senate.gov/hearings/medicare-advantage-annual-enrollment-cracking-down-on-deceptive-practices-and-improving-senior-experiences.*

[144] *Federal Communications Commission, FC–23–107. https://docs.fcc.gov/public/attachments/FCC-23-107A1.pdf.*

[145] *Federal Communications Commission, FC–23–107, Page 16. https://docs.fcc.gov/public/attachments/FCC-23-107A1.*

[146] *https://www.ecfr.gov/current/title-16/part-255#p-255.0(f).*

[147] *https://www.ecfr.gov/current/title-16/part-255#p-255.0(f).*

[148] Federal Trade Commission, *Guides Concerning the Use of Endorsements and Testimonials in Advertising (88 FR 48092),* updated July 26, 2023.

transfer or connect that beneficiary to another TPMO, such as an agent or broker during the call to provide real time assistance to the beneficiary. In that circumstance, where a live call can be transferred to another entity for assistance, we believe this is an acceptable approach that can be accomplished without obtaining prior express written consent as long as the beneficiary has verbally agreed or consented to be transferred during the live phone call. For purposes of this rule, we do not believe that transferring a live phone call from the beneficiary to an agent or broker that can provide immediate assistance to the beneficiary is considered ''sharing personal beneficiary data,'' which would require prior express written consent under our rule. However, if the TPMO would need to share a beneficiary's personal data with anyone that the beneficiary will not immediately be speaking with, they will need to comply with our rule and receive prior express written consent from the beneficiary to share their personal data.

Our final rule applies when personal beneficiary data is collected by a TPMO for purposes of marketing or enrolling them into an MA plan or Part D plan. Therefore, if a TPMO collects a beneficiary's personal beneficiary data with the purpose of eventually marketing or enrolling that beneficiary into an MA or Part D Plan, it would be inappropriate for that TPMO to share the beneficiary's data with a second TPMO without the beneficiary's consent, even if that second TPMO does not plan to conduct any marketing or enrollment activities. If the beneficiary's data was collected and sold with the purpose of eventually marketing to the person or enrolling them into an MA or Part D plan (*i.e.* a sales lead), then the beneficiary must consent to the sharing of that data with each TPMO that is involved in the marketing or enrollment chain. Finally, we note that selling personal beneficiary data may implicate the Federal anti-kickback statute.

Comment: A few commenters questioned CMS's statutory authority to limit beneficiary data sharing. Some commenters stated that the currently cited statutory authority does not address the distribution of personal beneficiary data and additionally, that under that authority, unsolicited outreach is already prohibited. This commenter stated the statute applies to all entities, and not just TPMOs, while CMS's proposal applies solely to TPMOs. A commenter requested that CMS clarify that it does not prohibit TPMOs from sharing directly with MA–PD plans and sponsors.

Response: We are finalizing changes to §§ 422.2274(g) and 423.2274(g) based on the statutory authorities at §§ 1851(j)(1)(A) and 1860D–04(l)(1) of the Act that prohibit unsolicited means of direct contact, as well as §§ 1851(h)(4)(C) and 1860D–01(b)(1)(B)(vi) of the Act, which allows CMS to establish fair marketing standards that shall not permit MA organizations and Part D plans (and the agents, brokers, and other third parties representing such organizations) to conduct the prohibited activities described in subsection 1851(j)(1) of the Act. Further, we rely in this situation on sections 1856(b)(1), 1857(e)(1) and 1860D–12(b)(3)(D) of the Act, which grant the Secretary authority to establish by regulation other standards that are consistent with and carry out the statute and to include additional contract terms and conditions that are not inconsistent with the statute and that the Secretary finds necessary and appropriate. Based on these authorities and comments received on our proposal that have informed this final rule, we are requiring that personal beneficiary data collected by a TPMO for marketing or enrolling the beneficiary into an MA or Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. This is necessary to prevent abusive practices by TPMOs that inundate beneficiaries with unwanted phone calls, text messages, and emails. Furthermore, this rule is consistent with the MA and Part D statutes because the restriction on sharing personal beneficiary data is limited to data collected for the purposes of marketing or enrollment.

As a commenter pointed out, the statute that prohibits certain marketing practices at § 1851(h)(4)(C) applies to MA organizations or *the agents, brokers, and other third parties representing such organization.* CMS has defined TPMOs to mean organizations and individuals, including independent agents and brokers, who are compensated to perform lead generation, marketing, sales, and enrollment related functions as a part of the chain of enrollment (the steps taken by a beneficiary from becoming aware of an MA plan or plans to making an enrollment decision). TPMOs may be a first tier, downstream or related entity (FDRs), as defined under § 422.2, but may also be entities that are not FDRs but provide services to an MA plan or an MA plan's FDR.[149] Therefore, the definition of TPMO broadly encompasses third parties involved in the marketing and enrollment functions and is a term that applies to entities that are prohibited from engaging in prohibited acts described in 1851(j)(1)(A) of the Act. We clarify here that the definition of TPMO does not apply to MA organizations or Part D sponsors, and therefore TPMOs may share personal beneficiary data with those entities without acquiring direct consent from the beneficiary under this rule. As noted earlier, covered entities and business associates would still need to ensure they are complying with HIPAA privacy rules when sharing personal beneficiary data.

Comment: Commenters stated that data distribution is already governed by other statutes that conflict with CMS's proposal. A commenter stated CMS did not explain how ''personal beneficiary data'' sits alongside data sets such as Personally Identifiable Information (PII), Personal Health Information and Personal Health Records as well as how the proposed rule comports with other applicable statutes, like the Telephone Consumer Protection Act (TCPA), which is enforced by the Federal Communications Commission (FCC), and the Telemarketing Sales Rule (TSR), which is enforced by the Federal Trade Commission (FTC). This commenter stated that, if finalized, CMS's proposal would essentially remove that right to consent to share their data that is provided through these other statutes. Lastly, a commenter noted that TPMOs and other industry participants distribute personal beneficiary data for reasons unrelated to direct contact with beneficiaries, such as for modeling, technology development, and other purposes unrelated to direct contact with beneficiaries.

Response: As previously discussed, our final policy does not take away a beneficiary's ability to consent to the sharing of their personal data. We are finalizing a modified policy that allows for personal beneficiary data to be shared where the TPMO has obtained prior express written consent from the beneficiary for each TPMO that will receive the data. Our modified policy provides beneficiaries with the ability to consent to their personal beneficiary data being shared, as is consistent with other agencies such as the FCC and FTC. At the same time, the ability for beneficiaries to provide express written consent for each TPMO strengthens beneficiary protections, by giving them more control over who can receive their contact information and how many TPMOs can contact them. We understand that TPMOs must comply with other statutes and regulations such as the HIPAA Privacy Rule, TCPA, and

[149] 42 CFR 422.2260.

TSR, and these informed our final policy in this rule. In the December 2022 proposed rule, we described ''personal beneficiary data'' as ''contact information,'' such as name, address, and phone number. We further clarify here that ''personal beneficiary data'' includes contact information but could also include any other information given by the beneficiary for the purpose of finding an appropriate MA or Part D plan. As examples, this could include health information or other personal information such as age, gender, or disability. For purposes of this rule, we describe the information collected from a beneficiary by a TPMO as ''personal beneficiary data.'' We are not attempting to classify this information as PII or PHI, which can have more specific meanings and definitions, such as those used in the HIPAA Privacy Rule. We recognize that the HIPAA Privacy Rule contains very specific disclosure and authorization rules that are more stringent than what we are finalizing in this rule, such as when it comes to covered entities or their business associates sharing information covered under the HIPAA Privacy Rule. We reiterate that the HIPAA Privacy Rule must be followed by TPMOs that are covered entities or business associates under the HIPAA Privacy Rule and it is the responsibility of the TPMO to determine their status as either a covered entity or business associate. A valid authorization under the HIPAA Privacy Rule must specify the name or other specific identification of the person, or class of persons, to whom the covered entity or business associate may make the requested use or disclosure. Since the recipient entities are specifically identified in a valid authorization such that an individual signing an authorization clearly understands the intended recipients, we would consider a disclosure pursuant to a valid authorization also compliant with our rule at §§ 422.2274(g) and 423.2274(g).

TPMOs that engage in the marketing and enrollment of Medicare beneficiaries must also comply with other rules that govern telephonic marketing and communication. The TCPA, governed by the FCC, restricts making telemarketing calls and texts with automatic telephone dialing systems or artificial or prerecorded voice. Similarly, the TSR, governed by the FTC, generally prohibits initiating any outbound telephone call that delivers a prerecorded message unless the seller has obtained from the recipient of the call an express agreement, in writing, that the seller obtained only after a clear and conspicuous disclosure that the purpose of the agreement is to authorize the seller to place prerecorded calls to such person.[150] Therefore, TPMOs must follow those rules when they engage in those kinds of activities (*i.e.,* calling leads through an automatic telephone dialing system using random number generation, using pre-recorded messages). However, TPMOs can also conduct telemarketing in ways that are not governed by the TCPA, such as by manually dialing a lead number and using a customer service or salesperson to speak with the person that answers the phone. Our final regulation seeks to place limits on the sharing of the personal beneficiary data collected by a TPMO in a way that allows TPMOs to develop disclosure and consent processes that easily conform to all applicable rules that may apply. By using a one-to-one consent structure in our rule, TPMOs may obtain permission to share personal beneficiary data with another TPMO at the same time they acquire permission to have that TPMO contact the beneficiary, which could fall under FTC or FCC rules depending on how the contact is made. Further, by requiring the TPMO to obtain prior express written consent from the beneficiary to share their personal data and be contacted for marketing or enrollment purposes through a clear and conspicuous disclosure for each TPMO, it ensures that the beneficiary has control over who is allowed to access their information. This also ensures that any manually dialed calls (calls that are not subject to consent rules under TCPA) that occur because a marketing lead was shared also have been consented to by the beneficiary.

As described at §§ 422.2264(a)(2)(iv) and 423.2264(a)(2)(iv), an MA organization, Part D sponsor or its agents and brokers may not make unsolicited telemarketing calls, and §§ 422.2264(a)(3) and 423.2264(a)(3) explains that calls are not considered unsolicited if the beneficiary provides consent or initiates contact with the plan. By requiring TPMOs to obtain a beneficiary's consent to be contacted along with their consent to share their personal data for purposes of marketing or enrollment, we are ensuring that any entity that receives the lead information that includes personal beneficiary data, has appropriate permission by way of one-to-one consent from the beneficiary to contact them in accordance with §§ 422.2264(a)(3) and 423.2264(a)(3). We note that rules at §§ 422.2264(b) and 423.2264(b) describe when MA organizations or Part D sponsors may contact current and former enrollees to discuss plan business. Calls that qualify as ''plan business'' are not considered ''unsolicited'' but in accordance with §§ 422.2264(b)(2) and 423.2264(b)(2), MA organizations and Part D sponsors must provide notice to all beneficiaries whom the plan contacts as least once annually, in writing, of the individual's ability to opt out of future calls regarding plan business.

A commenter pointed out that TPMOs share beneficiary data for reasons unrelated to direct contact with beneficiaries. For example, a TPMO could collect a beneficiary's personal data and have no intention of directly contacting them. They could sell it, use it for modeling or technology development, or for some other purpose. Ultimately, that information was provided by the beneficiary to assist in helping them select a health plan, and therefore prior express written consent to share that data with another TPMO must be given by the beneficiary under this rule. Our primary justification for imposing these data restrictions is to reduce or eliminate unwanted calls that potential enrollees are receiving from agents and brokers or other TPMOs. Therefore, if the data is de-identified or redacted in a way where the data cannot be used to contact the beneficiary as a potential sales lead, and the purpose of the data sharing is not related to marketing or enrollment, a TPMO can share the de-identified data with other TPMOs without prior express written consent. We are concerned that allowing the sharing of the full data under the guise of ''modeling'' or technology development'' could be abused by TPMOs as a means to move potential sales leads without consent. We reiterate that it makes no difference if the TPMO collects the personal beneficiary data without any intention of directly contact that person. It would be non-compliant with this rule to share the personal beneficiary data with another TPMO without prior express written consent from the beneficiary.

Comment: CMS received many comments on how this proposal would impact beneficiaries. Some commenters expressed support for the proposal and noted that, if finalized, this proposal would provide greater privacy and protection to beneficiaries from receiving an unreasonable number of marketing calls and inquiries. Additionally, a commenter stated that beneficiary autonomy and the ability to direct how they get information should take precedence over the business interests of lead generating companies

[150] 16 CFR 310.4(b)(v).

and those who use or purchase their information.

Response: We thank the commenters for their support. We value the importance of beneficiaries having greater privacy as well as autonomy over their contact information and who it is shared with, especially when it is used to contact them. By balancing beneficiary protections with beneficiary choice, we believe that this final rule will have a strong positive impact on beneficiaries who have been struggling with the volume of unwanted phone calls, texts, and emails. This rule enables beneficiaries to decide what best meets their health care needs by controlling who contacts them and for what purposes. If a beneficiary wants to provide consent to be contacted by multiple TPMOs, this rule ensures they have that flexibility. However, if a beneficiary is only seeking to speak with one or two TPMOs, our rule ensures that the beneficiary will not receive unwanted and unsolicited calls or be misled by difficult to read disclaimers. TPMOs should use a consent method where the default selection is that the beneficiary chooses to not share their data; there should be an affirmative action by the beneficiary to acknowledge that sharing their data with another TPMO is permitted. By being able to consent to each listed TPMO through a clear and conspicuous disclaimer, beneficiaries can make informed decisions that best fit their personal preference.

Comment: Some commenters expressed concern that this proposal would place a greater burden on beneficiaries. Without a TPMO's ability to distribute a beneficiary's personal data to another TPMO, these commenters believed beneficiaries would have fewer opportunities to receive information about plan options available to them, which would limit their plan options as well as their ability to find the best plan for their needs. As a commenter explained, beneficiaries are in a better position speaking with a broker that can sell many MA plans rather than an agent that can only sell one plan. Another commenter stated that under CMS's proposal, beneficiaries would have to identify each agent that represents the plans they are interested in, and if unable to do so, the beneficiaries would have to contact each individual plan to obtain plan benefit information.

Response: CMS appreciates commenters for sharing their concerns regarding how beneficiaries' access to plan information and options would change under this proposal. We appreciate the commenters for providing insight into the ways TPMOs use beneficiary data, such as some TPMOs' reliance on sharing personal data multiple times in order to connect beneficiaries with the agent or broker that can best assist the beneficiary. We agree that many TPMOs have an important role to play in making it easier for beneficiaries to find the plan that best fits their needs. As noted above, we have modified our proposal to allow TPMOs to continue sharing a beneficiary's data as long as they obtain prior express written consent, through a clear and conspicuous disclaimer, for each TPMO that will receive the beneficiary's information and contact them. We have received many complaints regarding the high volume of unwanted calls beneficiaries are experiencing, which can be distressing and confusing to beneficiaries when trying to enroll in a plan. By having the ability to provide clear consent to the TPMOs they with whom they would like to speak, this new rule will make it easier for beneficiaries to control who is contacting them and provide beneficiaries with a clearer understanding of what they are consenting to prior to being contacted. TPMOs can still connect beneficiaries with agents and brokers or other TPMOs with the new guarantee that the beneficiary is consenting to speak with that specific entity. At the same time, this rule creates a safer and clearer environment for the beneficiary to find the best health plan for their needs, by ensuring they do not receive unwanted or unsolicited phone calls. Additionally, we believe this rule will provide an opportunity for TPMOs to continue to make the experience more user friendly and accessible for all beneficiaries, as beneficiaries shouldn't need to opt in to potentially receiving calls from an unknown number of TPMOs in order to compare plans and find the plan that best fits their needs.

CMS understands the important role TPMOs can play in determining which is the best plan to meet a beneficiary's health needs. In this final rule, the beneficiary can still opt in to having their information shared with as many TPMOs as they'd like. A clear and conspicuous disclaimer will ensure that for each authorization for contact a beneficiary provides, they have full knowledge of who is receiving their information and the ability to knowingly and clearly consent to being contacted by this entity. We agree with commenters that beneficiaries should be able to easily and simply access information about plan options but disagree that putting some safeguards on how a beneficiary's personal data is shared will put a greater burden on beneficiaries. This final rule ensures that the beneficiary has the choice and ability to decide whether and who can contact them, while allowing TPMOs to continue supporting consenting beneficiaries by connecting them to the appropriate people that can help the beneficiary enroll in a plan that best meets their health care needs.

Comment: CMS received comments discussing the adverse impact of this proposed rule on TPMOs and the Medicare Advantage (MA) industry. Some commenters were concerned that CMS's proposal to prohibit the distribution of personal beneficiary data would result in entities, including individual insurance agencies, being put out of business. Commenters stated that leads are necessary to market, with a few commenters mentioning that individual agents or agencies do not have the bandwidth or financial means to perform lead generation, marketing, or communications on their own. A few commenters were concerned about how this would impact TPMOs and insurance agencies' ability to connect beneficiaries with an agent or broker. As one commenter stated, lead generators offer one of the main mechanisms to identify interested beneficiaries and connect them with the agents and brokers who represent plans in their area. Other commenters were concerned about the impact on marketing activities of agents and brokers, stating that if this proposal were finalized, agents and brokers would be unable to rely on marketing specialists that connect them with beneficiaries. One commenter stated that this proposed change would be detrimental because these specialists have the expertise and technology to navigate the health care options and connect beneficiaries with an agent. Another commenter stated that this provision would fundamentally change the current market by severely limiting legitimate pre-enrollment business engagement between first tier entities and downstream and related entities.

Response: CMS understands commenters' concerns about how this might affect the TPMO industry and specifically, the TPMOs that support MA organizations and Part D sponsors. We acknowledge that a complete prohibition on beneficiary data sharing would be detrimental to the TPMO industry and could adversely impact beneficiaries access to expertise when navigating their plan options. We believe the amended policy will mitigate these concerns and will balance the need to protect beneficiary data. While this final rule may require a shift

in current practices when TPMOs market or enroll beneficiaries, we expect that the overall effect on the industry will be positive as beneficiaries will have stronger protections against unwanted calls and transparency about who is calling them, while still having access to agents and brokers that provide plan options and choice. Our final rule does not place a limit on the number of TPMOs that a TPMO may share personal beneficiary data with, but it does require that a beneficiary consent to each TPMO that will receive their data. Lead generators, field marketing organizations, agents, brokers and other TPMOs will still be able to share a beneficiary's personal data, as long as they ensure the beneficiary consents through a clear and conspicuous disclaimer to each TPMO prior to receiving their data. We understand this may initially have an impact on TPMOs' processes and operations when adjusting to this new method of obtaining one-to-one consent through a clear and conspicuous disclaimer, but CMS is not, through this rule, prohibiting the ability of TPMOs to share personal beneficiary contact data.

We believe TPMOs and beneficiaries will benefit from this rule because it will ensure that beneficiaries are receiving information and being contacted by the entities they explicitly consent to speaking with and TPMOs will be better able to support the individual beneficiary. The clear and conspicuous disclaimer will allow TPMOs to further educate beneficiaries about who they need to be connected with in order to find the best plan for their healthcare needs while ensuring a safer and more engaging environment for beneficiaries. Additionally, this rule applies solely to sharing personal beneficiary data for the purposes of marketing or enrollment and ensures that TPMOs are still able to share this data for other activities, provided they are compliant with other agencies that govern personal information and data sharing (such as the OCR).

We acknowledge that this may shift how some TPMOs currently share personal beneficiary data but there are a variety of approaches that TPMOs can use to ensure obtaining a beneficiary's one-to-one consent is easy, accessible and straightforward for beneficiaries. For example, through a clear and conspicuous disclosure on a website, a TPMO could provide a check box list that allows the beneficiary to choose each TPMO that they want to hear from. We believe beneficiaries are best served by having the ability to affirmatively consent to who is contacting them.

Comment: One commenter argued that the more robust the lead generation environment is, the more competition there is, as lead generators enable compliant companies to stay in the market. The commenter argues that this should mean more competition, which they argue leads to more informative consumer engagement. Another commenter stated that the proposed changes would have a negative economic impact as it would result in less awareness of MA plans and would likely lead to decreased enrollment.

Response: We understand the importance of competition for a successful business but reiterate that our priority is to protect beneficiaries from misleading, inaccurate, or otherwise abusive communication and marketing practices and ensure that they are able to make coverage choices that best meet their health care needs. Our modified policy will mitigate commenter concerns and still allow competition in the marketplace for TPMOs that can operate in accordance with these rules. It will provide a safer environment for beneficiaries and still allow for numerous TPMO options from which a beneficiary may choose to assist in the selection of a health plan. We do not believe that this amended final policy will result in less awareness of MA plans or less enrollment. Beneficiary complaints received by CMS convey to us that beneficiaries are receiving too many calls, causing confusion, resulting in beneficiaries being overwhelmed, and unable to make a good choice for their health care needs. We believe more informative consumer engagement will not come from competition between lead generators, but from beneficiaries being able to consent to each TPMO from which they would like to receive a contact. Moreover, allowing beneficiaries to review a clear and conspicuous disclaimer will empower them with transparent information, greater choice, and personal autonomy.

Comment: A few commenters expressed concern about how the proposed rule limits data sharing among downstream entities, or as some commenters called them, ''affiliated entities.'' One commenter stated that an independent agent could not share personal beneficiary information that the agent collects with another independent agent operating within the same field marketing organization. Another commenter stated that this CMS proposal would limit a plan's ability to distribute personal beneficiary information to their downstream entities, disrupting the hierarchical distribution of leads that match agents with leads and prevent lead duplication. The commenter stated that this chain of data sharing within affiliated entities ensures compliant leads, which is in the best interest of plans and beneficiaries. The commenter stated that the proposal would require TPMOs to generate their own leads, which may mean more duplicate leads or leads without proper consent. A few commenters were concerned that the data sharing prohibition would result in companies being unable to utilize the complex technology TPMOs use to determine what agent can best serve the needs of a specific beneficiary. One commenter mentioned that individual agents and agencies do not have the expertise, resources, and complex technologies to support marketing and outreach that are currently handled by large TPMOs. Some commenters noted that TPMOs provide services to independent agents that they contract with such as training, administrative support, customer service and marketing/lead generation and that this proposal would prevent those TPMOs from providing these services that licensed agents rely on. A commenter noted that TPMOs and other industry participants distribute personal beneficiary data for reasons unrelated to direct contact with beneficiaries, such as for modeling, technology development, and other purposes unrelated to direct contact with beneficiaries.

Response: We thank commenters for their perspectives on how the proposed rule would impact data sharing among affiliated entities, downstream entities, independent agents, and when it could be appropriate to share beneficiary information across these entities. However, because we are amending the policy discussed in the proposed rule, we will discuss these topics in the context of the modified final policy.

Under amended regulations that CMS is adopting in this final rule at §§ 42 CFR 422.2274(g)(4) and 423.2274(g)(4), a TPMO may not share any personal beneficiary data with a TPMO that is a different legal entity unless prior express written consent has been given by the beneficiary. This includes sharing information with another legal entity that shares the same parent organization or has a contract to perform a downstream function of the organization; prior express written consent from the beneficiary is required under both circumstances. We do not believe that just because another entity is ''affiliated'' with an organization, that the organization has the right to share a beneficiary's information with that other entity without the knowing consent of the beneficiary. This includes the sharing of beneficiary data among two

independent agents affiliated with the same FMO. An independent agent that shares personal beneficiary data with another independent agent even if both are affiliated with the same FMO would be out of compliance with our rule, unless prior express written consent is given by the beneficiary. As mentioned earlier, an exception to this is where a beneficiary provides verbal consent on a live phone call to be transferred to another entity for immediate assistance; we believe this is an acceptable approach that can be accomplished without obtaining prior express written consent. However, two agents that work directly for the same FMO as employees (not independent contractors) may share personal beneficiary data as long as the beneficiary has freely given that data to the FMO or it was obtained with the beneficiary's consent.

Comment: CMS received comments addressing CMS's reasons for prohibiting TPMOs from sharing personal beneficiary information with each other. Some commenters were supportive of CMS's proposal and the assertions about this form of misleading marketing, where beneficiaries are being inundated with unwanted phone calls that they are unwittingly consenting to due to vague consent and difficult-to-read disclaimers. As a commenter mentioned, many SHIPs, agencies, beneficiaries, and their families have expressed concern about the misleading and confusing marketing activities conducted by TPMOs.

Response: We appreciate commenters for the support of our proposal and for recognizing the impact of these unwanted phone calls on beneficiaries. We continue to ensure strong beneficiary protections against misleading marketing and communications and being inundated with unwanted phone calls while still ensuring they have access to plan options and choice. Our final rule reflects this balance of beneficiary protection and privacy with beneficiary access to information to inform their choices.

Comment: A few commenters had general issues with our proposal. Some commenters stated that CMS is punishing all TPMOs for the behavior of some bad actors. One commenter suggested CMS is incorrectly assuming that many TPMOs sell beneficiary personal information to multiple unaffiliated entities. The commenter added that while some lead generators or performance marketers may misbehave, not all sales and distribution practices are problematic or should be prohibited. Another commenter argued that agent error is the main cause of most complaints and therefore this proposal would not have any impact.

Response: We understand that many TPMOs and other entities act in good faith to aid beneficiaries in making an informed health care choice. We reiterate that CMS is not punishing TPMOs, but rather creating a more supportive and conducive environment for beneficiaries to access the information they need to make plan decisions while not being inundated with unwanted phone calls. Currently, as we've seen through routine surveillance of TPMO websites and information received from Congressional hearings and testimonies, personal beneficiary data is shared among many TPMOs with no ability for the beneficiary to select who or how many entities with and from whom they wish to consent to contact them. As an example, there are TPMO websites that provide an opportunity for a beneficiary to opt into being contacted and, within a small disclaimer with a lot of small text, includes a hyperlink to over 100 licensed agents/brokers who may all call the beneficiary. The current activities have resulted in numerous complaints by beneficiaries. CMS's final rule provides stronger beneficiary protection while still enabling TPMOs to provide the vital support of ensuring beneficiaries are connected with an agent/broker or other TPMO who can help them find the plan that best fits their needs.

In summary, we are not finalizing the rule as proposed at §§ 422.2274(g)(4) and 423.2274(g)(4) that personal beneficiary data collected by a TPMO may not be distributed to other TPMOs. After considering the comments received in response to this proposal, and for the reasons that we have discussed in our responses, we are finalizing §§ 422.2274(g)(4) and 423.2274(g)(4) with revisions that provide that personal beneficiary data collected by a TPMO for marketing or enrolling them into an MA or Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Also, we explain that prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained through a clear and conspicuous disclosure that lists each entity receiving the data and allows the beneficiary to consent or reject to the sharing of their data with each individual TPMO. To align with our other marketing changes for agent broker compensation, and to coincide with the beginning of marketing and enrollment activities for the 2025 contract year, we are delaying the applicability of these changes to §§ 422.2274(g) and 423.2274(g) October 1, 2024. Therefore, any personal beneficiary data shared by a TPMO with another TPMO for purposes of marketing or enrollment must have prior express written consent by the beneficiary beginning on October 1, 2024. This includes beneficiary data that is collected prior to October 1, 2024, but will be transferred or shared with another TPMO on or after October 1, 2024. Simply put, TPMOs must have prior express written consent to share a beneficiary's personal data on or after October 1, 2024.

B. Marketing and Communications Requirements for Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.2267)

Section 1851(h) and (j) of the Act provide a structural framework for how MA organizations may market to beneficiaries and direct CMS to set standards related to the review of marketing materials and establish limitations on marketing activities, as part of the standards for carrying out the MA program under section 1856(b) of the Act. In the January 2021 final rule, CMS used this statutory authority to codify guidance from the Medicare Communications & Marketing Guidelines (MCMG) into subpart V of part 422 (86 FR 5864). Several commenters in that prior rulemaking urged CMS to add specific provisions in the marketing and communications regulations regarding how MA organizations may market SSBCI described in § 422.102(f). In response, CMS established a new requirement for a disclaimer to be used when SSBCI are mentioned. The SSBCI disclaimer was originally codified at § 422.2267(e)(32), and it currently appears at paragraph (e)(34). Currently, that regulation requires MA organizations to: (i) convey that the benefits mentioned are a part of special supplemental benefits, (ii) convey that not all members will qualify for these benefits; and (iii) include the model content in the material copy which mentions SSBCI benefits. Section 422.2267(e)(34) does not explicitly state that it applies to both marketing and communications materials, but our sub-regulatory guidance is clear that it applies whenever SSBCI are mentioned; the disclaimer is required regardless of whether the material that mentions the benefits is a marketing or communications material. The purpose of the SSBCI disclaimer is to ensure that beneficiaries are aware that SSBCI are not available to all plan enrollees and that the eligibility for these benefits is

limited by section 1852(a)(3)(D) of the Act and § 422.102(f). Ensuring a clear statement of these limitations in a disclaimer will guard against beneficiary confusion or misunderstanding of the scope of SSBCI, and thus lessens the chance that a beneficiary will enroll in a certain plan believing they can access an SSBCI for which they may not ultimately be eligible.

Per the January 2021 final rule, MA organizations were required to comply with the new SSBCI disclaimer requirement for coverage beginning January 1, 2022. Since MA organizations had over a year to implement their use of the SSBCI disclaimer at the time of the November 2023 proposed rule, we took an opportunity to reevaluate the requirement at § 422.2267(e)(34), considering our observation of its actual implementation.

MA organizations market SSBCI by advertising various benefits, including coverage of groceries, pest control, prepared meals, household items, gasoline, utility bills, auto repair, pet supplies or grooming, and more. Although some of these SSBCI items and services may be available under a given plan, the enrollee must meet the criteria established to receive a particular SSBCI. In many instances, MA organizations have been found to use marketing to potentially misrepresent the benefit offered, often not presenting a clear picture of the benefit and limits on eligibility. In a May 2022 letter sent to Congress, the National Association of Insurance Commissioners (NAIC) detailed its findings from surveys with state departments of insurance, showing ''an increase in complaints from seniors about confusing, misleading and potentially deceptive advertising and marketing of these plans.'' [151] Additionally, as discussed in prior rulemaking, CMS has seen an increase in complaints related to marketing, with more than twice as many complaints related to marketing in 2021 compared to 2020.[152] As evidenced by complaints CMS has received, some of the current marketing of SSBCI has the potential to give beneficiaries the wrong impression by leading them to believe they can automatically receive all SSBCI available by enrolling in the plan.

CMS has seen multiple examples of such misleading SSBCI ads among MA organizations. We have seen ads (for example, online, billboards, television) in which the MA organization presents an extensive list of benefits that are available, with this list being displayed prominently in large font and the SSBCI disclaimer appearing in very small font at the end of the ad. Often the disclaimer is brief, merely stating that the enrollee must have one of the identified chronic conditions in order to receive the benefit and that eligibility will be determined after enrollment, with no other information provided. A beneficiary reading such an ad could easily miss the small-size disclaimer at the end because their attention is immediately drawn to the long, attractive list of appealing benefits prominently displayed in large, bold font. This type of SSBCI marketing is potentially misleading because, at face value, it might appear to a beneficiary that if they enroll in the advertised plan, they can receive all the highlighted benefits, without any question as to the beneficiary's eligibility, what an eligibility determination entails, or when eligibility is assessed.

Based on our findings, we proposed to expand the current required SSBCI disclaimer to include more specific requirements, with the intention of increasing transparency for beneficiaries and decreasing misleading advertising by MA organizations. Our proposed expansion of the SSBCI disclaimer included a clarification of what must occur for an enrollee to be eligible for the SSBCI. That is, per § 422.102(f), the enrollee must first have the required chronic condition(s), then they must meet the definition of a ''chronically ill enrollee'' at section 1852(a)(3)(D)(iii) of the Act and § 422.102(f)(1)(i)(A), and finally the MA organization must determine that the enrollee is eligible to receive a particular SSBCI under the plan's coverage criteria. (See section IV.C. of this final rule for a more detailed discussion of the requirements for SSBCI.) An MA organization designs and limits its SSBCI to target specific chronic conditions. An enrollee might meet the definition of ''chronically ill enrollee'' but nonetheless be ineligible for the MA organization's advertised SSBCI because they do not have the specific chronic condition(s) required for the particular SSBCI being advertised. Taking these important SSBCI eligibility requirements into account, we proposed to amend the required SSBCI disclaimer content to clearly communicate the eligibility parameters to beneficiaries without misleading them. Specifically, at § 422.2267(e)(34), we proposed three key changes to the regulation and two clarifications.

First, we proposed to redesignate current paragraph (e)(34)(ii) as paragraph (e)(34)(iii) and add a new paragraph (e)(34)(ii), in which we proposed to require MA organizations offering SSBCI to list, in their SSBCI disclaimer, the chronic condition or conditions the enrollee must have to be eligible for the SSBCI offered by the MA organization. Per § 422.102(f)(1)(i)(A), a ''chronically ill enrollee'' must have one or more comorbid and medically complex chronic conditions to be eligible for SSBCI. (See section IV.C. of this final rule for a more detailed discussion of the definition of ''chronically ill enrollee'' and eligibility for SSBCI as part of our finalized provision to strengthen the requirements for how determinations are made that a particular item or service may be offered as SSBCI and eligibility determinations for SSBCI.) We proposed that if the number of condition(s) is five or fewer, then the SSBCI disclaimer must list all condition(s), and if the number of conditions is more than five, then the SSBCI disclaimer must list the top five conditions, as determined by the MA organization. For this top five list, we proposed that the MA organization has discretion to determine the five conditions to include. In making this determination, an MA organization might consider factors such as which conditions are more common or less obscure among the enrollee population the MA organization intends to serve. We explained that five was a reasonable number of conditions for the MA organization to list, so that a beneficiary might have an idea of the types of conditions that might be considered for eligibility for the SSBCI, without listing so many conditions that a beneficiary ignores the information.

Second, we proposed to revise newly redesignated paragraph (e)(34)(iii). Section 422.2267(e)(34)(ii) currently requires that MA organizations that offer SSBCI convey that not all members will qualify. We proposed to expand this provision to require that the MA organization must convey in its SSBCI disclaimer that even if the enrollee has a listed chronic condition, the enrollee may not receive the benefit because coverage of the item or service depends on the enrollee being a ''chronically ill enrollee'' as defined in § 422.102(f)(1)(i)(A) and on the MA organization's coverage criteria for a specific SSBCI item or service required

[151] *https://content.naic.org/sites/default/files/State%20MA%20Marketing%20Authority%20Senate%20Letter%20.pdf.*

[152] See Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency Final Rule (87 FR 27704), *which appeared in the* ***Federal Register*** on May 9, 2022.

by § 422.102(f)(4). Section 1852(a)(3)(D) of the Act and § 422.102(f) provide that SSBCI are a permissible category of MA supplemental benefits only for a ''chronically ill enrollee,'' as that term is specifically defined, and the item or service must have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. In other words, just because an enrollee has one of the conditions listed in the SSBCI disclaimer, it does not automatically mean that the enrollee is eligible to receive the relevant SSBCI, as other criteria will also need to be met. In addition, a particular item or service must meet the requirements in § 422.102(f)(1)(ii) to be offered as an SSBCI. Likewise, as finalized in section IV.C. of this final rule, the requirements for the item or service to be covered as an SSBCI at § 422.102(f) also apply in the sense that an MA organization would also need to meet those requirements to offer SSBCI. Determinations on whether an MA organization may offer coverage of a particular item or service as an SSBCI will generally be made before an MA organization begins marketing or communicating the benefits, therefore, we did not include those requirements for when an MA organization may offer SSBCI in the proposed expansion of the SSBCI disclaimer. Our proposed newly redesignated § 422.2267(e)(34)(iii) referred to the eligibility requirements and MA organization responsibilities in § 422.102(f) because we expected the MA organization to use this information in developing their SSBCI disclaimer to clearly convey that not all enrollees with the required condition(s) will be eligible to receive the SSBCI. Per § 422.102(f) currently and with the revisions finalized in section IV.C. of this final rule, MA organizations offering SSBCI must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI.

The SSBCI disclaimer is model content, so each MA organization may tailor their disclaimer's language to convey that, in addition to having an eligible chronic condition, the enrollee must also meet other eligibility requirements (*i.e.,* the definition of a ''chronically ill enrollee'' and the coverage criteria of the MA organization for a specific SSBCI item or service) to receive the SSBCI. MA organizations would not need to specifically detail the additional eligibility requirements (such as the coverage criteria) in the disclaimer, but rather convey that coverage is dependent on additional factors, and not only that the enrollee has an eligible chronic condition. For example, an MA organization might use the following language in its SSBCI disclaimer: ''Eligibility for this benefit cannot be guaranteed based solely on your condition. All applicable eligibility requirements must be met before the benefit is provided. For details, please contact us.'' We are providing this language as an example, as the SSBCI disclaimer is model content. Therefore, in developing their SSBCI disclaimer, MA organizations may deviate from the model so long as they accurately convey the required information and follow CMS's specified order of content, if specified (§ 422.2267(c)). Currently, § 422.2267(e)(34) does not specify the order of content for the SSBCI disclaimer, and we did not propose to add such a requirement; however, MA organizations must accurately convey the required information listed in the regulatory text at § 422.2267(e)(34)(i)–(iii) in their SSBCI disclaimer. In addition, the disclaimer as drafted by the MA organization must be clear, accurate, and comply with all applicable rules on marketing, communications, and the standards for required materials and content at § 422.2267(a).

Third, at new proposed paragraph (e)(34)(iv), we proposed specific formatting requirements for MA organizations' SSBCI disclaimers in ads, related to font and reading pace. These proposed formatting requirements would apply to SSBCI disclaimers in any type of ad, whether marketing or communications. For print ads, we reiterated our existing requirement under paragraph (a)(1) that MA organizations must display the disclaimer in 12-point font, Times New Roman or equivalent. For television, online, social media, radio, or other-voice-based ads, we proposed that MA organizations must either: (1) read the disclaimer at the same pace as the organization does for the phone number or other contact information mentioned in the ad, or (2) display the disclaimer in the same font size as the phone number or other contact information mentioned in the ad. For outdoor advertising (ODA)—which is defined in § 422.2260 and includes billboards—we proposed that MA organizations must display the disclaimer in the same font size as the phone number or other contact information appearing on the billboard or other ODA. The specific font and reading pace requirements for the SSBCI disclaimer in ads would appear at new proposed paragraphs (e)(34)(iv)(A) and (B).

Finally, in revisiting the requirement at § 422.2267(e)(34), we explained that additional clarification of current requirements was appropriate. In the introductory language at paragraph (e)(34), we proposed a minor addition to clarify that the SSBCI disclaimer must be used by MA organizations who offer CMS-approved SSBCI (as specified in § 422.102(f)). Also, we proposed to revise current paragraph (e)(34)(iii) (requiring the MA organization to include the SSBCI disclaimer in the material copy which mentions SSBCI benefits) and move it to new proposed paragraph (v). In this newly redesignated paragraph (v), we proposed to clarify that MA organizations must include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI. We also proposed a slight adjustment in this paragraph to delete the redundant word ''benefits'' after ''SSBCI.''

In summary, we stated in the proposed rule that this proposal would expand upon the current SSBCI disclaimer requirements at § 422.2267(e)(34) in several important ways. Requiring a more robust disclaimer with specific conditions listed would provide beneficiaries with more information to determine whether a particular plan with SSBCI is appropriate for their needs. We explained that the revised disclaimer would diminish the ambiguity of when SSBCI are covered, thus reducing the potential for misleading information or misleading advertising. We also stated that our goal was to ensure that beneficiaries enrolling in MA choose a plan that best meets their health care needs. Transparency and precision in marketing and communications to current and potential enrollees was of utmost importance in our proposal.

We did not score this provision in the COI section since we believe all burden impacts of this provision have already been accounted for under OMB control number 0938–1051 (CMS–10260). In addition, this provision is not expected to have any economic impact on the Medicare Trust Fund.

We solicited comment on this proposal, including on the accuracy of our assumptions regarding information collection requirements and regulatory impact. We did not receive comment on our information collection requirements nor regulatory impact analyses for the proposed revisions to § 422.2267(e)(34) regarding the SSBCI disclaimer. We thank commenters for their input on CMS's proposed amendments to § 422.2267(e)(34). We received the following comments on this proposal, and our response follows:

Comment: The majority of commenters overwhelmingly supported CMS's proposal to strengthen and add more specific requirements to the SSBCI disclaimer in order to decrease misleading advertising and increase transparency for beneficiaries. Many commenters believed that this proposal would enable beneficiaries to make the most informed decision about SSBCI based on their individual health conditions and select the plan that best meets their health care needs. These commenters agreed with CMS that some current SSBCI advertising could give the false impression that these benefits are available to all beneficiaries, which may confuse and mislead beneficiaries into enrolling in an MA plan with benefits they are not actually eligible for. Commenters emphasized the importance of a beneficiary being able to make fully informed choices and the need to decrease misleading marketing and communications. Several commenters noted the importance of the strengthened SSBCI disclaimer requirements to provide more clarity for beneficiaries and supported the language added to the disclaimer, such as the required list of chronic conditions and eligibility restrictions. For example, a commenter agreed that the proposed expansion of the SSBCI disclaimer would clarify what must occur for an enrollee to be eligible for the SSBCI. Another commenter stated that listing the relevant chronic condition(s) the beneficiary must have to be eligible in the marketing and communications materials, as well as adding the caveat that other coverage criteria also apply and may affect eligibility, will help provide more clarity to enrollees, their family members, and enrollment assisters or advisors.

Response: We thank commenters for their support of our proposal to strengthen and expand the SSBCI disclaimer. We appreciate commenters' deeper insight and feedback into the importance of these requirements to both protect beneficiaries from misleading marketing and communications tactics and ensure beneficiaries can make informed health care choices.

Comment: Many commenters offered recommendations for CMS's SSBCI disclaimer proposal. Some commenters suggested that the disclaimer language should be simple, straightforward, and easy to understand, using plain language at an appropriate reading level. A commenter suggested CMS could consider simplifying the disclaimer by using straightforward language to convey eligibility criteria, limitations, and the fact that eligibility does not guarantee benefits. The commenter also suggested CMS could provide a standardized template, language format, or utilize visual aids or bullet points to make the information more digestible and easier for a beneficiary to navigate. There was a recommendation to test the communication with beneficiaries. Another commenter appreciated the detailed benefit description but recommended refining the language to ensure clarity and ease of understanding for beneficiaries of varying literacy levels, promoting inclusive communication. A commenter suggested that CMS consult health literacy experts in the creation of SSBCI disclaimers.

Response: We thank commenters for providing recommendations on how to ensure the updated SSBCI disclaimer is clear and easy for beneficiaries to understand given that the intent of our proposal is to ensure beneficiaries are clearly informed about their options. At the same time, we are aware and concerned about the many marketing and communications materials that mention SSBCI, but do not clearly communicate that beneficiaries have to meet certain criteria to be eligible for those benefits. Specifically, SSBCI are available to a small number of individuals that must meet specific eligibility criteria. As per section 1852(a)(3)(D) of the Act and § 422.102(f), the specific benefit must be within the scope of the definition of SSBCI, including that the benefit be reasonably expected to improve or maintain the health or overall function of the chronically ill enrollee; the enrollee must first have the required chronic condition(s); the enrollee must meet the definition of a ''chronically ill enrollee'' at § 422.102(f)(1)(i)(A); and finally the MA organization must determine that the enrollee is eligible to receive the particular SSBCI under the plan's coverage criteria for the specific SSBCI. To accurately advertise these benefits, MA organizations must make beneficiaries aware that certain eligibility criteria are used to determine who can receive SSBCI. A significant way to further this purpose is the SSBCI disclaimer. As such, it is important that this disclaimer thoroughly conveys all pertinent eligibility information that a beneficiary needs to determine whether they might be able to access the SSBCI. While the revisions and additions to the disclaimer that we proposed and are finalizing in this rule may be more substantial than before, we strongly believe that the benefits of the disclaimer outweigh any potential risks raised by commenters.

We reiterate that the SSBCI disclaimer, currently and as revised in this rule, is model content, and MA organizations are not required to conform with a standardized template or model format provided by CMS, so long as the MA organization's materials accurately convey the required materials' vital information.

However, as provided earlier, some example SSBCI disclaimer language that MA organizations might use includes, ''Eligibility for this benefit cannot be guaranteed based solely on your condition. All applicable eligibility requirements must be met before the benefit is provided. For details, please contact us.'' We believe this example language is clear and simple. To address commenters' concerns about using simple, straightforward, and plain language, we offer here another example of some SSBCI disclaimer language that MA organizations might use: ''Eligibility is determined by whether you have a chronic condition associated with this benefit. Standards may vary for each benefit. Contact us to confirm your eligibility for these benefits.'' Again, we believe this additional example language is clear and easy to understand, which is vital to allowing beneficiaries to make informed health care decisions. We note that these examples of SSBCI disclaimer language capture only the requirements at § 422.2267(e)(34)(iii) and not paragraphs (e)(34)(i) or (ii). In addition to the information required at paragraph (e)(34)(iii), MA organizations must also provide the list of chronic conditions as required by paragraph (e)(34)(ii) as finalized.

MA organizations may decide how to present the SSBCI disclaimer and make the information within it more digestible so long as the content and formatting requirements in § 422.2267(e)(34), as finalized, are met. There is nothing precluding MA organizations from using visual aids or bullet points, provided they comply with the minimum requirements at § 422.2267(e)(34) as finalized. Regarding the comment recommending CMS test the communication with beneficiaries, we appreciate this recommendation and will take it under consideration for the future. We agree with commenters that the SSBCI disclaimer language should be clear for varying literacy levels, and we encourage MA organizations to consider these things as they develop their own unique disclaimers. We also encourage MA organizations to consult with health literacy experts as necessary to ensure the information contained in their SSBCI disclaimers is accessible and inclusive for all beneficiaries.

Comment: Some commenters expressed concern about the SSBCI disclaimer length, arguing that lengthy disclaimer language might cloud helpful information that was meant to increase beneficiary education of available benefits. These commenters were also concerned that the added language may have the unintended effect of discouraging beneficiaries from reaching out to access SSBCI services. A commenter explained that, as disclaimers get longer, more complicated, and less individualized, there is a greater risk that they are ignored, misunderstood, or dissuade a beneficiary from selecting an MA plan. A few commenters were concerned that the SSBCI disclaimer may get lost amidst other required CMS disclaimers and further confuse beneficiaries.

Response: We appreciate the points commenters raised about the SSBCI disclaimer length and the possibility that added language may discourage beneficiaries from reaching out to access SSBCI services. However, we believe that the SSBCI disclaimer can be said succinctly as long as all the requirements at § 422.2267(e)(34) are met and the eligibility restrictions are clear and accurate. We do not agree with commenters that the added language may discourage beneficiaries from reaching out to access SSBCI services. Instead, since SSBCI have limited eligibility, the added language would enable beneficiaries to have a clearer understanding of whether they may even be eligible for the advertised SSBCI. We are prioritizing this change to the SSBCI disclaimer because it is essential that beneficiaries have the information they need in order to select the plan that best meets their health care needs. If a beneficiary is interested in an advertised benefit, we believe that the SSBCI eligibility criteria are key information for beneficiaries to make an informed choice. The purpose of the disclaimer is to ensure that a beneficiary does not base their decision to sign up for a plan on advertised SSBCI for which the beneficiary turns out to be ineligible. This type of marketing and communications is potentially misleading and confusing to beneficiaries and could be out of compliance with CMS regulations. We believe transparently advertised SSBCI, accompanied by disclaimers that meet the revised requirements at § 422.2267(e)(34) finalized here, will help to ensure beneficiaries have the information they need to make health care choices that best fit their needs. Moreover, we again stress our belief that the benefits outweigh any potential risks raised by commenters.

Comment: Many commenters expressed their support for CMS's proposed formatting requirements for the SSBCI disclaimer. A commenter noted that listing the specific chronic condition in the same format, whether it be read at the same speed or displayed in the same font size, as the phone number listed in the ad, will better inform beneficiaries in making the right decision. Another commenter added that they appreciated the proposal that the disclaimer cannot be in smaller font than other key text in print communications and must be read at a comparable speed to other plan information for radio/television ads. They further added that SSBCI and other supplemental benefits continue to be a draw for beneficiaries, so this effort will help ensure that they are not misled about which benefits might be available to them. A commenter believed the additional formatting requirements are appropriate for the older adult population and indicated that the current SSBCI disclaimer information was not easy for beneficiaries to understand.

Response: We thank commenters for expressing their support for the formatting requirements we proposed for the SSBCI disclaimer. We wish to ensure that in every marketing and communications advertising modality, beneficiaries can read or hear and clearly understand the disclaimer and be informed about SSBCI and the specific eligibility criteria.

Comment: A few commenters voiced concerns about CMS's proposed formatting requirements for the SSBCI disclaimer. A few commenters were concerned that there would not be enough ad space for the full SSBCI disclaimer, and that the disclaimer could be longer than the ad itself. A commenter argued that due to the disclaimer length and font size, it could potentially fill the page or ad to where a beneficiary might become disinterested or confused with too much information. The commenter added that due to limited space on such ads, MA organizations may be deterred from promoting SSBCI that could provide beneficiaries with what they possibly need. A commenter also stated that the disclaimer accounts for almost 30 seconds of a radio ad, which is an important media avenue for the target population, and thus more CMS disclaimer requirements might be difficult to achieve due to media limitations. A few commenters recommended CMS work with MA organizations on communication standards, such as font size or disclaimer presentation, to ensure the ad modality is considered, giving specific suggestions for modalities such as social media ads, television commercials, out-of-home signs, search ads, and verbal ads like radio or streaming audio. Commenters suggested that for certain digital or offline modalities with limited space, CMS should permit a link to the disclaimer via a URL weblink or a QR code that would direct beneficiaries to the full SSBCI disclaimer elsewhere. A commenter noted that character counts and content limits enforced by some website owners create additional barriers to adding SSBCI disclaimer language. These commenters generally recommended that CMS adopt more flexible requirements or explicit exceptions for certain modalities that offer limited text display or are of short display duration, like banner ads, other online or television ads, and billboards.

Response: We understand some commenters are concerned about the formatting requirements and how much space the SSBCI disclaimer might take up on a given marketing or communications ad. Our priority, however, is to ensure that SSBCI ads are not misleading or confusing for beneficiaries. Ensuring that beneficiaries have the information they need to make an informed choice is a paramount consideration, and the SSBCI disclaimer requirements adopted in this rule further that goal. Each MA organization's approach to ads is a business decision that depends, in part, on their marketing and communications strategy. Importantly, all aspects of our new SSBCI disclaimer requirements should be significant factors in the MA organization's decision-making process, in conjunction with any potential ad space limitations or other ad roadblocks. It is vital that beneficiaries have all the information necessary to select the plan that best meets their health care needs. If a beneficiary is interested in an advertised benefit, we believe that the SSBCI eligibility criteria are important for beneficiaries to make an informed choice, as they would not be able to access that benefit if they are ineligible. Without the SSBCI disclaimer, the beneficiary might end up enrolling in a plan only to find out that they cannot access the SSBCI, and it is possible that they, due to lacking the information necessary to make an informed enrollment choice, may have sacrificed other enrollment opportunities for the ability to access those advertised SSBCI. SSBCI are not benefits that everyone can access, so it should be clear that when

such a benefit is advertised, these benefits are not guaranteed unless specific eligibility criteria are met.

We disagree with commenters that there should be a separate link for the full SSBCI disclaimer and are finalizing the formatting requirements as proposed. The disclaimer needs to be on the ad itself because a link would not make it clear to the beneficiary that there are specific chronic conditions and other eligibility requirements associated with being able to access a particular advertised SSBCI. The SSBCI disclaimer ensures that beneficiaries are immediately aware of the eligibility criteria for an advertised SSBCI and can make informed decisions about their health care coverage options. From a beneficiary's perspective, linking elsewhere would not make the information clear and more accessible, but would instead lead to an unnecessary delay in the amount of time it takes for the beneficiary to receive the information by adding a burdensome extra step of clicking on a link or QR code. Realistically, most beneficiaries would probably not click on such a link. Regarding character limits or any other text limitations in a specific modality, if the disclaimer does not fit, then it is likely not the most suitable modality for an SSBCI marketing ad given the nature of these benefits and nuances that are necessary for a beneficiary to make an informed choice when considering SSBCI. Our requirement is that the disclaimer must be included in all marketing and communications materials that mention SSBCI and must follow all content requirements as specified in the finalized regulatory text. If an ad mentions an SSBCI without the required disclaimer, then it is out of compliance with CMS rules.

Comment: A few commenters communicated support for CMS's proposal to require the SSBCI disclaimer in all marketing and communications materials that mention SSBCI. Other commenters were unclear as to whether the disclaimer should apply to all communications or only for pre-enrollment activity, rather than post-enrollment communications. A commenter noted that for post-enrollment communications, an enrollee would have already been notified they meet the necessary qualifications for the benefit and would have already been receiving educational material on the benefit, so the addition of the SSBCI disclaimer would create confusion. The commenter also expressed concerns about differences between VBID and SSBCI disclaimer requirements and that this could further confuse beneficiaries.

Response: We thank commenters for their support of our requirement that the SSBCI disclaimer be present in all marketing and communications materials that mention SSBCI. As finalized in § 422.2267(e)(34), the SSBCI disclaimer must appear in all communications materials produced by MA organizations, including both pre-enrollment and post-enrollment communications materials that mention SSBCI. We disagree with the commenter's sentiment that including the disclaimer on post-enrollment communications materials would confuse the enrollee. Even if an enrollee has already been notified that they meet the SSBCI qualifications, we do not believe there would be any harm or risk in including the disclaimer on a potential post-enrollment educational communications material for that enrollee. The enrollee could simply disregard the disclaimer since they already know that they qualify for the benefit. Moreover, we believe the likelihood of an MA organization sending post-enrollment communications materials on SSBCI to enrollees whom the MA organization has already notified that they qualify for the benefits is low because those enrollees would likely not need to be educated further on these benefits, but instead would probably be ready to utilize the benefits.

Regarding the comment about differences between VBID and SSBCI disclaimer requirements and potential beneficiary confusion, we note that the VBID model is administered under section 1115A of the Act, and there is authority to waive certain program requirements if necessary to test the payment or service model; we refer readers to the web page for the VBID model at: *https://www.cms.gov/priorities/innovation/innovation-models/vbid* for more information about the model and its requirements. Due to the nature of the VBID model and the flexibilities in benefits available under that model, there are specific marketing and communications requirements applicable to model participants. Given SSBCI and VBID benefits are different benefits with different requirements, both disclaimers are necessary.

Comment: A few commenters were concerned that the chronic conditions list would be difficult for MA organizations to implement and that it could lead to beneficiary confusion. Some commenters were worried it could get confusing for MA organizations to explain in an SSBCI disclaimer the chronic conditions that apply to the specific benefits listed or promoted in an ad. A commenter believed it was unclear how CMS intended MA organizations to proceed when an ad includes multiple SSBCI, for which there might be varying eligibility criteria or condition requirements. Another commenter added that for an MA organization offering multiple SSBCIs, the disclaimer, as worded, might result in an overly long and complex disclaimer, and most prospective enrollees would not read or understand it. Some commenters had concerns about how to implement the list of top five chronic conditions and how that list might impact beneficiaries, and requested CMS further clarify their expectations. These commenters requested CMS clarify that the SSBCI disclaimer needs to identify up to five chronic conditions for which one or more SSBCI may be available, rather than specifying up to five chronic conditions for each individual SSBCI, which may be lengthy. A few commenters were concerned that by listing only five conditions for an SSBCI, enrollees with eligible conditions not listed may inadvertently believe that they are not eligible for the SSBCI because it gives the impression that the five conditions listed are the only ones covered.

Response: We agree with commenters that some clarification of the requirements for the chronic conditions list in the SSBCI disclaimer is needed. We recognize that an MA organization may include more than one type of SSBCI in its marketing or communications material. Consequently, there is a strong possibility that each type of SSBCI may have different eligible chronic conditions or there may be some overlap because some chronic conditions apply to more than one type of SSBCI mentioned in the material. There is also the possibility that an MA organization may have multiple plans with different SSBCI, and consequently may choose to either advertise the SSBCI specific to each plan or advertise SSBCI for all plans generally. After considering these nuances, we acknowledge that there are many different potential scenarios for how MA organizations might advertise SSBCI and use their SSBCI disclaimer to associate the listed chronic conditions with the types of SSBCI mentioned. We are therefore finalizing § 422.2267(e)(34)(ii) with revisions compared to our proposal in the November 2023 proposed rule, as follows.

First, we are changing the reference in paragraph (e)(34)(ii) from ''MA organization'' to ''applicable MA plan(s)'' to clarify that the SSBCI the MA organization advertises must be

clearly tied to the applicable MA plan or plans that offer that SSBCI. For similar reasons, we are finalizing paragraph (e)(34)(iii) with a modification that clarifies that the disclaimer used by the MA organization must communicate that coverage depends on the enrollee being a ''chronically ill enrollee'' and on ''the applicable MA plan's coverage criteria'' for a specific SSBCI. Therefore, if an MA organization is advertising SSBCI for all of the MA organization's plans that offer SSBCI, and there are differences between those plans in terms of the types of SSBCI and types of chronic conditions the enrollee must have to be eligible for the SSBCI, then the MA organization must make those differences explicitly clear.

Next, we are clarifying the requirements for the chronic conditions list in the SSBCI disclaimer by outlining several different scenarios and the requirements associated with each. Specifically, we are finalizing the regulation text with revisions to address: (1) when only one type of SSBCI is mentioned, and (2) when multiple types of SSBCI are mentioned. When only one type of SSBCI is mentioned, the regulation addresses two scenarios: (1) If the number of condition(s) is five or fewer, then the MA organization must list all condition(s); and (2) If the number of conditions is more than five, then the MA organization must list the top five conditions (as determined by the MA organization). When multiple types of SSBCI are mentioned, the regulation addresses two scenarios: (1) If the number of condition(s) is five or fewer, then the MA organization must list all condition(s), and if relevant, state that these condition(s) may not apply to all types of SSBCI mentioned; and (2) If the number of condition(s) is more than five, then the MA organization must list the top five conditions (as determined by the MA organization) for which one or more listed SSBCI is available.

We believe that making these modifications to clearly outline the different scenarios achieves the goal of limiting ambiguity for MA organizations, while simultaneously preserving our intention to ensure that SSBCI marketing and communications is transparent and not misleading for beneficiaries. Additionally, we believe an alternate approach of tying each listed chronic condition to each type of SSBCI mentioned would have been overly burdensome and resulted in a long, complex SSBCI disclaimer. Lastly, we would like to address the comment that listing only five chronic conditions may inadvertently lead enrollees with eligible conditions not listed to believe that they are not eligible for the SSBCI because it may give the impression that the five conditions listed are the only ones that are eligible. We agree that this is a valid concern, therefore, we are finalizing § 422.2267(e)(34)(ii) with a revision which requires that, in instances where the MA organization lists the top five conditions, but there are more than five conditions that may be eligible for the benefit, MA organizations must convey that there are other eligible conditions not listed. We believe that all these modifications are responsive to comments and further strengthen and clarify our SSBCI disclaimer requirements.

Comment: A commenter was worried about giving deference to MA organizations to choose the top five conditions they will list, suggesting CMS use a metric for MA organization determinations on what conditions would constitute such a ''top five,'' or, in the alternative, that the MA organization be required to list all the applicable conditions. A different commenter had a similar request with concerns that if CMS were to finalize this amendment as proposed, then MA organizations could select conditions in a way that increases racial health disparities (such as by omitting sickle cell anemia from the list).

Response: We acknowledge the commenter's concern about giving deference to MA organizations to choose the top five conditions they will list. However, we are finalizing our proposal to allow the MA organization's discretion as to which top five conditions to include because we believe the MA organization is best positioned to make this determination since they are most familiar with their own SSBCI and corresponding eligibility and coverage criteria. Regarding the suggestion for CMS to use a metric for MA organizations to determine whether a specific qualifying condition is one of the top five conditions, we remind commenters that in the proposed rule, we provided some factors that an MA organization might consider, such as which conditions are more common or less obscure among the enrollee population the MA organization intends to serve. Other approaches an MA organization might take are to list the top five conditions that are most prevalent in the service area of the MA plan offering the SSBCI, or to list the top five conditions that are used most commonly in determining eligibility for the SSBCI. We believe these examples are sufficient and defer to MA organizations to make their own decisions on their chosen top five conditions using these considerations so long as there is a reasonable explanation for why the selected conditions are the ''top five'' using a reasonable interpretation of the regulation. We believe that the MA organization should not be required to list all applicable chronic conditions because, as stated previously, a beneficiary may ignore the information if many conditions are listed.

Regarding the concern about MA organizations potentially selecting conditions in a way that increases racial health disparities, we note that MA organizations are subject to anti-discrimination provisions under 45 CFR Part 92. Therefore, an MA organization that is found to be deliberately selecting chronic conditions for the list in their SSBCI disclaimer in a discriminatory manner, including a racially discriminatory manner, may face compliance action.

Comment: Some commenters worried that CMS's proposed new requirements for the SSBCI disclaimer would make SSBCI less accessible to beneficiaries because they might think they are ineligible if they do not see their chronic condition listed. Regarding the disclaimer content, another commenter stated that they believed this change might be confusing to beneficiaries who may not know if they meet the § 422.102(f)(1)(i)(A) definition of ''chronically ill enrollee.'' They instead recommended that the standard for eligibility be simple to understand, such as, if a beneficiary has an eligible chronic condition, then they will be eligible for the benefit.

Response: We agree with commenters' concerns that if a beneficiary does not see their chronic condition listed in the SSBCI disclaimer, then they might think they are ineligible for the benefit. Therefore, we are finalizing § 422.2267(e)(34)(ii) with changes to require the MA organization, where relevant, to state in its disclaimer that there may be other eligible chronic conditions that are not listed. We believe this will decrease the likelihood of beneficiaries assuming they cannot access SSBCI if their chronic condition is not listed in the disclaimer.

Regarding comments about the disclaimer content (specifically proposed § 422.2267(e)(34)(iii)) being potentially confusing to beneficiaries, we clarify here that MA organizations should not cite the CMS regulatory definition of ''chronically ill enrollee'' in their actual SSBCI disclaimer, as this would not make sense to beneficiaries. In addition, MA organizations must not simply state that if a beneficiary has an eligible chronic condition, then they

will be eligible for the benefit because this is not accurate. Rather, as noted in the proposed rule, each MA organization may tailor their disclaimer's language to convey that, in addition to having an eligible chronic condition, the enrollee must also meet other eligibility requirements to receive the SSBCI. In the proposed rule and in a previous response to a comment, we offered some example language to this effect that an MA organization might use in its disclaimer. To reiterate, the SSBCI disclaimer is model content, therefore, MA organizations may deviate from the model so long as they accurately convey the required regulatory information in their disclaimer. As previously stated, we encourage MA organizations to use simple and easy to understand disclaimers written in plain language. The policy we proposed and are finalizing is that the SSBCI disclaimer must convey that even if the enrollee has a listed chronic condition, the enrollee will not necessarily receive the listed SSBCI because coverage of the item or service depends on the enrollee meeting other eligibility and coverage criteria.

Comment: A few commenters opposed our proposal, claiming that the disclaimer is not the right approach or not the most effective way to address misleading SSBCI marketing and communications. Commenters expressed support for increasing the transparency of available supplemental benefits that beneficiaries are eligible to utilize but disagreed that additional disclaimer requirements are an effective way to do this. A commenter expressed concern that the additional SSBCI disclaimer requirements would not truly address CMS's concerns with deceptive marketing and communications practices by bad actors. Some commenters recommended CMS withdraw the proposal and not change the current SSBCI disclaimer requirements, which they claimed are more streamlined than the proposed disclaimer. A commenter stated that the longer and more complicated the disclaimers get, the less effective they become. Another commenter suggested CMS withdraw the proposal and work with stakeholders to determine a more effective strategy whereby SSBCI transparency for beneficiaries can be meaningfully improved. A commenter noted their beneficiary complaint tracking suggests that disclaimers are not as effective as direct communication with sales representatives, agents and brokers, and customer service representatives. The commenter expressed the critical role agents and brokers play in explaining the types of supplemental benefits, eligibility requirements, access, and other critical information that can be distilled down from the disclaimers in an easy-to-understand format tailored for each beneficiary.

Response: We understand that some commenters are not fully supportive of this policy for various reasons, however, we have decided to finalize our proposal with slight modifications. While we recognize that there may be a range of different approaches to solve the problems we have historically observed in SSBCI marketing and communications, in formulating our proposal, we have decided that strengthening the SSBCI disclaimer was an effective option to address misleading and non-transparent SSBCI marketing and communications. We have received numerous complaints and concerns from a variety of sources, such as beneficiaries, advocacy groups, and State Health Insurance Programs, about the draw of these benefits and the harm caused when insufficient information about these benefits leads a beneficiary to enroll in an MA plan that does not meet their health care needs. These instances have led to beneficiaries enrolling in plans because they were lured by ads mentioning these special benefits only to discover that they are ineligible for the advertised SSBCI. We believe that the strengthened SSBCI disclaimer could decrease confusing or potentially deceptive marketing and communications practices as it is clearer and more comprehensive than the current disclaimer. We believe this is in fact the right approach and will be effective in delivering SSBCI marketing and communications messaging to beneficiaries in a clear, transparent way that is not misleading or confusing.

Therefore, we decline commenters' suggestions to withdraw this proposal. We note that we will continue to provide guidance to MA organizations and answer questions about the requirements for the SSBCI disclaimer and compliance with our other regulatory requirements. Lastly, we agree with commenters that agents and brokers, sales representatives, and customer service representatives play a critical role in communicating with beneficiaries and explaining SSBCI in a way that is easy for beneficiaries to understand.

Comment: A few commenters believed CMS's proposed changes to the SSBCI disclaimer requirements may confuse or mislead dually eligible individuals. A commenter argued that some dually eligible individuals, in response to SSBCI advertising or communications, may choose an MA plan to receive some limited additional benefits that are unavailable under traditional Medicare; the commenter expressed concern that such individuals may make this enrollment choice because they are unaware that as dually eligible individuals they can access some of the same benefits through a Medicaid program. The commenter stated that the SSBCI disclaimer language should be amended to transparently advise potential enrollees what they may be giving up by choosing one of these MA plans, as many dually eligible individuals are misled into choosing an MA plan based on the extra benefits, when they may already be eligible for such benefits under Medicaid. Another commenter urged CMS to prohibit misleading marketing and communications of SSBCI that duplicate Medicaid benefits, arguing that advocates report that many dually eligible individuals are lured by these ads and report not understanding the limits of the extra benefits or restrictions. The commenter requested more robust SSBCI disclaimer language than contemplated by this rule. Another commenter suggested that CMS should require D–SNPs specifically to indicate (through their SSBCI disclaimer, on all plan marketing, and communications materials, and in the EOC) which benefits are also available through Medicaid, to reduce misleading marketing and communications of SSBCI that duplicate Medicaid benefits. The commenter believed that this would not be an unduly burdensome requirement because D–SNPs already tailor each plan's information to a particular state and frequently advertise benefits to which dually eligible individuals are already entitled to receive more comprehensively in both duration and scope under Medicaid.

Response: We understand commenters' concerns regarding the potential for misleading marketing and communications of SSBCI that duplicate Medicaid benefits. This is an important consideration, and we appreciate commenters raising the issue. CMS is committed to protecting all beneficiaries, including dually eligible individuals, from confusing and potentially misleading marketing and communications practices, while also ensuring that they have accurate and necessary information to make coverage choices that best meet their health care needs. While we are not including SSBCI disclaimer language specifically for dually eligible individuals or D–

SNPs, we do want to clarify our existing authority related to MA marketing.

Sections 1851(h) and 1852(j) of the Act provide CMS with the authority to review marketing rules, develop marketing standards, and ensure that marketing materials are accurate and not misleading. Additionally, these provisions provide CMS with the authority to prohibit certain marketing activities conducted by MA organizations and, when applicable, agents, brokers, and other third parties representing these organizations. Pursuant to section 1851(h)(1) and (2) of the Act and CMS's implementing regulations, MA organizations may not distribute any marketing material to MA-eligible individuals (including dually eligible individuals, when applicable) unless the material has been submitted to CMS for review and CMS has not disapproved such material. CMS's regulations at § 422.2262 provide, among other things, that MA organizations may not mislead, confuse, or provide materially inaccurate information to current or potential enrollees, or engage in activities that could misrepresent the MA organization. Section 422.2262 applies to all MA communications and marketing materials, including advertising on behalf of MA organizations. In accordance with regulations at § 422.2261, MA organizations must submit all marketing materials for CMS review and may not distribute or otherwise make available any marketing materials unless CMS has reviewed and approved the material, the material has been deemed approved, or the material has been accepted via CMS's File and Use process. Additionally, CMS routinely monitors MA marketing materials and may take compliance action if we determine that an MA organization is out of compliance with our rules. Considering the existing authority CMS has for oversight and enforcement, we believe this is sufficient to address commenters' concerns regarding dually eligible individuals and the SSBCI disclaimer.

We expect and require MA organizations whose audience may include dually eligible individuals to craft their ads and their SSBCI disclaimers in a way that is accurate and not misleading or confusing, in accordance with CMS rules. We recognize that partial-benefit dually eligible individuals and full-benefit dually eligible individuals have different levels of access to Medicaid benefits. For example, while full-benefit dually eligible individuals would generally have access to non-emergency transportation (NEMT) through their Medicaid coverage, partial-benefit dually eligible individuals generally would not. An MA organization advertising SSBCI that include NEMT would offer a new benefit for partial-benefit dually eligible individuals, but the NEMT generally would not be a new benefit for full-benefit dually eligible individuals. Given that both categories of dually eligible individuals may enroll in almost any non-SNP, it does not seem practical for MA organizations to tailor the SSBCI disclaimer in a way that describes which SSBCI would be covered under Medicaid, depending on the eligibility category of the dually eligible individual. In some states, Medicaid benefits may be limited to certain waiver participants or only covered in specific situations. At this time, we will not be modifying the SSBCI disclaimer further, but we understand commenters' concerns and will consider this for future rulemaking.

Comment: A commenter suggested that the actual SSBCI eligibility criteria must be available in the MA organization's existing plan materials (such as the Evidence of Coverage (EOC), Summary of Benefits (SB), and plan website) and that the SSBCI disclaimer should tell the beneficiary how they can obtain these eligibility criteria and hyperlink to them from any online reference.

Response: To the extent that the materials noted by the commenter already contain the same (or more detailed) content as required in the SSBCI disclaimer in a manner that achieves the same purpose, CMS would consider the MA organizations producing these materials compliant with § 422.2267(e)(34) as finalized, for purposes of the disclaimer content. Thus, in these cases, there is no need for the MA organization to add redundant information to these materials in the form of an SSBCI disclaimer because the required information is already present, and in some cases more detailed, for the beneficiary. This would be the case, for example, in the EOC, an important plan material where covered benefits are described. We note that the EOC is a standardized communications material, meaning that, per § 422.2267(b), it must be used in the form and manner provided by CMS without alteration, aside from a few exceptions. In chapter 4, section 2 (Medical Benefits Chart) of the current 2024 EOC standardized document, CMS requires MA organizations offering SSBCI to include all applicable chronic conditions, information regarding the process and/or criteria for determining eligibility for SSBCI, the actual CMS-approved benefits, and the applicable copays, coinsurance, and deductible for the SSBCI. Per § 422.111(b)(2), (b)(6), and (f)(9), MA organizations are required to disclose in the EOC the benefits offered under a plan, including applicable conditions and limitations, any other conditions associated with the receipt or use of benefits, any mandatory or optional supplemental benefits, and the terms and conditions for those supplemental benefits.

CMS disagrees with the commenter that the disclaimer should also include details about how a beneficiary can obtain the specific SSBCI eligibility criteria used by the MA organization. We agree that the potential eligibility criteria restrictions should be transparent and straightforward for beneficiaries, but the disclaimer is model content that is intended to ensure beneficiaries are aware that there are eligibility criteria and to understand some of the eligible conditions that apply. This will ensure beneficiaries are informed that there are SSBCI restrictions and to notify the beneficiary that they may inquire further with the MA organization about the details of these restrictions if they so choose. We would also like to clarify that the disclaimer is meant to be easy to read and understand, and to quickly alert beneficiaries that they may not be eligible for certain listed benefits. Adding additional information or a hyperlink would further lengthen the disclaimer, so we are not requiring that. We are also not prohibiting MA organizations from electing to provide additional information not required by § 422.2267(e)(34) as finalized in this rule. There are ways that MA organizations can help guide beneficiaries in their SSBCI education. As mentioned earlier, an MA organization can encourage a beneficiary to reach out to them, using simple language such as, ''For details, please contact us'' which would offer beneficiaries an easy and straightforward way to learn more about whether they are eligible for a specific SSBCI. The SSBCI disclaimer requirements, as finalized, are designed to ensure that beneficiaries are immediately aware that SSBCI is not a guaranteed benefit, and they may inquire further with the MA organization if they want to learn more about the eligibility restrictions.

Comment: Another commenter requested that CMS clarify that there will be an exception for marketing and communications materials that do not currently require the Federal Contracting Statement, such as social media, SMS text messages, outdoor ads, banners, and envelopes.

Response: As finalized, there will not be an exception to the SSBCI disclaimer requirement for marketing and communications materials that do not currently require the Federal Contracting Statement. The intent of the disclaimer is to ensure that any place where SSBCI is mentioned, beneficiaries are fully aware that eligibility restrictions apply so that they can make informed health care choices. We believe that the marketing and communications modalities such as those listed by the commenter are modalities where beneficiaries tend to be most at risk of being misled by SSBCI ads and where the content appears to offer benefits that a beneficiary wants and suggests they can easily access or receive by enrolling in the plan. If the beneficiary is unaware that there is a chance they may not qualify, then they may unwittingly sign up for the plan because of benefits that they will not ultimately be able to receive. The exceptions for the Federal Contracting Statement are relevant to that specific provision only and do not apply to the SSBCI disclaimer as finalized here.

Comment: A commenter remarked that ODA are inclusive of billboards and bus shelter ads, which are often read by motorists. The commenter believed imposing new requirements for ODA decreases legibility, impact, and potential safety and requested that CMS allow SSBCI ads to have varying disclaimer requirements based on the ODA medium.

Response: We thank commenters for sharing their concerns about safety for motorists when it comes to including the SSBCI disclaimer on ODA. We agree that these are important considerations for MA organizations when making SSBCI advertising decisions. It is the MA organization's discretion regarding where to advertise SSBCI. If an MA organization has concerns regarding legibility, impact, and potential safety when it comes to including the SSBCI disclaimer on a particular ODA, then they may wish to reconsider their pursuit of that ad modality for SSBCI. MA organizations have ample choice in how they choose to advertise, however, they must comply with our SSBCI disclaimer requirements, including ODA formatting requirements.

Comment: Other commenters encouraged CMS to make the SSBCI disclaimer's model language even clearer by explicitly stating that not everyone who has Medicare is eligible for the benefit and explaining how enrollment in an MA plan differs from traditional Medicare. A commenter suggested that the SSBCI disclaimer should include information about the trade-offs between MA and traditional Medicare and describe potential hurdles in MA, for example, provider networks, utilization management, and prior authorization.

Response: We believe the SSBCI disclaimer requirements, as finalized, do already make it clear that not everyone who has Medicare is eligible for the SSBCI, as MA organizations are required to note SSBCI eligibility restrictions in the disclaimer. Regarding comments recommending that the disclaimer explain the differences between MA and traditional Medicare, we disagree and believe this would not be appropriate nor align with the core purpose of the SSBCI disclaimer. CMS does not require MA organizations to include information about the trade-offs or any comparison between MA and traditional Medicare in their marketing and communications materials, and we are not establishing such a requirement for the SSBCI disclaimer. However, we note that per § 422.2262, CMS does require MA organizations to provide materially accurate information to current or potential enrollees. Therefore, MA organizations must provide accurate information about provider networks, utilization management, and prior authorization wherever MA organizations choose to include such information in their marketing and communications materials.

Comment: Some commenters recommended CMS ensure proper enforcement against misleading SSBCI marketing and communications tactics. One commenter urged CMS to impose high penalties on MA organizations that fail to comply with all the revised marketing and communications requirements for the MA program and that such enforcement action should include civil monetary penalties, suspensions, and for the most abusive actors, permanent bans from MA program participation. Another commenter noted that the current procedures for enforcement of marketing and communications regulations that CMS has in place are not working, and marketing and communications practices that are confusing and misleading to seniors need to stop.

Response: We thank commenters for raising the important topic of enforcement against misleading marketing and communications in general, and we want to assure commenters that CMS takes its enforcement efforts seriously, especially as they relate to the SSBCI disclaimer requirements, as finalized. Accordingly, we would like to provide an overview of our approach to MA enforcement.

CMS engages in various enforcement efforts across the MA program to help ensure the health and wellbeing of MA enrollees. The Office of Program Operations and Local Engagement (OPOLE) routinely monitors MA organizations, with dedicated CMS account managers across ten regions of the country assigned to each MA organization. CMS also maintains MA organization marketing monitoring projects which consist, as provided in § 422.2261, of reviewing and approving (if in accordance with CMS regulations) marketing materials produced by MA organizations and their TPMOs.

Through routine oversight and monitoring, CMS may take compliance actions if it determines that an MA organization is out of compliance with the terms of its contract with CMS. Based on an assessment of the circumstances surrounding non-compliance, CMS may issue a compliance action such as a notice of non-compliance, warning letter, or corrective action plan. As described in § 422.504(m)(3), a notice of non-compliance may be issued for any failure to comply with the requirements of the MA organization's current or prior contract with CMS; a warning letter may be issued for serious and/or continued non-compliance with the MA organization's current or prior contract with CMS; and a corrective action plan may be issued for repeated, not corrected, or particularly serious non-compliance. CMS's criteria for issuing a compliance action depends on six key factors listed at § 422.504(m)(2).

In addition to account management, routine monitoring efforts, auditing, and compliance actions, CMS also has the authority to impose financial penalties, marketing and enrollment sanctions, or contract terminations against MA organizations whose non-compliance meets certain statutory thresholds. CMS evaluates circumstances of documented non-compliance against those thresholds in determining an appropriate action. In circumstances when non-compliance by an MA organization is pervasive, ongoing, and may require significant time and resources to identify and correct, CMS might require a corrective action plan or, if the statutory threshold for non-compliance is met, impose enrollment and marketing sanctions in an effort to protect additional beneficiaries from enrolling in the plan until the MA organization can demonstrate that their issues have been sufficiently corrected and no longer likely to recur. If, however, it is determined that an MA organization's non-compliance has already been corrected by the time it

was identified through CMS's oversight and enforcement efforts, and enrollees or prospective enrollees are no longer in danger of experiencing inappropriate delays or denials to their benefits, a civil money penalty might be the most appropriate response if the non-compliance met statutory standards. If standards for a financial penalty are not met, CMS may still issue a notice of non-compliance which will count against the MA organization during CMS's annual review of their past performance.

In summary, we believe that the above outlined procedures for enforcement of marketing regulations that CMS currently has in place are appropriate and effective. We are confident that these procedures will sufficiently address any potential non-compliance with the SSBCI disclaimer rule by MA organizations.

Summary of Regulatory Changes

We received a range of comments pertaining to this proposal, the majority of which reflected support for the regulation. After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are amending § 422.2267(e)(34) largely as proposed, but with modifications. We are finalizing paragraph (e)(34)(ii) with revisions to adopt more specific requirements for when and how an MA organization must list up to five chronic conditions used to determine eligibility for SSBCI identified in marketing and communications materials. These requirements specify how an MA organization must structure its list of chronic conditions in the SSBCI disclaimer when only one type of SSBCI is mentioned and when multiple types of SSBCI are mentioned. Modifications in paragraph (e)(34)(ii) also include changing ''MA organization'' to ''applicable MA plan'' and requiring, where there are more than five eligible conditions, a note indicating that there are other eligible conditions not listed. We are finalizing paragraph (e)(34)(iii) with modifications to ensure that the specific coverage criteria of the MA plan that offers the SSBCI are referenced as additional eligibility requirements. We are also finalizing paragraph (e)(34)(iii) without the phrase ''items and services'' to avoid any implication that SSBCI that are reductions in cost sharing are not included in the SSBCI disclaimer requirement. The SSBCI disclaimer is required for all marketing and communications materials that mention SSBCI of any type. The new SSBCI disclaimer requirements, as finalized here, will apply to all contract year 2025 marketing and communications beginning October 1, 2024, and in subsequent years.

C. Agent Broker Compensation

Agents and brokers are an integral part of the MA and Part D industry, helping millions of Medicare beneficiaries to learn about and enroll in Medicare, MA plans, and PDPs by providing expert guidance on plan options in their local area, while assisting with everything from comparing costs and coverage to applying for financial assistance. Pursuant to section 1851(j)(2)(D) of the Act, the Secretary has a statutory obligation to establish guidelines to ensure that the use of agent and broker compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet beneficiaries' health care needs. In September 2008, we published the Revisions to the Medicare Advantage and Prescription Drug Benefit Programs interim final rule (73 FR 54237), our first regulation to establish requirements for agent and broker compensation, which included certain limitations on agent and broker compensation and other safeguards. In that rulemaking, we noted that these reforms addressed concerns that the previously permitted compensation structure resulted in financial incentives for agents to only market and enroll beneficiaries in some plan products and not others due to larger commissions. These incentives potentially resulted in beneficiaries being directed towards plans that were not best suited to their needs.

In that interim final rule, we noted that depending on the circumstances, agent and broker relationships can be problematic under the federal anti-kickback statute if they involve, by way of example only, compensation in excess of fair market value, compensation structures tied to the health status of the beneficiary (for example, cherry-picking), or compensation that varies based on the attainment of certain enrollment targets. These and other fraud and abuse risks exist among the current agent and broker relationships. We note that the HHS Office of the Inspector General (OIG) advisory opinion process is available to parties seeking OIG's opinion as to the legality of a particular arrangement. Information about this process remains available on the OIG's website at *http://oig.hhs.gov/fraud/advisoryopinions.html.* CMS has also periodically made updates to the agent and broker compensation requirements in subsequent rulemaking (73 FR 67406).

It has become apparent that the growth of MA and changes in MA marketing warrant further updates to ensure the appropriate guardrails are in place to protect beneficiaries and support competition. For example, shifts in the industry and resulting changes in contract terms offered to agents and brokers and other third-party marketing organizations (TPMOs) for enrollment-related services and expenses warrant further action to ensure compliance with statutory requirements and that the compensation paid to agents and brokers incentivizes them to enroll individuals in the MA plan that is intended to best meet their health care needs. CMS has also observed that the MA marketplace, nationwide, has become increasingly consolidated among a few large national parent organizations, which presumably have greater capital to expend on sales, marketing, and other incentives and bonus payments to agents and brokers than smaller market MA plans. This provides a greater opportunity for these larger organizations, either directly or through third parties, to use financial incentives outside and potentially in violation of CMS's rules to encourage agents and brokers to enroll individuals in their plan over a competitor's plan. For example, CMS has seen web-based advertisements for agents and brokers to work with or sell particular plans where the agents and brokers are offered bonuses and perks (such as golf parties, trips, and extra cash) framed as allowable administrative add-ons in exchange for enrollments. These payments, while being presented to the agents and brokers as bonuses or incentives, are implemented in such a way that allows the plan sponsor, in most cases, to credibly account for these anti-competitive payments as ''administrative'' rather than ''compensation'' and these payments are therefore not limited by the existing regulatory limits on compensation. We note these payments may implicate and, depending on the facts and circumstances, potentially violate the Federal anti-kickback statute.

CMS has also received complaints from a host of different organizations, including state partners, beneficiary advocacy organizations, and MA plans, among others. A common thread to the complaints is that agents and brokers are being paid, typically through various purported administrative and other add-on payments, amounts that cumulatively exceed the maximum compensation allowed under the current regulations. Moreover, CMS has observed that such payments have

created an environment similar to what prompted CMS to engage in the original agent and broker compensation rulemaking in 2008, where the amounts being paid for activities that MAOs do not characterize as ''compensation,'' are rapidly increasing. The result is that agents and brokers are presented with a suite of questionable financial incentives that are likely to influence which MA plan an agent encourages a beneficiary to select during enrollment.

We believe these financial incentives are contributing to behaviors that are driving an increase in beneficiary marketing complaints received by CMS in recent years. As was discussed in our most recent Medicare Program Contract Year 2023 Rule, based on the most recent data available at that time, in 2021, CMS received more than twice the number of beneficiary complaints related to marketing of MA plans compared to 2020, and for some states those numbers were much higher (87 FR 27704 through 27902). These complaints are typically filed by enrollees or their caregivers with CMS through 1–800–Medicare or CMS regional offices, and generally allege that a beneficiary was encouraged or pressured to join an MA plan, and that once enrolled, the plan was not what the enrollee expected or what was explained to them when they spoke to an agent or broker.

In the Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule (88 FR 22234 through 22256), which appeared in the **Federal Register** on April 12, 2023, we discussed at length the rapidly increasing use of various marketing activities that typically result in beneficiaries being connected with agents and brokers to be enrolled in MA plans. Based on a number of complaints CMS reviewed, as well as audio recordings of sale calls, it appears that the increased marketing of 1–800 numbers to facilitate enrollment in MA plans through national television advertisements combined with the subsequent actions of agents and brokers when beneficiaries responded to those ads resulted in beneficiary confusion. In some instances, through listening to call recordings, CMS observed that when beneficiaries reached an agent or broker in response to these television ads, the beneficiary was often pressured by the agent or broker to continue with a plan enrollment even though the beneficiary was clearly confused.

At the same time, these types of complaints have escalated at a pace that mirrors the growth of administrative or add-on payments, which we contend are being misused to pay agents and brokers over and above the CMS-set compensation limits on payment to agents and brokers. CMS is concerned that when the value of administrative payments offered to agents and brokers reaches the levels that CMS has observed in recent years, these payments may distort the process that agents and brokers are expected to engage in when they assist beneficiaries in weighing the merits of different available plans. This distortion disadvantages beneficiaries who enroll in a plan based on the recommendation or encouragement of an agent or broker who may be influenced by how much or what kind of administrative payment the agent or broker expects to receive, rather than enrolling the beneficiary in an option that is intended to best meet the beneficiary's health care needs.

Consequently, the rise in MA marketing complaints noted previously suggests that agents and brokers are being influenced to engage in high pressure tactics, which may in turn cause beneficiary confusion about their enrollment choices, to meet enrollment targets or earn ''administrative payments,'' either directly or on behalf of their employer or affiliated marketing organization, in excess of the capped compensation payment set by CMS. Although CMS' existing regulations already prohibit plans, and by extension their agents and brokers, from engaging in misleading or confusing communications with current or potential enrollees, in the proposed rule we noted that additional limitations on payments to agents and brokers may be necessary to adequately address the rise in MA marketing complaints described here.

Additionally, while our proposed rule largely focused on payments and compensation made to agents and brokers, we noted that CMS is also concerned about how payments from MA plans to TPMOs may further influence or obscure the activities of agent and brokers. In particular, CMS expressed interest in the effect of payments made from MA plans to Field Marketing Organizations (FMOs), which is a type of TPMO that employs or is affiliated with agents and brokers to complete MA enrollment activities, which have increased in influence in recent years. FMOs may also conduct additional marketing activities on behalf of MA plans, such as lead generating and advertising. In fact, at the time of our first agent and broker compensation regulation, CMS expressed concern about amounts paid to FMOs for services that do not necessarily relate directly to enrollments completed by the agent or broker who deals directly with the beneficiary (73 FR 54239). Some examples of such services are training, material development, customer service, direct mail, and agent recruitment.

As we noted in the preamble to the two interim final rules published in 2008 (73 FR 67406 and 73 FR 54226), all parties should be mindful that their compensation arrangements, including arrangements with FMOs and other similar type entities, must comply with the fraud and abuse laws, including the federal anti-kickback statute. Beginning as early as 2010, an OIG report indicated that ''plan sponsors may have created financial incentives that could lead FMOs to encourage sales agents to enroll Medicare beneficiaries in plans that do not meet their health care needs. Because FMOs, like sales agents, may influence Medicare beneficiaries' enrollment in MA plans, CMS should issue additional regulations more clearly defining how and how much FMOs should be paid for their services.'' [153] In the time since CMS first began to regulate agent and broker compensation, we have seen the FMO landscape change from mostly smaller, regionally based companies to a largely consolidated group of large national private equity-backed or publicly-traded companies.

Finally, in addition to the undue influence that perks, add-on payments, volume bonuses and other financial incentives that are paid by MA organizations to FMOs may have on agents and brokers, they also create a situation where there is an unlevel playing field among plans. Larger, national MA plans are likely able to more easily shoulder the added costs paid to FMOs, as compared to smaller, more locally based MA plans. Furthermore, we have received reports that some larger FMOs are more likely to contract with large national plans rather than smaller regional plans, negatively impacting competition. On July 9, 2021, President Biden issued Executive Order (E.O.) 14036: ''Promoting Competition in the American Economy,'' (hereinafter referred to as E.O. 14036). E.O. 14036 describes the Administration's policy goals to promote a fair, open, competitive marketplace, and directs

[153] Levinson, Daniel R, BENEFICIARIES REMAIN VULNERABLE TO SALES AGENTS' MARKETING OF MEDICARE ADVANTAGE PLANS (March 2010); *https://oig.hhs.gov/oei/reports/oei-05-09-00070.pdf.*

the U.S. Department of Health and Human Services to consider policies that ensure Americans can choose health insurance plans that meet their needs and compare plan offerings, furthering competition and consumer choice. The regulatory changes included in the 2023 proposed rule also aimed to deter anti-competitive practices engaged in by MA organizations, agents, brokers, and TPMOs that prevent beneficiaries from exercising fully informed choice and limit competition in the Medicare plan marketplace among Traditional Medicare, MA plans, and Medigap plans.

CMS is concerned that the more recent increases in fees being paid to larger FMOs have resulted in a ''bidding war'' among MA plans to secure anti-competitive contract terms with FMOs and their affiliated agents and brokers. If left unaddressed, such bidding wars will continue to escalate with anti-competitive results, as smaller local or regional plans that are unable to pay exorbitant fees to FMOs risk losing enrollees to larger, national plans who can. In addition to seeking comment to help us develop additional regulatory action, we specifically requested comments regarding how CMS can further ensure that payments made by MA plans to FMOs do not undercut the intended outcome of the agent and broker compensation proposals included in this final rule; we thank commenters for the wealth of information they have shared and we will continue to integrate this new knowledge as we explore potential future rulemaking.

In addition, the comments that we received in response to the November 2023 proposed rule indicate that there is, in fact, an additional force at work in misaligning the incentives of agents and brokers enrolling Medicare beneficiaries into MA plans. Commenters brought to our attention that agents and brokers who are direct employees of FMOs, call centers, and other TPMOs typically receive an annual salary from their employer. We note that the salary received by employees of a TPMO from their employer does not currently fall under our regulatory definition of ''compensation.'' Commenters stated that an agent who is not directly employed by a call center may receive renewal payments for a beneficiary who remains enrolled in the plan that agent has helped the beneficiary select. By contrast, commenters also stated that a call center employee who is salaried may never be eligible to receive renewal payments and may only be incentivized to generate new enrollments. In this way, commenters expressed concerns that the incentives between the two types of agents and brokers may be different, and so a one-size fits all approach to regulating agent and broker compensation for all agents who enroll beneficiaries into MA plans has inherent limitations. This is an area of policy we will consider in future rulemaking.

As noted previously, sections 1851(j)(2)(D) and 1851(h)(4)(D) of the Act direct the Secretary to set limits on compensation rates to ''ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet their health care needs,'' and that the Secretary ''shall only permit a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization) to conduct the activities described in subsection (j)(2) in accordance with the limitations established under such subsection.'' In this final rule, we are focusing on current payment structures, including the use of administrative payments, among MA organizations and agents, brokers, and TMPOs, specifically FMOs, that may incentivize some agents or brokers to emphasize or prioritize one plan over another, irrespective of the beneficiary's needs, leading to enrollment in a plan that does not best fit the beneficiary's needs and a distortion of the competitive process.

Our regulations at § 422.2274 set out limitations regarding various types of payments and compensation that may be paid to agents, brokers, and third parties who represent MA organizations. Each of these limitations is intended to better align the professional incentives of the agents and brokers with the interests of the Medicare beneficiaries they serve. Our regulations specify maximum compensation amounts that may be paid to agents and brokers for initial enrollment and renewals. The regulations also currently allow for payment to agents and brokers for administrative costs such as training and operational overhead, as long as the payments are at or below the value of those services in the marketplace. The maximum compensation for initial and renewal enrollments and the requirement that administrative payments reflect fair market value for actual administrative services have been intended to ensure incentives for agents and brokers to help enroll beneficiaries into MA plans that best meet their health care needs.

However, while CMS has affirmatively stated the types of allowable payment arrangements and the parameters for those payments in regulations at § 422.2274, as previously discussed, some recent studies suggest that MA plans offer additional or alternative incentives to agents and brokers, often through third parties such as FMOs, to prioritize enrollment into some plans over others. These incentives are both explicit (in the form of higher payments purportedly for administrative services) and implicit (such as in the case of passing on leads, as discussed later in this section).[154]

As previously mentioned, we believe payments categorized by MA organizations as ''administrative expenses,'' paid by MA organizations to agents and brokers, have significantly outpaced the market rates for similar services provided in non-MA markets, such as Traditional Medicare with Medigap. This is based on information shared by insurance associations and focus groups and published in research articles by groups such as the Commonwealth Fund, which found that ''most brokers and agents in the focus groups recalled receiving higher commissions [total payments, including compensation and administrative payments]—sometimes much higher—for enrolling people in Medicare Advantage plans compared to Medigap.'' [155]

Similarly, some MA organizations are paying for things such as travel or operational overhead on a ''per enrollment'' basis, resulting in instances where an agent or broker may be paid multiple times for the same one-time expense, if the agent incurring the expense happened to enroll more than one beneficiary into the plan making the payment. For example, an agent could be reimbursed for the cost of traveling to an event where that agent enrolls a beneficiary into an MA plan; if the cost of travel is paid on a ''per enrollment'' basis, the agent would be reimbursed the price of the trip multiplied by the number of enrollments the agent facilitated while at that event. In this scenario, whichever MA organization reimburses for travel at the highest rates would effectively be offering a higher commission per enrollee, as the increased amount paid for travel, in additional to the allowable compensation, would be higher. While

[154] The Commonwealth Fund, The Challenges of Choosing Medicare Coverage: Views from Insurance Brokers and Agents (Feb. 28, 2023); *https://www.commonwealthfund.org/publications/2023/feb/challenges-choosing-medicare-coverage-views-insurance-brokers-agents.*

[155] The Commonwealth Fund, The Challenges of Choosing Medicare Coverage: Views from Insurance Brokers and Agents (February. 28, 2023); *https://www.commonwealthfund.org/publications/2023/feb/challenges-choosing-medicare-coverage-views-insurance-brokers-agents.*

this would not violate existing MA regulations, this would inherently create a conflict of interest for the agent. As statute requires that the Secretary ''ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that is intended to best meet their health care needs,'' we believe this type of conflict must be addressed.

We are also concerned that other activities undertaken by a TPMO, as a part of their business relationships with MA organizations, may influence the plan choices offered or how plan choices are presented by the agent or broker to a prospective enrollee. For example, we have learned of arrangements where a TPMO, such as an FMO, provides an MA organization with both marketing and brokering services. As part of the arrangement, the MA organization pays the FMO for leads generated by the FMO and then the leads are given directly to the FMO's agents instead of to the MA organization itself (or the MA organization's other contracted agents and brokers). When the FMO's agents then contact the individual and enroll the individual into an MA plan, the MA organization pays the agent or the FMO the enrollment compensation described in § 422.2274(d), separate and apart from any referral fee paid to the FMO under § 422.2274(f).

While MA organizations that are engaged in these types of arrangements (such as paying FMOs for lead generating activities and marketing, then giving the leads to the FMO's agents and then paying compensation for that same enrollment) might argue that they are not intending to influence an agent or broker in determining which plan ''best meets the health care needs of a beneficiary,'' we believe it is likely that these arrangements are having this effect. We believe that current contracts in place between FMOs and MA organizations can trickle down to influence agents and brokers in enrolling more beneficiaries into those plans that also provide the agents and brokers with leads, regardless of the appropriateness of the plan is for the individual enrollees. In fact, FMOs could leverage these leads as a form of additional compensation by ''rewarding'' agents who enroll beneficiaries into a specific plan with additional leads. Therefore, CMS is required under section 1851(j)(2)(D) of the Act to establish guidelines that will bring the incentives for agents and brokers to enroll individuals in an MA plan that is intended to best meet their health care needs, in accordance with the statute and as such is CMS' intention here.

In the proposed rule we proposed to: (1) generally prohibit contract terms between MA organizations and agents, brokers, or other TMPOs that may interfere with the agent's or broker's ability to objectively assess and recommend the plan which best fits a beneficiary's health care needs; (2) set a single agent and broker compensation rate for all plans, while revising the scope of what is considered ''compensation;'' and (3) eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services. We also proposed to make conforming edits to the agent broker compensation rules at § 423.2274. We will continue to monitor the MA marketing ecosystem and the influence of FMOs, lead generators, call centers, web-based sources, TV ads, and other fast-moving aspects of MA marketing to ensure beneficiaries are protected from misleading or predatory behavior while also having access to the information and support they need to make an informed decision about their Medicare coverage. For example, CMS will continue to monitor the behaviors addressed in this final rule at VI.A, which limit the distribution of personal beneficiary data by TPMOs (§§ 422.2274(g)(4) and 423.2274(g)(4)).

1. Limitation on Contract Terms

We proposed to add at § 422.2274(c)(13) that, beginning in contract year 2025, MA organizations must ensure that no provision of a contract with an agent, broker, or TPMO, including FMO, has the direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent's or broker's ability to objectively assess and recommend which plan best meets the health care needs of a beneficiary.

Examples of the anti-competitive contract terms we proposed to prohibit included, for instance, those that specify renewal or other terms of a plan's contract with an agent broker or FMO contingent upon preferentially higher rates of enrollment; that make an MA organization's contract with an FMO or reimbursement rates for marketing activities contingent upon agents and brokers employed by the FMO meeting specified enrollment quotas; terms that provide for bonuses or additional payments from an MA organizations to an FMO with the explicit or implicit understanding that the money be passed on to agents or brokers based on enrollment volume in plans sponsored by that MA organization; for an FMO to provide an agent or broker leads or other incentives based on previously enrolling beneficiaries into specific plans for a reason other than what best meets their health care needs.

As we explained in the November 2023 proposed rule, CMS believes that the proposed limitations on contract terms would give plans further direction as to the types of incentives and outcomes that must be avoided without being overly prescriptive as to how the plans should structure these arrangements.

We received the following comments on this proposal.

Comment: Commenters generally indicated their support for this proposal to require that MA organizations must ensure that no provision of a contract with an agent, broker, or TPMO has the direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best meets the health care needs of the beneficiary.

Response: We thank commenters for their support.

Comment: Some commenters requested additional information about the types of incentives and contract terms we intended to limit and the means by which we intend to enforce these restrictions.

Response: We thank commenters for their thoughtful input. While we recognize that it is impossible to anticipate every scenario that could present itself, it is important that we are clear in our meaning of the phrase ''direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best suits the beneficiaries' health care needs.''

Relying on a ''reasonableness standard,'' we would not, for example, read our regulation to prohibit MA plans from contracting with independent agents who have not been appointed to represent all possible competitors in a market. In this case, an agent who does not represent all possible competitors is inherently more likely to enroll beneficiaries into the plan(s) with which he or she is contracted. However, provided there is no contractual or financial incentive that would prevent the agent from choosing to seek additional arrangements and sell competitors' plans, the agent and the MAO(s) with which it contracts would be in compliance with our rule.

If, by way of another example, a TPMO or agent was offered a bonus or other payment by a plan or a TPMO

contracted by a plan or plans, in exchange for declining to represent a competing MA plan, this would be an example of a contract term that would likely violate the rule, as it is inherently anti-competitive in nature and on its face has the effect of encouraging enrollment in one plan over another based largely on the receipt of a financial reward for not representing or promoting a competitor plan's product.

Similarly, depending on the facts and circumstances, bonuses for hitting volume-based targets for sales of a plan may not be directly anti-competitive if they do not outwardly discourage or preclude a TPMO from marketing other plans, but it would likely have the indirect effect of creating an incentive for the TPMO to prioritize sales of one plan over another based on those financial incentives and not the best interests of the enrollees. Because the indirect effect of volume-based bonuses of this kind would be anti-competitive in nature, they would likely run afoul of the provision, and, like other potential scenarios described herein, could implicate fraud and abuse laws as well.

CMS expects to review contracts as part of routine monitoring, as well as relying on complaints and other methods of investigation, and work conducted by the Office of the Inspector General, to enforce this regulation. We also may pursue additional data collection regarding these contract arrangements as part of our established Part C reporting requirements process in future years.

After considering public comments, and the overwhelming support for this proposal, and for the reasons described in the November 2023 proposed rule and in our earlier responses, we are finalizing the policy as proposed at § 422.2274(c)(13) requiring that MA organizations must ensure that no provision of a contract with an agent, broker, or TPMO has the direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent's or broker's ability to objectively assess and recommend which plan best meets the health care needs of a beneficiary; we are including one modification to the regulatory text to make clear that this requirement is applicable beginning with marketing and communications activities related to the 2025 contract year. We are continuing to consider whether additional guidance in this space may be necessary in future rulemaking.

2. Compensation Rates

Under current regulations, compensation for agents and brokers (described at § 422.2274(d)(2) and excluding administrative payments as described in § 422.2274(e)) may be paid at a rate determined by the MA organization but may not exceed caps that CMS calculates each year, based on fair market value (FMV) as specified at § 422.2274(a). For example, the CY2024 national agent/broker FMV compensation caps are $611 for each MA initial enrollment, $306 for a MA renewal enrollment, $100 for each Part D initial enrollment, and $50 for a Part D renewal enrollment.

We have learned that overall payments to agents and brokers can vary significantly depending on which plan an individual enrolls in. In the November 2023 proposed rule, we expressed concern that the lack of a uniform compensation standard across plans can encourage the types of arrangements that provide strong financial incentives for agents and brokers to favor some plans over others and that these incentives could result in beneficiaries enrolling in plans that do not best fit their needs. To eliminate this potential for bias and make certain that CMS' regulations governing agent and broker compensation ensure that agents and brokers are incented to enroll individuals in the MA plan that is intended to best meet their health care needs, we proposed to amend our regulations to require that all payments to agents or brokers that are tied to enrollment, related to an enrollment in an MA plan or product, or are for services conducted as part of the relationship associated with the enrollment into an MA plan or product must be included under compensation, as defined at § 422.2274(a), including payments for activities previously excluded under the definition of compensation at § 422.2274(a)(ii), and are regulated by the compensation requirements of § 422.2274(d)(1) through (3). We also proposed to make conforming amendments to the regulations at § 422.2274(e)(2) to clarify that all administrative payments are included in the calculation of enrollment-based compensation; this proposal is further discussed in section VI.B. (X)(c) of this final rule, ''Administrative Payments.''

Further, we proposed to change the caps on compensation payments that are currently provided in § 422.2274 to set fixed rates that would be paid by all plans across the board. As proposed, agents and brokers would be paid the same amount either from the MA plan directly or by an FMO. We noted that our proposal does not extend to payments for referrals as described at § 422.2274(f); we believe the cap set on referral payments is sufficient to avoid the harms described previously, and that a referral payment is often made in lieu of a compensation payment, and so it does not provide the same incentives as compensation payments.

We believe that this approach may help level the playing field for all plans represented by an agent or broker and promotes competition. In addition, by explicitly saying that compensation extends to additional activities as a part of the relationship between the agent and the beneficiary, we reinforce CMS' longstanding understanding that the initial and renewal compensation amounts are based on the fact that additional work may be done by an agent or broker throughout the plan year, including fielding follow-up questions from the beneficiary or collecting additional information from a beneficiary.

Comment: A few commenters requested clarification regarding the timing and applicability of this proposed policy for the 2025 contract year and expressed concern that activities necessary to prepare for the 2025 contract year AEP begin far in advance of the 2025 calendar year. Commenters stated that a rule finalized in the Spring of 2024 with an effective date 60 days later may put many agents and brokers who have already begun securing their annual training, testing, and state appointments out of compliance before the AEP has even begun.

Response: We understand that the narrow timeline between finalization of this rule and the time at which agents and brokers will begin engaging in necessary and mandatory activities to prepare for the 2025 contract year may make it difficult for them to remain in compliance with this rule. In recognition of the timing concerns noted by commenters, we are the clarifying that applicability of these changes to §§ 422.2274 and § 423.2274 until October 1, 2024, so these updates will coincide with the beginning of marketing activities for the 2025 contract year. We are clarifying in our regulatory text that prior to that date, CMS's existing agent and broker compensation requirements will continue to apply, meaning that, for instance, arrangements between MAOs and TPMOs or agents that are not in compliance with our proposals will not be subject to remedial action for activities engaged in before October 1, 2024, even if they were related to 2025 contract year plans.

After considering feedback in public comments, we are finalizing our policy to require that, beginning with contract year 2025, all payments to agents or

brokers that are tied to enrollment, related to an enrollment in an MA plan or product, or are for services conducted as part of the relationship associated with the enrollment into an MA plan or product must be included under compensation, as defined at § 422.2274(a), including payments for activities previously excluded under the definition of compensation at § 422.2274(a)(ii), and are regulated by the compensation requirements of § 422.2274(d)(1) through (3). To memorialize this updated policy, we are finalizing an updated definition of compensation at § 422.2274(a) that will apply beginning with contract year 2025, meaning that MAOs and the TPMOs that they work with will need to begin to comply with these updated standards beginning on October 1, 2024, when marketing activities for contract year 2025 begin. We are also adopting language to the existing definition of compensation to make clear that this definition will apply for contract years through contract 2024, meaning that MAOs and TPMOs should continue to comply with CMS's existing agent and broker compensation policies until marketing activities for contract year 2025 begin on October 1, 2024. We are also finalizing our policy to make conforming amendments to the regulations at § 422.2274(e)(2) to clarify that all administrative payments are included in the calculation of enrollment-based compensation, with an applicability date of October 1, 2024.

MA organizations are also currently required, under § 422.2274(c)(5), to report to CMS on an annual basis the specific rates and range of rates they will be paying independent agents and brokers. We proposed to remove the reporting requirement at § 422.2274(c)(5), as all agents and brokers would be paid the same compensation rate in a given year under our proposal.

We did not receive any comments on this aspect of our proposal and are finalizing it as proposed.

3. Administrative Payments

As discussed previously, CMS proposed that all payments to an agent or broker relating to the initial enrollment, renewal, or services related to a plan product would be included in the definition of compensation. For consistency with that proposed policy, we also proposed to incorporate ''administrative payments'' currently described at § 422.2274(e)(1) into compensation, and to amend § 422.2274(e)(2) to clarify that administrative payments would be included in the calculation of enrollment-based compensation beginning in Contract Year 2025. As we discussed in the proposed rule, we believe this step is necessary to ensure that MA organizations cannot utilize the existing regulatory framework allowing for separate payment for administrative services to effectively circumvent the FMV caps on agent and broker compensation. For instance, we stated in the November 2023 proposed rule that we understand that many plans are paying agents and brokers for conducting health risk assessments (HRAs) and categorize these HRAs as an ''administrative service.'' We understand the fair market value of these services, when provided by non-medical staff, to be approximately $12.50 per hour and the time required to complete an HRA is intended to be no more than twenty minutes.[156] However, we explained that we have been made aware of instances of an agent or broker enrolling a beneficiary into a plan, asking the enrollee to complete one of these short assessments, and then being compensated at rates of up to $125 per HRA. Compensation at these levels is not consistent with market value and CMS believes that compensation at these levels far exceeds the fair market value of the actual service being performed and therefore should not be categorized as an ''administrative service.'' Moreover, a study funded by the CDC to provide guidance for best practices ''recommend that HRAs be tied closely with clinician practice and be collected electronically and incorporated into electronic/patient health records [. . .] agents/brokers lack the necessary health care knowledge, information technology capabilities, and provider relationships to link HRAs in the recommended way.'' [157] For this reason, we believe that the HRAs completed by agents and brokers do not have the same value as those performed and interpreted by health care providers or in a health care setting.

Similarly, we explained in the November 2023 proposed rule that according to recent market surveys and information gleaned from oversight activities, payments purportedly for training and testing and other administrative tasks for agents and brokers selling some MA plans seem to significantly outpace payments for similar activities made by other MA plans, as well as payments for similar activities undertaken by insurance agents and brokers in other industries. The higher overall cost as compared to other industries, combined with the otherwise inexplicable difference in payments for administrative activities for some MA organizations compared to others, further points to the payment for these administrative activities being used as a mechanism to effectively pay agents and brokers enrollment compensation amounts in excess of the limits specified at § 422.2274(a) and (d).

By eliminating separate payment for administrative services, we stated that we expected that this proposal would eliminate a significant method which some plans may have used to circumvent the regulatory limits on enrollment compensation. Furthermore, we explained that we believed ensuring a fixed payment rate for agents will result in compensation greater than what is currently provided through typical contractual arrangements with FMOs, as there would no longer be a range of compensation rates at which the MA organizations could pay for agents and brokers' services. While our proposal would prohibit separate administrative payments, as described below, we proposed to adjust the FMV for compensation to take into account costs for certain appropriate administrative activities.

We recognized in the proposed rule that this approach could result in some agents and brokers being unable to directly recoup administrative costs such as overhead or lead purchasing from its compensation from Medicare health and drug plans, unless the agent has a certain volume of business. For instance, the cost of a customer relationship management (CRM) system (the software used to connect and log calls to potential enrollees) is estimated to be about $50 per month. Under our proposed rule, this expense would require at least one enrollment compensation per year to cover these costs, whereas under our current regulations it is currently permissible for an MA organization to pay for these costs directly, as administrative costs, leaving the entire compensation for enrollments as income for the agent or broker. However, we explained in the proposed rule that given the high volume of enrollees that use an agent or broker for enrollment services, we did

[156] CDC, Interim Guidance for Health Risk Assessments and their Modes of Provision for Medicare Beneficiaries; *https://www.cms.gov/files/document/healthriskassessmentscdcfinalpdf.*

[157] The Commonwealth Fund, The Challenges of Choosing Medicare Coverage: Views from Insurance Brokers and Agents (Feb. 28, 2023); *https://www.commonwealthfund.org/publications/2023/feb/challenges-choosing-medicare-coverage-views-insurance-brokers-agents; cf.* Guidance on Development of Health Risk Assessment as Part of the Annual Wellness Visit for Medicare Beneficiaries—(Section 4103 of the Patient Protection and Affordable Care Act) *https://www.cdc.gov/policy/paeo/hra/hraawvguidancereportfinal.pdf.*

not believe there to be a large risk of agents or brokers failing to cross that initial threshold to recoup their administrative costs.

We also explained in the proposed rule that we considered an alternate policy proposal wherein we would maintain our current definitions of compensation and administrative payments but would remove the option for a plan to make administrative payments based on enrollment, as currently codified at § 422.2274(e)(2). We considered instead requiring that administrative payments be made a maximum of one time per administrative cost, per agent or broker. We considered the argument that these expenses, such as payments for training and testing, or nonmonetary compensation such as leads, should be paid at their FMV and not as a factor of overall enrollment because the value of such administrative tasks is usually a fixed rate, regardless of how many enrollments are ultimately generated by the agent or broker engaged in these administrative tasks.

We also considered whether, under this alternative policy approach, it would be best to require that each administrative expense be reimbursed at the same rate by each contracting MA organization as a means of encouraging agents and brokers to represent multiple plans at any given time. However, as we noted in the proposed rule, this alternative policy would, of necessity, be comparatively prescriptive and could present challenges for all parties as it relates to the tracking these expenses. We believe our proposal to include all payments to an agent or broker under the definition of compensation is likely to reduce the ability of plans and/or TPMOs to circumvent the maximum compensation rates defined by CMS via the annual FMV determination.

We sought comment on this proposal.

Comment: Similar to what we note previously, a few commenters requested clarification regarding the timing and applicability of this proposed policy for the 2025 Contract Year, and expressed concern that activities necessary to prepare for the 2025 contract year AEP begin far in advance of the 2025 calendar year, noting that if the rule was finalized in the Spring of 2024 and effective 60 days later, many agents and brokers would have already begun securing their annual training, testing, and state appointments out of compliance before the 2025 AEP has even begun.

Response: As previously stated, we understand that the narrow timeline between finalization of this rule and the time at which agents and brokers will begin engaging in necessary and mandatory activities to prepare for the 2025 contract year may make it challenging for them to remain in compliance, however, we believe that implementing these payment guardrails as soon as possible is necessary to protect the interests and health of Medicare beneficiaries. In recognition of the timing considerations related to the 2025 contract year on the effective date of this final rule, we are clarifying that the applicability of this and all marketing provisions begins on October 1, 2024, per § 422.2263(a).

Comment: Many commenters expressed support for these proposals, indicating that they believe this move to make compensation amounts uniform for the sale of all plans will help curb the aggressive marketing tactics used by certain agents and brokers, and will reduce pressure placed on Medicare beneficiaries to enroll in plans that they do not fully understand, or which may not best suit their individual health care needs.

Response: We thank commenters for their support.

Comment: Many commenters stated that they supported this proposal because they believe it is important to make payments to agents and brokers clear and knowable, rather than subject to add-on administrative payments that are paid ''under the table'' and where neither CMS nor the consumer have any insight into these payment relationships or amounts.

Response: We thank commenters for their support and believe that by making compensation amounts universal, agents and brokers will hopefully be free from undue influence to enroll beneficiaries in one plan over another, but the beneficiaries themselves can be confident that their agent or broker is indeed working to ensure that they are enrolled in the MA plan that is best suited to meet their health care needs.

Comment: Some commenters expressed support for the proposal because it would enable small carriers to remain competitive with larger carriers, as they would not have to compete with larger carriers in offering ever-increasing incentives for agents, brokers, and TPMOs to represent these plans. Additionally, without additional incentives to increase steerage, smaller plans may have a better opportunity to compete in the marketplace.

Response: We thank commenters for their support of the proposal.

Comment: A commenter requested clarification about whether or how a plan could stop compensation for new enrollments in a plan mid-year if plans are no longer permitted to submit a range of compensation rates that would be applicable for that plan year.

Response: As proposed § 422.2274(d)(2) stated that for an initial enrollment year a plan may pay an agent or broker compensation at FMV. However, in proposing to set a fixed rate for compensation levels that plans ''may'' pay to agents and brokers, we did not intend to eliminate the option for a plan to choose not to pay compensation for an enrollment at all. Therefore, we are clarifying that under the regulations governing agent broker compensation at §§ 422.2274 and 423.2274 that CMS is adopting in this final rule, a plan may choose at any time to communicate to the agents and brokers representing it that it will no longer be compensating them for enrollments into that plan without being out of compliance of these regulations.

Comment: A few commenters expressed concerns that requiring plans to pay agents and brokers the same amount for compensation would have a negative impact on smaller MA organizations and Part D sponsors who may not be able to afford to pay the new uniform compensation rate and would therefore be unable to afford to pay agents and brokers to represent their plans.

Response: We understand the concern that smaller MA organizations may not be as well equipped to pay the mandatory compensation rate as a larger MA organization and will be prevented from negotiating with agents and brokers for a lower rate below the compensation cap as they can under our current rules. However, our data [158] suggests that negotiating below the payment cap was a very rare phenomenon, and we believe that the advantages gained by eliminating the continual increase in administrative payments, and therefore the need to increase payments made and offered to agents, brokers, and TPMOs will offset any financial losses caused by this increase to compensation expenses, as it is our understanding that the administrative fees paid per enrollee far exceed the compensation paid for that enrollment.

Comment: Many commenters disagreed with this proposal as a whole and argued that the types of aggressive marketing tactics we discussed in the preamble are most often engaged in by agents and brokers who are employees of FMOs and call centers, and that the incentives for these employed agents and brokers would not be mitigated by

[158] *https://www.cms.gov/medicare/health-drug-plans/managed-care-marketing/medicare-marketing-guidelines/agent-broker-compensation.*

our proposed compensation policies because employed agents receive a salary, whereas other independent agents and brokers make their living on commissions for enrollments. They contend that this policy, as a whole, does not distinguish between the different types of agents and their employment relationships, and is not narrowly targeted to rein in the abusive behaviors discussed.

Response: We thank commenters for their thoughtful comments and the information that they provided about the different types of relationships between agents and other TPMOs in the MA industry. We understand that, while our policy would have the desired effect of changing the incentives for some agents and brokers to ensure that they are aligned with the best interests of the Medicare beneficiaries whom they serve, there is a subset of agents and brokers who are directly employed by TPMOs—specifically FMOs and call centers—and these agents and brokers may not experience the same change in incentives because their salaried income may not be directly based on the CMS-defined compensation rates. We recognize that this distinction is an important part of the agent and broker ecosystem, and one which we will continue to explore as we contemplate future rulemaking.

However, we do not believe that the possibility that our policy may not reach a subset of the agents and brokers in this ecosystem is a reason not to finalize it. We believe this policy will have the desired effect of better aligning incentives for agents and brokers to ensure that they are enrolling beneficiaries in the MA plan that best meets the beneficiaries' health care needs, and not the plans that offer the agents and brokers the highest payments per enrollee. We also note that the policy to generally prohibit certain types of contract terms being finalized in this final rule at § 422.2274(c)(13), will afford a level of protection with regard to contract terms between MA organizations and TPMOs that direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker, including salaried agents and brokers, from being able to objectively assess and recommend which plan best fits the health care needs of a beneficiary. Importantly, MA organizations, agents, brokers, and other TPMOs also must comply with all applicable fraud and abuse laws including, but not limited to, the Federal anti-kickback statute.

Comment: Many commenters expressed their opposition to our proposal because many agents and brokers rely on the payment of administrative fees (sometimes also referred to as overrides) from an MA organization to their FMO to provide them with ''free'' services, such as access to plan comparison and enrollment tools, trainings, as well as contracting and compliance support. The FMOs are able to provide these ''free'' services to agents and brokers by negotiating with the MA organizations to pay the FMO the administrative fees associated with the agent or brokers' enrollments. Without the availability of such fees, commenters expressed concern that FMOs would no longer provide agents and brokers with these extra services without which they did not believe agents and brokers could effectively accomplish their enrollment work.

Response: We understand that removing the category of ''administrative payments'' (*i.e.* overrides), would change the current flow of payments from an MA organization to agents and brokers for an enrollment. We believe that by making the full payments directly to the agents and brokers, agents and brokers themselves will have the opportunity to decide which services are truly essential and how much those services are worth.

After considering public comments, we are generally finalizing our substantive proposal to include all payments to an agent or broker under the definition of compensation as proposed; in recognition of the timing considerations related to the 2025 contract year on the effective date of this final rule, we are clarifying that the applicability of this and all marketing provisions begins on October 1, 2024, per § 422.2263(a). To memorialize this updated policy, we are finalizing our policy to incorporate ''administrative payments'' currently described at § 422.2274(e)(1) into compensation, and to amend § 422.2274(e)(2) to clarify that administrative payments would be included in the calculation of enrollment-based compensation beginning in Contract Year 2025. This means that that MAOs and the TPMOs that they contract or work with will need to begin to comply with these updated standards beginning on October 1, 2024, when marketing activities for contract year 2025 begin, per § 422.2263(a). We are also adopting language to the existing regulatory text to make clear that this definition will apply to contract years through contract year 2024, meaning that MAOs and TPMOs should continue to comply with CMS's existing agent and broker compensation policies until the date that marketing activities for contract year 2025 begin.

We also proposed to increase the compensation rate described at § 422.2274(a) to add certain appropriate administrative costs. In particular, we indicated that we believed that the administrative cost associated with the licensing, training and testing, and recording requirements at §§ 422.2274(b) and 422.2274(g)(2)(ii) may warrant an increase in the rate of compensation, given the significant and predictable cost of these mandatory activities.[159] Based on our fair market value analysis, we believed these activities would warrant increasing the base compensation rate by $31,[160] to be updated annually as part of the scheduled compensation rate update described at § 422.2274(a). Therefore, we proposed, beginning in 2025, that FMV would be increased by $31 to account for administrative payments included under the compensation rate, and to be updated annually in compliance with the requirements for FMV updates.

When proposed, we believed it was necessary to increase the rate for compensation by $31, based on the estimated costs for licensing, training, testing, and call recording that would need to be covered by this single enrollment-based payment. We proposed to begin with a one-time $31 increase, including various locality-specific adjustments, with annual FMV updates to this amount as described by the regulation, including ''adding the current year FMV and the product of the current year FMV and MA Growth Percentage for aged and disabled beneficiaries.'' In the November 2023 proposed rule, we also noted that we did not explicitly propose a proportionate increase to compensation for renewals and that we considered this in determining the amount by which we proposed to increase the rate for compensation for enrollments.

We sought comment on our proposal to increase the rate of compensation to account for necessary administrative costs that would be incorporated into this rate under our previous proposal. Specifically, CMS requested comment on the administrative costs that should be considered, and how else we might determine their value, as we consider the future of the compensation structure.

[159] *https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment/agent-broker-compenstation.*

[160] Our calculations arriving at this number are further discussed in the COI in section X.B.10 of this final rule, titled ICRs Regarding Agent Broker Compensation (§ 422.2274).

Comment: As in the previous policies, commenters indicated their concern that an effective date immediately after finalization of the policy would be difficult if not impossible to comply with.

Response: As with the modifications to the compensation rate discussed above, we are delaying the applicability date for the changes to the agent and broker compensation requirements at §§ 422.2274 (a), (c), and (d) to October 1, 2024, and therefore will not be applicable prior to the start of marketing and enrollment activity for the 2025 contract year.

In recognition of the timing considerations related to the 2025 contract year on the effective date of this final rule, we are clarifying that the applicability of this and all marketing provisions begins on October 1, 2024, per § 422.2263(a).We believe that implementing these payment guardrails as soon as possible, will enhance the beneficiary experience with agents and brokers during the 2025 AEP. The benefit of this implementation date offsets any concerns about complexity or potential extra payment generated by this implementation framework.

Comment: A commenter requested clarification regarding how this proposal would affect renewals.

Response: As indicated in the proposed rule at 88 FR 78556, we did not separately propose a specific numeric increase in renewals proportionate to the proposed increase in initial compensation. However, the proposed regulation text governing renewal compensation, at § 422.2274(d)(3), as proposed, states that ''For each enrollment in a renewal year, MA plans may pay compensation at a rate of 50 percent of FMV.'' The reference to FMV within § 422.2274(d)(3) refers to the FMV for agent broker compensation specified in CMS's regulations at § 422.2274(a). Therefore, any updates to the FMV, including those which is CMS finalizing here, would automatically be incorporated into the calculation of compensation rate for renewals and would not need a separate proposal to achieve this result. See Tables FC–1 and FC–2 for more detail.

Comment: Many commenters indicated that CMS's proposed $31 increase to the flat-rate compensation amount would be insufficient to cover even the two primary activities we listed in the proposed rule (call recording and training and testing). Commenters indicated that agents and brokers have many other business expenses, such as plan comparison tools and appointment fees which were not included in calculating the rate update. Furthermore, some commenters explained that agents and brokers often engage in work and provide services that are unlikely to result in enrollment but are for the benefit of those beneficiaries, such as providing guidance to estate planners. We also heard from many commenters, including agents and brokers as well as beneficiaries, about additional services agents and brokers provide beneficiaries through their knowledge of plans and access to industry-standard technology; for instance, commenters noted that a local agent may help a beneficiary identify a plan that includes a preferred doctor, or help an enrolled beneficiary find the local in-network pharmacy with the lowest prices on that beneficiary's drugs.

Commenters argued that these activities, and the fair market value of the tools and services agents and brokers need to perform their jobs, warranted a significantly higher per-enrollee compensation rate. Some commenters suggested figures for a more appropriate compensation increase ranging from $50 to $500 more, per new enrollee, while others recommended that the increase be a percentage of the base compensation amount.

Commenters suggested that without sufficient compensation, many agents and brokers would no longer be able to serve the MA market, and new agents and brokers would not have the resources to enter the market in the first place.

Response: We thank the many commenters who provided us with a more complete picture of the many administrative and other services and expenses agents and brokers undertake when assisting beneficiaries with enrollments. These comments have made us aware that, in our initial proposal, we may not have adequately accounted for the array of services that agents and brokers may provide when we calculated our proposed payment increase. It was not our intention to make the MA compensation rate so low that agents and brokers would be driven out of the industry or would be unable to enter it in the first place.

However, we do believe it is important to ensure that, while we support agents and brokers and the services they provide, the MA program and its funds are not being used to subsidize other programs and industries. For example, we understand that in the proposed rule we may have undervalued the cost of CRM (customer-relationship management) tools which provide call recording software. However, it is our understanding that these tools serve additional functions beyond the mandatory call recording and transcription, and that this functionality may be used by an agent or broker when soliciting an enrollment for a non-Medicare, private market plan. Therefore, we believe that it is reasonable for MA compensation rates to reflect less than 100 percent of the cost of purchasing or licensing these tools.

After considering what we have learned and the many responses we received through public comment, we have concluded that our original proposed increase to compensation was too low. Commenters' feedback, both general and specific, was closely considered and we believe it is necessary to update the compensation rate increase to better reflect the costs of MA agent or broker services. Commenters suggested many different figures and means of calculating an appropriate amount. As discussed previously, the true cost of most administrative expenses can vary greatly from one agent or broker to another and is based in data and contracts that CMS does not have access to, so it would be extremely difficult for us to accurately capture, making a line-item calculation not practicable. This was further reflected in the wide variation among alternate rates posed by commenters, with a few commenters suggesting an alternate rate increase of $50, another $75, while the majority recommended higher rates beginning at $100 and some going as high as $500. Some commenters suggested that we should calculate the compensation increase as a percentage of the base rate, such as 30% or 33% of the current $611 compensation figure.

Considering the complexities involved, we believe that choosing a flat rate for calculating the increase is an appropriate path forward to create parity among agents, regardless of which plan, plan type, or type of Medicare enrollment they effectuate on behalf of the beneficiary. Administrative payments are intended to cover administrative costs faced by the agent or broker and those costs should be the same regardless of the type of plan in which a beneficiary enrolls, including a standalone PDP. Therefore, there is no need to vary administrative payments based on plan type and a flat rate approach is the most appropriate way to achieve our goal of eliminating financial incentives in the form of larger, purported administrative payments which are over and above FMV from a particular plan or plans, that may have the effect of encouraging agents and brokers to steer enrollment in one plan

or plan type versus another. A uniform, flat rate achieves this goal.

Several commenters suggested that an increase of $100 would be an appropriate starting point and reflects the minimum monthly costs of necessary licensing and technology costs. We understand that other commenters recommended an increase of more than $100, including some commenters that suggested an increase of $200 or more. However, we believe, based on the totality of comments that recommendations for an increase above $100 may have been inflated to include the full price of all technology and systems that are also utilized to effectuate sales in other markets or for different product types other than MA or PDP products. In addition, it appears that these higher dollar recommendations may reflect the agent and brokers' loss of ''bonus payments'' and other purported ''administrative payments'' they may previously have received, some of which were always beyond the scope and FMV of the services involved in enrolling beneficiaries into MA and PDP plans and therefore should not have been included under compensation or administrative payments.

We believe that increasing the FMV rate for new enrollments by a total of $100, and therefore applied to renewals at a maximum amount of 50 percent of the total compensation amount, should provide agents and brokers with sufficient funds to continue to access necessary administrative tools and trainings, to offset appointment fees and encourage the representation of multiple plans, and therefore to continue providing adequate service to Medicare beneficiaries. Accordingly, based on the information provided in comments and for the reasons discussed in this final rule, we are finalizing a policy to make a one-time $100 increase to the FMV compensation rate for agents and brokers for initial enrollments into MA plans for the 2025 plan contract year.

TABLE FC-1: AGENT BROKER COMPENSATION UPDATES CY 2024–2026

	2024	2025	2026
Initial Enrollment	$611	(FMV TBD) + $100	FMV TBD
Renewal	$305	(FMV TBD +100)*0.5	FMV TBD*0.5

By way of example, if we were to assume that the FMV increase in years 2025 and 2026 is 2.5 percent, the payment rates for those years would be as follows:

TABLE FC-2: EXAMPLE AGENT BROKER COMPENSATION UPDATES CY 2024-2026

	2024	2025	2026
Initial Enrollment	$611	$726	$744
Renewal	$305	$313	$372

Comment: Several comments expressed confusion about whether this payment is an ''all-in cap'' that is intended to include all fees paid by an MA organization to an agent, broker, or other TPMO, and what that would mean for payments related to marketing activities.

Response: This proposal, and all agent broker compensation rules at § 422.2274(d) are limited to independent agents and brokers, and do not extend to TMPOs more generally. Therefore, this policy represents a limitation on payments in excess of those paid under ''compensation'' only for commissions paid for enrollments to independent agents and brokers. Though we are continuing to consider future rulemaking in this space, our current policy does not extend to placing limitations on payments from an MAO to a TPMO who is not an independent agent or broker for activities that are not undertaken as part of an enrollment by an independent agent or broker.

After considering public comments on this proposal, for the 2025 contract year, we are finalizing at § 422.2274(a) a one-time FMV increase of $100, which will then be added to the base compensation rate for 2025; the sum of the 2025 compensation rate and the $100 will form a new base compensation rate that will be updated annually according to our FMV updates described in § 422.312. We are also finalizing changes to § 422.2274(d)(1)(ii) that beginning with contract year 2023, MA organizations are limited to the compensation amounts outlined in § 422.2274(a).

We received many out-of-scope comments related to agent and broker compensation as part of this rulemaking. We received many comments indicating the need for a regulatory distinction between agents employed by call centers and those who are truly independent and only contract with TPMOs. We appreciate these comments and will continue to explore ways in which further regulation in this space may further our goals of ensuring that the use of compensation creates incentives for agents and brokers to enroll individuals in the MA plan that best meets their health care needs.

We also received many comments encouraging more robust enforcement of our current regulations, and comments encouraging CMS to relax our rules somewhat to ensure that all agents have the ability to effectuate sales for all plans. We received feedback asking for more regulation in this policy space, and comments asking us to slow regulatory action to give the policies finalized in the past few years, time to mature. We have read and considered all comments and will consider these suggestions as we contemplate future rulemaking.

4. Agent Broker Compensation for Part D Plans

Finally, we also are finalizing our proposal to apply each of the policies described previously, governing agent and broker compensation for the sale of MA plans, to also apply to compensation for agents and brokers that market PDP plans, as codified at § 423.2274.

Pursuant to sections 1851(j)(2)(D) and 1860D–4(l) of the Act, the Secretary has a statutory obligation to establish guidelines to ensure that the use of agent and broker compensation creates incentives for agents and brokers to enroll individuals in the MA and Part D prescription drug plans that are intended to best meet beneficiaries' health care needs.

As we explained in the November 2023 proposed rule, because the same agents and brokers are often licensed to sell both MA plans and PDPs, we believe it is necessary under our statutory authority to apply the same compensation rules to the sale of both MA plans and PDPs in order to ensure that both plan types are being held to the same standards and are on a 'level playing field' when it comes to incentives faced by agents and brokers. This includes increasing the FMV rate compensation rate.

In the November 2023 proposed rule we also stated that we think it is necessary to extend these regulations to the sale of PDPs to avoid shifting the incentives discussed at length previously, such as the incentive for agents to favor one plan over another based upon bonuses or other payments that are not currently accounted for under the definition of ''compensation.'' If conforming changes are not made to the sale of PDP plans, the PDP plans may have an unfair advantage in that they have the opportunity to offer additional payments and perks to FMOs and agents, while MA plan sponsors are limited by the policies proposed previously. Therefore, for the same reasons that we described in the proposed rule for adopting the proposed changes to § 422.2274, we also proposed to make conforming amendments to § 423.2274.

We sought comment on this proposal, and specifically whether and to what extend modifications to these proposals should be made to account for differences between MA and Part D plan types.

We did not receive any comments on the proposal to extend these changes to the sale of PDP plans. Thus, we are finalizing updates to 42 CFR 423.2274 (a), (c), (d), and (e) largely as proposed. However, in light of the changes to the MA compensation rate described in section X.C.3. of this final rule and the need for parity between MA and PDP plan sales discussed in this section, we are conforming changes to the PDP compensation rates at § 423.2274 (to increase the PDP compensation rate for initial enrollments by $100. Likewise, where CMS is finalizing the regulation text in § 422.2274(a), (c), and (d) with minor organizational and editorial changes for clarity, we are adopting conforming changes to the regulation text that we are finalizing in § 423.2274(a), (c), and (d). Our policies are in alignment with the rules being finalized for MA agents and brokers, with an applicability date for these rules on October 1, 2024, for the 2025 plan contract year.

5. Summary of the Final Policy

We are finalizing the following policies with regard to agent and broker compensation:

- For contract year 2025 and subsequent contract years, generally prohibit contract terms between MA organizations and agents, brokers, or other TMPOs that may directly or indirectly interfere with the agent's or broker's ability to objectively assess and recommend the plan which best fits a beneficiary's health care needs, as reflected in § 422.2274(c)(4) of this final rule.
- Set a single agent and broker compensation rate for all plans, as reflected in § 422.2274(d)(2), while revising the scope of what is considered ''compensation,'' applicable to contract year 2025 and subsequent contract years, as reflected in § 422.2274(a) and (e).
- Eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services, applicable to contract year 2025 and subsequent contract years, as reflected in § 422.2274(e).
- Make conforming edits to the PDP agent broker compensation rules at § 423.2274.

VII. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (42 CFR 422.164, 422.166, 422.260, 423.184, and 423.186)

A. Introduction

CMS develops and publicly posts a 5-star rating system for Medicare Advantage (MA)/Part C and Part D plans as part of its responsibility to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D–1(c) of the Act and based on the collection of different types of quality data under section 1852(e) of the Act. The Part C and Part D Star Ratings system is used to determine quality bonus payment (QBP) ratings for MA plans under section 1853(o) of the Act and the amount of MA beneficiary rebates under section 1854(b) of the Act. We use multiple data sources to measure quality and performance of contracts, such as CMS administrative data, surveys of enrollees, information provided directly from health and drug plans, and data collected by CMS contractors. Various regulations, including §§ 417.472(j) and (k), 422.152(b), 423.153(c), and 423.156, require plans to report on quality improvement and quality assurance and to provide data which help beneficiaries compare plans. The methodology for the Star Ratings system for the MA and Part D programs is codified at §§ 422.160 through 422.166 and 423.180 through 423.186, respectively, and we have specified the measures used in setting Star Ratings through rulemaking. In addition, the cost plan regulation at § 417.472(k) requires cost contracts to be subject to the Parts 422 and 423 Medicare Advantage and Part D Prescription Drug Program Quality Rating System. (83 FR 16526–27). As a result, the policies and regulatory changes finalized here will apply to the quality ratings for MA plans, cost plans, and Part D plans. We generally use ''Part C'' to refer to the quality measures and ratings system that apply to MA plans and cost plans.

We have continued to identify enhancements to the Star Ratings program to ensure it is aligned with the CMS Quality Strategy as that Strategy evolves over time. To support the CMS National Quality Strategy, CMS is moving towards a building-block approach to streamline quality measures across CMS quality and value-based care programs. Across our programs, where applicable, we are considering including the Universal Foundation [161] of quality measures, which is a core set of measures that are aligned across CMS programs. CMS is committed to aligning a core set of measures across all our quality and value-based care programs and ensuring we measure quality across the entire care continuum in a way that promotes the best, safest, and most equitable care for all individuals. Improving alignment of measures across federal programs and with private payers would reduce provider burden while also improving the effectiveness

[161] *https://www.nejm.org/doi/full/10.1056/NEJMp2215539.*

and comparability of measures. Using the Universal Foundation of quality measures would focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps. The Universal Foundation is a building block to which programs would add additional aligned or program-specific measures. This core set of measures would evolve over time to meet the needs of individuals served across CMS programs. We submitted the Initiation and Engagement of Substance Use Disorder Treatment (IET) measure (Part C) (a Universal Foundation measure) to the 2023 Measures under Consideration list as part of the Pre-Rulemaking Measure Review process as a step toward proposing use of that measure in the Star Ratings system through future rulemaking to align with the Universal Foundation. We also note that, beginning with measurement year 2023, Part C contracts are beginning to report to CMS additional measures that are part of the Universal Foundation, such as Adult Immunization Status, Depression Screening and Follow-Up for Adolescents and Adults, and Social Need Screening and Intervention, for the display page. We have previously solicited feedback regarding potentially proposing these measures as Star Ratings in the future through both the Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies and the Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. We intend to submit these measures to the Pre-Rulemaking Measure Review process in the future and propose them through future rulemaking as additional Star Ratings measures. The remaining measures that are part of the Universal Foundation are already part of the current Part C and Part D Star Ratings program.

In the December 2022 proposed rule, in addition to the policies addressed in the April 2023 final rule,[162] we proposed to make changes in the specific measures used in the Star Ratings System:

- Remove the stand-alone Part C Medication Reconciliation Post-discharge measure;
- Add the updated Part C Colorectal Cancer Screening measure with the National Committee for Quality Alliance (NCQA) specification change;
- Add the updated Part C Care for Older Adults—Functional Status Assessment measure with the NCQA specification change;
- Add the Part D Concurrent Use of Opioids and Benzodiazepines measure;
- Add the Part D Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults measure; and
- Add the Part D Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults measure.

We also proposed a series of technical clarifications of the existing rules related to Quality Bonus Payment (QBP) appeals processes and weighting of measures with a substantive specification change.

In the December 2022 proposed rule, we proposed these changes to apply to the 2024 measurement period and the 2026 Star Ratings, but as discussed in and given the timing of this final rule, we are finalizing these policies (that is, data would be collected, and performance measured) for the 2025 measurement period and the 2027 Star Ratings unless otherwise stated.

In the November 2023 proposed rule, we proposed to update the Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) measure (Part D). We also proposed the following methodological enhancements, clarifications, and operational updates:

- Revise the process for identifying data completeness issues and calculating scaled reductions for the Part C appeals measures.
- Update how the Categorical Adjustment Index (CAI) and health equity index (HEI) reward are calculated in the case of contract consolidations.
- Revise an aspect of the QBP appeals process.
- Add that a sponsor may request CMS review of its contract's administrative claims data used for the Part D Patient Safety measures no later than the annual deadline set by CMS for the applicable Star Ratings year.

Unless otherwise stated, finalized changes would apply (that is, data would be collected and performance measured) for the 2025 measurement period and the 2027 Star Ratings.

CMS appreciates the feedback we received on our proposals in both proposed rules. In the sections that follow, which are arranged by topic area, we summarize each proposal and comments we received and provide our responses.

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

The regulations at §§ 422.164 and 423.184 specify the criteria and procedures for adding, updating, and removing measures for the Star Ratings program. In the ''Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program'' final rule which appeared in the **Federal Register** on April 16, 2018 (83 FR 16532) hereinafter referred to as the April 2018 final rule, we stated we are committed to continuing to improve the Part C and Part D Star Ratings system and anticipated that over time measures would be added, updated, and removed. We also specified at §§ 422.164(d) and 423.184(d) rules for measure updates based on whether they are substantive or non-substantive. The regulations, at paragraph (d)(1), list examples of non-substantive updates. See also 83 FR 16534–37. Due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and their specifications) adopted for the Part C and Part D Star Ratings program. CMS lists the measures used for the Star Ratings each year in the Medicare Part C & D Star Ratings Technical Notes or similar guidance issued with publication of the Star Ratings.

We are committed to continuing to improve the Part C and Part D Star Ratings system by focusing on improving clinical and other health outcomes. Consistent with §§ 422.164(c)(1) and 423.184(c)(1), we continue to review measures that are nationally endorsed and in alignment with the private sector. For example, we regularly review measures developed by

[162] In the April 2023 final rule, we finalized several policies from the December 2022 proposed rule, including the introduction of a health equity index reward and removal of the existing reward factor starting with the 2027 Star Ratings and a series of measure updates: removing the Part C Diabetes Care—Kidney Disease Monitoring measure; updating the Part D Medication Adherence for Diabetes Medication, Medication Adherence for Hypertension (RAS Antagonists), and Medication Adherence for Cholesterol (Statins) measures; and adding the Part C Kidney Health Evaluation for Patients with Diabetes measure. In the April 2023 final rule, we also finalized several methodological changes: reducing the weight of patient experience/complaints and access measures; adding an additional basis for the subregulatory removal of Star Ratings measures; and removing the 60 percent rule for the adjustment for extreme and uncontrollable circumstances. Finally, we also finalized a series of technical clarifications of the existing rules related to adjustments for disasters and contract consolidations, as well as a technical amendment to §§ 422.162(a)(2)(i) and 423.186(a)(2)(i) to fix a codification issue. 88 FR 22263 through 22297.

NCQA and Pharmacy Quality Alliance (PQA).

1. Measure Removals

a. Medication Reconciliation Post-Discharge (Part C)

We proposed to remove the Medication Reconciliation Post-Discharge (MRP) measure as it would be duplicative of the MRP component of the Transitions of Care (TRC) measure included beginning with the 2024 Star Ratings. In the January 2021 final rule at 86 FR 5921–24, CMS finalized inclusion of the TRC measure (Part C) in the 2024 Star Ratings. The TRC measure includes four indicators: MRP, Notification of Inpatient Admission, Patient Engagement After Inpatient Discharge, and Receipt of Discharge Information. Currently, MRP appears in both the Medicare Part C Star Ratings as a stand-alone measure and as one of the four indicators included in the TRC measure. As discussed at 86 FR 5921–24, transitions from an inpatient stay back to home often result in poor care coordination, including communication gaps between inpatient and outpatient providers; planned and inadvertent medication changes; incomplete diagnostic work-ups; and insufficient understanding of diagnoses, medication, and follow-up care needs. Although at this time CMS is only implementing the TRC measure in the Part C Star Ratings program, it is a HEDIS measure and over time, it may be used in other programs. Based on the importance of care coordination in the Part C program and how the TRC measure provides a more comprehensive picture of how plans manage transitions across settings for care, we believe its inclusion in the Part C Star Ratings is appropriate.

For measurement year 2020, NCQA provided multiple updates to the TRC measure as described at 86 FR 5921–22. In one of these updates, NCQA revised the requirement of using one medical record from a specific provider to, instead, allow numerator information to be captured from additional communication forms accessible to the primary care provider or ongoing care provider (for example, admissions, discharges, and transfers (ADT) feeds, shared electronic medical records (EMRs)) that occur regularly in the field and meet the intent of the measure. This change also ensured that scores for the MRP indicator in the TRC measure and the stand-alone MRP measure would match. Currently, the MRP measure for the Part C Star Ratings comes from the MRP indicator collected through the TRC measure. This is because NCQA decided that the stand-alone MRP measure no longer needed to be separately reported since it could be pulled from the medication reconciliation indicator in the TRC measure.

CMS proposed to remove the stand-alone MRP measure from the Part C Star Ratings since the same information about medication reconciliation is now also incorporated as a component of the TRC measure and, consequently, it is duplicative to have MRP as a stand-alone measure and as a component of the TRC measure for Part C Star Ratings. We solicited comments on this proposal.

Comment: Most commenters supported the removal of the MRP measure. Some commenters raised concerns regarding having both the stand-alone MRP measure and having MRP as a component of the TRC measure for a period of time until the stand-alone measure is retired. A few commenters suggested the removal of the MRP measure should coincide with the addition of the TRC measure, which was added to the 2024 Star Ratings.

Response: We thank the commenters for their support of our proposal. The stand-alone MRP measure is being removed beginning with the 2025 measurement year, which provides MA organizations with notice of the measures being used for quality ratings in advance of the measurement year. During this interim period, having MRP as a stand-alone measure as well as a component of the TRC measure gives it a slightly higher weight in the Star Ratings. Since both the stand-alone MRP measure and the TRC measure are weighted as process measures (which is a weight of 1), the weight of MRP across these two measures is still relatively low. In light of this and the importance of reconciling medications following an inpatient stay, we do not believe that the short period during which both the MRP measure and the TRC measure are included in the Part C Star Ratings is problematic.

Comment: A commenter noted that plans will be disincentivized to focus on MRP once the stand-alone measure is removed.

Response: We understand the commenter's concern but note that plans should continue focusing on reconciling medications following an inpatient stay given this also impacts the TRC measure and other measures in the Star Ratings such as reducing hospital readmissions and improving care coordination.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the removal of the MRP measure from the Part C Star Ratings starting with the 2025 measurement year and the 2027 Star Ratings.

2. Measure Updates

In the April 2018 final rule, we specified at §§ 422.164(d) and 423.184(d) rules for measure updates based on whether they are substantive or non-substantive. (83 FR 16534 and 16535). Where an update is substantive within the scope of §§ 422.164(d)(2) and 423.184(d)(2), 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 and then engage in rulemaking to make substantive changes to a Star Ratings measure. Per §§ 422.164(d)(2) and 423.184(d)(2), 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. This 2-year period for the updated measure to be on the display page may overlap with the period during which CMS solicits comment and engages in rulemaking. Further, the legacy measure may continue to be used in the Star Ratings during this period.

a. Colorectal Cancer Screening (Part C)—Substantive Change

CMS proposed a substantive update to the existing colorectal cancer screening measure because of changes in the applicable clinical guidance and by the measure steward. In May 2021, the U.S. Preventive Services Task Force (USPSTF) released updated guidance for the age at which colorectal cancer screenings should begin. Subsequently, NCQA, the measure steward, has updated its colorectal cancer screening measure to include a rate for adults 45–49 years of age for measurement year 2022. Therefore, CMS proposed expanding the age range for the Colorectal Cancer Screening measure to adults aged 45–49, for an updated age range of 45–75, for the 2024 and subsequent measurement years. The expanded age range for this screening measure significantly increases the size of the population covered by this measure and is therefore a substantive measure specification change within the scope of § 422.164(d)(2). Other CMS programs, such as for the qualified health plans (QHPs) that participate in Exchanges [163] and the adult core set for

[163] *https://www.cms.gov/files/document/final-2022-call-letter-qrs-qhp-enrollee-survey.pdf.*

Medicaid plans,[164] have introduced this change into their programs as they also use the same HEDIS measure.

CMS solicited feedback on making this substantive update to the measure in the Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, and most commenters supported this change. As described in the April 2018 final rule (83 FR 16534), we may keep a legacy measure in the Star Ratings during the period that an updated version of the measure is on the display page. The legacy measure with the narrower age range of 50–75 years will remain available and be used in Star Ratings until the updated measure has been adopted through rulemaking and has been on the display page for 2 years. We first displayed the updated measure for the 2022 measurement year, on the 2024 display page.

We solicited comments on this proposal.

Comment: Most commenters strongly supported CMS expanding the age range for the Colorectal Cancer Screening measure to include beneficiaries starting at age 45, with many citing data on the importance of earlier colorectal cancer screenings.

Response: We appreciate the support to expand the age range for the colorectal cancer screening measure, following updated clinical guidelines established by the USPSTF.

Comment: A commenter was concerned that the expanded age range may negatively impact the measure rate because more enrollees will be included in the denominator.

Response: We strive to ensure the Star Rating measures reflect the most recent clinical guidelines. The USPSTF recommends offering colorectal cancer screening at age 45 due to recent trends of increasing colorectal cancer in adults younger than 50 years old and the benefits of screening in reducing cancer diagnoses. CMS will maintain the legacy measure with the narrower age range in the Star Ratings through the end of the 2024 measurement year and the 2026 Star Ratings. Because the updated measure with the broader age range has been on the display page beginning with the 2022 measurement period, plans will have a total of 3 measurement years to transition to the most recent clinical guidelines, which are reflected in the updated measure. We do not believe that additional time is necessary or appropriate because the change in the USPSTF recommendation was nearly 3 years ago as of the time this final rule is published. Ensuring that the Star Ratings reflect up to date clinical guidelines is an important consideration both for providing comparative information to beneficiaries about MA plan quality and ensuring that the MA program furnishes appropriate care and access to covered services.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing expanding the age range for the Colorectal Cancer Screening measure. Given the timing of the finalization of this rule, we are finalizing the addition of the Colorectal Cancer Screening measure with the expanded age range starting with the 2025 measurement year and the 2027 Star Ratings. Table VII.1 summarizes the updated Colorectal Cancer Screening measure finalized in this rule. The measure description listed in this table is a high-level description.

b. Care for Older Adults—Functional Status Assessment (Part C)—Substantive Change

We proposed to add the Care for Older Adults (COA)—Functional Status Assessment measure back to the Star Ratings after it has been on the display page following a substantive measure specification change. The COA measure is collected for Special Needs Plans (SNPs) and includes three indicators—Medication Review, Functional Status Assessment, and Pain Assessment.

For HEDIS data reported in 2021, based on the 2020 measurement year, NCQA implemented a change for the COA—Functional Status Assessment.[165] Previously the measure specification was that documentation of a complete functional status assessment must include: (1) notation that Activities of Daily Living (ADLs) were assessed; (2) notation that Instrumental Activities of Daily Living (IADLs) were assessed; (3) result of assessment using a standardized functional assessment tool; or (4) notation that at least three of the following four components were assessed: (a) cognitive status, (b) ambulation status, (c) hearing, vision, and speech (that is, sensory ability), and (d) other functional independence (for example, exercise, ability to perform job). Because the clinical field of functional status assessment was moving toward agreement on assessment using ADLs, IADLs, or another standardized tool, and to improve the clarity of the specification, NCQA removed the fourth option for meeting the numerator requirements for this indicator for HEDIS data reported in 2021.

The measure change for the COA—Functional Status Assessment measure is a substantive update under § 422.164(d)(2) because removal of a mechanism for positive performance on the measure may meaningfully impact the numerator. The updated measure was moved to the display page starting with the 2022 Star Ratings.

CMS proposed to return this updated measure to the Star Ratings, beginning with the 2026 Star Ratings and 2024 measurement period. With the updated specification, documentation of a complete functional status assessment must include: (1) notation that ADLs were assessed; (2) notation that IADLs were assessed; or (3) result of assessment using a standardized functional assessment tool.

We solicited comments on this proposal.

Comment: Most commenters supported returning the updated COA—Functional Status Assessment measure back to the Star Ratings noting the importance of assessing functional status in older beneficiaries.

Response: We thank the commenters for their support of our proposal.

Comment: A commenter raised concerns with duplicative efforts in monitoring functional status in the Star Ratings program since it includes other measures such as the SNP Care Management measure and the Physical Functioning Activities of Daily Living (PFADL) measure.

Response: We disagree that this measure duplicates information and performance monitored through other measures. The PFADL measure is currently on the display page and is different than the COA—Functional Status Assessment measure in that it measures changes in functional status over time for all MA enrollees, not only SNP enrollees, and does not measure whether an enrollee had an assessment. The SNP Care Management measure is broader in that it focuses on whether a SNP enrollee had an assessment of their health needs and risks and is not about assessments specifically of functional status.

Comment: A commenter recommended delaying the return of this measure to the Star Ratings until NCQA decides whether the measure will be retired because the 2024

[164] *https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/adult-and-child-health-care-quality-measures/adult-health-care-quality-measures/index.html.*

[165] We solicited feedback on these changes in the Advance Notice of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

Advance Notice noted that NCQA was considering an alternative measure that may replace the COA—Functional Status Assessment measure.

Response: At this time NCQA is no longer considering the retirement of this measure and there is therefore no reason to delay the return of this measure to the Star Ratings.

Comment: A commenter requested additional guidance as to how the HEDIS measure specifications delineate ''standardized functional assessment tools.''

Response: In Volume 2 of the HEDIS Technical Specifications for Health Plans,[166] there are examples of standardized functional status assessment tools that may be used to satisfy the measure, such as the SF–36,® Assessment of Living Skills and Resources (ALSAR), Independent Living Scale (ILS), Katz Index of Independence in ADL, Klein-Bell ADL Scale, Lawton & Brody's IADL scales, and Patient Reported Outcome Measurement Information System (PROMIS) Global or Physical Function Scales.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing adding back the COA—Functional Status Assessment measure to the Star Ratings. Given the timing of the finalization of this rule, we are finalizing the addition of the COA—Functional Status Assessment measure starting with the 2025 measurement year and the 2027 Star Ratings. Table VII.1 summarizes the updated COA—Functional Status Assessment measure finalized in this rule. The measure description listed in this table is a high-level description.

c. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) (Part D)—Substantive Change

Section 1860D–4(c)(2) of the Act requires all Part D sponsors to have an MTM program designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. Section 1860D–4(c)(2)(A)(ii) of the Act requires Part D sponsors to target those Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary. CMS codified the MTM targeting criteria at § 423.153(d)(2).

CMS also uses the MTM Program Completion Rate for CMR measure, which is defined as the percent of MTM program enrollees who received a CMR during the reporting period to show how many members in a plan's MTM program had an assessment from their plan by a pharmacist or other health professional to help them manage their medications. As part of the completion of a CMR, a Part D enrollee receives a written summary of the discussion in CMS's Standardized Format, including an action plan that recommends what the member can do to better understand and use their medications.[167]

In the December 2022 proposed rule, CMS proposed changes to the MTM program targeting criteria, including: (1) requiring plan sponsors to target all core chronic diseases identified by CMS, codifying the current 9 core chronic diseases [168] in regulation, and adding HIV/AIDS for a total of 10 core chronic diseases; (2) lowering the maximum number of covered Part D drugs a sponsor may require from 8 to 5 drugs and requiring sponsors to include all Part D maintenance drugs in their targeting criteria; and (3) revising the methodology for calculating the cost threshold ($4,935 in 2023) to be commensurate with the average annual cost of 5 generic drugs ($1,004 in 2020). We estimated that the proposed changes would increase the number and percentage of Part D enrollees eligible for MTM from 4.5 million (9 percent) to 11.4 million (23 percent).

As noted in the April 2023 final rule, we did not address comments received on the provisions of the proposed rule that were not finalized in that rule, such as the proposed MTM program targeting criteria changes, and stated that they would be addressed at a later time, in a subsequent rulemaking document, as appropriate. If those proposed changes were to be finalized, the number of Part D enrollees eligible for MTM programs would increase, and the denominator of the MTM Program Completion Rate for CMR measure would expand accordingly; therefore, such changes in the targeting criteria would be substantive updates to the Star Rating measure per § 423.184(d)(2). Specifically, the proposed changes to the targeting criteria would not update the actual measure specifications but would meaningfully impact the number of Part D enrollees eligible for MTM services from 9 percent to an estimated 23 percent and, thus, substantially increase the number of enrollees included in the denominator of the MTM Program Completion Rate for CMR measure, if finalized.

Accordingly, CMS proposed that if the changes to eligibility for the MTM program in the December 2022 proposed rule (as previously described) are finalized, we would move the MTM Program Completion Rate for CMR measure to the display page for at least 2 years due to substantive measure updates associated with the change in MTM program eligibility criteria (88 FR 78558). Since there is no change to the measure specifications other than the eligibility for the MTM program, there would be no legacy measure to calculate while the updated measure is on the display page. The MTM-eligible denominator population would have meaningfully increased due to changes in the program requirements, and CMS would not have the means to calculate the measure using the previous MTM eligibility criteria. Therefore, we proposed that the measure would be removed from the Star Ratings entirely for the 2025 and 2026 measurement years and would return to the Star Ratings program no earlier than the 2027 measurement year for the 2029 Star Ratings. CMS did not anticipate any additional burden associated with the measure update, as burden tied to the changes in the MTM eligibility criteria was already considered in estimates for the December 2022 proposed rule. Under our proposal for the MTM Program Completion Rate for CMR measure, if the proposed changes to eligibility for MTM programs were not finalized, CMS would not make any substantive changes to the measure—that is, we would also not finalize the proposal in this rule to update the Star Rating measure. Readers should refer to section III.E. of this final rule for discussion of proposal to change the MTM program eligibility criteria.

We invited public comment on this proposal to update the MTM Program Completion Rate for CMR measure and received several comments. A discussion of these comments, along with our responses follows.

Comment: Most commenters supported the proposal to move the MTM Program Completion Rate for CMR measure to the display page for at

[166] *https://www.ncqa.org/hedis/measures/.*

[167] The Medicare Part C & D Star Ratings Technical Notes provide details on existing measures and are available at: *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/performancedata.*

[168] The current core chronic diseases are diabetes*, hypertension*, dyslipidemia*, chronic congestive heart failure*, Alzheimer's disease, end stage renal disease (ESRD), respiratory disease (including asthma*, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders), bone disease-arthritis (osteoporosis, osteoarthritis, and rheumatoid arthritis), and mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions). Enumerated in statute (*).

least two years if the proposed changes to the MTM program targeting criteria are finalized.

Response: We appreciate the supportive comments. As discussed in section III.E. Part D MTM Program in this final rule, CMS is finalizing changes to the targeting criteria at § 423.153(d)(2). CMS estimates that the number of Part D enrollees eligible for MTM will increase from 3.6 million (7 percent of Part D enrollees) to 7.1 million (13 percent of Part D enrollees) based on updated 2022 data.

Comment: A few commenters specifically did not support moving the MTM Program Completion Rate for CMR measure to the display page because they do not support changes to the MTM program targeting criteria. A few commenters expressed concern regarding the increased impact of the remaining Part D Star Rating measures if the MTM Program Completion Rate for CMR measure was moved to the display page and not included in the Star Ratings.

Response: Refer to section III.E. Part D MTM Program section in this final rule for information on the MTM program changes that will be applicable on January 1, 2025. Comments on the substance of the changes to the Part D MTM program that were timely received (that is, received during the comment period for the December 2022 proposed rule, which closed February 13, 2023) are addressed in that section.

We understand the concerns raised by commenters that there would be one less Part D measure included in the calculations to determine the overall Star Rating for MA–PD plans and/or the Part D summary Star Rating; however, there is no legacy measure to include in the Star Ratings because the MTM-eligible population for the denominator would change. Due to these substantive increases to the MTM-eligible measure denominator population, and the rules for substantive measure updates per § 423.184(d)(2), the MTM Program Completion Rate for CMR measure must move to the display page for at least 2 years before using the updated measure in the Star Ratings. While on the display page, CMS will continue to monitor the rates as the MTM program eligibility criteria changes are implemented.

Comment: A few commenters suggested that CMS work with a measure steward, such as the PQA, to develop alternate or companion measures that measure the success or impact of MTM services on health outcomes. A commenter recommended that CMS implement the PQA Medication Therapy Resolution Monitoring metric.

Response: CMS encourages the industry and the PQA to develop new MTM quality measures that CMS may consider for use in the Star Ratings program in the future. We believe the commenter was referencing the PQA's Medication Therapy Problem Resolution monitoring measure. According to the PQA, monitoring measures such as this do not fit the characteristics or intended use of a performance measure.[169]

After consideration of the comments received, we are finalizing the proposed update to move the MTM Program Completion Rate for CMR measure to the display page for at least two years before adding it to the Star Ratings. As discussed in section III.E. in this final rule, CMS is finalizing changes to the targeting criteria at § 423.153(d)(2) that will be effective on January 1, 2025. Therefore, the MTM Program Completion Rate for CMR measure will move to the display page entirely for the 2025 and 2026 measurement years and would return as a new measure to the Star Ratings program for the 2027 measurement year for the 2029 Star Ratings. Table VII.1 summarizes the updated MTM Program Completion Rate for CMR measure finalized in this rule.

3. Measure Additions

a. Concurrent Use of Opioids and Benzodiazepines (COB), Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH), and Polypharmacy Use of Multiple Central Nervous System Active Medications in Older Adults (Poly-CNS) (Part D)

We are committed to continuing to improve the Part C and Part D Star Ratings system by focusing on improving clinical and other health outcomes. Consistent with §§ 422.164(c)(1) and 423.184(c)(1), we continue to review measures that are nationally endorsed and in alignment with the private sector. 83 FR 16521, 16533. For example, we regularly review measures developed by NCQA and the PQA.

CMS proposed to add the following three Part D measures to the 2026 Star Ratings (2024 measurement year), which are measures developed by the PQA: COB, Poly-ACH, and Poly-CNS. The new Part D measures are calculated from Prescription Drug Event (PDE) or CMS administrative data, so they do not require any new data collections. Additionally, as announced in the Advance Notice of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies [170] the added measures would include a non-substantive update to align with the PQA measure specifications by using continuous enrollment (CE) and no longer adjusting for member-years (MYs).

These measures reflect the following performance:

- Concurrent Use of Opioids and Benzodiazepines (COB) (Part D)—analyzes the percentage of Medicare Part D beneficiaries 18 years and older with concurrent use of prescription opioids and benzodiazepines during the measurement period.
- Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH) (Part D)—analyzes the percentage of Medicare Part D beneficiaries, 65 years or older, with concurrent use of two or more unique anticholinergic medications during the measurement period.
- Polypharmacy Use of Multiple Central Nervous System-Active Medications in Older Adults (Poly-CNS) (Part D)—analyzes the percentage of Medicare Part D beneficiaries, 65 years or older, with concurrent use of three or more unique CNS-active medications during the measurement period.

These measures help plans identify enrollees who are at risk of respiratory depression or fatal overdoses, cognitive decline, or falls and fractures, respectively, and help plans encourage appropriate prescribing when medically necessary.

Per § 423.184(c)(3) and (4), new Part D measures added to the Star Ratings program must be on the display page for a minimum of 2 years prior to becoming Star Ratings measures. In addition, these measures were submitted through the 2021 Measures Under Consideration (MUC) process, a pre-rulemaking process for the selection of quality and efficiency measures under section 1890A of the Act, and were reviewed by the Measure Applications Partnership (MAP) for input and recommendations to HHS on measure selection for CMS programs.[171] The Polypharmacy measures received conditional support for rulemaking pending additional consensus based entity (CBE) endorsement (that is, approval and full support for rulemaking was conditional only because the measure was not

[169] *https://www.pqaalliance.org/pqa-measures s.*

[170] Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies at *https://www.cms.gov/files/document/2024-advance-notice.pdf.*

[171] Pre-Rulemaking MUC Lists and Recommendation Reports at *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

already National Quality Forum (NQF) endorsed), and the COB measure is a CBE-endorsed measure by NQF; therefore, the COB measure received support for rulemaking. NQF endorsement is not a requirement under §§ 422.164 and 423.184 to add a measure to the Medicare Part C and D Star Ratings System. CMS reviews measures that are nationally endorsed and in alignment with the private sector, such as measures developed by NCQA and the PQA, for adoption and use in the Star Ratings, and may develop its own measures. CMS has determined that these three PQA-endorsed measures are clinically important and reliable measures, and we proposed to add these three measures to the Star Ratings.

These three measures have been on the display page on *www.cms.gov* since 2021 (2019 measurement year) using MYs as part of the specifications. CMS adapted these measures from the PQA to adjust for partial enrollment by using MYs, however, the PQA's measure specifications have been always based on CE. Therefore, to align more closely with the PQA measure specifications, CMS is updating these measures, making a non-substantive update to use CE instead of MYs during the display period and subsequently will continue to use CE in using these measures (on the display page or as part of the Star Ratings). We described the non-substantive update in the December 2022 proposed rule to provide complete information on the measures we proposed to add to the Star Ratings and discussed the non-substantive updates in the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies as required by § 423.184(d)(1).

In this section of this rule, we summarize the comments we received on adding the COB, Poly-ACH, and Poly-CNS measures to the Star Ratings, with the non-substantive updates, and provide our responses and final decisions.

Comment: A few commenters strongly supported incorporating the COB and the two Polypharmacy measures to the Star Ratings as these measures are important to address areas of significant risk to beneficiaries. The commenters noted that there is also support in peer-reviewed literature that concurrent use of therapies targeted by these measures should be limited. Additionally, a few commenters supported adding these measures to the Star Ratings since all three were submitted for review by the MUC pre-rulemaking process and were approved by the MAP committees.

Response: We appreciate the support for adding these three measures to the Star Ratings.

Comment: A majority of commenters did not support moving the COB, Poly-ACH, and Poly-CNS measures from the display page to the Star Ratings. Additionally, commenters requested that only one of the two Polypharmacy measures be selected due to overlap of National Drug Codes (NDCs) and medication classes included in the measure specifications. One commenter supported the Poly-CNS over the Poly-ACH measure out of concern for the mental health population and that deprescribing anticholinergics in beneficiaries who have been clinically stable may compromise their health.

Response: We thank the commenters for their feedback. The measures are important areas of focus for the Medicare Part D population from a clinical perspective. The COB measure will help plans identify beneficiaries who have concurrent opioids and benzodiazepine prescriptions since taking these medications concurrently exposes these beneficiaries to high risk of respiratory depression and fatal overdose. According to the Centers for Disease Control and Prevention (CDC) 2022 Clinical Practice Guideline for Prescribing Opioids for Pain (''CDC Guideline''), the CDC recommended that there should be particular caution when prescribing opioid pain medication and benzodiazepine concurrently.[172] We believe that the COB measure is an important and appropriate way to focus on this clinical concern. The PQA Measure Development Team, Stakeholder Advisory Panel, and the American Geriatrics Society (AGS) Beers Criteria Update Panel co-chairs recommended the two separate Polypharmacy measures (the Poly-CNS and Poly-ACH measures) because of different supporting evidence, concurrent use thresholds (three for Poly-CNS and two for Poly-ACH), additive pharmacodynamic effects, and associated clinical outcomes (falls with CNS-active medications and cognitive decline with anticholinergics). The AGS 2019 Updated Beers Criteria provided a strong recommendation based on moderate to high evidence (depending on the drug therapy) to avoid concurrent use of three or more CNS-active medications in older adults because of an increased risk of falls, and for some CNS-active combinations, fractures. Additionally, a study published in JAMA Internal Medicine in 2017, analyzing data from the National Ambulatory Medical Care Survey, demonstrated that CNS polypharmacy in older adult has been trending upward and found that CNS polypharmacy in older adults more than doubled from 2004 to 2013.[173] Furthermore, for the Poly-ACH measure, the updated Beers Criteria provided a strong recommendation based on moderate evidence to avoid concurrent use of two or more anticholinergic medications in older adults because of an increased risk of cognitive decline. A systematic literature review which examined 27 studies from 1966 to 2008 determined that a high burden of anticholinergic use consistently showed a negative association with cognitive performance in older adults.[174] Based on clinical recommendations and supporting evidence, CMS concurs with the PQA, the measure steward, that two separate Polypharmacy measures are appropriate to assess these two areas of focus separately.

We conducted additional data analyses on overlap across the three measures from both medication specification and beneficiary-level perspectives based on public comments we received. We found that the COB and Poly-ACH measures do not have duplicative medication classes or overlapping NDCs. However, the Poly-CNS measure includes medication classes and NDCs that overlap with both the Poly-ACH and COB measures.

Also, we identified Part D beneficiaries who met the numerator inclusion criteria in each of the three measures and evaluated if they had overlapping contract enrollment periods (''enrollment episodes'') across the measures. Note, if a beneficiary has multiple enrollment episodes in the same Part D contract or different contracts, they must meet the numerator criteria separately for each episode. The highest percent of overlapping numerator beneficiary enrollment episodes was between the COB and Poly-CNS measures but below 50 percent (approximately 26.8 percent of the numerator beneficiary enrollment episodes in the COB measure were found in the Poly-CNS measure and 40.9 percent of the numerator beneficiary enrollment episodes in Poly-

[172] CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022 at *https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w*.

[173] Maust DT, Gerlach LB, Gibson A, et al. Trends in Central Nervous System-Active Polypharmacy Among Older Adults Seen in Outpatient Care in the United States. JAMA Intern Med. 2017; 177(4):583–585. PMID: 28192559.

[174] Campbell N, Boustani M, Limbil T, et al. The cognitive impact of anticholinergics: a clinical review. Clin Interv Aging. 2009; 4:225–33. PMID: 19554093.

CNS were found in COB). The overlap between the Poly-ACH and Poly-CNS measures' numerators was lower (almost 26.3 percent of the numerator beneficiary enrollment episodes in the Poly-ACH measure were found in the Poly-CNS measure and 9.0 percent were found in Poly-ACH). As expected, the beneficiary overlap was even lower between the COB and Poly-ACH measures because there are no medication overlaps between the two measure specifications, but beneficiaries may meet the numerator inclusion criteria based on their medication regimens (about 2.1 percent of the numerator beneficiary enrollment episodes in the COB measure were found in the Poly-ACH measure and 9.2 percent in Poly-ACH were found in COB).

Based on these comments and data analysis on overlap rates, at this time we are only adding the COB and Poly-ACH measures to the Star Ratings; the Poly-CNS measure will not be added to the Star Ratings at this time due to concerns raised about overlapping medication classes and to monitor for potential duplicative medication therapy classes across the three measures. Because the Poly-CNS measure is a clinically relevant measure for the Part D population, we will retain this measure on the display page. Similar to the Star Ratings, measures on the display page and their numeric measure scores are publicly reported for information purposes. However, unlike the Star Ratings, measures on the display page are not assigned a star and are not associated with QBPs for MA organizations. We may reconsider adding the Poly-CNS to the Star Ratings in the future through rulemaking.

We do not expect a zero-percentage measure rate for these measures as, in some rare cases, it may be medically necessary for beneficiaries to take multiple anticholinergics. Additionally, CMS does not establish a pre-determined threshold to assign stars to these measures and uses the clustering methodology. Therefore, CMS does not have specific cut points or thresholds for performance of Part D contracts in the Star Ratings. Rather, for these measures, contracts are compared based on their contract type and how beneficiaries enrolled in the contracts are taking multiple concurrent prescriptions. In light of the clinical considerations, including the Poly-ACH and the COB measure in the Star Ratings is appropriate as a means to ensure that these important areas of focus are reflected in the overall measure of quality and performance provided by the Star Ratings. We will also share the specification comments with the PQA, the measure steward.

Comment: A few commenters were concerned that these measures pose similar challenges as the retired Star Ratings High Risk Medication (HRM) measure, and addition of the measures to the Star Ratings may lead to tighter utilization management (UM) and safety edits that could result in additional administrative burden to prescribers, pharmacists, and beneficiaries or access issues or disruption of therapy for beneficiaries. Commenters recognized the measures' importance but were concerned with prescriber burden. Additionally, commenters believed that other policies in the Part D program to address these areas of concern already exist, such as Drug Management Programs (DMPs), concurrent drug utilization review and point-of-sale (POS) edits, MTM programs, and UM such as prior authorizations.

Response: We strongly believe that the COB, Poly-CNS, and Poly-ACH measures are important measures that address specific clinical risks in the Medicare Part D population. We do not anticipate that there will be increased workload for plans or providers due to adding any of these measures to the Star Ratings. These measures are not new and have been on display page since 2021 (using data from the 2019 measurement year); therefore, plans, providers, and beneficiaries are familiar and experienced with these measures. The long-term benefits of improved medication safety, reduce medication errors, and better patient outcomes significantly outweigh some potential burden associated with efforts to address over-utilization. Additionally, we understand that use of these medications may be medically necessary for some beneficiaries 65 and older, and as noted in the response earlier in this section of the preamble, CMS does not expect a zero-percentage rate in the COB, Poly-CNS, or Poly-ACH measures. As demonstrated in the annual data included in the December 2022 proposed rule (87 FR 79619), the rates are decreasing for all three measures, suggesting improvement is occurring.

Furthermore, these three measures are not duplicative of existing policies in Part D which are complementary tools to target specific types of concurrent use of medications among Medicare Part D enrollees and drive quality improvement. The COB and Polypharmacy measures are intended as retrospective plan performance measures; concurrent drug utilization reviews, as required under § 423.153(c)(2), and opioid safety edits are reviews at POS to proactively engage beneficiaries and prescribers to address prescription opioid overuse; DMPs are required statutorily in section 1860D–4(c)(5)(A) of the Act for plans to monitor beneficiaries who are at-risk for misuse or abuse of frequently abused drugs. Frequently abused drug, as defined at 42 CFR 423.100, is a controlled substance that the Secretary determines, based on several factors, is frequently abused or diverted. CMS has determined that opioids (except buprenorphine for opioid use disorder and injectables) and benzodiazepines are frequently abused drugs for purposes of Part D DMPs. MTM helps beneficiaries and their caregivers improve their medication use and optimize therapeutic outcomes.

As a reminder, sponsors may apply UM controls to reduce inappropriate use of concurrent therapies. UM controls must be submitted and approved by CMS through HPMS formulary submissions, unless they are POS safety related edits that can be implemented without submission or approval by CMS pertaining to duplicative therapy or when FDA labeling clearly indicates the dispensing is unsafe, duplicative, or contraindicated, such as edits regarding specific age-related contraindications. Edits based upon warnings and precautions in the label, as opposed to contraindications or doses that exceed those supported by the label, must be submitted to CMS for approval. Sponsors that implement unapproved edits for these medications may be found to have data integrity issues. Per §§ 422.164(g) and 423.184(g), CMS may reduce a contract's measure rating to 1 star for concerns such as data inaccuracies, partiality, or incompleteness. 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). Implementation of unapproved edits for these measures may bias sponsors' PDE data used for these measures and thus be subject to this policy. Inclusion of polypharmacy medications in the measures is not a contraindication to use, but rather an opportunity to evaluate the use of concurrent polypharmacy medications in Medicare Part D beneficiaries 65 years and older.

Comment: Some commenters requested that CMS delay adding these measures to the Star Ratings by at least 2 years to provide sponsors additional time to prepare for the transition because it may be difficult to improve

the measures or incentivize prescribers and to minimize unnecessary disruptions in therapy.

Response: Sponsors were given advance notice that CMS planned rulemaking to add these measures to the Star Ratings in the Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, which was released in April 2019. Per § 423.184(c)(3), new Part D measures are posted on the display page for at least 2 years prior to becoming a Star Ratings measure. Sponsors have been on notice for more than 4 years that these measures could be added to the Star Ratings, and all three measures have been on the display page since 2021 (2019 measurement year). We are finalizing the adoption of the COB and Poly-ACH measures beginning with the 2025 measurement period for the 2027 Star Ratings. Part D plans have had sufficient time to gain experience with these measures and to prepare for these measures to be added to the Star Ratings.

Comment: Commenters requested that CMS add socio-demographic status (SDS) risk-adjustment to the COB and Polypharmacy measures because Medicare Advantage organizations, in particular those that offer dual eligible or special needs plans, will be disproportionately affected as these plans enroll a greater number of complex patients with mental health conditions or disabilities.

Response: Currently these measures have not been tested for SDS risk-adjustment because the Poly-ACH, Poly-CNS, and COB measures are process measures and are not recommended for SDS risk adjustment by the PQA. We will share this comment with the PQA, the measure steward.

Comment: Some commenters opposed the COB and Poly-CNS measures because they believe these measures contradict the updated CDC 2022 Clinical Practice Guideline for Prescribing Opioids for Pain. These commenters noted that the CDC Guideline discourages including inflexible dose thresholds in policies involving opioid pain medications.

Response: The COB and Poly-CNS measure specifications do not contradict the CDC Guideline [175] which recommends particular caution when prescribing opioid pain medication and benzodiazepines concurrently and that prescribers should consider whether benefits outweigh risks of concurrent prescribing of opioids and other central nervous system depressants. These measures do not include dosage thresholds in the measure specifications and are not intended to guide clinical-decision-making for individual patients, but rather, these measures evaluate the use of concurrent therapies.

For the COB and Polypharmacy measures, since there are no dosage thresholds, a beneficiary would be potentially eligible for the COB and polypharmacy measures once they have overlapping days supply for concurrent use of unique target medications included in these measures. Specifically, the COB measure evaluates the percentage of beneficiaries 18 years of age or greater with concurrent use of prescription opioids and benzodiazepines. The COB numerator is defined as the number of beneficiaries from the denominator with 2 or more prescription claims for any benzodiazepines with different dates of service and concurrent use of opioids and benzodiazepines for 30 or more cumulative days. The COB denominator is defined as beneficiaries with 2 or more prescription claims for opioid prescriptions on different dates of service and with 15 or more cumulative days' supply during the measurement year. The Poly-CNS measure evaluates the percentage of beneficiaries 65 years of age or older with concurrent use of 3 or more unique CNS-active medications. The numerator is defined as the number of beneficiaries from the denominator with concurrent use of 30 or more cumulative days of 3 or more unique CNS-active medications, each with 2 or more prescription claims on different dates of service during the measurement year. The denominator is defined as beneficiaries with 2 or more prescription claims for the same CNS-active medication on different dates of service during the measurement year.

Comment: Commenters requested that CMS expand exclusions for both Polypharmacy measures to include diagnoses of significant mental health (such as schizophrenia or bipolar disorder) since these conditions are typically treated with multiple antipsychotics, anti-depressants, and/or anti-epileptics. Commenters noted that these measures may have limited benefits to beneficiaries with Alzheimer's disease and dementia, recommended that CMS consider extending overlap days to at least 120 days or more to ensure that plans and providers can work collaboratively in developing realistic plans around deprescribing, and recommended that CMS consider dosage reduction or tapering therapy of concurrent anticholinergic medications. Another commenter recommended excluding benzodiazepine prescriptions that are less than 5 days' supply due to a procedure for the COB measure. Commenters requested that long-term care (LTC) residents be excluded from the COB measure since benzodiazepines are used in the LTC population to treat anxiety or used as a muscle relaxant which could result in delay in therapy. Furthermore, a commenter noted that concomitant use of opioids and benzodiazepines are closely monitored in LTC facilities. Additionally, a commenter suggested that CMS consider dosages of concurrent anticholinergic medications and their overall anticholinergic potential, as opposed to a count of medications, before identifying members for potential overprescribing since beneficiaries with severe mental illnesses may be using multiple antipsychotics, or anti-depressants, and/or anti-epileptics.

Response: We appreciate the commenters' feedback. As a reminder, both Polypharmacy measures exclude beneficiaries in hospice care. Additionally, beneficiaries with a seizure disorder diagnosis during the measurement year are excluded from the Poly-CNS measure. The current exclusions for the COB measure are beneficiaries in hospice care, with a cancer diagnosis, with sickle cell disease diagnosis, and in palliative care during the measurement year. Older adults with co-occurring mental health disorders and multiple anticholinergic medications face an elevated risk of adverse consequences, particularly cognitive decline, increased fall risks, and central nervous system side effects. Continuous monitoring of these individuals is crucial for early detection, medication optimization, and quality of life improvement. Studies have demonstrated positive outcomes when healthcare providers implemented routine anticholinergic burden assessment and medication-switching interventions; these findings underscore the critical need for continuous monitoring and proactive management of the anticholinergic burden in this vulnerable population.[176] [177] [178]

[175] Centers for Disease Control and Prevention (CDC) Clinical Practice Guideline for Prescribing Opioid for Pain—United States, 2022 at *https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w.*

[176] Eum, S., Hill, S.K., Rubin, L.H., Carnahan, R.M., Reilly, J.L., Ivleva, E.I., . . . & Bishop, J.R. (2017). Cognitive burden of anticholinergic medications in psychotic disorders. Schizophrenia research, 190, 129–135.

[177] Lupu, A.M., Clinebell, K., Gannon, J.M., Ellison, J.C., & Chengappa, K.R. (2017). Reducing anticholinergic medication burden in patients with psychotic or bipolar disorders. The Journal of Clinical Psychiatry, 78(9), 17141.

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Therefore, CMS will apply the measure specifications as intended by PQA, the measure steward. PQA employs a highly rigorous and transparent process for developing and endorsing quality measures. This multi-phase lifecycle involves several crucial phases like measure conceptualization, specification, testing, endorsement, and implementation and maintenance. In the final implementation and maintenance stage, endorsed measures are reviewed and updated periodically to reflect evolving practice standards and data availability. This ongoing process ensures that measures remain clinically relevant and valid.

We will share measure specification comments for expanding the exclusions and the methodology considerations with the PQA, the measure steward for the COB and polypharmacy measures.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the addition of the Poly-ACH and COB measures in the Star Ratings program beginning with the 2025 measurement year for the 2027 Star Ratings. The Poly-CNS measure will remain on the display page and not be added to the Star Ratings.

In addition, we announced the non-substantive updates to the Poly-CNS, Poly-ACH, and COB measures to align with the PQA measure specifications to use CE and no longer adjust for MYs in the Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies as required by § 423.184(d)(1). CMS will make the update to change from MYs to CE for the 2024 measurement year for all three measures. The Poly-ACH and COB measures will be added to the Star Ratings program beginning with the 2025 measurement year for the 2027 Star Ratings with these updates.

4. Summary of Measure Changes for the Part C and D Star Ratings

Table VII.1 summarizes the additional and updated measures addressed in this final rule, beginning with the 2027 Star Ratings. The measure descriptions listed in this table are high-level descriptions. The annual Star Ratings measure specifications supporting document, the *Medicare Part C & D Star Ratings Technical Notes,* provides detailed specifications for each measure. Detailed specifications include, where appropriate, more specific identification of a measure's: (1) numerator, (2) denominator, (3) calculation, (4) timeframe, (5) case-mix adjustment, and (6) exclusions. The Technical Notes document is updated annually. In addition, where appropriate, the Data Source descriptions listed in this table reference the technical manuals of the measure stewards. The annual Star Ratings are produced in the fall of the prior year. For example, Stars Ratings for the year 2027 are produced in the fall of 2026. If a measurement period is listed as ''the calendar year 2 years prior to the Star Ratings year'' and the Star Ratings year is 2027, the measurement period is referencing the January 1, 2025 to December 31, 2025 period.

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[178] Mukku, S.S., Sinha, P., Sivakumar, P.T., & Varghese, M. (2021). Anticholinergic burden among hospitalised older adults with psychiatric illnesses—a retrospective study. Current Drug Safety, 16(3), 264–271.

Table VII.1. Summary of New and Revised Individual Star Rating Measures for Performance Periods Beginning on or after January 1, 2025

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	CMIT ID	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Part C Measures								
Colorectal Cancer Screening (COL)*	Percent of plan members aged 45 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	00139-02-C-PARTC	Clustering	MA-PD and MA-only
Care for Older Adults (COA) – Functional Status Assessment*	Percent of Special Needs Plan enrollees 66 years and older who received a 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	00109-01-C-PARTC	Clustering	Special Needs Plans
Part D Measures								
Concurrent Use of Opioids and Benzodiazepines (COB)	The percentage of individuals ≥18 years of age with concurrent use of prescription opioids and benzodiazepines.	Drug Safety and Accuracy of Drug Pricing	Process Measure of Weight of 1	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year		Clustering	MA-PD and PDP
Polypharmacy Use of Multiple Anticholinergic Medications in Older Adults (Poly-ACH)	The percentage of individuals ≥65 years of age with concurrent use of ≥2 unique anticholinergic medications.	Drug Safety and Accuracy of Drug Pricing	Process Measure of Weight of 1	Prescription Drug Event (PDE)	The calendar year 2 years prior to the Star Ratings year		Clustering	MA-PD and PDP
Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR)**	The percent of MTM program enrollees, 18 years or older, who received a CMR during the reporting period.	Drug Safety and Accuracy of Drug Pricing	Process Measure Weight of 1	Part D Plan Reporting Requirements	The calendar year 2 years prior to the Star Ratings year	00454-01-C-PARTD	Clustering	MA-PD and PDP

*Revised Measures

** Effective for the 2027 measurement year.

C. Revising the Rule for Non-Substantive Measure Updates (§§ 422.164(d) and 423.184(d))

We proposed to add collection of survey data through another mode of survey administration to the non-exhaustive list of non-substantive measure updates that can be made without rulemaking. This proposal was only adding another example to the non-exhaustive list of non-substantive measure changes that the current regulations permit to be done through the Advance Notice/Rate Announcement process. For example, as described in the CY 2024 Rate Announcement, we are implementing the web-based mode (as an addition to the current mixed mode protocol) for the 2024 Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey implementation used for the 2025 Star Ratings. The rules CMS adopted to address measure updates based on whether an update is substantive or non-substantive are specified at §§ 422.164(d) and 423.184(d). As described at 83 FR 16534 when §§ 422.164(d) and 423.184(d) were initially adopted, we incorporate updates without rulemaking for measure specification changes that do not substantively change the nature of the measure. In paragraphs (d)(1)(i)–(v) of §§ 422.164 and 423.184, we provided a non-exhaustive list of circumstances that would constitute a non-substantive update. Currently, paragraph (d)(1)(v) of each regulation identifies the addition of an alternative data source as a non-substantive update; the proposed additional example is the collection of

alternative data sources or expansion of modes of data collection. These two examples are similar but not exactly the same, so we proposed to clarify in the regulation that an expansion in the data sources used, whether by adding an alternative source of data or adding an alternative way to collect the data, is a non-substantive change in measure specifications. The expansion of how data are collected is non-substantive because there would be no change to the information that is being collected; the only change would be the way in which it is collected. For example, adding a web mode of survey administration to the current survey administration of mail with telephone follow-up of non-respondents to the mail survey that historically has been used for CAHPS and Health Outcomes Survey (HOS) would not change what is being measured, but would only expand the way the data can be collected. Therefore, that is a non-substantive update to the measures.

We proposed to revise the regulation text at §§ 422.164(d)(1)(v) and 423.184(d)(1)(v) by adding that another example of a non-substantive change would include a new mode of data collection.

We solicited comments on this proposal.

Comment: We received several comments supporting the proposal to revise regulation text by adding a new mode of data collection as another example of a non-substantive change.

Response: CMS thanks the commenters for their support.

Comment: We received a few comments opposed to this proposal. Commenters stated that a new mode of data collection should be considered a substantive change. A couple of commenters were concerned a change in survey modality would produce different survey results and that survey modality preferences differ by age groups, which may affect the population responding. A commenter expressed concerned that web-based respondents could create a source of bias in the data due to differences in socioeconomic factors, plan type, or geography and could impact contract performance.

Response: CMS disagrees that changes to expand modes of data collection would be a substantive change to a measure. Notwithstanding an expansion of the modes of data collection, the denominator will remain the same. Expanding the modes of data collection will generally result in more data regarding performance on the measure. As a result, the measure will better reflect actual performance of the organization and provide more information to CMS and the public.

For example, for the survey administration for CAHPS and HOS measures used as the example in the proposed rule, the denominator for the measures continues to include plan enrollees. The addition of web surveys to the mail-phone survey protocol in no way changes the numerator or denominator of the measure. Further, our study of using web surveys as well as mail-phone surveys did not indicate any significant change in the resulting data or measure scores, consistent with other studies.[179] The CAHPS survey measures and results are unchanged as a result of our proposed change to add a new mode of data collection as a non-substantive change. In the field test, a majority of respondents in the web-mail-phone protocol still chose to respond by mail or phone. Among respondents with an available email address, 79 percent chose to respond by mail or phone. Further, the composition of respondents is similar in the web-mail-phone and mail-phone protocols. We compared respondents to the web-mail-phone and mail-phone protocols by age, sex, receipt of a low-income subsidy or dual eligible status (LIS/DE), race/ethnicity, education, and health status, and found that respondents were quite similar; the overall pattern of differences was consistent with chance.

The use of a three-phase sequential multimode approach, web followed by mail followed by telephone, allows MA enrollees choices about how to respond. It maintains or increases response rates for all groups of MA enrollees and is available to those with or without broadband or telephone access. While the increases in response rates vary slightly by enrollee characteristics, this does not create bias, as scores from those randomized for the web-mail-phone protocol were similar to those randomized for the mail-phone protocol in our field test. Of 39 items compared between the web-mail-phone and mail-phone protocols, none differed in case-mix adjusted mean score at $p<0.01$ and only two differed at $p<0.05$, a pattern consistent with chance. Thus, there is no evidence of a mode effect on scores from the web-mail-phone protocol relative to the mail-phone protocol.

While different plan rates of email availability may influence response rates gains, they do not bias plan scores because response by web results in scores similar to those obtained under the mail-phone protocol. Similarly, no overall effect on scores over time is anticipated with the addition of the web mode.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the clarification to the regulation text at §§ 422.164(d)(1)(v) and 423.184(d)(1)(v). As this clarification is consistent with current practice and policy, CMS is applying it immediately on the effective date of the final rule and for measures in the 2025 Star Ratings where CMS has complied with §§ 422.164(d)(1) and 423.184(d)(1) in adopting the non-substantive change.

D. Weight of Measures With Substantive Updates (§§ 422.166(e)(2) and 423.186(e)(2))

We proposed to adopt regulation text clarifying how we treat measures with substantive updates when they return to the Star Ratings program. The general rules that govern updating measures are specified at §§ 422.164(d) and 423.184(d), including rules for non-substantive and substantive measure updates. As described at 83 FR 16534 when these regulations were first adopted, the process for adopting substantive measure specification updates is similar to the process for adopting new measures. Historically, we have treated measures with substantive updates as new measures when they are added back to the Star Ratings following two or more years on the display page and adoption through rulemaking.

Currently, new measures receive a weight of 1 for their first year in the Star Ratings program as specified at §§ 422.166(e)(2) and 423.186(e)(2). We proposed to add language to §§ 422.166(e)(2) and 423.186(e)(2) to clarify that when a measure with a substantive update moves back to Star Ratings from the display page following rulemaking, it is treated as a new measure for weighting purposes and therefore would receive a weight of 1 for its first year back in the Star Ratings program. This is consistent with our current and prior practice and with the explanation provided in the January 2021 final rule about the weight provided to substantively updated measures for the first year they are returned to the Star Ratings (86 FR 5919). In the second and subsequent years after the measure returns to the Star Ratings after being on the display page with a substantive update, the measure would be assigned the weight associated with its category, which is what happens with new measures as

[179] For example, Fowler FJ, Cosenza C, Cripps LA, Edgman-Levitan S, Cleary PD. The effect of administration mode on CAHPS survey response rates and results: A comparison of mail and web-based approaches. *Health Serv Res.* 2019; 54: 714–721. *https://doi.org/10.1111/1475-6773.13109.*

well. In addition, we proposed to revise the heading for paragraph (e)(2) to reflect how the provision addresses the weight of both new and substantively updated measures.

We solicited comments on this proposal.

Comment: All commenters supported the proposal to clarify how we treat measures with substantive updates when they return to the Star Ratings program. Some commenters noted that this proposal would result in a phase-in approach reducing potential volatility, and it provides plans sufficient notice to familiarize themselves with a measure's updated specifications, assess potential impacts, and incorporate changes to internal processes if needed. A commenter requested CMS confirm that when the three Part D medication adherence measures return to the Star Ratings after adding risk adjustment for sociodemographic status, they will each have a weight of 1 for the first year.

Response: We appreciate the commenters' support. In the April 2023 final rule, CMS finalized the substantive update to the three medication adherence measures for the 2028 Star Ratings (2026 measurement year). The first year (2028 Star Ratings) the updated medication adherence measures will be in the Star Ratings they will have a weight of 1, but then beginning with the following Star Ratings year, the weight will increase to 3, as these measures are categorized as intermediate outcome measures.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the additional language added to §§ 422.166(e)(2) and 423.186(e)(2) with a slight clarification that in subsequent years, a new or substantively updated measure will be assigned the weight associated with its category, and we are finalizing the update to the heading for paragraph (e)(2). As this clarification is consistent with current practice and policy, CMS is applying it immediately on the effective date of the final rule and to the 2025 Star Ratings.

E. Data Integrity (§§ 422.164(g) and 423.184(g))

We currently have rules specified at §§ 422.164(g) and 423.184(g) to reduce a measure rating when CMS determines that a contract's measure data are incomplete, inaccurate, or biased. For the Part C appeals measures, we have statistical criteria to reduce a contract's appeals measures for missing Independent Review Entity (IRE) data. Specifically, these criteria allow us to use scaled reductions for the appeals measures to account for the degree to which the data are missing. See 83 FR 16562 through 16564. The data underlying a measure score and Star Rating must be complete, accurate, and unbiased for them to be useful for the purposes we have codified at §§ 422.160(b) and 423.180(b). In the April 2018 final rule (83 FR 16562), CMS codified at §§ 422.164(g)(1)(iii) and 423.184(g)(1)(ii) a policy to make scaled reductions to the Part C and D appeals measures' Star Ratings when the relevant IRE data are not complete based on the Timeliness Monitoring Project (TMP) or audit information. Following the process in § 423.184(e)(2) and for the reason specified in § 423.184(e)(1)(ii), we removed the two Part D appeals measures (Appeals Auto-Forward and Appeals Upheld) beginning with the 2020 measurement year and 2022 Star Ratings in the 2020 Rate Announcement [180] due to low statistical reliability; thus, the scaled reductions are no longer applicable to the Part D appeals measures. However, we made no changes to the scaled reductions used with the Part C appeals measures, Plan Makes Timely Decisions about Appeals and Reviewing Appeals Decisions, because there were no similar statistical reliability issues with those measures. Therefore, these two Part C measures continue to be subject to the scaled reductions authorized at § 422.164(g)(1)(iii) based on TMP or audit information.

Because the Part D appeals measures are no longer part of the Star Ratings, we proposed to remove and reserve the paragraphs at §§ 422.164(g)(1)(iii)(B), (1)(iii)(F), (1)(iii)(I), and 423.184(g)(1)(ii). Paragraphs (B), (F), and (I) of § 422.164(g)(1)(iii) all address how the error rate on the TMP for the Part D appeals measures had been used in calculating scaled reductions for MA–PDs that are measured on both Part C and Part D appeals. Currently, § 423.184(g)(1)(ii) addresses the scaled reductions for Part D appeals measures based on the TMP. Given the removal of the Part D appeals measures from the Star Ratings, these provisions are moot. We proposed to reserve the relevant paragraphs to avoid the risk that redesignating the remaining paragraphs would cause unintended consequences with any existing references to these provisions.

The completeness of the IRE data is critical to support fair and accurate measurement of the two Part C appeals measures. Since the 2019 Star Ratings we have used data from the TMP, which uses the Part C audit protocols for collecting Organization Determinations, Appeals and Grievances (ODAG) universes, to determine whether the IRE data used to calculate the Part C appeals measures are complete. As described at § 422.164(g)(iii), we use scaled reductions to account for the degree to which the IRE data are missing. The current regulations describe how scaled reductions are based on the TMP. However, due to a change in the Part C audit protocols for collecting universes of ODAG data, we proposed to modify, and in one case reserve, paragraphs (g)(1)(iii), (g)(1)(iii)(A)(*1*) and (*2*), (g)(1)(iii)(H), (g)(1)(iii)(J), (g)(1)(iii)(K)(*2*), and (g)(1)(iii)(O) to change how we address reductions in the Star Ratings for Part C appeals measures using different data. We proposed to revise the introductory language in § 422.164(g)(1)(iii) to remove references to the timeliness monitoring study and audits and replace them with references to data from MA organizations, the IRE, or CMS administrative sources. In addition, our proposed revisions to this paragraph included minor grammatical changes to the verb tense. We also proposed to modify § 422.164(g)(1)(iii)(A) to use data from MA organizations, the IRE, or CMS administrative sources to determine the completeness of the data at the IRE for the Part C appeals measures starting with the 2025 measurement year and the 2027 Star Ratings. Currently, data collected through § 422.516(a) could be used to confirm the completeness of the IRE data; however, data collected from MA organizations through other mechanisms in addition to data from the IRE or CMS administrative sources could be used in the future. The proposed amendment to § 422.164(g)(1)(iii)(A) was not intended to limit the data CMS uses to conduct analyses of the completeness of the IRE data in order to adapt to changing information submissions that could be reliably used for the same purpose in the future. The revisions proposed for the other paragraphs provided for a new calculation to implement scaled reductions for the Part C appeals measures for specific data integrity issues.

Part C contracts are required to send partially favorable (partially adverse) and unfavorable (adverse) decisions to the IRE within applicable timeframes as specified at § 422.590(a) through (e). In order for the existing Part C appeals measures (Plan Makes Timely Decisions

[180] Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (*cms.gov*).

about Appeals and Reviewing Appeals Decisions) to accurately reflect plan performances in those areas, the appeals must be sent to the IRE because the data source for these measures is based on the data that have been submitted to the IRE. Currently, through the Part C Reporting Requirements established under § 422.516(a), CMS collects information at the contract level from MA organizations about the number of partially favorable reconsiderations (that is, the number of partially favorable claims and the number of partially favorable service requests by enrollees/representatives and non-contract providers) and unfavorable reconsiderations (that is, the number of unfavorable claims and the number of unfavorable service requests by enrollees/representatives and non-contract providers) over a calendar year.[181] These data are subject to data validation requirements, in accordance with specifications developed by CMS, under § 422.516(g), to confirm that they are reliable, valid, complete, and comparable. CMS would use this information to determine the total number of cases that should have been sent to the IRE over the measurement year (that is, number of partially favorable reconsiderations + number of unfavorable reconsiderations) to compare to information from the IRE about submissions received from each MA organization. In the future, CMS may use detailed beneficiary-level data collected on the number of partially favorable reconsiderations and the number of unfavorable reconsiderations if such more detailed information is collected under CMS's statutory and regulatory authority to require reporting and data submission from MA organizations (such as the reporting requirements in §§ 422.504(f)(2) and/or 422.516(a)).

To determine if a contract may be subject to a potential reduction for the Part C appeals measures' Star Ratings, we proposed to compare the total number of appeals received by the IRE that were supposed to be sent to the IRE per regulations as specified at § 422.590(a) through (e) and (g) (which are explained in guidance at section 50.12.1 of the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance [182]), including all appeals regardless of their disposition (for example, including appeals that are dismissed or withdrawn), to the total number of appeals that were supposed to go to the IRE. The total number of appeals that were supposed to be sent to the IRE would be based on the sum of the number of partially favorable reconsiderations and the number of unfavorable reconsiderations from the Part C Reporting Requirements during the measurement year (January 1st to December 31st). We proposed to modify the calculation of the error rate at § 422.164(g)(1)(iii)(H) by taking 1 minus the quotient of the total number of cases received by the IRE and the total number of cases that were supposed to be sent to the IRE (Equation 1). The total number of appeals that were supposed to be sent to the IRE in Equation 2 would be calculated from the data described in the revisions to § 422.164(g)(1)(iii)(A):

Equation (1)

Equation (1)

$$Part\ C\ Calculated\ Error\ Rate = 1 - \frac{Total\ number\ of\ cases\ received\ by\ the\ IRE}{Total\ number\ of\ cases\ that\ should\ have\ been\ forwarded\ to\ the\ IRE}$$

Equation (2)

Total Number of Cases that should have been forwarded to the IRE = Number of partially favorable reconsiderations + Number of unfavorable reconsiderations

We proposed to remove and reserve § 422.164(g)(1)(iii)(J) because we intend to calculate the Part C error rate based on 12 months rather than a projected number of cases not forwarded to the IRE in a 3-month period as has historically been done with the TMP data. Currently, a contract is subject to a possible reduction due to lack of IRE data completeness if the calculated error rate is 20 percent or more and the projected number of cases not forwarded to the IRE is at least 10 in a 3-month period as described at § 422.164(g)(1)(iii)(K). We proposed to modify § 422.164(g)(1)(iii)(K)(*2*) so that the number of cases not forwarded to the IRE is at least 10 for the measurement year (that is, total number of cases that should have been forwarded to the IRE minus the total number of cases received by the IRE is at least 10 for the measurement year). 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 specified in paragraph (K), the contract would not be subject to reductions for IRE data completeness issues.

We proposed at § 422.164(g)(1)(iii)(O) that the two Part C appeals measure Star Ratings be reduced to 1 star if CMS does not have accurate, complete, and unbiased data to validate the completeness of the Part C appeals measures. For example, the data collected in the Part C Reporting Requirements go through a data validation process (§ 422.516(a)). CMS has developed and implemented data validation standards to ensure that data reported by sponsoring organizations pursuant to § 422.516 satisfy the regulatory obligation. If these data are used to validate the completeness of the IRE data used to calculate the Part C appeals measures, we would reduce the two Part C appeals measure Star Ratings to 1 star if a contract fails data validation of the applicable Part C Reporting Requirements sections for reconsiderations by not scoring at least 95 percent or is not compliant with data validation standards (which includes sub-standards as applicable), since we cannot confirm the data used for the Part C appeals measures are complete.

We also proposed to update § 422.164(g)(1)(iii)(A)(*2*) to change the data source in the case of contract consolidations so that the data described in paragraph (g)(1)(iii)(A)(*1*) are combined for consumed and surviving contracts for the first year after consolidation. In addition, we proposed to delete the phrase ''For contract consolidations approved on or after January 1, 2022'' as unnecessary.

We did not propose to update the steps currently described at § 422.164(g)(1)(iii)(C), (D), (E), (G), K(*1*), (L), (M), and (N) to determine whether a scaled reduction should be applied to the two Part C appeals measures. We welcomed feedback on this updated approach for making scaled reductions

[181] In the Medicare Part C Technical Specifications Document for Contract Year 2023, elements E through L in Subsection #4 on page 15 are currently used to identify unfavorable and partially favorable reconsiderations (*https://www.cms.gov/files/document/cy2023-part--technical-specifications-222023.pdf*).

[182] *https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.*

proposed at § 422.164(g)(1)(iii), (1)(iii)(A)(*1*) and (*2*), (1)(iii)(H), (1)(iii)(K)(*2*), and (1)(iii)(O), the removal of the Part D related provisions at § 422.164(g)(1)(iii)(B), (1)(iii)(F), and (1)(iii)(I), and § 423.184(g)(1)(ii), and removal of the provision at § 422.164(g)(1)(iii)(J), and we received several comments. A discussion of these comments, along with our responses follows.

Comment: We received a number of comments in support of our proposal to update the methodology for applying scaled reductions for the Part C appeals measures. A couple of commenters expressed strong support for this update, because it will help ensure data integrity by discouraging MA plans from not sending required appeals to the IRE to earn higher Star Ratings.

Response: CMS appreciates the support of the update to the methodology for applying scaled reductions for the Part C appeals measures. Given the financial and marketing incentives associated with higher performance in Star Ratings, CMS agrees that safeguards are needed to protect the Star Ratings from actions that inflate performance or mask deficiencies.

Comment: A few commenters asked for clarifications about the types of cases that CMS is reviewing for the scaled reductions and the types of cases that need to be sent to the IRE. A commenter asked if it was CMS's intent to send all favorable cases to the IRE.

Response: We are only examining the appeals that are currently required to be sent to the IRE. Part C contracts are required to send partially favorable (partially adverse) and unfavorable (adverse) decisions to the IRE within applicable timeframes as specified at § 422.590(a) through (e) and (g). (88 FR 78560). It is not CMS's intent for plans to send all favorable cases (from the plan level) to the IRE.

CMS has also addressed and explained the obligation of an MA plan to send cases to the IRE in current Medicare guidance in the *Parts C & D Enrollee Grievances, Organization/ Coverage Determinations, and Appeals Guidance: Effect of Failure to Meet the Timeframe for Level 1 Appeals.*[183] If a plan fails to provide the enrollee with a level 1 appeal decision within the required timeframes, this failure constitutes an adverse decision. In this case, the plan must forward the complete case file to the IRE pursuant to § 422.590(d) and (g). See also section 50.12.1 regarding forwarding adverse level 1 appeals to the IRE. CMS guidance also permits an exception to this when a plan makes a fully favorable determination on a level 1 appeal less than 24 hours after the end of the adjudication timeframe and effectuates the favorable determination. In this case, the plan should consider effectuating and notifying the enrollee of the favorable appeal decision in lieu of forwarding the appeal to the IRE.

For the updates to the scaled reductions methodology, which we are finalizing as proposed with one clarification, we are examining all cases that were sent to the IRE that should have been sent versus the ones that were supposed to be sent per regulation and guidance. The denominator would include the number of level 1 appeals where the plan made an unfavorable or partially favorable decision for the appeal. The numerator would include all the cases that the IRE received regardless of the disposition the IRE subsequently gave the case (*i.e.,* unfavorable (upheld); favorable (overturn), partially favorable (partially overturn), received by but not evaluated by the IRE because the MA plan approved coverage or dismissed). We are adopting additional language at § 422.164(g)(1)(iii)(H) to clarify that the numerator is the total number of cases received by the IRE that should have been sent.

Comment: A commenter asked for clarification on how a negative error rate would be treated, noting that would be possible since CMS is reviewing all cases regardless of disposition.

Response: CMS clarifies that there cannot be a negative error rate unless a plan sends cases to the IRE that they should not be sending. CMS is comparing all cases sent to the IRE relative to all cases that should have been sent to the IRE. We are adding language at § 422.164(g)(1)(iii)(H) to clarify that the numerator is the total number of cases received by the IRE that were supposed to be sent to the IRE. The denominator remains the number of cases that should have been forwarded to the IRE.

Comment: A commenter recommended that CMS reconsider the inclusion of dismissed appeals, noting that such appeals are dismissed due to a variety of reasons and inclusion in the Star Ratings may inappropriately impact performance. A couple of commenters asked for clarification on what other kinds of dismissals would be included. They noted that CMS proposes the total number of cases received by the IRE would include all appeals regardless of their disposition and gives the example of appeals dismissed for reasons other than the plan's agreement to cover disputed services.

Response: There are no changes to the current Part C appeals measures and which appeals are included. The proposed methodology to apply scaled reductions is a mechanism to ensure that the data used for evaluating performance for these measures are accurate, complete, and unbiased. Through this methodology, we are determining if all of the cases that should have been sent to IRE were sent. For the Plan Makes Timely Decisions about Appeals (Part C) measure, the denominator includes unfavorable (upheld) appeals, favorable (overturned) appeals, partially favorable (partially overturned) appeals, and appeals received by but not evaluated by the IRE because the MA plan approved coverage. The Reviewing Appeals Decisions (Part C) measure excludes dismissed and withdrawn appeals and appeals received but not evaluated by the IRE because the MA plan approved coverage.

As a reminder, Part C sponsors are required to send all adverse or partially adverse cases to the IRE. In some cases, the IRE could dismiss the appeal or the appeal (that is, reconsideration request) could be withdrawn after the appeal is sent to the IRE. Cases may be dismissed for a variety of reasons under § 422.590(d). For example, if the enrollee requested a pre-service appeal but then passes away before the appeal process is complete, the case is dismissed. If a plan processed an appeal, but the plan should not have because a proper party did not file the appeal request, such as an individual who is not the enrollee and who does not have a valid power of attorney or appointment of representation form, the IRE will also dismiss it. Cases can be withdrawn when the appellant contacts the IRE directly and advises them that they no longer wish to proceed with their appeal.

Comment: A few commenters recommended a transition year so Part C sponsors can get used to the new approach for scaled reductions. A commenter wanted additional time since they suggested that plans may need to put in additional efforts to ensure that they pass data validation for the Part C Reporting Requirements.

Response: Part C sponsors currently collect and submit to CMS the data that would be used for the scaled reductions through the Part C Reporting Requirements established by CMS under § 422.516(a). CMS does not believe that a transition year is needed since we

[183] *https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf.*

would be using existing data collected at the contract level from MA organizations about the number of partially favorable reconsiderations (that is, the number of partially favorable claims and the number of partially favorable service requests by enrollees/representatives and non-contract providers) and unfavorable reconsiderations (that is, the number of unfavorable claims and the number of unfavorable service requests by enrollees/representatives and non-contract providers) over the measurement year. (Partially favorable and unfavorable reconsiderations must all be forwarded to the IRE.) In the future, we noted in the proposed rule that alternative data sources could be used that collect similar information. To help in the transition to the updated methodology, CMS will add information to HPMS for the 2026 Star Ratings to provide information about the scaled reductions that would have been applied if this methodology was in place for that year. This information most likely will be posted in HPMS following the release of the 2026 Star Ratings plan previews.

Comment: A few commenters questioned whether CMS expected plans to achieve a 95 percent or greater accuracy rate. A commenter was concerned this would impact smaller plans more.

Response: CMS did not propose to use a 95 percent error rate as part of the scaled reductions implemented pursuant to § 422.164(g)(1)(iii). We did not propose any changes to the error rates at § 422.164(g)(1)(iii)(D) to determine the size of the scaled reductions. The thresholds used for determining the reduction are now and will continue to be under this revision to § 422.164(g)(1)(iii), as follows: (1) 20 percent, 1 star reduction; (2) 40 percent, 2-star reduction; (3) 60 percent, 3-star reduction; and (4) 80 percent, 4 star reduction. However, these scaled reductions are specific to the evaluation of missing cases that have not been forwarded to the IRE when they should have been for calculation of the appeals measures.

Per § 422.164(g)(1)(ii), CMS has a different downgrade policy for Star Ratings measures based on whether the data that an MA organization must submit to CMS under § 422.516 do not pass data validation. Since we will use data submitted under § 422.516 to evaluate data completeness of the cases submitted to the IRE for the Part C appeals measures, we will use similar rules to evaluate the quality of the appeals information submitted that is used to determine data completeness of the Part C appeal measures that is described at § 422.164(g)(1)(iii)(O).

Per § 422.164(g)(1)(ii) (which we did not propose to amend and are not revising in this final rule), if a contract fails data validation of the applicable Part C Reporting Requirements sections (that is, the reporting required under § 422.516) for reconsiderations by not scoring at least 95 percent or is not compliant with data validation standards, we proposed to reduce the appeals measures' Star Ratings to 1 star. Our longstanding policy has been to reduce a contract's measure rating if we determine that a contract's data are inaccurate, incomplete, or biased. The validation score of 95 percent on Part C and Part D Reporting Requirements is an existing data integrity policy that applies to other measures. CMS finalized these data integrity policies at §§ 422.164(g)(1)(ii) and 423.184(g)(1)(i) to distinguish between occasional errors and systematic issues. (see *83 FR 16562*) Currently, the two Star Ratings measures based on Part C and D Reporting Requirements data (SNP Care Management (Part C) and Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Reviews (CMR) (Part D)) are calculated using data reported by plan sponsors and validated via an independent data validation using CMS standards. Per the Part C and D Star Ratings Technical Notes, contracts that do 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 these measures, and the contract's measure score is reduced to 1 star. CMS has relied on the Part C and D Reporting Requirements data validation audit to confirm the integrity of these plan-reported data since these two measures were first added to the Star Ratings program.

Since we will be using the Part C Reporting Requirements data to calculate scaled reductions, we proposed to reduce the Part C appeals measures to 1 star if we do not have data that passed the Part C Reporting Requirements data validation audit to validate the data completeness of these measures. Plan size should not affect accuracy of data validation for the reporting sections. Additionally, as established under §§ 422.164(g)(2) and 423.184(g)(2), CMS can reduce a measure Star Rating to 1 for additional issues related to data accuracy not described in §§ 422.164(g)(1)(i) through (iii) or 423.184(g)(1)(i).

Comment: A commenter opposed the change in timeframe from a 3-month period to the measurement year because they believe without a change in the case minimum it would increase the burden on contracts, particularly low-volume contracts. Another commenter strongly supports the change to a 12-month period since it aligns with the measurement period for the measure.

Response: CMS does not agree that the proposed scaled reductions methodology would increase the burden to contracts, and we appreciate the support for the 12-month timeframe. CMS is planning to use data that are already provided by MA organizations and available to CMS. The data from the current Part C Reporting Requirements established under § 422.516 would be used to calculate the scaled reductions; therefore, there is no increased burden for sponsors. The proposed timeframe of 12 months more accurately aligns with the measurement period for both Part C appeals measures. We exclude from the scaled reductions contracts that have 10 or fewer cases that should have been forwarded to the IRE and were not during the measurement year to address statistical concerns with precision. Increasing this number to greater than 10 cases would create incentives for contracts not to forward cases to the IRE that they should be forwarding.

Comment: A commenter asked whether the TMP data will continue to be leveraged to determine data completeness and calculate the scaled reductions for the Part C appeals measures.

Response: The TMP data will no longer be used for determining scaled reductions of the Part C appeals measures.

After consideration of the public comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing as proposed this updated approach for making scaled reductions at § 422.164(g)(1)(iii), (1)(iii)(A)(*1*) and (*2*), (1)(iii)(H), (1)(iii)(K)(*2*), and (1)(iii)(O) for the 2027 Star Ratings (2025 measurement year) with a modification to clarify that the numerator is the total number of cases received by the IRE that should have been sent at § 422.164(g)(1)(iii)(H). We are finalizing the removal of the Part D related provisions at § 422.164(g)(1)(iii)(B), (1)(iii)(F), and (1)(iii)(I), and § 423.184(g)(1)(ii), and the removal of the provision at § 422.164(g)(1)(iii)(J) without modification.

F. Review of Sponsor's Data (§§ 422.164(h) and 423.184(h))

Currently, §§ 422.164(h) and 423.184(h) provide that an MA organization (and a cost plan organization as the regulations are applied under § 417.472(k)) and a Part D plan sponsor may request a review of certain administrative data (that is, the contracts' appeals data and Complaints Tracking Module data) before Star Ratings are calculated. The regulations provide for CMS to establish an annual deadline by which such requests must be submitted. In the November 2023 proposed rule, CMS proposed to expand the policy for requests that CMS review certain data used for Star Ratings to include administrative data used for their contract's Part D Star Rating Patient Safety measures by adding new §§ 422.164(h)(3) and 423.184(h)(3). These requests would also have to be received by the annual deadline set by CMS. We intended that the requests could include CMS's review of PDE, diagnosis code, and enrollment data that are used for the Part D Star Rating Patient Safety measures, but the requests are not necessarily limited to these specific data.

CMS reports and updates the rates for the current Part D Star Ratings Patient Safety measures (that is, Medication Adherence for Cholesterol (Statins) (ADH-Statins), Medication Adherence for Hypertension (RAS Antagonists) (ADH-RAS), Medication Adherence for Diabetes Medications (ADH-Diabetes), and Statin Use in Persons with Diabetes (SUPD) measures) via the Patient Safety Analysis Web Portal for sponsors to review and download. Part D sponsors can use the Patient Safety reports to compare their performance to overall averages and monitor their progress in improving their measure rates. In the April 17, 2023, HPMS memorandum titled, *Information to Review Data Used for Medicare Part C and D Star Ratings and Display Measures,* CMS reminded sponsors of the various datasets and reports available for sponsors to review their underlying measure data that are the basis for the Part C and D Star Ratings and display measures, including the monthly Part D Patient Safety measure reports. We expect sponsors to review their monthly Patient Safety reports that include measure rates along with available underlying administrative data and alert CMS of potential errors or anomalies in the rate calculations per the measure specifications in advance of CMS's plan preview periods to allow sufficient time to investigate and resolve them before the release of the Star Ratings.

Reviewing administrative data for the Patient Safety measures is a time-consuming process. In addition, once CMS implements SDS risk adjustment for the three Medication Adherence measures, as finalized in the April 2023 final rule (88 FR 22265 through 22270), the final measure rates, which are calculated in July after the end of the measurement period, would require increased processing time to calculate. To allow enough time for CMS to review a sponsor's administrative data and ensure the accuracy of the final calculated Patient Safety measure rates, we proposed that sponsoring organizations' requests for CMS review of administrative data must be received no later than the annual deadline set by CMS.

Beginning with the 2025 measurement year (2027 Star Ratings), we proposed at §§ 422.164(h)(3) and 423.184(h)(3) that any requests by an MA organization or Part D sponsor to review its administrative data for Patient Safety measures be made by the annual deadline set by CMS for the applicable Star Ratings year. We stated in the November 2023 proposed rule that, similar to the implementation of §§ 422.164(h)(1) and (2) and 423.184(h)(1) and (2), to provide flexibility to set the deadline contingent on the timing of the availability of data for plans to review, we intend to announce the deadline in advance either through the process described for changes in and adoption of payment and risk adjustment policies section 1853(b) of the Act (that is, the annual Advance Notice and Rate Announcement) or an HPMS memorandum.

Given the timing of the publication of the Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies and of this proposal, we stated that we would announce the deadline for measurement year 2025 in the final rule that addresses proposed §§ 422.164(h)(3) and 432.184(h)(3). In subsequent years, we would announce annual deadlines in advance via annual Advance Notice and Rate Announcement, or by a HPMS memorandum. For the 2025 measurement year (2027 Star Ratings), we stated that we expected this deadline to be May 18, 2026. In establishing this deadline, we factored in data completeness along with operational deadlines to produce the final Star Ratings. These requests may be time-consuming to review, and it is beneficial to receive the requests before the final rates are calculated and before the first plan preview. Historically, we find that PDE data for performance measurement are complete by April of the following year (that is, PDE data for Year of Service (YOS) 2025 is generally complete by April of 2026) even though the PDE submission deadline is established at the end of June following the payment year.

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses follows.

Comment: Most commenters supported the proposal to set an annual deadline for MA organizations or Part D sponsors to request reviews of its administrative data for the Patient Safety measures. A few commenters supported the proposal but requested to move the deadline to mid-late June or have a phased-in approach to set multiple deadlines based on PDE dates of service to facilitate a complete review.

Response: We appreciate the support received for this proposal. We proposed May 18, 2026, as the initial deadline for the 2025 measurement year for the 2027 Star Ratings and announced the date in the proposed rule due to the timing of the publication of the CY 2025 Advance Notice and Rate Announcement. The deadline was selected due to the time to complete the reviews and calculate the rates, and because the PDE data used to calculate the Patient Safety measures are generally complete by that point based on our analysis. We will continue to monitor the number of sponsor requests for administrative reviews for the Patient Safety measures, the time it takes for CMS to complete the reviews, and data completeness. In future years, we intend to announce the deadline through the annual Advance Notice and Rate Announcement or an HPMS memorandum and may adjust the deadline accordingly. We note that § 422.164(h)(3) and 423.184(h)(3), as proposed and finalized, do not require CMS to announce the deadline through the Advance Notice and Rate Announcement, which permits CMS the flexibility to use other means (such as an HPMS memo) to announce the deadline by which sponsoring organizations may request CMS to review their administrative data for the Patient Safety measures.

Comment: A commenter noted they supported the proposal for plans to request that CMS review their administrative claims data used for the Part D Patient Safety measures.

Response: We proposed to establish a deadline for sponsors to request that CMS review their administrative data

used for the Star Ratings Part D Patient Safety measures because the requests are time consuming, and we need to allow sufficient time for the reviews especially after implementation of the SDS risk adjustment for the Medication Adherence measure calculations. However, CMS has always permitted sponsors to make these requests. We provide detailed Patient Safety measure reports to sponsors on a monthly basis via the Patient Safety Analysis Web Portal to monitor their performance and alert CMS if potential errors or anomalies are identified. Then, CMS provides instructions on how to securely submit data for review. We will continue to provide information through HPMS memoranda on the process and procedures to request CMS review of these administrative data.

Comment: We received some suggestions to expand the administrative reviews to include other forms of payment outside of the Medicare PDEs for Patient Safety reports such as cash payment data, Veteran Affairs benefits, or other supplemental data.

Response: The Medicare Part C & D Star Ratings Technical Notes, available on the Part C and D Performance Measure web page [184] for each year's Star Ratings, outline the data sources used to calculate the Star Ratings Part D Patient Safety measures. Per § 423.184(d)(1)(v), non-substantive updates, including updates to data sources, to the Part D measures must be announced during or in advance of the measurement period through the Advance Notice process. (The same general rule applies as well to Part C measures per § 422.164(d)(1)(v).) CMS does not accept PDEs for claims that were not submitted for processing and/or reimbursement under the plan by either a network pharmacy or enrollee as discussed in the May 11, 2012, HPMS memorandum, *Prohibition on Submitting PDEs for non-Part D Prescriptions.* The April 23, 2013, HPMS memorandum, *May 2013 Updates to the Drug Data Processing System,* provides scenarios in which sponsors are allowed to submit PDE records with $0.00 in drugs costs.

After reviewing the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposal at §§ 422.164(h)(3) and 423.184(h)(3) that any requests by an MA organization or Part D sponsor to review its administrative data for Patient Safety measures be made by the annual deadline set by CMS for the applicable Star Ratings year. For the 2025 measurement year (2027 Star Ratings) the deadline will be May 18, 2026. For subsequent years, we intend to announce the annual deadlines via the annual Advance Notice and Rate Announcement or by an HPMS memorandum.

G. Categorical Adjustment Index (§§ 422.166(f)(2) and 423.186(f)(2))

We proposed to calculate the percentage of LIS/DE enrollees and percentage of disabled enrollees used to determine the CAI adjustment factor in the case of contract consolidations based on the combined contract enrollment from all contracts in the consolidation beginning with the 2027 Star Ratings. The methodology for the CAI is codified at §§ 422.166(f)(2) and 423.186(f)(2). The CAI adjusts for the average within-contract disparity in performance associated with the percentages of LIS/DE and disabled enrollees within that contract. Currently, the percentage of LIS/DE enrollees and percentage of disabled enrollees for the surviving contract of a consolidation that are used to determine the CAI adjustment factor are calculated using enrollment data for the month of December for the measurement period of the Star Ratings year for the surviving contract as described at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B). To more accurately reflect the membership of the surviving contract after the consolidation, we proposed to determine the percentage of LIS/DE enrollees and percentage of disabled enrollees for the surviving contract by combining the enrollment data across all contracts in the consolidation.

We proposed to modify §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B) to calculate the percentage of LIS/DE enrollees and the percentage of disabled enrollees for the surviving contract for the first 2 years following a consolidation by combining the enrollment data for the month of December for the measurement period of the Star Ratings year across all contracts in the consolidation. Once the enrollment data are combined across the contracts in the consolidation, all other steps described at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B) for determining the percentage LIS/DE enrollees and percentage disabled enrollees would remain the same, but we proposed to restructure that regulation text into new paragraphs (f)(2)(i)(B)(*2*) through (*4*). We proposed this change since §§ 422.166(b)(3) and 423.186(b)(3) do not address the calculation of enrollment for the CAI in the event of a contract consolidation; rather, they focus on the calculation of measure scores in the case of consolidations.

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses follows.

Comment: A commenter supported finalizing as proposed and another commenter appreciated CMS providing clarity on the calculation of the CAI.

Response: We thank these commenters for their support.

Comment: A commenter felt there are several benefits to the proposal but also raised some concerns. The commenter asked for clarification on how data from multiple contracts are weighted or integrated. The commenter also requested transparent and accessible information about the adjustments so beneficiaries and advocacy groups can understand the changes and their implications. The commenter also raised concerns that if the adjustment favors larger entities or provides incentives for improved ratings post-consolidation, healthcare organizations might strategically consolidate to maximize their performance ratings.

Response: Data from the contracts involved in the consolidation are not weighted in the process we proposed and are finalizing at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B). Rather the percentage of LIS/DE enrollees and the percentage of disabled enrollees will be calculated for the surviving contract of the consolidation based on all enrollees across all of the contracts involved in the consolidation. For example, if Contract A is consolidating into Contract B as of January 1, 2025, the percentage of LIS/DE enrollees and the percentage of disabled enrollees used in determining the CAI adjustment factor for Contract B for the 2025 Star Ratings will be calculated across all enrollees in Contract A and Contract B.

Data and information related to the CAI are shared publicly in multiple ways. The CAI adjustment categories are shared each year on *CMS.gov* at the time the Advance Notice is released. Each year on the Part C and D Performance Data page on *CMS.gov*, CMS shares the CAI measure supplement with details related to the adjusted measure set for the CAI and data tables with the final adjustment categories for each contract for the given Star Ratings year: *https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data.*

Regarding the commenter's concern about this adjustment potentially favoring larger entities and making

[184] *https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data.*

consolidations more likely, there is nothing about this approach that would favor a larger entity. Currently, measure-level scores are already combined across the surviving and consumed contracts, so we do not believe this relatively small technical change would create new incentives for contracts to consolidate. This approach will also not make consolidations more likely because this approach will more accurately reflect the membership of the surviving contract after the consolidation including members from the consumed contracts. In addition, the Star Ratings measure scores for the surviving contract of a consolidation are calculated so that the scores reflect the membership of the surviving contract after the consolidation as specified at §§ 422.162(b)(3) and 423.182(b)(3).

After consideration of the public comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the revision at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B) to calculate the percentage LIS/DE enrollees and the percentage disabled enrollees for the surviving contract for the first 2 years following a consolidation by combining the enrollment data for the month of December for the measurement period of the Star Ratings year across all contracts in the consolidation as proposed without modification.

G. Health Equity Index Reward (§§ 422.166(f)(3) and 423.186(f)(3))

We proposed how to calculate the HEI reward in the case of contract consolidations beginning with the 2027 Star Ratings. (The 2027 Star Ratings would be the first Star Ratings to include the HEI.) The methodology for the HEI reward is codified at §§ 422.166(f)(3) and 423.186(f)(3). The HEI rewards contracts for obtaining high measure-level scores for the subset of enrollees with the specified social risk factors (SRFs). The goal of the HEI reward is to improve health equity by incentivizing MA, cost, and PDP contracts to perform well among enrollees with specified SRFs. In calculating the HEI reward for the surviving contract of a consolidation, we want to avoid masking the scores of contracts with low performance among enrollees with the specified SRFs under higher performing contracts. We also want to avoid masking contracts that serve relatively few enrollees with the specified SRFs under contracts that serve relatively many more of these enrollees.

For the first year following a consolidation, we proposed to add new paragraphs §§ 422.166(f)(3)(viii)(A) and 423.186(f)(3)(viii)(A) to assign the surviving contract of a consolidation the enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using enrollment from July of the most recent measurement year used in calculating the HEI reward; the existing rules laid out at §§ 422.162(b)(3)(iv) and 423.182(b)(3)(iv) address how CMS handles combining measures scores for consolidations, but do not address how CMS would handle the calculation of the HEI when contracts consolidate since the HEI is not a measure. We proposed that contracts that do not meet the minimum percentage of enrollees with the specified SRF thresholds or the minimum performance threshold described at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) would have a reward value of zero used in calculating the enrollment-weighted mean reward. For the second year following a consolidation, we proposed at new paragraphs §§ 422.166(f)(3)(viii)(B) and 423.186(f)(3)(viii)(B) that, when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score would be combined across the contracts in the consolidation prior to calculating the HEI score. The HEI score for the surviving contract would then be used to calculate the HEI reward for the surviving contract following the methodology described in §§ 422.166(f)(3)(viii) and 423.186(f)(3)(viii).

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses follows.

Comment: Most commenters supported the proposal, and another commenter appreciated the additional clarity on how the HEI will be calculated across a broad range of situations.

Response: CMS thanks these commenters for their support.

Comment: A commenter asked for additional clarification and examples of how the surviving contract's HEI reward would be calculated and combined across contracts noting that it is unclear how CMS intends to combine patient-level data ''across contracts prior to calculating the HEI score.'' The commenter stated that the proposal referenced the enrollment-weighted mean, but additional clarification and examples would be helpful.

Response: The methodology for combining data across contracts in the consolidation when calculating the HEI reward for the surviving contract will depend on which year the consolidation is in. In the first year following a consolidation, the HEI reward for the surviving contract will be calculated as the enrollment-weighted mean reward of the HEI rewards for all contracts in the consolidation using July enrollment from the most recent measurement year used in calculating the HEI.

In the second year following a consolidation, patient-level data for the measurement years used in calculating the HEI will be combined across contracts in the consolidation by assigning members from the consumed contract(s) to the surviving contract. These combined patient-level data will be used to calculate the HEI score and reward for the surviving contract, including the calculation of the percentage of enrollees with the specified SRFs for the surviving contract and the surviving contract's measure scores for the subset of enrollees with the specified SRFs following the methodology at §§ 422.166(f)(3) and 423.186(f)(3).

For example, if Contract A is consolidating into Contract B as of January 1, 2027, the first year following the consolidation is 2027. Therefore, the HEI reward for the 2027 Star Ratings will be calculated for Contract A and Contract B separately using data from measurement years 2024 and 2025. The final HEI reward for Contract B (the surviving contract) will then be calculated as the enrollment-weighted mean of the HEI rewards for Contracts A and B using enrollment from July 2025. If Contract A had an HEI reward of 0.066667 and July 2025 total enrollment of 10,000 and Contract B had an HEI reward of 0.235897 and July 2025 total enrollment of 5,000, then the final HEI reward for Contract B would be 0.123077 ((0.066667 * 10,000 + 0.235897 * 5,000)/(10,000 + 5,000)).

Continuing this example when calculating the HEI reward for the 2028 Star Ratings for Contract B (that is, the surviving contract), the patient-level data from measurement years 2025 and 2026 will be combined for Contracts A and B. That is, the patient-level data from measurement years 2025 and 2026 used to calculate the HEI score and reward for Contract B will contain all enrollees from Contracts A and B.

Comment: A commenter recommended CMS specify that total enrollment, as opposed to enrollment of beneficiaries with the specified SRFs, will be used in calculating the enrollment-weighted mean of the HEI rewards.

Response: Total contract enrollment as of July of the most recent measurement year used in calculating

the HEI will be used to calculate the enrollment-weighted mean HEI reward for the surviving contract in the first year following the consolidation. Based on this, we are finalizing as proposed with an additional revision to §§ 422.166(f)(3)(viii)(A) and 423.186(f)(3)(viii)(A) to clarify that total contract enrollment is used from July of the most recent measurement year. As illustrated in the example above where Contract A is consolidating into Contract B as of January 1, 2027, we use total enrollment as of July 2025 to calculate the enrollment-weighted mean HEI reward for Contract B (the surviving contract) in the 2027 Star Ratings.

Comment: A few commenters stated that expanding eligibility for the HEI reward to more MA plans would reduce the likelihood that currently ineligible plans might pursue contract consolidations to ''game'' the system.

Response: The proposed approach to calculating the HEI reward in the case of consolidations is appropriate because the HEI reward captures the entire population of enrollees with SRFs in the surviving contract. With regard to expanding eligibility for the HEI reward, one of the goals CMS considered when developing the HEI reward was to avoid rewarding contracts that may do well among enrollees with the SRFs included in the HEI but serve few enrollees with those SRFs relative to their total enrollment, making it easier to do well. As discussed in the April 2023 final rule, requiring both a minimum HEI score and a minimum percentage of enrollees in a contract with the specified SRFs is intended to avoid rewarding contracts that serve very few enrollees with the specified SRFs or do not perform well among enrollees with the specified SRFs relative to other contracts.

Comment: A commenter stated the proposal should be closely evaluated for the impacts of private equity, specifically the impacts mergers and acquisitions with private equity involvement may have on enrollment of systemically excluded populations, beneficiaries who meet the SRF threshold requirements, and the level of integration within plans.

Response: We do not believe that there is anything in the proposal, which we are finalizing with clarifications, for how to calculate the HEI reward for consolidating contracts that would make private equity involvement more likely. Calculating the HEI reward for the surviving contract in a consolidation as proposed will ensure the HEI reward accurately reflects the membership of the surviving contract after the consolidation. In addition, the Star Ratings measure scores for the surviving contract of a consolidation are calculated so they reflect the membership of the surviving contract after the consolidation as specified at §§ 422.162(b)(3) and 423.182(b)(3).

After consideration of the public comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the addition of §§ 422.166(f)(3)(viii)(A) and (B) and 423.186(f)(3)(viii)(A) and (B) as proposed with a modification to clarify that total contract enrollment from July of the most recent measurement year is used in calculating the enrollment weights in the first year following the consolidation.

H. Quality Bonus Payment Appeal Rules (§ 422.260)

Sections 1853(n) and 1853(o) of the Act require CMS to make QBPs to MA organizations that achieve at least 4 stars in a 5-star quality rating system. In addition, section 1854(b)(1)(C) of the Act ties the share of savings that MA organizations must provide to enrollees as the beneficiary rebate to the level of an MA organization's QBP rating. The administrative review process for an MA contract to appeal its QBP status is laid out at § 422.260(c). As described in the final rule titled ''Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes,'' which was published in the **Federal Register** on April 15, 2011 (76 FR 21490 and 21491), §§ 422.260(c)(1) and (2) create a two-step administrative review process that includes a request for reconsideration and a request for an informal hearing on the record, and § 422.260(c)(3) imposes limits on the scope of requests for an administrative review.

1. Administrator Review

In the November 2023 proposed rule, we proposed to revise the language at § 422.260(c)(2)(vii) to provide the CMS Administrator the opportunity to review and modify the hearing officer's decision within 10 business days of its issuance. We proposed that if the Administrator does not review and issue a decision within 10 business days, the hearing officer's decision is final and binding. Under this proposal, if the Administrator does review and modify the hearing officer's decision, a new decision would be issued as directed by the Administrator. This proposed amendment would be implemented for all QBP appeals after the effective date of the final rule.

We invited public comment on this proposal and received several comments. A discussion of these comments, along with our responses follows.

Comment: Commenters supported providing the Administrator the opportunity to review hearing officer decisions. A few asked for clarification of the criteria that trigger a review by the Administrator, including whether plans can request this review. A commenter requested we modify this proposal such that Administrator review serves as another level of appeal opportunity for plans, and another asked that we document clear modes of communication to ensure timely receipt of information.

Response: CMS appreciates the support. The Administrator will have the discretion to review (or review and modify) all hearing officer decisions during the 10 business day period established in the regulation. This is not another appeal opportunity for MA organizations. Information about QBP appeals is communicated promptly via email.

After consideration of the public comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing as proposed the revision of § 422.260(c)(2)(vii) to state that the CMS Administrator has the discretion to review and modify the hearing officer's decision on a QBP appeal within 10 business days of its issuance by the hearing officer.

2. Permissible Bases for Review

Historically, every November CMS has released the preliminary QBP ratings for MA contracts to review their ratings and to submit an appeal request under § 422.260(c) if they believe there is a calculation error or incorrect data are used. In the December 2022 proposed rule, we proposed to clarify in § 422.260(c)(3)(iii) some additional aspects of that administrative review process for appeals of QBP status determinations that are consistent with how we have historically administered the appeals process.

When an MA organization requests an administrative review of its QBP status, permissible bases for these requests include a calculation error (miscalculation) or a data inaccuracy (incorrect data). A calculation error could impact an individual measure's value or the overall Star Rating. Historically, if an MA organization believes the wrong set of data was used in a measure (for example, following a different timeframe than the one in the measure specifications as adopted in the

applicable final rule), this is considered a calculation error.

Currently, § 422.260(c)(3)(i) provides that CMS may limit the measures or bases for which an MA organization may request an administrative review. As described in 76 FR 21490, the appeals process is limited to data sets that have not been previously subject to independent validation. We proposed to add a new paragraph in § 422.260(c)(3)(iii) to clarify that certain data sources would not be eligible for requesting an administrative review. We proposed to clarify at § 422.260(c)(3)(iii) that an administrative review cannot be requested based on data accuracy for the following data sources: HEDIS, CAHPS, HOS, Part C and D Reporting Requirements, PDE, Medicare Plan Finder (MPF) pricing files, data from the Medicare Beneficiary Database Suite of Systems, Medicare Advantage Prescription Drug (MARx) system, and other Federal data sources. The listed data sources have already been validated or audited or come from the CMS system of record for that type of data such as enrollment data, which make it inappropriate to use the QBP appeal process to challenge the accuracy of the data. For example, HEDIS measures and measures using data collected through the Part C and D Reporting Requirements have previously been audited or validated for accuracy; NCQA has a formal audit process for all HEDIS measures to check for accuracy, and MA plans sign off on the accuracy of the data following the audit and prior to the data being submitted to NCQA. Similarly, data from the Part C and D Reporting Requirements are validated through an independent contractor (see 42 CFR 422.516(g) and § 423.514(j)) before the data are submitted by MA organizations and Part D plan sponsors to CMS and used for Star Ratings measures. (With regard to Part D data and measures, the MA organization offering an MA–PD must comply with the applicable Part D regulations per § 422.500.) Because the MA organization bears the responsibility of data accuracy as well as signs off on audit findings in these situations, it is inappropriate to use the QBP appeal process to challenge the accuracy of these data. Organizations would have ample opportunity to raise any concerns about these data prior to submission to CMS for use in the Star Ratings.

We also proposed that MA organizations cannot appeal measures that are based on feedback or surveys that come directly from plan enrollees. Measures derived from CAHPS and HOS data are not appealable because plans cannot challenge the validity of an enrollee's response since that is the enrollee's perspective. MA and PDP contracts contract with the CMS-approved vendor of their choice to conduct CAHPS and HOS, and these independent survey vendors conduct the surveys for contracts using detailed specifications provided by CMS and in some cases contract-specific information such as telephone numbers and language preference information provided directly by the MA and PDP contract. There are detailed specifications for data collection [185] for vendors to follow; CMS conducts oversight of the data collection efforts of the approved survey vendors.

Measures derived from PDE data, Medicare Beneficiary Database Suite of Systems, enrollment data from the MARx system, and other Federal data sources (for example, FEMA disaster designations) also cannot be appealed for data accuracy because we are pulling data from the system of record or authoritative data source. Part D sponsors submit PDE to CMS via the Drug Data Processing System (DDPS), which processes and validates the data with extensive system edits.[186] CMS also has an outside analytic contractor independently review PDEs and work with sponsors on data integrity issues.[187] Sponsors must meet the PDE submission deadline to be included in the annual Part D payment reconciliation, and sponsors must certify the claims data (42 CFR 423.505(k)(3)). As another example, enrollment data used in the Star Ratings are also used for the monthly payment of contracts and any discrepancies would have been resolved through retroactive adjustments as needed. Similarly, MPF pricing files cannot be appealed. Plans use the Health Plan Management System (HPMS) Part D Pricing File Submission (PDPFS) module to submit their drug pricing and pharmacy data for posting on the MPF. After the data are submitted, CMS performs a multi-step validation. Validation results are provided to sponsors to correct their data or to attest to the accuracy of the data prior to display on MPF. Part D sponsors are required to perform their own quality assurance checks before submission to ensure that the files are complete and accurate.[188]

Further, in conducting the reconsideration under § 422.260(c), the reconsideration official reviews the QBP determination, the evidence and findings upon which it was based, and any other written evidence submitted by the organization or by CMS before the reconsideration determination is made. Currently, § 422.260(c)(1)(i) provides that the request for reconsideration must specify the given measure(s) in question and the basis for the MA organization's reconsideration request; the alleged error could impact a measure-level score or Star Rating, or the overall Star Rating. The request must include the specific findings or issues with which the MA organization disagrees and the reason for the disagreement, as well as any additional evidence that the MA organization would like the reconsideration official to consider, as the basis for reconsideration. We proposed to modify § 422.260(c)(2)(v) so that the MA organization must provide a preponderance of evidence that CMS's calculations of the measure(s) and value(s) in question were incorrect; in other words, the burden is on the MA organization to prove an error was made in the calculation of their QBP rating. We also proposed to add language at § 422.260(c)(2)(v) clarifying that the burden of proof is on the MA organization to prove an error was made in the calculation of the QBP status.

If the reconsideration official or hearing officer's decision is in favor of the MA organization, the MA organization's QBP status is recalculated using the corrected data and applying the rules at §§ 422.160 through 422.166. Under our current implementation of § 422.260, recalculation could cause the requesting MA organization's QBP rating to go higher or lower. In some instances, the recalculation may not result in the Star Rating rising above the cut-off for the higher QBP rating. We proposed additional language at § 422.260(c)(1)(i) to clarify that ratings can go up, stay the same, or go down

[185] MA and PDP CAHPS Survey administration protocols are contained in the *MA & PDP CAHPS Survey Quality Assurance Protocols & Technical Specifications and are available at https://ma-pdpcahps.org/en/quality-assurance/*. The *HOS Quality Assurance Guidelines and Technical Specifications* manual details the requirements, protocols, and procedures for the HOS administration and are available at *https://www.hosonline.org/en/program-overview/survey-administration/*.

[186] DDPS edit list effective for CY2024 is available at *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/PFYJBZSUNW~Prescription%20Drug%20Program%20(Part%20D)~References*.

[187] For background on this process see April 29, 2022, memorandum to sponsors *Continuation of the Prescription Drug Event (PDE) Reports and PDE Analysis Reporting Initiatives for the 2022 Benefit Year* available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/Continuation_PDE_Reports_and_Analysis_Reporting_Initiatives_2022_508_0.pdf*.

[188] See May 28, 2021 HPMS memorandum, Contract Year (CY) 2022 Part D Pricing Data Submission Guidance. *https://www.cms.gov/files/document/cy2022drugpricingsubmissionguidelines05282021final.pdf*.

based on an appeal of the QBP determination.

Under § 422.260(d), CMS may revise an MA organization's QBP status at any time after the initial release of the QBP determinations through April 1 of each year on the basis of any credible information, including information provided during the administrative review process by a different MA organization, that demonstrates that the initial QBP determination was incorrect. CMS issues annual guidance to MA organizations about the QBP appeal process available under § 422.260 each November titled, for example, ''Quality Bonus Payment Determinations and Administrative Review Process for Quality Bonus Payments and Rebate Retention Allowances.'' We interpret and implement § 422.260 through this guidance and our administration of the annual administrative review process.

When the reconsideration official or hearing officer's decision for a particular appeal or other credible information suggests that there was a systematic error impacting all or a subset of contracts, the QBP status of all contracts is re-calculated using the corrected data and applying the rules at §§ 422.160 through 422.166. If the re-calculated QBP rating for a contract other than the appealing contract results in a lower rating, the original preliminary QBP rating will be used. Thus, a contract's QBP rating will not be decreased by CMS as a result of a systematic recalculation for the current Star Ratings and associated QBP year to correct a systematic calculation error; however, the issue identified will be addressed in the next year's Star Ratings. However, if the QBP rating is higher for a contract after the systematic recalculation, the new rating will be used. For example, if CMS has to do a systematic recalculation for the 2024 Star Ratings following the release of the preliminary 2025 QBP ratings, a contract's 2024 Star Ratings used for the 2025 QBP ratings will not be decreased but the change that caused a systematic recalculation will be addressed when the 2025 Star Ratings are calculated (*e.g.,* if the recalculation resulted in an update to the 2024 Star Ratings cut points for a measure, the updated cut points would be used to determine guardrails for the 2025 Star Ratings. Likewise, if the recalculation resulted in a change in measures scores, the updated measure scores would be used in calculating the improvement measures). If the recalculation of the 2024 Star Ratings results in a higher rating for a contract, the higher rating will be used. We proposed to add language at § 422.260(d) to clarify that a reopening of a QBP determination to address a systemic calculation issue that impacts more than the MA organization that submitted an appeal would only be updated if it results in a higher QBP rating for other MA organizations that did not appeal. This is how we have historically noted how we would handle this type of systemic calculation error as described in our annual HPMS memo released in November each year.

We solicited comments on this proposal.

Comment: A handful of commenters did not support CMS's proposal to add a provision to the QBP appeals process to clarify that certain data sources would not be eligible for requesting an administrative review. They did not support restricting the opportunity to appeal to certain measures. A commenter noted that if a sponsoring organization believes it may have been unfairly penalized in the Star Ratings calculations, the organization should have a venue to bring that argument forward, regardless of measure source. A commenter stated that the survey data collected for CAHPS and HOS measures are subjective, and the collection methods for these surveys may result in bias due to the diverse beneficiary responses and differences in survey and digital literacy across member populations. This commenter noted that plans should retain the right to raise methodological questions about the accuracy of survey measure scores given that the measures are case-mix adjusted, the potential for incorrect adjustments, and invalid responses from beneficiaries.

Response: As we noted in the proposed rule, this proposal was to clarify and codify in regulation existing subregulatory guidance on how we have historically administered the appeals process. The data sources that cannot be appealed for data inaccuracy have already been validated or audited or come from the CMS system of record for that type of data such as enrollment data, which make it inappropriate to use the QBP appeal process to challenge the accuracy of the data. For survey data, contracts may (and under this final rule may continue to) appeal calculation errors such as incorrectly calculating the case-mix adjustments, but they cannot claim that there is a data inaccuracy in beneficiary responses or appeal beneficiary responses. CMS does not agree that CAHPS or HOS survey responses are subjective. These responses represent the viewpoint of the beneficiary but that is the goal and purpose of the surveys—to gather and reflect the beneficiary's experience with the plan. A contract cannot dispute how a beneficiary responds to a survey and the rating the beneficiary gives their plan, for example. Part C and D sponsors contract with CMS-approved survey vendors to administer the surveys, and these vendors follow detailed data administration protocols to ensure the accuracy of the data collected and that the data collection process, including the survey administration, is free from bias.

Comment: A commenter noted that PDE changes are allowed for approximately 5 years after the close of a contract year, and while it is rare to need to appeal these rates, the possibility exists. Therefore, the commenter believed that prohibiting QBP appeals on data inaccuracies in PDE data used for Star Rating measures was not appropriate.

Response: For the Part D measures that use PDE data, the 2024 Medicare Part C & D Star Ratings Technical Notes [189] state that original and adjustment final action PDEs submitted by the sponsor and accepted by the drug data processing system (DDPS) prior to the annual PDE submission deadline are used to calculate this measure and that PDE adjustments made post-reconciliation are not reflected in this measure. Therefore, changes that the Part D sponsors make to their PDE data post-reconciliation will not be considered in the Part D Star Rating calculations and any potential impact to the QBP as a result of post-reconciliation changes are not appealable.

As we stated in the proposed rule, CMS validates the PDE data submitted by the Part D sponsors. Part D sponsors submit PDE records to CMS through DDPS which performs detailed validation, reports processing outcomes, and stores PDE records. Through the PDE edit or error code process, DDPS performs checks of the PDE records for format, integrity, and validity before storing the data for future payment calculations. There are numerous checks that could trigger PDE error codes related to missing/invalid data, beneficiary eligibility, low-income eligibility, benefit phase, NDC-level validity and coverability, basic costs accounting, detailed financial field calculations, among others.[190] Error correction/resolution is a central component in ensuring the acceptance, accuracy, and completeness of a sponsor's PDE records. Sponsors should

[189] *https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data.*

[190] See the DDPS Edit download available at *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/FGSMOX8LWK~Prescription%20Drug%20Program%20(Part%20D)~References.*

resolve issues that triggered PDE edits/error codes in a timely manner.[191] The data must be submitted and accepted by the PDE submission deadline to be included in the annual Part D payment reconciliation, and sponsors must certify (based on best knowledge, information, and belief) that the claims data it submits are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement (42 CFR 423.505(k)(3)). CMS uses PDE data that were submitted prior to the PDE submission deadline for the Part D payment reconciliation and certified by the Part D sponsor in the Part D Star Ratings calculations.

We have historically not allowed sponsors to appeal Part D Star Rating measures based on incorrect PDE data because there is already an alternative process to help sponsors identify issues through the PDE error code process, as well as a process in place for sponsors to make PDE data corrections prior to the PDE submission deadline for the Part D payment reconciliation. However, there are many opportunities for sponsors to review their data to ensure accurate data are used in the Star Ratings program. CMS annually reminds sponsors of the various datasets and reports available to review their underlying measure data that are the basis for the Part C and D Star Ratings and display measures. Every April, we remind sponsors to alert CMS of potential errors or anomalies in advance of CMS's plan preview periods to allow sufficient time to investigate and resolve them before the release of the Star Ratings. Another memorandum, sent annually in April, outlines updates to the Medicare Part D Patient Safety measures and reports. In addition, Patient Safety User Guides and monthly reports are available for Patient Safety measures through the Patient Safety Analysis Web Portal. Revising the QBP appeal process from how it is currently administered to provide additional opportunities for sponsoring organizations to retroactively challenge their PDE data would unnecessarily burden the QBP appeal process, undermine the existing PDE submission, review, and correction processes, and eliminate the incentive of plans to ensure that CMS has accurate data on which to calculate the Star Ratings.

Comment: A commenter expressed concern that ''other Federal Data Sources'' is a very broad term.

Response: As we noted in the preamble, an example of Federal data sources used in the Star Ratings is FEMA data regarding disaster declarations. Federal data sources are any systems of record or authoritative data sources held by the federal government. To the extent that any new Star Ratings measure is based on Federal data sources that are not specifically listed in § 422.260(c)(3)(iii), we encourage commenters in future rulemakings proposing such new Star Ratings measures to submit concerns about whether such Federal data sources are the appropriate authoritative data or should be subject to additional opportunities for sponsoring organizations to challenge data issues using the QBP appeal process.

Comment: A commenter supported the proposal, stating that the two plan preview periods provide sufficient opportunities to refute suspected errors.

Response: We appreciate the support.

3. Burden of Proof

We received no comments on the additional language at § 422.260(c)(2)(v) clarifying that the burden of proof is on the MA organization to prove an error was made in the calculation of the QBP status, § 422.260(c)(1)(i) clarifying that ratings can go up, stay the same, or go down based on an appeal of the QBP determination, and § 422.260(d) clarifying that a reopening of a QBP determination to address a systemic calculation issue that impacts more than the MA organization that submitted an appeal would only be updated if it results in a higher QBP rating for other MA organizations that did not appeal.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the proposed clarifications at § 422.260(c)(1)(i), (c)(2)(v), (c)(3)(iii), and (d) with a small revision to paragraph (d) to clarify that information provided during the administrative review process may include information from other MA organizations and slight reorganization to § 422.260(c)(3)(iii) to improve the clarity of the regulation. As these clarifications and revisions to the regulation are consistent with current practice and policy and do not substantively change the appeal rights of an MA organization, CMS is applying these changes immediately on the effective date of the final rule and to the 2025 Star Ratings.

VIII. Improvements to Special Needs Plans

A. Defining Institutional Special Needs Plans and Codifying Beneficiary Protections (§ 422.2)

Under section 1859(b)(6)(B) and (f)(2) of the Act, Institutional Special Needs Plans (I–SNPs) are MA special needs plans (SNPs) that restrict enrollment to MA-eligible individuals who meet the definitions of ''institutionalized'' or ''institutionalized-equivalent'' in § 422.2, which are based on section 1859(b)(6)(B)(i) and (f)(2)(A) of the Act. ''Institutionalized'' is defined, for the purposes of defining a special needs individual and for the open enrollment period for institutionalized individuals at § 422.62(a)(4), as an MA-eligible individual who continuously resides or is expected to continuously reside for 90 days or longer in one of the following long-term care facility settings: skilled nursing facility (SNF) as defined in section 1819 of the Act (Medicare); nursing facility (NF) as defined in section 1919 of the Act (Medicaid); intermediate care facility for individuals with intellectual and developmental disabilities as defined in section 1905(d) of the Act; psychiatric hospital or unit as defined in section 1861(f) of the Act; rehabilitation hospital or unit as defined in section 1886(d)(1)(B) of the Act; long-term care hospital as defined in section 1886(d)(1)(B) of the Act; hospital which has an agreement under section 1883 of the Act (a swing-bed hospital); and last, subject to CMS approval, a facility that is not explicitly listed as part of the definition of ''institutionalized'' at § 422.2 but meets both of the following criteria: (i) it furnishes similar long-term, healthcare services that are covered under Medicare Part A, Medicare Part B, or Medicaid; and (ii) its residents have similar needs and healthcare status as residents of one or more facilities listed in the definition of ''institutionalized'' at § 422.2. We define, at § 422.2, the term ''institutionalized-equivalent,'' for the purpose of identifying a special needs individual as an MA-eligible individual who is living in the community but requires an institutional level of care; in addition, the definition of the term ''institutionalized-equivalent'' includes specific limitations on how an assessment is made whether an individual meets the definition.

Per the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), I–SNPs, along with C–SNPs and D–SNPs, are MA plans that are specifically designed to provide targeted care and limit enrollment to special needs individuals.

[191] See HPMS memorandum, ''Revision to Previous Guidance Titled ''Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs,'' '' October 6, 2011.

CMS currently permits MA organizations to submit SNP applications that are restricted to institutionalized individuals only or institutionalized-equivalent individuals only, or to submit an application for a combination I–SNP that covers beneficiaries who qualify for either institutionalized or institutionalized-equivalent status but are enrolled under the same plan.

We proposed to add four definitions at § 422.2: a definition of I–SNPs, and three additional definitions for each of the current I–SNP types that correspond to CMS's current MA application process. In addition, we proposed to codify, as part of the definitions for I–SNPs that enroll special needs individuals who are institutionalized, current policies that address the need for the I–SNP to contract with the institutions where such special needs individuals reside. We explained that adding these four definitions would clarify the specific standards that are applicable to I–SNPs, as distinguished from other MA plans and from other MA SNPs. The proposed revisions to the definitions include tying the definitions of ''institutionalized'' and ''institutionalized-equivalent'' in § 422.2 and the list of eligible institutions set forth in that definition to the proposed definition of I–SNP. In addition, our proposed definitions of the terms ''facility-based institutional special needs plan (FI–SNP)'' and ''hybrid institutional special needs plan (HI–SNP)'' included specific performance requirements tied to the type of special needs individual enrolled in the plan, while the proposed definition of ''institutional-equivalent special needs plan (IE–SNP)'' focused on how IE–SNPs restrict enrollment to MA-eligible individuals who meet the definition of ''institutionalized-equivalent.'' Specifically, we proposed that the definition of the term facility-based institutional special needs plan (FI–SNP) would include that such plans own or contract with at least one institution in each county in the plan's service area and with each institution that serves enrollees in the plan. This approach of specifying certain requirements as part of the definition of a specific type of plan is consistent with how CMS has adopted regulatory definitions for D–SNPs, FIDE SNPs, and HIDE SNPs in § 422.2. The proposed definitions clarified that MA organizations may offer I–SNPs that are: exclusive to beneficiaries meeting the definition of ''institutionalized'' under § 422.2; are exclusive to beneficiaries meeting the definition of ''institutionalized-equivalent'' under § 422.2; or are exclusive to beneficiaries who meet either of those definitions. Our proposed language linking I–SNP enrollment to the definitions noted here codifies our current sub-regulatory guidance and those practices CMS has historically used during the MA application process and would not change current or future eligibility and enrollment requirements for I–SNP plan subtypes. In addition, adopting regulatory definitions that are specific to the type of I–SNP and the populations served by the I–SNPs allows clearer distinctions and rules about regulatory requirements that are applicable to a specific type of I–SNP. For example, we proposed in the Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (the ''November 2023 proposed rule'') [192] to amend § 422.116 to adopt an exception to existing network adequacy requirements for facility-based I–SNPs, which are special needs plans that restrict enrollment to individuals who meet the definition of institutionalized, own or contract with at least one institution, and own or have a contractual arrangement with each institutional facility serving enrollees in the plan. See section VIII.B of the November 2023 proposed rule and section VIII.E of this final rule for more information about that proposal.

Lastly, we proposed to amend § 422.101(f)(2) to add a requirement that the models of care for I–SNPs ensure that contracts with long-term care institutions (listed in the definition of the term ''institutionalized'' at § 422.2) contain requirements allowing I–SNP clinical and care coordination staff access to enrollees of the I–SNP who are institutionalized. The proposed new § 422.101(f)(2)(vi) would codify longstanding sub-regulatory guidance in section 20.3 of Chapter 16B of the Medicare Managed Care Manual (MMCM) that is designed to provide I–SNP enrollees protections regarding access to care coordination and communication between providers and I–SNP staff. Under our proposal, access would be assured for I–SNP enrollees to care coordination services from I–SNP clinical and care coordination staff that are employed by the MA organization offering the I–SNP or under contract with the I–SNP to furnish healthcare, clinical or care coordination services. As we noted in the December 2022 proposed rule, I–SNP clinical and care coordination staff may be employed by the MA organization offering the I–SNP or be under contract with the I–SNP to furnish healthcare, clinical, or care coordination services. CMS has received feedback in the past that institutional providers sometimes fail to share relevant information regarding an I–SNP enrollee's health status or need for care or services with I–SNP staff. In the proposed rule, we explained that codifying this requirement for I–SNP MOCs to ensure that the contracts between the I–SNP and these institutions where I–SNP enrollees reside would include provisions allowing access for ISNP staff would better protect beneficiaries.

We received the following comments on our proposals, and our responses follow:

Comment: A commenter sought clarification regarding the contracting requirements for Hybrid Institutional SNPs (HI–SNPs); specifically, the commenter asked that CMS clarify the requirement that HI–SNPs ''must own or have a contractual arrangement with each institutionalized facility serving enrollees.'' The commenter stated that it may not be possible to have a contract with a nursing home in a rural area, or the existing single facility may be of low quality, but enrollees in that facility would be well-served by having access to providers located in adjacent counties for service, and still benefit from the additional support and coordination offered by the I–SNP.

Response: We appreciate the commenter's concerns related to service area requirements and access for their enrollees who might be able to seek services in counties adjacent to the HI–SNP's service area. In setting the proposed requirements for HI–SNPs, CMS considered that the plan would be a hybrid and thus include both MA-eligible individuals who meet the definition of ''institutionalized'' and MA-eligible individuals who meet the definition of ''institutionalized-equivalent.'' Because HI–SNPs may enroll individuals that meet the definition of ''institutionalized'' under § 422.2, the performance requirements for FI–SNPs that exclusively serve institutionalized individuals must also apply to the HI–SNP in order to ensure that the institutionalized enrollees of the HI–SNP are similarly protected and receive the necessary services. We proposed that FI–SNPs must own or have a contractual arrangement with

[192] The November 2023 proposed rule can be found here: *https://www.federalregister.gov/d/2023-24118.*

each institutionalized facility serving enrollees in the plan to align with longstanding sub-regulatory guidance in section 20.3 of Chapter 16B of the MMCM. Under Chapter 16B, CMS has interpreted contractual arrangement to mean a network participation contract and will continue to do so in this final rule. This policy provides an important beneficiary protection as it ensures that the MA organization that offers the FI–SNP or HI–SNP contracts with the institution in order to ensure that the institution adheres to critical care management measures and MOC standards that apply to the I–SNP. Therefore, HI–SNPs that also enroll and cover institutionalized special needs individuals must own or contract with at least one institution, specified in the definition of ''institutionalized'' in § 422.2, for each county within the plan's service area; and must own or have a contractual arrangement with each institutionalized facility serving enrollees in the plan in order to comply with the requirements set forth at § 422.2 for the purposes of defining a special needs individual. For example: if a Medicare beneficiary seeks to enroll in a HI–SNP, the plan must own or have a contract with the long-term care facility where the beneficiary resides—otherwise, the beneficiary is not eligible for enrollment. This requirement is consistent with sub-regulatory guidance in section 20.3.4 the Chapter 16B of the MMCM.

In CMS's experience, I–SNPs have been able to successfully comply with this requirement to own or contract with the necessary institutions. CMS will continue to monitor compliance with this requirement in reviewing applications for I–SNPs and in monitoring and overseeing the MA program. In addition, we are adopting a slight clarification to the definition of FI–SNP, which will also apply to HI–SNPs, to use the phrase ''in the plan's service area'' Instead of the proposed phrase ''within the plan's county-based service area.'' This revision better aligns with the definition of Service Area in 42 CFR 422.2 ''Service area.'' This revision does not change the substance of the requirement that each FI–SNP and HI–SNP own or have a contract with at least one institution in each county of the plan's service area.

Comment: A commenter expressed concern that I–SNPs do little to assist enrollees who wish to return to a community setting because of incentives to maintain plan enrollment, and that most I–SNP enrollees would be better served in a D–SNP or in Traditional Medicare. While the commenter did not specify, based on the context of the comment, CMS interprets that the commenter was referring to all I–SNPs that enroll beneficiaries who are institutionalized. The commenter further stated that alternative coverage (that is, D–SNPs or Traditional Medicare) avoids the strong incentives that plague facility-based I–SNPs to keep enrollees in settings that are inappropriate for their health needs and/or does not meet their wishes. The commenter stated that more regulation of I–SNPs is required to ensure that enrollee needs are met. Another commenter expressed concerns with the increased enrollment in I–SNPs, and evidence identified in a report by MedPAC in 2013 [193] that I–SNPs are prescribing inappropriate medications, specifically, the commenter's interpretation that the report found that I–SNPs have higher rates than regular MA plans for the use of potentially harmful drugs among the elderly as well as reporting the use of drug combinations with potentially harmful interactions; and that I–SNPs could be denying beneficiaries needed hospital care, or that plan ownership of a SNF could result in denials of coverage of needed, but expensive care.

Response: We thank the commenters and share the concerns that an enrollee's residency wishes be met, and that appropriate care be provided to I–SNP enrollees by the I–SNP. In implementing a SNP model of care, the MA organization must conduct a comprehensive initial, and then annual, health risk assessment of the individual's physical, psychosocial, and functional needs as required by § 422.101(f)(1)(i). Per 42 CFR 422.101(f)(1)(ii), the MA organizations offering a SNP must also develop and implement a comprehensive individualized care plan (ICP) through an interdisciplinary care team in consultation with the enrolled beneficiary, as feasible, identifying goals and objectives including measurable outcomes as well as specific services and benefits to be provided. The requirement at § 422.101(f)(1)(ii) for consultation with the enrolled beneficiary means that the enrollee's goals and wishes, with regards to living in the community, as well as access to covered services or treatment plans, must be captured in their ICP.

As far as evaluating whether an institutionalized individual is better served by a D–SNP, I–SNP, or Traditional Medicare, Medicare beneficiaries are free to make their own enrollment decisions regarding how to receive Medicare benefits; section 1851 of the Act provides that each MA-eligible beneficiary is entitled to elect to receive Part A and B benefits through the Traditional Medicare program or enrollment in an MA plan for which the individual is eligible. We encourage all beneficiaries to review their coverage options whether it be Traditional Medicare or Medicare Advantage and believe that the educational tools and materials we make available on *Medicare.gov* help to facilitate that decision-making. Beneficiaries may also find helpful information through the ''Medicare & You'' handbook, by calling 1–800–MEDICARE, or by contacting the State Health Assistance Program (SHIP) in their state.[194] Healthcare providers, including the long-term care institutions in which institutionalized special needs individuals reside, must respect the choice that beneficiaries make in electing their Medicare coverage whether it is through Traditional Medicare or an MA plan.[195]

We also share the commenter's concern that beneficiaries may be prescribed inappropriate medications. We note that MedPAC acknowledges in their report that this particular finding may be a result of monitoring practices among I–SNPs. MedPAC noted in 2013 that ''[a]lthough I–SNPs also have higher rates than regular MA plans for the use of potentially harmful drugs among the elderly and the use of drug combinations with potentially harmful interactions, their higher rates of monitoring of persistently used drugs suggest that drugs with potential interactions or adverse effects are also being closely monitored.'' [196] As the report notes, MedPAC suggests that I–SNPs do enroll a population with a higher use of potentially harmful drugs when compared to non-I–SNPs, but then suggests that I–SNPs are closely monitoring for potential adverse events. CMS publishes SNP data pertaining to the Star Ratings quality measure Care for Older Adults—Medication Review,

[193] The commenter cites MedPAC, Chapter 14 (March 2013); found here: *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/chapter-14-medicare-advantage-special-needs-plans-march-2013-report-.pdf.*

[194] Beneficiaries can find their local SHIP through *https://www.shiphelp.org/,* and clicking on ''Find Local Medicare Help.''

[195] CMS previously addressed this matter in the memo ''Memo to Long Term Care Facilities on Medicare Health Plan Enrollment (October 2021), see *https://www.cms.gov/files/document/ltcfdisenrollmentmemo.pdf.*

[196] See MedPAC, Report to the Congress: Medicare Payment Policy, March 2013, ''Medicare Advantage special needs plans.'' *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/chapter-14-medicare-advantage-special-needs-plans-march-2013-report-.pdf.*

which MA special needs plans are required to submit as part of the Healthcare Effectiveness Data and Information Set (HEDIS) reporting requirements, and Use of High-Risk Medications in Older Adults (a HEDIS measure), as part of Final Medicare Special Needs Plans HEDIS® Performance Results annual reports, and will continue to review this performance data for all I–SNPs.[197]

Comment: A commenter expressed support of the HI–SNP model and stated that restricting enrollment in HI–SNPs to include both MA-eligible individuals who meet the definition of ''institutionalized'' and MA-eligible individuals who meet the definition of ''institutionalized-equivalent'' will ensure individuals in both categories receive necessary supports across the continuum of their care needs without having to experience the disruption of changing Medicare coverage types should an enrollee need for more extensive long-term care. They also believe the HI–SNP and IE–SNP models create an incentive for an I–SNP to serve people who can safely live in the community and could significantly improve continuity and coordination of care for individuals residing in states that do not offer integrated duals programs.

Another commenter expressed support for the proposed clarification of I–SNP types and requested that CMS report enrollment in the different types of I–SNP in the CMS MA monthly publicly available enrollment reports to better understand the growth in these plans.

Response: We thank the commenters for their support of our proposal. We note that CMS currently publishes monthly SNP enrollment data on the CMS website.[198] These monthly reports provide I–SNP enrollment totals as well as the number of active I–SNP plans. CMS may explore the possibility of providing enrollment and plan data at the SNP subtype level in the future.

Comment: A commenter noted that CMS requested comment on whether the proposed regulatory text needs to more specifically address information-sharing or other issues related to I–SNPs being able to access information about and gain access to facilities where their enrollees reside. The commenter cited a statement in the December 2022 proposed rule related to the I–SNP proposal that CMS has received reports that providers sometimes fail to share relevant information regarding an enrollee's health or need for care with the I–SNP staff. The commenter recommended that, prior to revising the MA regulations, CMS should review the issue for substance and specifics, including looking at best practices related to joint facility staff and plan staff participation in care management, which could provide CMS with some useful examples or evidence suggesting that facilities requiring plan reliance on paper documentation over in person or virtual participation in facility activities is a sub-optimal alternative.

Response: We thank the commenter for supporting our proposal to amend § 422.101(f)(2) to add a requirement that the models of care for I–SNPs ensure that contracts with long-term care institutions (listed in the definition of the term ''institutionalized'' in § 422.2) contain requirements allowing I–SNP clinical and care coordination staff access to enrollees of the I–SNP who are institutionalized. As proposed and finalized here, § 422.101(f)(2)(vi) reflects longstanding sub-regulatory guidance in section 20.3 of Chapter 16B of the MMCM that is designed to provide I–SNPs enrollees with protections regarding access to care coordination and to ensure communication between providers and I–SNP staff. We expect MA organizations sponsoring I–SNPs to have communication provisions in their contracts with network long-term care providers where enrollees reside that should stem barriers to information sharing. While our experience with this long-standing sub-regulatory guidance has given us insight into the need for this policy as set forth in our proposed rule, we welcome continued input on this topic should additional guidance or rulemaking be needed in this area.

Comment: Another commenter noted codifying CMS's sub-regulatory guidance for I–SNPs is appropriate as I–SNPs continue to grow in enrollment. The commenter further elaborated by noting that is essential that the facility share data with the I–SNP such as data regarding the clinical, psychosocial, health-related social needs of their I–SNP enrolled residents, as well as other data relevant to the plan of care is essential to achieving the best possible outcomes for enrollees living in an institutional setting. The commenter noted that CMS's expectations and requirements for MA plans should align across health plan types and be consistent with the health information-sharing requirements of the Medicare and Medicaid programs.

Response: We thank the commenter for their support of the proposed rule and agree that data-sharing among plans, facilities and providers is crucial to supporting the health care needs of I–SNP enrollees. We note, however, that as proposed and finalized, § 422.101(f)(2)(iv) imposes obligations on I–SNPs, and policy modifications regarding data-sharing more broadly, such as between non-SNP MA plans and providers or facilities, is outside the scope of this rule.

Comment: A commenter noted that CMS should apply the level of care requirements in the definition of ''institutionalized-equivalent'' under § 422.2, which would be applied to the proposed definitions of IE–SNP and HI–SNPs, to improve the Part D program, that is, that CMS should require Part D plans to engage in a similar assessment of whether enrollees that are living in the community require an institutional level of care. The commenter further noted that enrollees in IE–SNPs/HI–SNPs and Part D programs have substantially similar chronic conditions and cognitive impairments, including the prevalence of these conditions, the dual eligibility of enrollees, and prescription drug needs of Medicare enrollees. The commenter suggested that if CMS amended various aspects of Part D regulations to address the subset of enrollees with such needs, it would significantly improve the care and services enrollees receive through the Part D program as well as the Medicare and Medicaid programs overall. For example, the commenter noted that if CMS were to increase LTC pharmacy services regardless of setting, medication management would be more effective, patient outcomes would improve, and overall health care spending would be lower. The commenter noted that CMS should consider tools and processes to allow Part D plans to identify enrollees' institutional level of care needs and incorporate that into the information Part D plans must obtain regarding Part D enrollees.

Response: We appreciate the commenter's suggestion regarding the use of a tool to assess the level of care (LOC) needs of enrollees in the Part D program. We note that the use of these tools for determining that the individual requires an institutional LOC is codified at 42 CFR 422.2 ''institutionalized-equivalent,'' for purposes of I–SNP eligibility and enrollment. We proposed

[197] The Care for Older Adults—Medication Review measure is used in the Medicare Advantage and Part D Quality Star Ratings that are available online at *https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data.* In addition, multi-year reports covering a selection of HEDIS measures reported by MA SNPs can be found here: *https://www.cms.gov/medicare/enrollment-renewal/special-needs-plans/data-information-set.*

[198] A PDF and Excel version of each monthly report can be found here: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.*

and are finalizing clarifications of the specific standards that are applicable to I–SNPs, as distinguished from other MA plans and from other MA SNPs, as well as codify FI–SNP and IE–SNP enrollee protections regarding access to care coordination and communication between providers and I–SNP staff. CMS is implementing this proposal by adding four definitions at § 422.2: a definition of I–SNPs and three additional definitions for each of the current I–SNP types that correspond to CMS's current MA application process, and only addresses requirements that I–SNPs must implement for their enrollees. We did not propose changes to Part D requirements of the nature suggested by the commenter. Thus, the comment to apply I–SNP requirements more broadly to Part D plans is out of scope for this rule.

All MA SNPs must cover the Medicare Part D benefit per the definition of specialized MA plans for special needs individuals in § 422.2; therefore, the individual care plan for all I–SNP enrollees should address Part D benefits as well as MA basic benefits (that is, Part A and B benefits) and MA supplemental benefits.

After considering all the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing definitions of the terms Facility-based Institutional special needs plan (FI–SNP), Hybrid Institutional special needs plan (HI–SNP), Institutional special needs plan (I–SNP), and Institutional-equivalent special needs plan (IE–SNP) at § 422.2 largely as proposed. In the definitions of FI–SNP, HI–SNP, and I–SNP, we are slightly reorganizing the definitions to improve their readability. We are modifying the definition of FI–SNP to more clearly provide how FI–SNPs must own or contract with institutions as described in the definition. Finally, we are also revising the definition of FI–SNP by replacing ''with the plan's county-based service area'' with ''in the plan's service area.'' This revision better aligns with the definition of Service Area in 42 CFR 422.2 ''Service area.''

In addition, after considering all the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing revisions to § 422.101(f) to add a new paragraph (f)(2)(vi) as proposed to require the model of care for each I–SNP (regardless of the type of I–SNP) to ensure that contracts with long-term care institutions (listed in the definition of the term ''institutionalized'' in § 422.2) contain requirements allowing I–SNP clinical and care coordination staff access to enrollees of the I–SNP who are institutionalized.

B. Codification of Special Needs Plan Model of Care Scoring and Approval Policy (§ 422.101)

Congress first authorized special needs plans (SNPs) to exclusively or disproportionately serve individuals with special needs through passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (hereinafter referred to as the MMA) (Pub. L. 108–173). The law authorized CMS to contract with Medicare Advantage (MA) coordinated care plans that are specifically designed to provide targeted care to individuals with special needs. Originally, SNPs were statutorily authorized for a limited period, but after several extensions of that authority, section 50311(a) of the BBA of 2018 permanently authorized SNPs. Under section 1859(f)(2) through (4) of the Act, SNPs are required to restrict enrollment to Medicare beneficiaries who are: (1) Institutionalized individuals, who are currently defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long-term care facility, and institutionalized equivalent individuals who reside in the community but need an institutional level of care when certain conditions are met; (2) individuals entitled to medical assistance under a State plan under Title XIX; or (3) other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP. Section 1859(f)(5)(A) of the Act, added by Section 164 of the Medicare Improvements for Patients and Providers Act (hereinafter referred to as MIPPA) (Pub. L. 110–275), imposes specific care management requirements for all SNPs effective January 1, 2010. As a result, all SNPs are required to implement care management requirements which have two explicit components: an evidence-based model of care (MOC) and a series of care management services. For more discussion of the history of SNPs, please see Chapter 16B of the Medicare Managed Care Manual (MMCM).

In the December 2022 proposed rule, we proposed to codify certain sub-regulatory guidance from Chapters 5 and 16B of the MMCM about current SNP MOC scoring protocols; annual C–SNP MOC submissions as required by the BBA of 2018; and processes for amending SNP MOCs after National Committee for Quality Assurance (NCQA) approval.

We provide additional summaries of the proposed MOC provisions and responses to comments received below.

1. Codification of Model of Care (MOC) Scoring Requirements for Special Needs Plans (SNPs) (§ 422.101(f)(3)(iii))

Section 1859(f)(7) of the Act requires that, starting in 2012, all SNPs be approved by NCQA based on standards developed by the Secretary. As provided under §§ 422.4(a)(iv), 422.101(f), and 422.152(g), the NCQA approval process is based on evaluation and approval of the SNP MOC. In the CMS final rule titled Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS–4190–F2) (hereinafter referred to as the January 2021 final rule), we adopted several regulatory amendments to implement requirements for the SNP MOC that were enacted as part of the BBA of 2018 and our extension of certain C–SNP specific standards to all SNP MOCs.

All SNPs must submit their MOCs to CMS for NCQA evaluation. An MA organization sponsoring multiple SNPs must develop a separate MOC to meet the needs of the targeted population for each SNP type it offers. MA organizations that wish to offer a SNP must submit an application, as required under part 422, subpart K, to demonstrate that they meet SNP specific requirements, including the requirements in § 422.101(f) that MA organizations offering a SNP implement an evidence-based MOC to be evaluated by the NCQA; in § 422.107 that D–SNPs have a contract with the State Medicaid agencies in the states in which they operate; and in § 422.152(g) that SNPs conduct quality improvement programs. SNP applicants follow the same process in accordance with the same timeline as applicants seeking to contract with CMS to offer other MA plans. In the January 2021 final rule, CMS revised and amended § 422.101(f) to improve plan implementation of enrollee care management practices and to strengthen the review process by establishing a minimum benchmark score of 50 percent for each element of a plan's MOC (§ 422.101(f)(3)(iii)).

Since the beginning of the MOC approval process, CMS has developed, issued, and updated guidance on the MOC to improve plan performance and beneficiary care. Section 1859(f)(5) of the Act outlines requirements for an evidence-based model of care that include—(1) an appropriate network of

providers and specialists to meet the specialized needs of the SNP target population; (2) a comprehensive initial health risk assessment (HRA) and annual reassessments; (3) an individualized plan of care containing goals and measurable outcomes; and (4) an interdisciplinary team to manage care. These provisions in section 1859(f)(5) of the Act are the statutory foundation for much of our subsequent regulatory standards for the MOC. In the September 2008 interim final rule with comment (73 FR 54226, 54228) and the January 2009 final rule (74 FR 1493, 1498), we finalized standards for the required model of care at § 422.101(f). CMS provided guidance and instructions in the CY 2010 Final Call Letter issued March 30, 2009, in a section titled, ''Model of Care Reporting for New Applicants and Existing SNPs,'' in order to more clearly establish and clarify delivery of care standards for SNPs. Additional background on our existing guidance and the importance of the MOC is in the proposed rule at 87 FR 79572 through 79573.

In the December 2022 proposed rule, we proposed to codify the SNP MOC scoring protocols by amending § 422.101(f)(3)(iii) to include the current sub-regulatory scoring protocols. This proposal, and these scoring protocols, align with the minimum benchmark for each element of the SNP MOC of a plan that is currently reflected at § 422.101(f)(3)(iii), as added by the January 2021 final rule. Our adoption of these scoring standards is authorized by section 1859(f)(7) of the Act for NCQA review and approval to be based on standards established by the Secretary and our authority in section 1856(b) of the Act to establish standards to carry out the MA program.

First, we proposed to amend § 422.101(f)(3)(iii) to add the minimum overall score requirement for approval of a SNP's MOC, using the term aggregate minimum benchmark; we proposed to use the same minimum standard for the aggregate minimum benchmark as is currently used by NCQA in reviewing and approving MOCs. Currently, SNP MOCs are approved for 1, 2, or 3-year periods. Each element of the SNP's submitted MOC is reviewed and scored. As provided in § 422.101(f)(3)(iii), the minimum benchmark for each element is 50 percent. The MOC is scored by NCQA based on the review of four elements: Description of the SNP Population; Care Coordination; SNP Provider Network; and MOC Quality Measurement & Performance Improvement. Each of these four elements has a number of sub-elements and factors to address the necessary scope and detail of the MOCs. Currently, each of the four SNP model of care elements is valued at 16 points. The aggregate total of all possible points across all elements equals 64, which is then converted to percentage scores based on the number of total points received. CMS provides additional information regarding MOC scoring criteria in Section 20.2.2 of Chapter 5 of the MMCM. A full list of the most recent elements and factors used in evaluating and scoring the MOCs is in the Model of Care Scoring Guidelines for Contract Year 2025; CMS also includes the list of elements as part of attachment A (or the MOC Matrix) of the ''Initial and Renewal Model of Care Submissions, and Off-cycle Submission of Model of Care Changes.'' [199] In addition to the current element-level minimum benchmark regulatory requirement at § 422.101(f)(3)(iii), SNPs are also required to meet a minimum benchmark score for the aggregate total—otherwise known as the aggregate minimum benchmark. Currently, the aggregate minimum benchmark is 70 percent of the total 64 points.

We proposed to codify this current practice by amending § 422.101(f)(3)(iii) to add that, in addition to the current requirement that all SNPs must meet a minimum benchmark score of 50 percent on each element, each SNP's MOC must meet an aggregate minimum benchmark of 70 percent. As reflected in the proposed revision to paragraph (f)(3)(iii), a SNP's model of care will only be approved if each element of the model of care meets the minimum benchmark and the entire model of care meets the aggregate minimum benchmark.

Second, we proposed to codify at § 422.107(f)(3)(iii)(A) the requirement, from section 1859(f)(5)(B) of the Act, that C–SNP MOCs are annually reviewed and evaluated. Beginning in 2020, under the MOC review process, C–SNPs are only eligible to receive a MOC approval for 1-year and therefore are subject to annual review and approval processes. Specifically, we proposed at paragraph (f)(3)(iii)(A) to codify that an MOC for a C–SNP that receives a passing score is approved for 1 year. We also proposed, at new paragraph (f)(3)(iii)(B), to codify different the approval time limits for the MOCs of I–SNPs and D–SNPs, basing the approval period on the final score of the MOC on the aggregate minimum benchmark. We proposed that: (1) an MOC for an I–SNP or D–SNP that receives an aggregate minimum benchmark score of 85 percent or greater is approved for 3 years; (2) an MOC for an I–SNP or D–SNP that receives a score of 75 percent to 84 percent is approved for 2 years; and (3) an MOC for an I–SNP or D–SNP that receives a score of 70 percent to 74 percent is approved for 1 year. This proposed scoring process matches the current process NCQA uses to score initial and annual MOCs. We believe it is prudent to maintain the current scoring process as it has worked well to incentivize improvements in MOCs and strikes a balance with respect to the burden associated with reviews and approvals for all stakeholders by allowing higher scoring MOCs remain in place longer.

Third, we proposed a new paragraph (f)(3)(iii)(C) to provide an opportunity for a SNP to cure deficiencies in its MOC if the MOC fails to meet any minimum element benchmark or the aggregate minimum benchmark when reviewed and scored by NCQA. Currently, the review and evaluation process includes a second opportunity to submit an initial or renewal MOC, known as ''the cure process.'' Regardless of the final score by NCQA of an MOC resubmitted using the cure process (provided the MOC has the minimum scores to be approved), SNPs that need to use the cure process to reach a passing aggregate minimum and/or minimum element benchmark score will receive only a 1-year approval under this proposal. This policy provides added incentive for SNPs to develop and submit comprehensive and carefully considered MOCs for initial NCQA approval and rewards those SNPs that have demonstrated ability to develop quality MOCs without requiring additional time. We also proposed that the opportunity to cure deficiencies in the MOC is only available once per scoring cycle for each MOC submission. We noted that under this proposal, a MA organization that fails to meet either the minimum element benchmark for any MOC element or the aggregate minimum benchmark for the entire MOC after having an opportunity to cure deficiencies will not have its MOC approved for a contract year. MOCs that do not receive NCQA approval after the cure review will not have a third opportunity for review. As a result, the SNP(s) that use that MOC would need to be nonrenewed by the MA organization or terminated by CMS for

[199] The Model of Care Scoring Guidelines for Contract Year 2025 can be found here: *https://snpmoc.ncqa.org/static/media/CY2025SNP_MOC_Scrng_Gdlns_508.4c71d8c17b37b33ff079.pdf.* The ''Initial and Renewal Model of Care Submissions, and Off-cycle Submission of Model of Care Changes'' can be found here: *https://omb.report/icr/202105-0938-005/doc/original/111555400.pdf.*

failure to meet a necessary qualification for SNPs.

We received the following comments regarding the aforementioned provisions and provide our responses later in this section.

Comment: We received several comments addressing the SNP Model of Care Element Matrix (the Matrix),[200] which reflects the content and evaluative criteria of the MOC. One commenter suggested that CMS reduce duplication and the level of detail within the Matrix, particularly redundancies across factors, elements, and/or where there is evidence that the element or factor is not required to be part of a robust care management program.

Response: We did not propose to codify the content and evaluation criteria for approval of the MOC, and as such, we do not believe these comments regarding the level of specificity in the Matrix are within scope of the proposed rule. However, we will take these comments into consideration when renewing the next MOC Paperwork Reduction Act (PRA) package and for future rulemaking. CMS currently publishes the Matrix for comment under the PRA package ''Initial and Renewal Model of Care Submissions, and Off-cycle Submission of Summaries of Model of Care Changes'' (CMS–10565, OMB 0938–1296). We encourage all parties to submit comments during the next PRA package renewal regarding MOC burden estimates.

Comment: A commenter suggested that CMS reevaluate the MOC submission process and NCQA's review of initial and renewal MOCs and to coordinate with CMS audit processes for efficiency, consistency, and effectiveness to the extent that the burden placed on SNPs to submit MOCs is commensurate with current CMS burden estimates.

Response: While we believe our current burden estimates fairly capture the MOC process, CMS will take comments suggesting a more effective MOC review process and audit system under advisement. In regard to consistency, NCQA and CMS work collaboratively to ensure MOCs are reviewed in the manner appropriate to and in alignment with the MOC submission requirements and CMS audit protocols.

Comment: A commenter recommended that CMS consider the potential impact of environmental disasters or other major shifts, such as the COVID–19 pandemic, on the implementation of the MOC's approved care management processes and policies. This commenter recommended CMS provide for the ability of plans to diverge from regular processes and activities contained in the MOC during such an event or shift.

Response: We appreciate this comment and recognize the value of such a discussion. NCQA is required by § 422.101(f)(3)(ii) to evaluate whether goals from the previous MOC were fulfilled when reviewing a new or subsequent MOC for approval. To the extent that the commenter was addressing review of an MA organization's overall implementation of its MOC, that is outside of the scope of the proposal to codify the minimum scoring benchmarks, the length of the approval period, and the availability of a cure period when a MOC fails to meet the minimum benchmarks. Actual implementation of the MOC is reviewed as part of CMS's auditing and oversight. We note that CMS does have a framework in place to convey any temporary changes needed to the MOC process or requirements through the issuance of departmental or agency communications that may be necessary during a public health emergency or similar situation, as evidenced by policy updates provided during the coronavirus disease 2019 (COVID–19) public health emergency (see CMS memo ''Information Related to Coronavirus Disease 2019—COVID–19'').[201] As we noted in that memo at the time, CMS recognized that in light of the COVID–19 outbreak, an MAO with one or more SNPs may need to implement strategies that do not fully comply with their approved SNP MOC in order to provide care to enrollees while ensuring that enrollees and health care providers are also protected from the spread of COVID–19. CMS stated then that we would consider the special circumstances presented by the COVID–19 outbreak when conducting MOC monitoring or oversight activities. For instance, CMS could permit SNPs to use real-time, audio-visual, interactive virtual means of communication to meet the face-to-face encounter requirements in an emergency if the SNP's MOC states that care coordination visits and encounters are in person. We continue to believe that this is an appropriate way to address MOC implementation during a public health emergency or similar situation. In addition, we remind MA organizations of the existing requirements at § 422.100(m) that apply during a disaster or emergency; those also apply to MA SNPs. We also reiterate, however, that even during an emergency or disaster, all enrollees, including SNP enrollees, must receive all medically necessary items and services, including care coordination.

Comment: A commenter recommended that CMS require each D–SNP to make its model of care publicly available. This commenter suggested that this would help beneficiaries and other stakeholders determine whether a given D–SNP is fulfilling obligations outlined in its own model of care.

Response: We did not propose and are not finalizing at this time a requirement for D–SNPs to publish their MOCs. All SNPs (including D–SNPs) must identify and clearly define measurable goals and health outcomes for the MOC as part of their MOC submission under MOC 4 Element B. This includes but is not limited to: identifying and clearly defining the SNP's measurable goals and health outcomes; describing how identified measurable goals and health outcomes are communicated throughout the SNP organization; and evaluating whether goals were fulfilled from the previous MOC. NCQA reviews the information provided by the SNP and will assign a failing score if the plan cannot meet all factors within the element. SNPs are also required to submit documentation showing plan compliance to their approved MOC as part of the current CMS SNP audit process. Following NCQA's review, each SNP is assigned a score and an associated approval period. These MOC scores are available on NCQA's website, cover the past three years of submissions, and include NCQA's detailed scoring of each MOC Element. We encourage interested parties to review the materials and information posted by NCQA. CMS will continue to employ a robust audit protocol to ensure that all SNPs are implementing their MOCs appropriately.

After consideration of the comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed amendments to § 422.101(f)(3)(iii) substantially as proposed but with minor grammatical and organizational changes. As finalized, § 422.101(f)(3)(iii) establishes the aggregate minimum benchmark score for a MOC to be approved, the time period of approval, and the opportunity for an MA organization to submit a corrected MOC for re-evaluation if the MOC is scored below

[200] The MOC Element Matrix cand be found on *CMS.gov* at: *https://www.cms.gov/files/document/cy2023attachmentamodelofcarematrixinitialandrenewalsubmissionmnfnl.docx.*

[201] The memo can be found here: *https://www.cms.gov/files/document/updated-guidance-ma-and-part-d-plan-sponsors-42120.pdf.*

the minimum benchmarks on NCQA's first review.

4. Amending SNP MOCs After NCQA Approval (§ 422.101(f)(3)(iv))

CMS also proposed to codify current policies and procedures for an MA organization to amend its MOCs after NCQA approval. CMS has labeled this the ''off-cycle MOC submission process.'' CMS has acknowledged in the past that in order to more effectively address the specific needs of its enrollees, a SNP may need to modify its processes and strategies for providing care in the midst of its approved MOC timeframe. CMS announced a process for SNPs to submit MOC changes for review in the CY 2016 Final Call Letter. Currently, a DSNP or I–SNP that decides to make substantive revisions to their existing approved MOC may submit a summary of their off-cycle MOC changes, along with the red-lined MOC, in the Model of Care module in HPMS for NCQA review and approval. Substantive revisions are those that have a significant impact on care management approaches, enrollee benefits, and/or SNP operations. These kinds of MOC changes are at the discretion of the applicable MA organization offering the SNP and it is the responsibility of the MA organization to notify CMS of substantive changes and electronically submit their summary of changes to their MOC in HPMS for review and approval. However, beginning with CY 2020, C–SNPs were required to submit MOCs annually, and thus, their MOCs receive approvals for a period of one-year. As a result of the annual review and approval of C–SNP MOCs, C–SNPs were not permitted to submit a revised MOC through an off-cycle submission.

At the time of the CY 2016 Final Call Letter, based on our previous experience with the small number of SNPs seeking to amend their MOCs, we expected that mid-cycle amendments to MOCs would be relatively rare, and CMS did not anticipate that the off-cycle process would result in a higher incidence of such MOC changes. We believed that only relatively unusual circumstances would require SNPs to make changes to their MOCs that are so substantive that notification to CMS and review of the changes to the MOC by NCQA and CMS would be warranted. However, CMS and NCQA have seen the number of off-cycle MOC submissions steadily rise over the past four years, and plans have expressed frustration and confusion over what plan changes merit or require submission to NCQA for an off-cycle approval. The proposed adoption of § 422.101(f)(3)(iv) was intended to address stakeholder feedback regarding the off-cycle review process and to mitigate the SNP community's concerns regarding continued plan burden in this area.

In general, CMS intends the MOC review and approval process to include an MA organization's submission of a MOC only in the following scenarios: the MA organization seeks to offer a new SNP; the MA organization's SNP's MOC approval period ends; or CMS deems revision and resubmission of the MOC necessary to ensure compliance with the applicable standards and requirements, such as a change in applicable law or when CMS discovers a violation. We explained in the proposed rule that for this the last scenario, an off-cycle MOC submission may be necessary if, during an audit, it appears that the MOC (including in practice as the SNP applied the MOC) is not meeting applicable standards. In such cases, CMS may ask the SNP to correct and resubmit the MOC. Other examples include regulatory changes or when a State Medicaid agency requires changes to the MOC of a D–SNP to meet State-specific requirements.

In order to ensure a stable care management process and to ensure appropriate oversight by CMS of SNPs and their operation, SNPs may not implement any changes to a MOC until NCQA has approved the changes. Based on our experience, additional situations may justify the submission of a revised MOC for review and approval. As part of the December 2022 proposed rule, we proposed to establish when an MA organization may submit updates and corrections to its approved MOC.

First, we proposed to codify the off-cycle process at § 422.101(f)(3)(iv). We proposed that MA organizations offering SNPs that need to revise their MOC mid-cycle during their MOC approval period may submit the revised MOC for review by NCQA at specific times. CMS has historically restricted the period that SNPs can submit an off-cycle submission from June 1st to November 30th of any contract year, which is meant to allow for the efficient and prudent administration of the annual initial and review MOC process, with the exception of C–SNPs which are prohibited from submitting off-cycle submissions. However, CMS has also allowed SNPs to submit off-cycle MOCs outside of this window when CMS deems it necessary to ensure the SNP or its MOC was meeting statutory or regulatory requirements, to guarantee the safety of enrollees, or to meet State Medicaid requirements. Although we did not propose to codify this specific language in the December 2022 proposed rule nor are we finalizing it here, CMS will continue to use this discretion when reviewing applicable submission requests. We proposed to maintain this process and codify it at § 422.101(f)(3)(iv)(A). We proposed that SNPs may submit updates and corrections to their NCQA-approved MOC between June 1st and November 30th of each calendar year or when CMS requires an off-cycle submission to ensure compliance with applicable law.

We stated in the proposed rule that we were proposing to use the phrase ''applicable standards and requirements'' to encompass the situations described here in the preamble or similar situations where a potential or existing violation needs to be addressed. We also stated that we were proposing, in an effort to ensure consistent application of this standard and demonstrate our intent, that these be limited situations where a revision is truly necessary, the finalized regulation text would provide that CMS would make this determination and provide directions to the MA organization. We also stated in the proposed rule that if an MA organization believed that this standard for when revision is necessary to ensure compliance by the SNP and its MOC is met, the MA organization should contact CMS for guidance and approval to submit a revision. However, the proposed regulation text did not include this standard and proposed paragraph (f)(iv)(A) stated that D–SNPs and I–SNPs may submit updates and corrections to their NCQA-approved MOC any number of times between June 1st and November 30th of each calendar year or when CMS requires an off-cycle submission to ensure compliance with applicable law. We read the phrase ''to ensure compliance with applicable law'' to encompass the situations described in the preamble of the proposed rule (and here in the final rule) or similar situations where CMS has determined that a potential or existing violation needs to be addressed. ''Applicable law'' encompasses MA regulations and statutes, and for D–SNPs, certain Medicaid regulations and statutes; where a MOC would potentially result in harm to enrollees or changes to a MOC are necessary to ensure the safety of enrollees, we view these changes as changes required by applicable law, because the fundamental nature and purpose of the MOC is to ensure that the SNP addresses the needs of the special needs individuals enrolled in the SNP. We also stated in the proposed rule that if an MA organization believed that this standard for when revision is necessary to ensure compliance by the SNP and its

MOC is met, the MA organization should contact CMS for guidance and approval to submit a revision.

Since the beginning of the off-cycle submission process, CMS has provided guidance clarifying which MOC changes require submission to CMS and how SNPs should submit their MOC changes to CMS. We have previously said that SNPs that make significant changes to their MOCs must submit (in HPMS) a summary of the pertinent modifications to the approved MOC and a redlined version of the approved MOC with the revisions highlighted. However, given the level of questions we have received over the years regarding what constitutes a significant change, we proposed to codify a list of reasons for when a SNP must use an off-cycle submission of a revised MOC for review and approval. Proposed § 422.101(f)(3)(iv)(B) provided that an MA organization must submit updates or corrections to a SNP's MOC to reflect the following:

- Changes in policies or procedures pertinent to:
  - ++ The health risk assessment (HRA) process;
  - ++ Revising processes to develop and update the Individualized Care Plan (ICP);
  - ++ The integrated care team process;
  - ++ Risk stratification methodology; or
  - ++ Care transition protocols;
- Target population changes that warrant modifications to care management approaches or changes in benefits. For example, we intend this to include situations like adding Diabetes to a Cardiovascular Disease and Congestive Heart Failure C–SNP;
- Changes in a SNP's plan benefit package between consecutive contract years that can considerably impact critical functions necessary to maintain member well-being and are related SNP operations. For example, changes in Medicaid services covered by a HIDE SNP or FIDE SNP through its companion Medicaid managed care plan or changes in Medicaid policy (such as benefits or eligibility) that require changes to an ICP for coordinating Medicare and supplemental benefits with the new Medicaid policy;
- Changes in level of authority or oversight for personnel conducting care coordination activities (for example, medical provider to non-medical provider, clinical vs. non-clinical personnel);
- Changes to quality metrics used to measure performance.

The proposed regulation text did not include examples of the type and scope of MOC policy changes that may be made by an MA organization to the SNP's approved MOC without any review or approval by CMS or NCQA. Changes to the MOC that are permitted but that do not need to be submitted through HPMS include but are not limited to:

- Changes in legal entity, parent organization, and oversight (novation/mergers, changes to corporate structure);
- Changes to delegated providers and agreements;
- Changes in administrative staff, types/level of staff that do not affect the level of authority or oversight for personnel conducting care coordination activities;
- Updates on demographic data about the target population;
- Updates to quality improvement metric results and technical quality measure specification updates;
- Additions/deletions of specific named providers;
- Grammatical and/or non-substantive language changes; and
- For D–SNPs, minor changes to Medicaid benefits.

We also proposed, § 422.101(f)(3)(iv)(D), that SNPs may not implement any changes to a MOC until NCQA has approved the changes. We explained in the proposed rule that NCQA will continue to review the summary of changes and a redlined copy of the revised MOC submitted in HPMS to verify that the revisions are consistent with the previously detailed list of applicable submissions and in line with acceptable, high-quality standards, as included in the original, approved MOC, but that the revised MOCs would not be rescored. We proposed to codify this policy at § 422.101(f)(3)(iv)(E), which provides that the successful revision of the MOC under proposed (f)(3)(iv) does not change the MOC's original period of approval original approval period (that is, 1-year or multi-year) by NCQA. Therefore, changes made to MOC cannot be used to improve a low score. We stated how we anticipate that the current procedures and documentation processes used to implement the requirements would continue under our proposal and explained our position that such procedures and operational practices do not require rulemaking and that CMS may change procedures as necessary (for example, use of HPMS as the system for submission, the mechanism for providing notice to MA organizations of the review of the MOC initially or any revisions, etc.). We stated that we intended that the current procedures will continue for NCQA reviewers to designate the summary as ''Acceptable'' or ''Non-Acceptable,'' and enter the findings in the HPMS character text box and that we would continue the current process in which a system-generated email is sent to the designated SNP Application Contact and the MA Quality Contact, as well as to the individual who submitted the revised MOC summary.

If NCQA determines that revisions to an initial or renewal MOC, as delineated in the MOC summary, do not reflect the quality standards as demonstrated by the original MOC and its associated score/approval period, the SNP will be notified via email with a ''Non-Acceptable'' determination and a list of all deficiencies. If the summary and redlined version is not acceptable after the second review, the SNP must continue implementing its approved MOC without any revisions for the remainder of its MOC approval period. We did not include NCQA's off-cycle scoring policy and the implications in the proposed regulation text, but we are clarifying in this final rule at § 422.101(f)(3)(iv)(D) to note that all changes, as applicable under § 422.101(f)(3)(iv)(B), that are part of a SNP's off-cycle submission are reviewed by NCQA as ''Acceptable'' or ''Non-acceptable.'' By ''Acceptable,'' we mean that the changes have been approved by NCQA and the MOC has been updated; whereas by ''Non-acceptable'' we mean that the changes have been rejected by NCQA and the MOC has not been changed.

We proposed under § 422.101(f)(3)(iv)(F) to codify existing operational practices with respect to off-cycle submissions by C–SNPs. As previously discussed, currently, C–SNPs are prohibited from submitting off-cycle MOC submissions. We proposed to codify that C–SNPs are prohibited from submitting an off-cycle MOC submission except when CMS requires an off-cycle submission to ensure compliance with the applicable regulations. Otherwise, C–SNPs must wait until the annual MOC submission period to make changes to their MOC. SNPs have one opportunity to correct (''cure'') deficiencies, as noted in our proposed rule § 422.101(f)(3)(iv)(G) to confirm that the revised MOC is consistent with the standards outlined in the original MOC. We proposed, at § 422.101(f)(3)(iv)(G), to permit a single opportunity for a SNP to revise its off-cycle submission to revise a MOC if there is a deficiency in the submission. The cure process proposed, which is the current operational process use by NCQA, would permit SNPs to resubmit a single revised off-cycle submission or cure until the end of the Off-cycle submission period to an Off-cycle MOC that was deemed unacceptable during

the off-cycle review process. We proposed to codify this policy of a single cure opportunity during the off-cycle time period under a new paragraph at § 422.101(f)(3)(iv)(G).

We also found that SNPs have sought to modify an initial or renewal MOC shortly after NCQA approval and before the MOC has gone into effect. We have generally rejected these submissions as the MOC has yet to go into effect. Under the proposal, we stated that we would continue to prohibit an off-cycle submission until the approved MOC has gone into effect. For example, if NCQA approved a SNP's MOC on April 1, 2022, the plan would be prohibited from submitting an off-cycle submission until the effective date of the MOC, which would be January 1, 2023, and then the start of the off-cycle submission window on June 1, 2023. In order to clarify this process, we proposed to codify this guidance at § 422.101(f)(3)(iv)(C). We proposed that NCQA will only review off-cycle submissions after the start of the effective date of the current MOC unless it is deemed necessary to ensure compliance with the applicable regulations or State Medicaid agency requirements for D–SNPs.

Finally, we reiterated in the proposed rule that we still believe that to substantively revise an MOC should be a rare occurrence rather than an eventuality. These proposed processes and procedures were intended to make certain that CMS and NCQA are apprised of up-to–date information regarding the MOC; strengthen our ability to adequately monitor the approved MOCs; and guarantee that SNPs continue to provide high quality care to enrollees. We sought comment on the codification of the current off-cycle MOC submission process.

We reiterated in the proposed rule that the proposed regulations reflect and would codify current policy and procedures. While we proposed that the regulations would be applicable beginning with a future year, we stated our intent to continue our current policy as reflected in the proposed rule. We also stated in the December 2022 proposed rule that the proposed changes carried no burden because the proposal was a codification of previously issued sub-regulatory guidance in Chapter 5 and other CMS transmittals to impacted MA organizations. We also explained that the proposed provisions are already captured under the PRA package ''Initial and Renewal Model of Care Submissions, and Off-cycle Submission of Summaries of Model of Care Changes (CMS–10565, OMB 0938–1296). As part of the PRA approval package, CMS reviews public comments directed towards the initial and renewal MOC process, MOC trainings, and the off-cycle MOC submission system. This position continues and we believe that this final rule, which finalizes § 422.101(f)(3)(iv) generally as proposed (with several modifications to clarify the regulation) is consistent with current procedures and the approved PRA package.

We received comments to these proposed provisions regarding off-cycle revisions to approved MOCs and our responses follow.

Comment: A commenter suggested that the need for off-cycle submissions will become more frequent as the increasing number of requirements, industry developments, and ever-evolving best practices around health equity, care coordination, provider networks, and other emerging standards make it more likely that substantive changes will need to be made. Thus, the commenter reasoned, SNPs are likely to find it necessary to more frequently submit an off-cycle review so that their MOCs remain current to structures, processes, practices, and programs that are operationalized for SNP members. The commenter suggested that CMS revise and/or clarify the language on what is considered a ''substantive change'' as it remains unclear, and plans will default to assuming they should submit their MOCs. The commenter also suggested that CMS allow for some flexibility in CMS audits around MOC compliance, suggesting that when the plan documents the deviations (including the purpose and extent of any deviation) from the written/approved MOC when needed, and the plan believes the deviations are ''not-substantive'' consistent with CMS criteria, the plan should not be penalized for its failure to submit their MOC for an off-cycle review.

Response: CMS recognizes that industry developments and changes in applicable federal health care laws may impact the nature of health care delivery and care coordination among SNPs and their members. We proposed and are finalizing at § 422.101(f)(3)(iv)(A) and (B) the standards that are to be used to identify when an off-cycle submission to revise an approved MOC will be permitted.

As proposed in new paragraphs (f)(3)(iv)(A) and (B), an MA organization that offers a D–SNP or I–SNP that seeks to revise the MOC before the end of the MOC approval period may submit changes to the MOC as off-cycle MOC submissions for review by NCQA as follows:

- D–SNPs and I–SNPs may submit updates and corrections to their NCQA approved MOC any number of times between June 1st and November 30th of each calendar year or when CMS requires an off-cycle submission to ensure compliance with applicable law.
- D–SNPs and I–SNPs are required to submit updates or corrections as part of an off-cycle submissions based on:
  - Substantial changes in policies or procedures pertinent to: the health risk assessment (HRA) process; revising processes to develop and update the Individualized Care Plan (ICP); the integrated care team process; risk stratification methodology; or care transition protocols;
  - Target population changes that warrant modifications to care management approaches;
  - Changes in a SNP's plan benefit package between consecutive contract years that can considerably impact critical functions necessary to maintain member well-being and are related SNP operations;
  - Changes in level of authority or oversight for personnel conducting care coordination activities (for example, medical provider to non-medical provider, clinical vs. non-clinical personnel); or
  - Changes to quality metrics used to measure performance.

We are making minor changes to proposed paragraphs (f)(3)(iv)(A) and (B) to increase the clarity of the regulation. We are finalizing paragraph (f)(3)(iv)(A) to provide that C–SNPs, D–SNPs and I–SNPs must submit updates and corrections to their NCQA-approved MOC when CMS requires an off-cycle submission to ensure compliance with applicable law. Finalizing new § 422.101(f)(3)(iv)(A) with these revisions makes it clear that when CMS requires an off-cycle submission, such as when CMS identifies an issue during an audit, the MA organization offering the C–SNP, D–SNP or I–SNP must submit off-cycle revision to NCQA for review and approval of the necessary changes to the MOC.

We are finalizing paragraph (f)(3)(iv)(B) to specify when D–SNPs and I–SNPs are permitted to use an off-cycle submission to submit updates and corrections to their MOCs to NCQA for review and approval. As we proposed, updates and revisions or corrections of this type are permitted only for certain reasons. As finalized, § 422.101(f)(3)(iv)(B) provides that D–SNPs and I–SNPs must submit updates and corrections to their NCQA-approved MOC between June 1st and November 30th of each calendar year if the I–SNP or D–SNP wishes to make any of the listed revisions. The list of revisions, at paragraphs (f)(3)(iv)(B)(*1*) through (*5*)

tracks the permitted changes we proposed to codify in paragraphs (f)(3)(iv)(B)(*1*) through (*5*). (87 FR 79713) We believe that the revisions we are finalizing in the regulation text are not substantive changes in policy compared to what CMS proposed in the December 2022 proposed rule but are a reorganization to clarify when requests to change the MOC are submitted. The final rule clarifies that the period between June 1st through November 30th of each calendar year is the time period for a D–SNP or I–SNP that seeks to make changes to its MOC off-cycle, to submit their updates and/or changes to the previously approved MOC. However, when CMS directs a C–SNP, D–SNP or I–SNP to make changes to their MOC in order to comply with applicable law, it is CMS who will direct the timing of the submission (and the June to November time period mentioned above might not necessarily apply). The changes described in paragraphs (f)(3)(iv)(B)(*1*) through (*5*) are generally voluntary changes that the D–SNP or I–SNP is making to its SNP operations and administration that subsequently require changes to the MOC. In these instances, D–SNP or I–SNP must seek an off-cycle revision to its MOC to implement the changes. In these cases, the changes in operation and administration are independent from any CMS direction to ensure compliance with applicable law.

A D–SNP or I–SNP that decides to make significant revisions to their existing approved MOC must submit a summary of their off-cycle MOC changes, along with the red-lined MOC, in the Model of Care module in HPMS for NCQA review and approval, before implementing and using the changes to the MOC. As discussed in the preamble to the proposed rule, significant revisions within the scope of § 422.101(f)(3)(iv)(B) are those that have a significant impact on care management approaches, enrollee benefits, and/or SNP operations. The intent of the rule under § 422.101(f)(3)(iv)(B) is to codify and clearly delineate events that would be considered by CMS as significant revisions. We believe that this language is sufficient to direct plans; however, CMS will monitor the initial off-cycle period to review whether SNPs continue to submit changes that fail to meet the intent of the requirement and will provide additional examples of what is considered a significant revision within the scope of this rule, as necessary.

The proposed rule (87 FR 79575) provided examples of the type of non-significant changes that an MA organization may make *without* using the off-cycle submission and approval process. Those changes as outlined in the proposed rule included, but were not limited to, revisions to the MOC to address a change in ownership of the MA organization, changes in administrative staff and changes to demographic data. When an MA organization that sponsors a SNP has a change that is not an immaterial change as noted here and the MA organization is unsure if the change is sufficiently similar in type and scope to the changes as noted above, the MA organization should seek guidance from CMS. The list of changes that do require an off-cycle submission of updates and corrections to the approved MOC in § 422.101(f)(3)(iv)(B) is sufficiently detailed to be applied by MA organizations and CMS in the future. It is not acceptable, and it is inconsistent with this final rule (specifically § 422.101(f)(3)(iv)(D)) for an MA organization to make a change within the scope of § 422.101(f)(3)(iv)(B) without review and approval from NCQA. We recommend that an MA organization that is unsure if a change it is contemplating to its approved MOC needs to be submitted for review and approval, the MA organization should contact CMS for guidance. In such cases, CMS will apply the regulation as finalized and instruct the MA organization whether the change is within the scope of § 422.101(f)(3)(iv) as finalized.

Lastly, although some comments expressed concern about alignment of audit standards with off-cycle review and approval of MOCs, we believe that the current audit process has consistently reviewed and treated approved off-cycle changes to MOCs (that is, off-cycle changes marked as approved or acceptable by NCQA) as acceptable. CMS will review and update our SNP audit protocols as warranted and CMS will consider feedback from stakeholders when determining if additional revisions are needed to ensure that CMS audits hold SNPs to their approved MOCs, including any approved changes to the MOCs.

Comment: A commenter did not support the proposal to include ''changes to quality metrics used to measure performance'' on the list of reasons requiring off-cycle submission and approval. The commenter noted that SNPs are required to conduct an annual quality improvement program that measures the effectiveness of its MOC. The commenter also stated that the goal of performance improvement and quality measurement is to improve the SNP's ability to deliver health services, improve member health outcomes, and increase organizational effectiveness. They noted that this includes examining current processes, including quality measures that should be modified. The commenter further noted that it may be necessary to change an entire quality measure to ensure that performance measures align with program goals and improve health outcomes. The commenter expressed that it would be an administrative burden to submit an off-cycle MOC for CMS approval of a change in quality metric(s) and that this submission requirement may have the effect of discouraging SNPs from making needed changes to their MOC, potentially impacting operational efficiencies and member health outcomes.

Response: We appreciate the commenter's suggestion, but we are not changing our policy on this topic. We believe it is important to review any changes to MOC quality metrics before such changes are implemented to ensure the operational integrity of the MOC by plans and so that SNPs are employing appropriate measurements so that NCQA can gauge the effectiveness overall of the MOCs implementation. As proposed and finalized here, the rule codified at § 422.101(f)(3)(iv)(B)(*3*) (that SNPs must submit off-cycle submissions based on changes to quality metrics used to measure performance) is from our long-standing off-cycle submission guidelines, and thus, a continuation of a policy that we believe SNPs are currently meeting. In addition, we note that the off-cycle revisions are for MOCs that SNPs have begun implementing after review and approval by NCQA; changing the quality metrics after performance has begun should also be reviewed to ensure that the changes in metrics are not designed to mask performance deficiencies or failure to implement the MOC as approved.

Comment: A commenter suggested that CMS increase the review capacity at NCQA to handle MOC reviews, especially off-cycle reviews in a timely, consistent, and effective way. They believe there should be a standard response timeline with standard, consistent, and timely communication. The commenter noted that a review should take no more than 30 days and the plans should be able to review the findings through an online portal.

Response: We do not believe that adopting a deadline for NCQA review of off-cycle MOC revisions would positively serve the MA program or lead to better or more efficient reviews of off-cycle submissions. NCQA already provides regular and timely review of off-cycle MOCs throughout the established review window. However,

we increasingly find that MA organizations that have many SNPs make a bulk submission of multiple changes to multiple MOCs (that is, making the same changes to multiple MOCs) at the end of the off-cycle window. When this occurs, it can cause some delay in NCQA's ability to finalize review of off-cycle submissions for all SNPs. We believe some SNPs struggled to find CMS' sub-regulatory guidance on significant versus non-significant changes and that this final rule will provide additional clarity in identifying when an off-cycle revision to an approved MOC is necessary. However, MA organizations that have a substantial number of off-cycle MOC submissions can avoid delays by submitting their MOCs at the beginning of the submission window timeframe, which is typically when fewer submissions have been received for review by NCQA. We also encourage, as a best practice, that MA organizations reach out to the Part C Policy mailbox prior to submission to provide notification to CMS and NCQA that the MA organization plans to submit a large bulk submission, as advance notice may assist NCQA to prepare and complete a more efficient review.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing new paragraph (f)(3)(iv) (for requirements on off-cycle changes to an approved MOC) largely as that regulation text was proposed but with modifications compared to our proposed regulation text. The modifications, listed here, are primarily to clarify and improve paragraph (f)(3)(iv):

In paragraph (f)(3)(iv), we are adding the text ''organization sponsoring'' between the proposed language ''An MA'' and ''a SNP that. . .'' for additional clarity. As finalized, the introductory language in paragraph (f)(3)(iv) reads: ''An MA organization sponsoring a SNP that seeks to revise the MOC before the end of the MOC approval period may submit changes to the MOC as off-cycle MOC submissions for review by NCQA as follows:'' This revision is clearer that the MA organization that offers the SNP is the legal entity responsible for the submissions.

In paragraphs (f)(3)(iv)(A) and (f)(3)(iv)(B), we are finalizing the paragraphs with revisions (described in more detail in a response to public comments earlier in this section) to clarify when off-cycle changes to an MOC must be submitted because CMS has directed the change to comply with applicable law and when off-cycle changes to an MOC must be submitted because of changes in how a D–SNP or I–SNP is administered or operates. As we noted earlier in this preamble, these changes are for additional clarity in the regulation.

We are also finalizing paragraph (f)(3)(iv)(B)(*1*) with organizational changes to make it easier to read and clearer that the standard ''substantial change'' applies to all of the listed areas. The areas under paragraph (f)(3)(iv)(B)(*1*) are now labeled as (i) the health risk assessment process; (ii) revising processes to develop and update the Individualized Care Plan (ICP); (iii) the integrated care team process; (iv) risk stratification methodology; and (v) care transition protocols. The revisions are more consistent with the intent of the proposal.

In paragraph (f)(3)(iv)(C), we have corrected the verb tense from ''will only review'' to ''only reviews.''

In paragraph (f)(3)(iv)(D), we are finalizing several changes to increase clarity in the regulation text but have not made substantive changes in policy. As finalized, paragraph (f)(3)(iv)(D)—in four sentences—clearly states that changes may not be made until NCQA has reviewed and approved the off-cycle changes and addresses how NCQA will review the changes. The first sentence states that SNPs may not make changes until NCQA has reviewed and approved the off-cycle MOC changes. A new second sentence states that NCQA does not rescore the MOC during the off-cycle process, but changes are reviewed and determined by NCQA to be either ''Acceptable'' or ''Non-acceptable.'' Two additional sentences follow to explain that ''Acceptable'' means that the changes have been approved by NCQA and the MOC has been updated; ''Non-acceptable'' means the changes have been rejected by NCQA and the MOC has not been changed; and that if NCQA determines that off-cycle changes are unacceptable, the SNP must continue to implement the MOC as originally approved. These revisions are consistent with the proposal and the current process.

In paragraph (f)(3)(iv)(F), we are finalizing the provision to use ''permitted'' rather than ''eligible'' as it better reflects our current policy so that it now reads: ''C–SNPs are only permitted to submit an off-cycle MOC submission when CMS requires an off-cycle submission to ensure compliance with applicable law.''

Finally, we are finalizing paragraph (f)(3)(iv)(G) to clarify the single opportunity for an SNP to submit a corrected off-cycle revision to the MOC if the initial off-cycle submission is not approved. The revisions generally use language that is consistent with § 422.101(f)(3)(iii)(C), which better signals that this part of the off-cycle revision process is similar to the cure period provided when the MOC submission is determined to have deficiencies. As finalized, paragraph (f)(3)(iv)(G) reads: ''When a deficiency is identified in the off-cycle MOC revision(s) submitted by a SNP, the SNP has one opportunity to submit a corrected off-cycle revision between June 1st and November 30th of each calendar year.''

Although there were inadvertent differences in how the preamble of the proposed rule explained the proposed regulation text, we are finalizing the substance of our proposed policy for how off-cycle revisions to the MOCs of I–SNPs and D–SNPs could be requested and would be subject to review and approval before changes could be implemented.

C. Amending the Definition of Severe or Disabling Chronic Condition; Defining C–SNPs and Plan Types; and Codifying List of Chronic Conditions (§§ 422.2, 422.4(a)(1)(iv), and 422.52(g))

A specialized MA plan for special needs individuals, generally known as a special needs plan or a SNP, is an MA plan specifically designed to provide targeted care and limits enrollment to special needs individuals. CMS defines Specialized MA Plans for Special Needs Individuals at § 422.2 as an MA coordinated care plan (CCP) that exclusively enrolls special needs individuals as set forth in § 422.4(a)(1)(iv) and that provides Part D benefits under part 423 to all enrollees; and which has been designated by CMS as meeting the requirements of an MA SNP as determined on a case-by-case basis using criteria that include the appropriateness of the target population, the existence of clinical programs or special expertise to serve the target population, and whether the proposal discriminates against sicker members of the target population. As provided in section 1859(b)(6) of the Act and the definition in § 422.2, a special needs individual could be any one of the following: an institutionalized or institutionalized-equivalent individual; a dual eligible individual; or an individual with a severe or disabling chronic condition and who would benefit from enrollment in a specialized MA plan. Chronic Condition Special Needs Plans (C–SNPs) are SNPs that restrict enrollment to special needs individuals with specific severe or

disabling chronic conditions, defined at § 422.2.

The Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) amended section 1859 of the Act to revise the definition of ''severe or disabling chronic condition'' for purposes of identifying the special needs individuals eligible to enroll in C–SNPs. The amendments had an effective date of January 1, 2022, and included the following related to the revision of this definition: a directing the Secretary to convene a Panel of clinical advisors to establish and update a list of severe or disabling chronic conditions that meet certain criteria; mandating the inclusion of several current C–SNP chronic conditions onto the list; and directing the Panel take into account the availability of benefits in the Medicare Advantage Value-Based Insurance Design model.

We proposed to codify the BBA of 2018's amendment to the definition of severe or disabling chronic condition; to codify the definition of C–SNP; to implement the BBA of 2018 by updating and codifying the recommended list of chronic conditions recommended by a Panel of clinical advisors as specified by the BBA; and to codify existing sub-regulatory guidance permitting the use of certain chronic condition combinations for the purposes of offering single standalone C–SNP plan benefit packages (PBPs).

A. Amending the Definition of Severe or Disabling Chronic Condition

Currently, § 422.2 defines ''severe or disabling chronic condition'' as meaning, for the purpose of defining a special needs individual, an MA eligible individual who has one or more co-morbid and medically complex chronic conditions that are substantially disabling or life-threatening, has a high risk of hospitalization or other significant adverse health outcomes, and requires specialized delivery systems across domains of care. As summarized in more detail in the December 2022 proposed rule this definition was adopted to track amendments to section 1859(b)(6)(B)(iii) of the Act made by section 164(e) of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) to define special needs individuals eligible for C–SNPs beginning January 1, 2010. (87 FR 79560) Section 164(e) of MIPPA also directed the Secretary to convene a Panel of clinical advisors to determine the chronic conditions used to identify special needs individuals for C–SNP eligibility. CMS subsequently convened the Panel in October 2008 and implemented the fifteen SNP-specific chronic conditions recommended by the Panel that met the definition of severe or disabling and needed specialized care management. The list was later incorporated into Chapter 16–B of the Medicare Managed Care Manual (MMCM). Starting in 2010, CMS adopted sub-regulatory guidance whereby a C–SNP could only offer a plan benefit package (PBP) that covered one of the fifteen SNP-specific chronic conditions identified in the guidance. Several of the chronic condition categories include a list of sub-categorical conditions or disorders that provide further information regarding the types of diseases that qualify under the chronic condition categories. Examples of conditions with sub-categorical disorders include autoimmune disorders, cardiovascular disorders, severe hematologic disorders, chronic lung disorders, chronic disabling mental health conditions, and chronic disabling neurologic disorders. Currently, C–SNPs that target several of the severe or disabling chronic conditions listed in our guidance must enroll an eligible beneficiary who has one or more of the targeted conditions, including the sub-categorical disorders; the C–SNP is not permitted to exclude an eligible beneficiary having the covered condition or a covered sub-categorical condition. For example, a C–SNP that enrolls special needs individuals with a chronic and disabling mental health condition must enroll special needs individuals with one or more of the following sub-categorical conditions: bipolar disorders, major depressive disorder, paranoid disorder, schizophrenia, or schizoaffective disorder. Currently, C–SNPs may only cover one of the fifteen qualifying chronic conditions in a single PBP, unless the C–SNP receives approval from CMS to focus on a group of severe or disabling chronic conditions. Generally, CMS believes that structuring a C–SNP to target multiple commonly co-morbid conditions that are not clinically linked in their treatment would result in a general market product rather than an MA plan that is sufficiently tailored for special needs individuals. Therefore, CMS will approve targeting of multiple severe or disabling chronic conditions by a C–SNP only for: (1) one of the CMS-developed group of commonly co-morbid and clinically linked conditions listed in section 20.1.3.1 of Chapter 16–B where the special needs individuals may have one or more of the conditions in the grouping or (2) a MA organization-customized group of multiple co-morbid and clinically linked conditions where the special needs individuals served by the C–SNP have all of the specified conditions.

In 2018, the BBA of 2018 amended section 1859(b)(6)(B)(iii) of the Act by adding a new definition of special needs individuals to apply beginning January 1, 2022. Under the new definition of special needs individual, an eligible individual that the Secretary may determine would benefit from enrollment in such a specialized MA plan for individuals with severe or disabling chronic conditions must, on or after January 1, 2022, ''have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits overall health or function, have a high risk of hospitalization or other adverse health outcomes, and require intensive care coordination and that is listed under [section 1859(f)(9)(A) of the Act].'' Section 1859(f)(9) of the Act, as added by the BBA of 2018, instructs the Secretary to convene the Panel of clinical advisors not later than December 31, 2020, and every 5 years thereafter, to establish and update a list of conditions that meet each of the following criteria:

- Conditions that meet the definition of a severe or disabling chronic condition under section 1859(b)(6)(B)(iii)(II) of the Act on or after January 1, 2022; and
- Conditions that require prescription drugs, providers, and models of care that are unique to the special needs individuals with several or disabling chronic conditions as defined in subsection (b)(6)(B)(iii)(II) of section 1859 of the Act as of that date and:

++ As a result of access to, and enrollment in, such a specialized MA plan for special needs individuals, individuals with such conditions would have a reasonable expectation of slowing or halting the progression of the disease, improving health outcomes and decreasing overall costs for individuals diagnosed with such condition compared to available options of care other than through such a specialized MA plan for special needs individuals; or

++ Have a low prevalence in the general population of beneficiaries under this title or a disproportionally high per-beneficiary cost under title XVIII of the Act.

In addition, sections 1859(f)(9)(B) and (C) of the Act require that:

- The list of severe or disabling chronic conditions used for C–SNPs include: HIV/AIDS, end stage renal disease (ESRD), and chronic and disabling mental illness.

• The Panel consider the availability of varied benefits, cost-sharing, and supplemental benefits under the Medicare Advantage Value-Based Insurance Design (VBID) model being tested by the Center for Medicare and Medicaid Innovation (CMMI).

In meeting its obligation under section 1859(f)(9)(A) of the Act to convene a Panel of clinical advisors not later than December 31, 2020, to establish the list of conditions that meet the statutory criteria, CMS was committed to engaging the public—industry, advocates, beneficiaries, and medical professional societies—in the discussion about appropriate SNP-specific chronic conditions. Panel members were tasked with assessing the statutory criteria for reviewing the appropriateness of potential conditions as required by section 1859(f)(9)(A) of the Act.

On August 8, 2019, CMS announced a Request for Information (RFI) related to the review of C–SNP specific chronic conditions as mandated by the BBA of 2018 to solicit comments from the public to assist the Panel of advisors convened by CMS under section 1859(f)(9)(A) of the Act. The 2019 SNP Chronic Condition Panel met for three sessions between September 9 and September 23, 2019. CMS provided panelists with a summary of comments received in response to the RFI. The panelists reviewed and discussed the written public comments from 14 stakeholders representing the industry, advocacy groups, medical societies, and beneficiaries. The panelists also examined the chronic conditions already covered by existing C–SNPs. They employed their collective national and international experience with chronic condition research and clinical practice to weigh inclusion of chronic conditions on the list. As in 2008, the panelists also considered the condition's prevalence in the Medicare population, a factor that would potentially affect the capacity of an MA organization to attract eligible enrollees and be viable in a given service area as well as being identified in section 1959(f)(9)(A)(ii)(II) of the Act as a criterion to be considered. The panelists were sensitive to the reality that C–SNPs require sufficient disease prevalence and access to a specialized provider network within a marketable service area to manage risk under a capitated payment system (even with risk-adjustment of those capitated payments), and effectively and efficiently serve the targeted special needs beneficiaries. The panelists also reflected on the need for beneficiaries, health care practitioners, and the health care industry to recognize the SNP-specific chronic conditions and consider them appropriate for a specialized service delivery system in order to stimulate participation. While the Panel did consider a condition's prevalence in the Medicare population as required by section 1859(f)(9)(A) of the Act, it was not charged with and did not make any additional judgments based on business considerations (that is, the potential profitability of the selected chronic conditions) as CMS expects interested MA organizations to reach their own conclusions about product offerings and markets in which they wish to operate.

Upon review and deliberation, the Panel identified the following 22 chronic conditions as meeting the statutory criteria:

1. Chronic alcohol use disorder and other substance use disorders;
2. Autoimmune disorders:
- Polyarteritis nodosa,
- Polymyalgia rheumatica,
- Polymyositis,
- Dermatomyositis
- Rheumatoid arthritis,
- Systemic lupus erythematosus,
- Psoriatic arthritis, and
- Scleroderma;

3. Cancer;
4. Cardiovascular disorders:
- Cardiac arrhythmias,
- Coronary artery disease,
- Peripheral vascular disease, and
- Valvular heart disease;

5. Chronic heart failure;
6. Dementia;
7. Diabetes mellitus;
8. Overweight, Obesity, and Metabolic Syndrome;
9. Chronic gastrointestinal disease:
- Chronic liver disease,
- Non-alcoholic fatty liver disease (NAFLD),
- Hepatitis B,
- Hepatitis C,
- Pancreatitis,
- Irritable bowel syndrome, and
- Inflammatory bowel disease;

10. Chronic kidney disease (CKD):
- CKD requiring dialysis/End-stage renal disease (ESRD), and
- CKD not requiring dialysis;

11. Severe hematologic disorders:
- Aplastic anemia,
- Hemophilia,
- Immune thrombocytopenic purpura,
- Myelodysplastic syndrome,
- Sickle-cell disease (excluding sickle-cell trait), and
- Chronic venous thromboembolic disorder;

12. HIV/AIDS;
13. Chronic lung disorders:
- Asthma,
- Chronic bronchitis,
- Cystic Fibrosis,
- Emphysema,
- Pulmonary fibrosis,
- Pulmonary hypertension, and
- Chronic Obstructive Pulmonary Disease (COPD);

14. Chronic and disabling mental health conditions:
- Bipolar disorders,
- Major depressive disorders,
- Paranoid disorder,
- Schizophrenia,
- Schizoaffective disorder,
- Post-traumatic stress disorder (PTSD),
- Eating Disorders, and
- Anxiety disorders;

15. Neurologic disorders:
- Amyotrophic lateral sclerosis (ALS),
- Epilepsy,
- Extensive paralysis (that is, hemiplegia, quadriplegia, paraplegia, monoplegia),
- Huntington's disease,
- Multiple sclerosis,
- Parkinson's disease,
- Polyneuropathy,
- Fibromyalgia,
- Chronic fatigue syndrome,
- Spinal cord injuries,
- Spinal stenosis, and
- Stroke-related neurologic deficit;

16. Stroke;
17. Post-organ transplantation care;
18. Immunodeficiency and Immunosuppressive disorders;
19. Conditions that may cause cognitive impairment:
- Alzheimer's disease,
- Intellectual and developmental disabilities,
- Traumatic brain injuries,
- Disabling mental illness associated with cognitive impairment, and
- Mild cognitive impairment;

20. Conditions that may cause similar functional challenges and require similar services:
- Spinal cord injuries,
- Paralysis,
- Limb loss,
- Stroke, and
- Arthritis;

21. Chronic conditions that impair vision, hearing (deafness), taste, touch, and smell;
22. Conditions that require continued therapy services in order for individuals to maintain or retain functioning.

We proposed to codify the list of chronic conditions created by the Panel as part of the definition of severe or disabling chronic condition at § 422.2. The proposal took into account the changes recommended by the Panel to the list of chronic conditions that are currently used by CMS to approve C–SNPs. These changes include:

• Removing the term ''limited'' in listing the severe or disabling chronic conditions that make an individual eligible to enroll in a C–SNP. The Panel chose this revision so that unlisted chronic conditions will not disqualify the enrollee from plan eligibility even if the unlisted or another listed condition is not the targeted condition that qualifies the beneficiary for a specific C–SNP. In other words, the beneficiary could have other conditions beyond the index condition (which is required to be present) and still be permitted to enroll in a specific C–SNP. For example, a beneficiary with heart failure could also have psoriasis or epilepsy and not be excluded from the Chronic Heart Failure C–SNP. Because our proposal would not exclude a beneficiary from being a special needs individual or eligibility for an applicable C–SNP if the beneficiary has conditions in addition to a severe or disabling chronic condition, we did not propose to use the word ''including'' in the proposed definition. We proposed to codify the list of specific conditions (and subconditions) that have been identified as meeting the statutory criteria and avoid ambiguity regarding related but unlisted conditions;

• Renaming ''Chronic alcohol and other drug dependence'' to ''Chronic alcohol use disorder and other substance use disorders;''

• Adding dermatomyositis, psoriatic arthritis, and scleroderma to the Autoimmune disorders chronic condition category;

• The Panel recommended changing title of ''Cancer, excluding pre-cancer conditions or in-situ status'' to ''Cancer;'' however; they did not recommend altering the current limitations to the chronic condition category, only a clerical change to the title;

• Adding valvular heart disease to the Cardiovascular disorders chronic condition category;

• Adding new chronic condition category, ''Overweight, Obesity, and Metabolic Syndrome;''

• Adding new chronic condition category, ''Chronic gastrointestinal disease'' with the following conditions: chronic liver disease, non-alcoholic fatty liver disease (NAFLD), hepatitis B, hepatitis C, pancreatitis, irritable bowel syndrome, and inflammatory bowel disease;

• Renaming the ''End Stage Renal Disease (ESRD) requiring dialysis'' condition category to ''Chronic kidney disease (CKD)'' with the following conditions: CKD requiring dialysis/end-stage renal disease (ESRD), and CKD not requiring dialysis;

• Adding Cystic Fibrosis and Chronic Obstructive Pulmonary Disease (COPD) to the Chronic lung disorders chronic condition category;

• Adding post-traumatic stress disorder (PTSD), eating disorders, and anxiety disorders to the Chronic and disabling mental health conditions category;

• Adding fibromyalgia, chronic fatigue syndrome, and spinal cord injuries to the Neurologic disorders conditions category;

• Adding post-organ transplantation care and immunodeficiency and immunosuppressive disorders as new chronic condition categories;

• Creating new chronic condition category ''Conditions that may cause cognitive impairment,'' including the following sub-conditions: Alzheimer's disease, intellectual disabilities, developmental disabilities, traumatic brain injuries, disabling mental illness associated with cognitive impairment, and mild cognitive impairment;

• Creating new chronic condition category ''Conditions that may cause similar functional challenges and require similar services,'' including the following sub-conditions: spinal cord injuries, paralysis, limb loss, stroke, arthritis, and chronic conditions that impair vision, hearing (deafness), taste, touch, and smell; and

• Creating new chronic condition category ''Conditions that require continued therapy services in order for individuals to maintain or retain functioning.''

As demonstrated in the last three bullets, the Panel recommended the creation of several new chronic condition categories that differ from how the current list of severe or disabling chronic conditions uses categories as a single condition or set of related diseases. By including these new categories, we proposed that C–SNPs would be permitted to create benefit packages and care coordination services to address the needs of beneficiaries who share the same functional needs even if their specific disease or chronic condition may differ. For example, using the condition categories ''Conditions associated with cognitive impairment;'' ''Conditions associated with similar functional challenges and require similar services;'' ''Chronic conditions that impair vision, hearing (deafness), taste, touch, and smell;'' and ''Conditions that require continued therapy services in order for individuals to maintain or retain functioning;'' MA organizations would have the opportunity to propose C–SNPs that seek to ameliorate specific disease outcomes such as impaired vision without having to target one specific chronic condition. In another example, MA organizations would be permitted to create specific care coordination services and benefit packages to address the functional challenges facing beneficiaries with spinal cord injuries and those suffering paralysis from stroke. The challenge for SNPs would be to address the needs not of enrollees who share the same disease or chronic condition, but those diagnosed with different diseases and chronic conditions that share similar impacts on health and functionality.

The proposed categories as finalized will apply the same statutory and regulatory considerations per the parameters of a severe or disabling chronic condition and as noted in Title XVIII of the Act and 42 CFR part 422. In finalizing the three categories that are focused on impacts on health and functionality rather than underlying disease or condition, we are not eliminating the need for the effect on the enrollee to meet the statutory criteria in section 1859(f)(9) of the Act. As we noted in the December 2022 proposed rule, we believe this new approach to creating a C–SNP is in line with types of services and benefits required of current C–SNPs in operation, and beneficiaries facing similar challenges would benefit from coordination of care among multiple providers for services found in a variety of settings appropriate for the enrollee's health challenges.

We received the following comments, and our responses follow:

Comment: Many commenters expressed general support for the list of chronic conditions; however, individual commenters provided specific support for certain additions to the list, such as: ''Dementia;'' the category ''Conditions that may cause cognitive impairment;'' ''chronic alcohol use disorder and other substance use disorders;'' chronic kidney disease (CKD); anxiety associated with chronic obstructive pulmonary disease (COPD); substance use disorders (SUD); chronic and disabling mental health conditions;; and the category ''Overweight, Obesity, and Metabolic Syndrome.'' There was also support for broadening the current set of chronic condition categories to a more holistic definition that accounts for the overall health and functional ability of an individual, including functional and cognitive needs. Commenters believe allowing enrollees with these conditions to enter into specialized C–SNPs will provide access to increased care coordination and improve health outcomes. Specifically, commenters who were supportive of adding CKD

noted that access to a specialized network of providers may prevent or slow disease progression toward ESRD.

Response: We appreciate the commenters support for these changes.

Comment: In responding to our solicitation of comment regarding the extent to which MA organizations would need more guidance with implementation of the proposed functional chronic condition categories, a commenter suggested that CMS take the approach of reviewing plan proposals for new C–SNPs organized around those functional categories and based on that experience, CMS should determine whether additional guidance is needed.

Response: We believe there is a great deal of merit to this suggestion. As CMS implements and operationalizes the new chronic condition list, we will assess whether additional guidance or information is needed to ensure compliance with the regulations (including those we are finalizing here) and the statute. Consistent with our current MA application procedures, all SNPs are currently required to submit their model of care (MOC) to CMS for NCQA evaluation and approval as per CMS guidance under 42 CFR 422.4(a)(1)(iv). CMS will consider the SNP's outline of care coordination activities as part of the MOC when determining whether additional guidance is necessary for submitting SNP applications under the new function-based C–SNPs.

Comment: A commenter suggested that CMS permit C–SNPs to offer plans that address the needs of beneficiaries, even if their specific disease or chronic conditions are different because it would an important step forward for integrated long-term care. The commenter notes that it is the needs of an individual, the activities of daily living (ADLs) and instrumental activities of daily living (IADLs) that should determine entry into a C–SNP, not the specific diagnosis.

Response: We appreciate the comment. It is unclear to us the specific needs the commenter believes should be addressed by defining the term severe or disabling chronic condition for purposes of establishing MA SNPs to address such conditions. As we noted in the December 2022 proposed rule, and in this final rule, the BBA of 2018 added requirements establishing chronic conditions. Section 1859(f)(9)(A) of the Act directs the Secretary to convene a Panel of clinical advisors every 5 years to review and revise a list of chronic conditions that meet two sets of criteria: the amended definition of a severe or disabling chronic condition in subsection (b)(6)(B)(iii) of the Act; and conditions that require prescription drugs, providers, and models of care that are unique to the specific population of enrollees in a specialized MA plan for special needs individuals and either: (1) as a result of enrollment in a C–SNP, the enrollee with the condition would have a reasonable expectation of meeting a certain standard regarding health status, outcomes and costs compared to other coverage options; or (2) the condition has a low prevalence in the general population of Medicare beneficiaries or a disproportionally high per-beneficiary cost.

While we agree that the use ADLs and IADLs can assist health care providers and payers determine the health needs of patients, the Panel did not specifically create a chronic condition category around these measurements. As noted earlier in the preamble, the 2019 chronic condition Panel was limited to using these criteria when determining the content of the chronic conditions list. The Panel did recommend some function-based additions to the list that may be associated with conditions leading to deterioration of abilities, such as chronic condition (20) ''Conditions with functional challenges and require similar services including the following: spinal cord injuries, paralysis, limb loss, stroke, and arthritis.'' Because of these requirements, CMS does not have the authority to establish C–SNPs as suggested by the commenter at this time.

Comment: A commenter noted that Table D–A 1 on page 79566 of the December 2022 proposed rule showed that only one C–SNP focused on substance use disorders between 2007–2022. The commenter recommends CMS work with stakeholders to identify recommendations and guidelines that would make it easier for other MA organizations to redevelop and deliver such plans.

Response: We thank the commenter for their perspective. We acknowledge that few MA organizations have sponsored C–SNPs focusing on substance use disorders since the beginning of the program. CMS will review this request and determine whether we can employ informational outreach efforts or forums to encourage the use of underutilized chronic condition categories by organizations sponsoring C–SNPs. We encourage the public to provide additional information regarding the difficulties of creating certain condition-specific C–SNPs.

Comment: A commenter supported the adoption of the revised definition of ''Severe or Disabling Chronic'' Conditions and adding a new chronic condition category for ''Overweight, Obesity, and Metabolic Syndrome.'' The commenter urged CMS to use its authority to recognize that FDA-approved anti-obesity medications (AOMs) as clinically recommended treatments for a chronic disease—obesity, and may therefore be covered under Part D.

Response: We thank the commenter. However, the comment regarding AOMs and Part D coverage is out of scope for this rulemaking.

Comment: A commenter suggested that our proposed amendment to the definition of severe or disabling chronic condition reinforces the linkage between C–SNP and special supplemental benefits for the chronically ill (SSBCI) eligibility in that the same definition also is used for SSBCI eligibility determination in the BBA of 2018. The commenter stated that this may encourage more plans to use functional and cognitive needs to target SSBCI eligibility.

Response: We appreciate the comment, but CMS believes that the Act distinguishes the targeted beneficiaries of these benefits and programs in different ways that potentially limit the chronic conditions that may be employed between SSBCI and C–SNPs.

As defined in section 1852(a)(3)(D)(iii) of the Act, for the purposes of SSBCI, a chronically ill enrollee means an enrollee in an MA plan that the Secretary determines:

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

CMS added this definition to our regulations at § 422.102(f)(1)(i)(A).

As we noted in the preamble to this final rule, the BBA of 2018 amended section 1859(b)(6)(B)(iii)(II) of the Act by adding a new definition of special needs individuals means an MA eligible individual who meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized MA plan described in subparagraph (A) for individuals with severe or disabling chronic conditions who on or after January 1, 2022, have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits overall health or function, have a high risk of hospitalization or other adverse

health outcomes, and require intensive care coordination and that is listed under 1859(f)(9)(A) of the Act.

The definition of chronically ill enrollee for the purposes of SSBCI is not specifically tied to the set of chronic conditions established by the Panel of clinical advisors under section 1859(f)(9)(A) as is the case for the definition of special needs individuals with ''severe or disabling chronic conditions'' that must be used in determining eligibility for C–SNPs. In addition, the definition of ''chronically ill enrollee'' in section 1852(a)(3)(D) of the Act does not include an assessment whether the Secretary determines the individual would benefit from enrollment in a specialized MA plan. CMS did not propose to specifically align eligibility for SSBCI with eligibility for C–SNPs and is not finalizing such a limitation for SSBCI in this rule. Rather, CMS proposed and finalized in the 2020 Final Rule (85 FR 33796) that for the purposes of SSBCI, the chronic conditions established by the Panel may be used to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee as required at 422.102(f)(1)(i)(A)(1). In the case of determining eligibility for SSBCI, MA plans are permitted to use other conditions not on the updated chronic condition list provided the condition is life threatening or significantly limits the overall health or function of the enrollee.

Comment: A commenter noted individuals that would be eligible for enrollment in a functional status-focused C–SNP would likely require robust functional, cognitive, and social determinants of health (SDOH) supports in addition to medical and behavioral health care services. The commenter expressed concerned that if enrollees in a functional-status focused C–SNP cannot access Medicaid funded LTSS, those enrollees would not fully benefit from this new C–SNP type. The commenter suggested that CMS work with stakeholders to identify new opportunities to provide appropriate and necessary functional and cognitive support services for this population, including SSBCI.

Response: We appreciate the comment and note that C–SNPs must have specific attributes that go beyond the provision of basic Medicare Parts A and B services and care coordination that is required of all coordinated care plans. For example, C–SNPs must develop and implement a comprehensive individualized plan of care through an interdisciplinary care team in consultation with enrollee, as feasible, identifying goals and objectives including measurable outcomes as well as specific services and benefits to be provided to the enrollee. (See § 422.101.(f)(1)(ii)) Additionally, C–SNPs may offer supplemental benefits, including SSBCI, to provide a more robust set of items and services than offered under Traditional Medicare that are tailored to the needs of the plan population. C–SNPs do not have Medicaid integration requirements as some D–SNP plans do, as indicated in the definitions of FIDE SNPs and HIDE SNPs at § 422.2. While LTSS services may be available for individual C–SNP enrollees who are also enrolled in Medicaid, it is not currently a requirement that C–SNPs contractually integrate Part A/B services with Medicaid services offered by a state Medicaid agency or a Medicaid managed care plan that serves the same enrollee. However, coordination of services that are medically necessary for an enrollee and covered for that enrollee by Medicaid is an appropriate consideration for a C–SNP in developing the individualized plan of care for the enrollee. CMS understands that integration of Medicaid funded LTSS can be a great benefit to dually eligible beneficiaries, and we will continue to look at opportunities to service this population.

Comment: MedPAC specifically provided comment that they did not support the proposal to increase the number of chronic conditions under the proposed definition of severe or disabling chronic condition at § 422.2, nor do they support the current number of chronic conditions as listed in Chapter 16B of the MMCM. MedPAC noted that the Commission has long expressed concern that the list of conditions that C–SNPs can address was too broad and recommended that the list be narrowed. They stated that MA plans that are not C–SNPs should be able to manage most of the clinical conditions on the list; and that 95 percent of C–SNP enrollees are in plans that focus on just three conditions—cardiovascular disorders, diabetes, and chronic heart failure—that are relatively common in the Medicare population. In addition, MA plans now have the flexibility, through the MA Value-Based Insurance Design (VBID) demonstration and changes to the uniformity requirement, to target reductions in cost sharing and supplemental benefits to enrollees with specific conditions, which weakens the rationale for offering a separate set of plans that focus on a specific condition. Lastly, MedPAC stated that C–SNPs are only warranted for a small number of conditions, including HIV/AIDS, ESRD, and chronic and disabling mental illness.

Response: We note that the list of chronic conditions contained in the proposed definition of severe or disabling chronic condition under § 422.2, like the current list of chronic conditions listed in Chapter 16B of the Medicare Managed Care Manual, is based on the recommendations by the expert Panel of clinical advisors. As noted in the proposed rule, the proposed chronic condition recommendations were reviewed by a Panel of clinical advisors in accordance with subsection 1859(f)(9)(A) of the Act, as modified by the BBA 2018, as well as all other requirements set by statute (for the specifics of those requirements, please see 87 FR 79452). CMS concurs with the Panel's recommendations, and believes the Panel was in the best position to provide an objective assessment of what constitutes a severe or disabling chronic condition.

CMS recognizes that MA organizations have chosen to utilize a small subsegment of chronic conditions when establishing C–SNPs since the inception of the program. However, we believe following the Panel's recommendations of increasing the number of severe or disabling chronic conditions may encourage MA organizations to establish innovative approaches to comprehensive care for those with other severe or disabling chronic conditions.

We acknowledge that MA plans should be able to manage most of the clinical conditions on the list without the need to sponsor a disease-specific C–SNP. However, we reiterate the unique statutory and regulatory SNP care management and quality improvement requirements that are expected of C–SNPs established under section 1859(f) of the Act, and §§ 422.101(f) and 422.152(g). Currently, non-SNP MA plans are not required to meet these same standards. For example, the requirement at § 422.101(f)(1) that SNPs must implement a MOC and the requirements at § 422.101(f)(1)(ii) and (iii) to develop and implement an individualized care plan and interdisciplinary team, respectively, are not required of all MA plans (or even all MA coordinated care plans) and provide important additional benefits for the beneficiaries who are eligible for and enroll in C–SNPs.

With respect to the comment that C–SNPs are only warranted for a small number of conditions such as HIV/AIDS, ESRD, and chronic and disabling

mental illness, as noted previously, our decision to increase the number of chronic conditions on the list is based on the recommendations by the Panel of clinical advisors as mandated by statute. Importantly, the statute does not set numerical limits when considering conditions that should be on the list, rather the statute sets standards the Panel must consider when deciding the merits of any disease in fitting the definition of a severe or disabling chronic condition. When considering the composition of the list of chronic conditions, CMS follows the direction the Panel provides in utilizing the review conditions established by statute. Again, the Panel was asked to consider changes to the new definition of special needs individual, which is an eligible individual that the Secretary may determine would benefit from enrollment in such a specialized MA plan for individuals with severe or disabling chronic conditions must, on or after January 1, 2022, ''have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits overall health or function, have a high risk of hospitalization or other adverse health outcomes, and require intensive care coordination and that is listed under [section 1859(f)(9)(A) of the Act].'' The Panel ensured that the updated definition speaks to the severity and medical complexity of the condition and its impact on the care considerations that the enrollee, their SNP care coordinator, and providers must navigate to optimize health outcomes for C–SNP enrollees.

Finally, we proposed in the December 2022 proposed rule that this new definition of severe or disabling chronic condition (that is, the new chronic condition list) would be applicable for plan years that begin on or after January 1, 2025, a delay of one additional year beyond the proposed applicability for most of the policies in that proposed rule. We proposed a delayed implementation of this for operational considerations and to allow plans and CMS to put in the place the necessary operational steps to permit transition from the current list of chronic conditions (and C–SNPs offered using that list) to the new definition and list of severe or disabling chronic conditions. Part of these considerations included the timing of MOC creation for C–SNPs that are due to CMS the February prior to upcoming contract year in which the MOC would take effect. After considering the gap in time between the issuance of the December 2022 proposed rule and the finalization of these provisions in the April 2024 final rule, we decided that it not necessary to delay the applicability of the new definitions for C–SNP and severe or disabling chronic condition under § 422.2 and the finalized rule at § 422.4 regarding groups of chronic conditions. This means that these rules will take effect with the effective date of this rule and be applicable beginning January 1, 2025. We acknowledge that C–SNP approval processes and MOC approval timelines mean that C–SNPs will not be able to effectively use this new definition to offer new C–SNPs until CY 2026 coverage. With the implementation of the new definition, several current chronic conditions would transition to new chronic condition categories, such as End Stage Renal Disease (ESRD) and End Stage Liver Disease. MA organizations seeking to establish a plan covering End Stage Liver Disease for CY 2026 would be able to do so under the new category of Chronic Gastrointestinal Disease. We also proposed a delay implementing the proposed new definition of severe or disabling chronic condition in order to give CMS time to collect data and information related to the structuring of the proposed CKD C–SNP plan bids. Per section 1853(a)(1)(H) of the Act, the capitation rates paid to MA plans for enrollees with ESRD are set separately from the capitation rates and bidding benchmarks applicable for other enrollees, which may complicate the transition to using this specific severe or disabling chronic condition category. We will move forward with the codification of the new definition of severe or disabling chronic conditions effective with the April 2024 final rule; however, CKD C–SNPs (like other conditions in the new list) will only be available starting with CY 2026. This allows CMS and plans time to review operational and bid considerations. At the time this final rule is issued, the MA rates for 2025 will have been (or will shortly be) released because MA rates for the next calendar year must be released the first Monday in April of the calendar year. Current ESRD C–SNPs plan bids are based on a distinct bidding methodology. CMS will provide additional bid pricing information to MA organizations consistent with current procedures.

After review of the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed definition for the term ''severe or disabling chronic condition'' as proposed with minor modifications to the formatting of the regulatory text to improve the clarity of the definition.

B. Chronic Condition Special Needs Plan Definition, Scope and Eligibility (§§ 422.2, 422.4, and 422.52)

A C–SNP must have specific attributes and meet certain standards that go beyond the provision of basic benefits (as defined in § 422.100(c)) and care coordination required of all coordinated care plans; such additional standards include the enrollment limitations, model of care, and care management requirements set forth in section 1859(f) of the Act and codified in the regulations at §§ 422.52(a) and (b), 422.101(f), and 422.152(g). While C–SNPs must generally meet requirements that are specified to all SNPs, we believe it is important to codify a definition of C–SNP that reflects how they are limited to serving special needs individuals who have a severe or disabling chronic condition, as defined in § 422.2. See section HC.1 of this final rule regarding our finalization of a revised definition for the term severe or disabling chronic condition. Adopting a definition of C–SNP in § 422.2 would be consistent with how we have previously adopted definitions for the term dual eligible special needs plan (D–SNP) and specific types of D–SNPs. We believe adopting a specific definition will help to clarify how C–SNP specific requirements and policies are distinguishable from requirements and policies for D–SNPs and I–SNPs as well as different from general MA coordinated care plans. As we explained in the proposed rule, because the proposed definition was intended to provide clarification for MA organizations and providers regarding the meaning and scope of C–SNPs, we believe this codification will have little to no impact on MA enrollees nor accrue operational or other costs to MA organizations. The December 2022 proposed rule generally reflected current policy and practice, with a few modifications as discussed where applicable. As part of current C–SNP sub-regulatory guidance and during the MA plan application process, MA organizations may apply to offer a C–SNP that targets any one of the following:

- A single CMS-approved chronic condition (selected from the list in section 20.1.2 of Chapter 16B);
- A CMS-approved group of commonly co-morbid and clinically-linked conditions (described in section 20.1.3.1 of Chapter 16B); or
- An MA organization-customized group of multiple chronic conditions

(described in section 20.1.3.2 of Chapter 16B).

CMS recognizes that there is value for C–SNPs to use groupings of severe or disabling chronic conditions in identifying their focus and limiting enrollment, and our proposals reflect how the MA organizations that offer C–SNPs must choose a single chronic condition from the definition of severe or disabling chronic condition or choose from a list of permitted multiple chronic conditions found in in the new subparagraphs (A) and (B) under § 422.4(a)(1)(iv).

First, we proposed, as part of the definition of C–SNP at § 422.2 and in the description of special needs plans at § 422.4(a)(1)(iv), to codify current guidance regarding the ability of MA organizations to offer a C–SNP that focuses on single or multiple chronic conditions. The proposed definition of a C–SNP provides that C–SNPs are SNPs that restrict enrollment to MA special needs eligible individuals who have a severe or disabling chronic condition as defined in § 422.2 under this section. In other words, the chronic conditions on which a C–SNP may focus are limited to those conditions listed in the definition of severe or disabling chronic condition. When a C–SNP focuses on one chronic condition, enrollees must have that severe or disabling chronic condition in order to enroll in the C–SNP. In addition to single chronic condition category PBPs, CMS currently permits MA organizations to apply to offer a C–SNP that includes specific combinations of CMS-approved group of commonly co-morbid and clinically linked conditions, as described in section 20.1.3.1 of Chapter 16B of the MMCM. We proposed to codify how a C–SNP may focus on multiple chronic conditions in two ways. The proposed definition of C–SNP provided that the restricted enrollment to individuals with severe or disabling chronic conditions includes restricting enrollment based on the multiple commonly co-morbid and clinically linked conditions groupings specified in § 422.4(a)(1)(iv).

Currently, CMS has identified five combinations of commonly co-existing chronic conditions that may be the focus of a C–SNP based on our data analysis and recognized national guidelines. The current set of combinations include:

- Diabetes mellitus and chronic heart failure;
- Chronic heart failure and cardiovascular disorders;
- Diabetes mellitus and cardiovascular disorders;
- Diabetes mellitus, chronic heart failure, and cardiovascular disorders; and
- Stroke and cardiovascular disorders.

Considering the established clinical connection between these conditions and the interest among plans and beneficiaries, we proposed to maintain the current policy. We proposed to codify this current list of combinations of chronic conditions that may be used by a C–SNP at § 422.4(a)(1)(iv)(A)(1) through (5).

A C–SNP may not be structured around multiple commonly co-morbid conditions that are not clinically linked in their treatment because such an arrangement results in a general market product rather than one that is tailored for a particular population. As part of its review, the 2019 clinical advisor Panel convened in accordance with section 1859(f)(9)(A) of the Act recommended the continuation of the current Chapter 16B linked conditions plus three additional groups. The Panel considered several relevant factors, including all statutory criteria required under the Act, when determining the appropriateness of additional pairings, including clinical considerations and the potential of these conditions to be successfully managed by a specialized provider network. The Panel recommended the following additional groupings conditions were as follows:

- Anxiety associated with COPD.
- CKD and post-renal organ transplantation.
- Substance Use Disorder (SUD) and Chronic and disabling mental health conditions.

In addition to our proposal to codify the current approved set of commonly co-morbid and clinically linked conditions, we proposed to add the three recommended pairings as permissible groupings of severe or disabling chronic conditions that may be used by C–SNPs at new § 422.4(a)(1)(iv)(B)(6) through (8). Under this proposal, a C–SNP may focus on one of the commonly co-morbid and clinically linked conditions specified in these eight specific combinations of co-morbid condition groupings upon CMS approval. We proposed to add a new § 422.52(g) to clarify that enrollees need only have one of the qualifying conditions for enrollment listed in the approved groupings in proposed § 422.4(a)(1)(iv).[202] This is consistent with current CMS operational practices regarding the current set of approved C–SNP groups.

Lastly, CMS did not propose to codify a C–SNP plan application option that is currently available under sub-regulatory guidance in section 20.1.3.2 of Chapter 16B of the MMCM. In effect, this would remove this approach as an option for C–SNPs beginning 2025. Under the current guidance, we permit MA organizations seeking to sponsor a C–SNP to apply for an MA organization-customized group of multiple chronic conditions. If a C–SNP uses such a customized group of conditions, enrollment in that C–SNP is limited to special needs individuals who have all of the severe or disabling conditions in the group. CMS has reviewed only a few SNP plan application proposals since the initial implementation of the C–SNP program and has not granted any applications for this type of C–SNP either due to the lack of clinical connection between the proposed conditions or because the MA organization failed to meet other conditions of the application process. No C–SNPs of this type have been approved nor will be operational in CY 2023. We proposed to remove this option from the C–SNP application process beginning in CY 2024. Given the historical lack of interest from MA organizations, beneficiaries, or patient advocacy groups, we explained in the proposed rule that we believed there will be minimal impact on stakeholders associated with the elimination of this current flexibility. In addition, with the addition of three new groupings and the ability to establish a C–SNP that is based on functional limitations that we are proposing with paragraphs (20) through (21) of the proposed definition of severe or disabling chronic condition, we believe that there is adequate flexibility for MA organizations to develop C–SNPs that meet the needs of the Medicare population.

We received the following comments, and our responses follow:

Comment: A commenter commended CMS for the changes to the list of severe or disabling chronic conditions under § 422.2; however, the commenter expressed concern that the further expansion of chronic condition groupings in proposed § 422.4(a)(1)(iv)(B) should be done in ways to minimize beneficiary and provider confusion, and to ensure conditions are clinically associated.

Response: We agree with the commenter that chronic conditions

[202] The December 2022 proposed rule inadvertently identified proposed § 422.4(a)(1)(iv)(A) as addressing this proposal that an enrollee of a C–SNP that focuses on a grouping of conditions would be required to only have one of the conditions to be eligible to enroll in that C–SNP; we use the correct reference here. 87 FR 79565.

should be clinically associated for a C–SNP that addresses multiple chronic conditions to be approved. As proposed and finalized here (at § 422.4(a)(1)(iv)(B)), consistent with current policy, a C–SNP may not be structured around multiple commonly co-morbid conditions that are not clinically linked in their treatment approaches and approved by CMS. As we noted in the December 2022 proposed rule, we believe that allowing a C–SNP to target a non-linked clinical arrangement results in a more general market product rather than a product that is tailored for a particular population. Further, as we stated in our proposed rule, the 2019 clinical advisor Panel convened in accordance with section 1859(f)(9)(A) of the Act recommended the continuation of the current Chapter 16B linked conditions plus three additional groups. The Panel considered several relevant factors, including all statutory criteria required under the Act, when determining the appropriateness of additional pairings, including clinical considerations and the potential of these conditions to be successfully managed by a specialized provider network. We believe the use of this process minimizes beneficiary and provider confusion and ensures that chronic condition groupings are clinically associated.

After considering the comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the revised definition of the term ''chronic condition special needs plan (C–SNP)'' at § 422.2, the revisions to § 422.4(a)(1)(iv) to establish how C–SNPs may target specific and specific groupings of severe or disabling chronic conditions, and the special eligibility rule for C–SNPs at § 422.52(g) as proposed.

D. Verification of Eligibility for C–SNPs (§ 422.52(f))

Section 1859(b)(6) of the Act defines specialized MA plans for special needs individuals, as well as the term ''special needs individual.'' Section 1859(f)(1) of the Act provides that notwithstanding any other provision of Part C of the Medicare statute and in accordance with regulations of the Secretary, an MA special needs plan (SNP) may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs individuals. The regulation governing eligibility for MA SNPs is at § 422.52. In addition to meeting the definition of a special needs individual in § 422.2 and the general eligibility requirements for MA enrollment in § 422.50, an individual must meet the eligibility requirements for the specific MA SNP in which the individual seeks to enroll. Currently, § 422.52(f) provides that each MA SNP must employ a process approved by CMS to verify the eligibility of each individual enrolling in the SNP. CMS adopted this provision in paragraph (f) in the final rule with comment period ''Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions,'' which appeared in the **Federal Register** on January 12, 2009 (74 FR 1494). Historically, we have provided operational guidance related to eligibility criteria for enrollment in an MA SNP that exclusively enrolls individuals who meet the definition of special needs individual under § 422.2 in our sub-regulatory manuals.[203]

We proposed to revise paragraph § 422.52(f) to codify, with minor modifications and clarifications, our longstanding guidance on procedural steps MA plans must take to verify an individual's eligibility for enrollment in a chronic condition SNP (C–SNP). C–SNPs are SNPs that restrict enrollment to special needs individuals with specific severe or disabling chronic conditions, defined at § 422.2. By codifying the verification requirements, we intend to provide transparency and stability for MA organizations offering C–SNPs and other interested parties about this aspect of the MA program. It will also clarify the SNP's roles and responsibilities and further assist MA organizations in meeting the requirements pertaining to verification of eligibility for C–SNPs.

Specifically, we proposed in new § 422.52(f)(1) to codify existing guidance stating that for enrollments into a C–SNP, the MA organization must contact the individual applicant's current physician to confirm that the enrollee has the specific severe or disabling chronic condition(s). Although the current sub-regulatory guidance in chapter 16B, section 40.2.1 refers only to the applicant's existing provider, we believe that a physician—either the applicant's primary care physician or a specialist treating the qualifying condition(s)—should provide the required verification of the applicant's condition to ensure the accuracy and integrity of the verification process. Therefore, we proposed to use the term ''physician'' throughout proposed new § 422.52(f).

To further clarify the verification process, we also proposed in new § 422.52(f)(1)(i) that the physician must be the enrollee's primary care physician or specialist treating the chronic condition, or conditions in the case of an individual seeking enrollment in a multi-condition C–SNP. The MA organization may either 1) as proposed at new § 422.52(f)(1)(i), contact the applicant's physician or physician's office and obtain verification of the condition prior to enrollment, or 2) as proposed at new § 422.52(f)(1)(ii), use a Pre-enrollment Qualification Assessment Tool (PQAT) prior to enrollment and subsequently (which can be after enrollment) obtain verification of the condition(s) from the enrollee's physician no later than the end of the individual's first month of enrollment in the C–SNP.[204] Both proposed options are discussed in the current guidance. We continue to believe that these procedures will allow the MA organization to efficiently serve special needs populations while maintaining the integrity of SNP offerings under the MA program.

As part of this process, we proposed at new § 422.52(f)(1)(i) that verification of the chronic condition(s) from the applicant's primary care physician or treating specialist must be in a form and manner authorized by CMS. Existing guidance states that this verification can be in the form of a note from a provider or the provider's office or documented telephone contact with the physician or physician's office confirming that the enrollee has the specific severe or disabling chronic condition. These would remain acceptable under this proposal. Performing this pre-enrollment verification with the applicant's primary care physician or specialist treating the qualifying condition will mean that the C–SNP may process the enrollment promptly.

Use of the PQAT requires both pre-enrollment and post-enrollment actions by the C–SNP to conduct an assessment and subsequently confirm the information. The PQAT, per existing

[203] This guidance can be found at *https://www.cms.gov/files/document/cy2021-ma-enrollment-and-disenrollment-guidance.pdf* and *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16B.pdf.*

[204] CMS provides an outline of the Pre-enrollment Qualification Assessment Tool in section 40.2.1 of Chapter 16B of the MMCM. In 2017, CMS released a memo entitled, ''Discontinuation of CMS Approval Process for C–SNP Pre-Enrollment Qualification Assessment Tool,'' stating that we would no longer require chronic condition special needs plans (C–SNPs) to seek CMS approval prior to using a Pre-Enrollment Qualification Assessment Tool. CMS approval is granted for tools that meet the standards articulated in section 40.2.1 of the MMCM and individual review and approval of plan-specific tools is not required. Therefore, MA organizations are no longer required to submit these tools individually to CMS for approval so long as the standards outlined in the guidance are met.

guidance,[205] would collect information about the chronic condition(s) targeted by the C–SNP directly from the enrollee and must include a signature line for a physician to confirm the individual's eligibility for C–SNP enrollment. In order for the PQAT to be complete, a physician must be the person who goes through the PQAT with the enrollee. The physician that goes through the PQAT with the enrollee can be either the enrollee's physician or a physician employed or contracted by the plan. A physician must later review the document to confirm that the information supports a determination that the enrollee is eligible for the C–SNP, even without their presence at the time of the determination by the physician. The physician providing the review and signature must be the enrollee's physician. Ultimately, a physician's review of and signature on the completed PQAT provide verification of the applicant's special needs status with regards to the applicable chronic condition(s). Currently, C–SNPs are not required to submit the PQAT to CMS for review and approval before the PQAT is used by the C–SNP and CMS proposed to codify that policy. The PQAT must meet the standards articulated in proposed § 422.52(f)(1)(ii)(A), and therefore review and approval of plan-specific tools by CMS are not required.

- As proposed at § 422.52(f)(1)(ii)(A)(*1*), the PQAT must include a set of clinically appropriate questions relevant to the chronic condition(s) on which the C–SNP focuses. For example, an MA organization sponsoring a Diabetes Mellitus C–SNP would perhaps include questions related to diagnoses of diabetes, such as blood glucose level or whether the enrollee is currently taking a medication for diabetes mellitus.
- As proposed at § 422.52(f)(1)(ii)(A)(*2*), the PQAT must gather information on the applicant's past medical history, current signs and/or symptoms, and current medications sufficient to provide reliable evidence that the applicant has the applicable condition(s).
- As proposed at § 422.52(f)(1)(ii)(A)(*3*), the PQAT must include the date and time of the assessment if completed during a face-to-face interview with the applicant, or the receipt date if the C–SNP receives the completed PQAT by mail or by electronic means (if available).
- As proposed at § 422.52(f)(1)(ii)(A)(*4*), the PQAT must include a signature line for and be signed by a physician to confirm the individual's eligibility for C–SNP enrollment. (We also proposed that this signature be from the applicant/enrollee's primary care physician or treating specialist.)
- As proposed at § 422.52(f)(1)(ii)(B), the C–SNP must conduct a post-enrollment confirmation of each enrollee's information and eligibility using medical information (medical history, current signs and/or symptoms, diagnostic testing, and current medications) provided by the enrollee's primary care physician or the specialist treating the enrollee's chronic condition.
- As proposed at § 422.52(f)(1)(ii)(C), the C–SNP must include the information gathered in the PQAT and used in this verification process in the records related to or about the enrollee that are subject to the confidentiality requirements in § 422.118.
- As proposed at § 422.52(f)(1)(ii)(D), the C–SNP must track the total number of enrollees and the number and percent by condition whose post-enrollment verification matches the pre-enrollment assessment and the data and supporting documentation must be made available upon request by CMS.

In addition, we proposed to codify at § 422.52(f)(1)(ii)(E) our longstanding guidance [206] to MA organizations offering C–SNPs that choose to use a PQAT that the MA organization has until the end of the first month of enrollment to confirm that the individual has the qualifying condition(s) necessary for enrollment into the C–SNP. If the C–SNP cannot confirm that the enrollee has the qualifying condition(s) within that time, the C–SNP has the first seven calendar days of the following month (that is, the second month of enrollment) in which to send the enrollee notice of disenrollment for not having the qualifying condition(s). Disenrollment is effective at the end of the second month of enrollment; however, as also outlined in current guidance, the C–SNP must continue the individual's enrollment in the C–SNP if confirmation of the qualifying condition(s) is obtained at any point prior to the end of the second month of enrollment. We proposed to codify at § 422.52(f)(1)(ii)(F), consistent with existing guidance, that the C–SNP must continue the enrollment of the individual in the C–SNP if the C–SNP confirms the qualifying condition(s) prior to the disenrollment effective date.

Lastly, we proposed to codify at § 422.52(f)(1)(iii) that the C–SNP is required to have the individual's current physician (primary care physician or specialist treating the qualifying condition) administer the PQAT directly with the enrollee or provide confirmation (with or without the presence of the enrollee) that the information in the document supports a determination that the individual is eligible for the C–SNP. Once the physician has confirmed that the PQAT contains information that supports the applicant's chronic condition and signs it, the PQAT is complete. Without a physician's signature, the process is incomplete, and thus, the applicant must be denied enrollment if the enrollment has not yet happened or disenrolled by the end of the second month if the applicant had been enrolled. If the individual is disenrolled because the person's eligibility cannot be verified, SNPs must recoup any agent/broker compensation consistent with § 422.2274(d)(5)(ii).

These proposals represent the codification of existing guidance outlining the procedural steps MA organizations currently take to verify an individual's eligibility for enrollment in a C–SNP, with minor modifications and clarifications. Therefore, we believe that this proposal would not result in a new or additional paperwork burden, as the policy to verify eligibility for C–SNPs has been in existence for some time. All burden impacts related to the SNP eligibility verification procedures have already been accounted for under OMB control number 0938–0753 (CMS–R–267). These requirements have been previously implemented and are currently being followed by MA organizations. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Fund.

We received the following comments, and our responses follow.

Comment: Several commenters expressed general support but recommended using a term other than ''physician'' when referring to the activities that must be completed to confirm a beneficiary's eligibility for the C–SNP. Commenters noted that many individuals receive treatment for their chronic condition from other providers (*e.g.,* nurse practitioners, physician assistants) and that by limiting the verification functions to the beneficiary's current physician, we were establishing a requirement that was too restrictive, would add operational

[205] This guidance can be found in Chapter 16–B: Special Needs Plans, Section 40.2 of the Medicare Managed Care Manual.

[206] This guidance can be found in Chapter 2, Section 20.10 and Chapter 16–B: Special Needs Plans, Section 40.2 of the Medicare Managed Care Manual.

complexity, and create procedural barriers that obstruct beneficiaries' access to needed healthcare. Commenters also stated that physicians may not provide timely verification in response to a direct request or a PQAT which affects a C–SNPs' ability to swiftly seek data to verify beneficiaries' conditions.

Commenters suggested that CMS codify a sufficiently broad term to allow a variety of healthcare professionals with requisite qualifications to confirm the applicant's specific severe or disabling chronic condition(s). Examples include the following terms: ''health care provider'' or ''practitioner'' to include those who work in clinic environments and any clinical staff in the physician's office, (*e.g.,* registered nurses), which would align with existing verification protocols and will enable MA plans to offer and enroll beneficiaries with chronic conditions in plans best suited to meet their healthcare needs and preferences more efficiently. Another commenter further suggested that an alternate person at the provider practice be able to conduct this administrative function on behalf of the provider so as to not create more administrative burden and also facilitate enrollment. Another commenter stated that CMS uses the term ''provider'' for confirming the patient has a qualified condition in its existing guidance.

Response: We appreciate the feedback and agree that the term ''physician'' may be overly restrictive or may not accurately reflect a beneficiary's overall care team. As such, we are modifying § 422.52(f)(1) to replace the term ''physician'' with language describing the three types of health care providers we believe are appropriate to furnish confirmation that an enrollee has a severe or disabling chronic condition: (1) a physician, as defined in section 1861(r)(1) of the Act; (2) a physician assistant, as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.74(c); or (3) a nurse practitioner, as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.75(b)(1)(i) and (ii). The modification will permit physician assistants and nurse practitioners who meet the specified qualification to provide the type of verification required under § 422.52(f).

The definition of physician in section 1861(r)(1) of the Act is defined to mean a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which the individual performs such functions or actions. Although CMS proposed that all physicians within the scope of the definition of section 1861(r) of the Act would qualify for purposes of the proposed requirements for verifying eligibility to enroll in a C–SNP, we believe it is more appropriate to limit this to physicians as defined in section 1861(r)(1) to be more consistent with and reflect our current subregulatory policies regarding chronic condition verification and our intent with codification of this policy. Because section 1861(r)(1) of the Act includes all doctors of medicine or osteopathy who are legally authorized to practice medicine and surgery by the State in which the individual performs such functions or actions, using ''physician'' as meaning this group is sufficiently broad for purposes of verifying that an individual has a specified severe or disabling chronic condition. Per section 1861(aa)(5)(A) of the Act, the terms ''physician assistant'' and ''nurse practitioner'' mean a physician assistant or nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations. Therefore, in addition to citing section 1861(aa)(5)(A) of the Act, we are also cross-referencing the additional Medicare regulations (§§ 410.74(c) and 410.75(b)(1)(i) and (ii)) that specify the qualifications for a physician assistants and nurse practitioners to define these providers.

In addition to these changes we are finalizing in § 422.52(f)(1), we are also finalizing changes throughout § 422.52(f) to replace the term ''physician'' with the phrase ''health care provider'' or ''health care provider specified in paragraph (f)(1)'' to be consistent with our final policy that physicians, physician assistants, and nurse practitioners may furnish the necessary verification. We use the term ''health care provider'' to avoid unintended ambiguity or confusion that § 422.52(f) is using the term ''provider'' as it is defined broadly in § 422.2. In addition, we are finalizing paragraph (f)(1)(iii) with revisions to specify that the PQAT must be signed by the enrollee's current health care provider as verification and confirmation that the enrollee is eligible for the C–SNP, especially as a provider employed or contracted by the plan may administer the PQAT with the enrollee. We believe allowing a SNP to use a provider employed or contracted by the plan permits operational flexibility without jeopardizing the independent verification of the applicant's condition. For example, a SNP may employ a registered nurse to administer the PQAT with the applicant that will then receive independent verification from the applicant's health care provider. CMS understands that establishing the same criteria for administering the PQAT under 422.52(f)(1)(ii)(B), as we propose under § 422.52(f)(1) for health care provider verification, would likely create operational burdens for SNPs. We are finalizing the revised process at paragraph (f)(1)(iii) that both acknowledges the potential burden to plans, but also ensures that the applicant's health care provider is still verifying of the existence of the chronic condition.

Comment: We received several comments pertaining to the PQAT. While commenters supported CMS' need to verify eligibility, several suggested the use of alternative data to support post-enrollment verification in lieu of the PQAT. For example, the use of existing institutional documentation, specifically the Minimum Data Set (MDS), to serve as documentation of a beneficiary's qualifying condition and the use of medical and pharmacy claims data to verify a C–SNP enrollee's chronic condition in cases where the enrollee's provider is unresponsive. Some commenters expressed concerns regarding the administrative challenges of acquiring a signature on the PQAT form, processing disenrollment due to a failure to obtain the required physician verification, and reliance on the information submitted by the beneficiary, which runs the risks of inaccuracies. Another commenter suggested that plans using the PQAT and post-enrollment verification process should be able to use the health care provider's verification via a recorded phone outreach, signature on the PQAT form, data from the enrollee's electronic health records, or other diagnoses received directly from the enrollee's provider. Some commenters were concerned that the proposal could disincentivize new or smaller MA organizations from establishing C–SNPs to offer coverage and care for this vulnerable population.

Response: We appreciate the suggestions for alternative methods to verify that a C–SNP applicant has a qualifying severe or disabling chronic condition. However, the applicant's current health care provider plays a critical role in verifying the beneficiary's chronic condition. We

believe that review by the applicant's current health care provider is an important step to maintain C–SNP program integrity and the involvement of a health care provider who has a current relationship with the applicant and is not an employee of the C–SNP (or of the MA organization that offers the C–SNP) reduces burden when compared to alternatives such as seeking an independent evaluation of the applicant from another health care provider. We reiterate that the MA organization may contact the applicant's current health care provider or that provider's office to obtain verification of the condition prior to enrollment and that the use of the PQAT is an optional substitute prior to enrollment. The MA organization is allowed additional time (post-enrollment) to obtain verification from the applicant's current provider if the MA organization elects to use the PQAT prior to enrollment in lieu of getting confirmation from the applicant's current health care provider (or that provider's office), as further clarified in 422.52(f)(1)(iii) and 422.52(f)(1)(ii)(B). We believe limiting the verification confirmation process to this group of providers best aligns with those providers most likely to diagnose and treat the type of severe or disabling chronic condition listed in the definition of that term being adopted elsewhere in section VIII.C. of this rule. We note that the proposal is the codification of long-standing guidance in Chapter 16–B with minor modifications. The rule as finalized does not prohibit plans from consulting data or records of the type mentioned by the commenters, but data review alone cannot be a method of independent verification, which only the applicant's current provider's review and signature can impart. As further clarified in 422.52(f)(1)(ii)(A)(*4*), the completed PQAT must be signed by the applicant's current health care provider. We are including the phrase ''once completed'' in the regulation to clarify that the health care provider would be signing the PQAT as filled in with the applicant's information as a means to verify the PQAT; blank PQAT forms should not be signed in advance.

Comment: A commenter expressed concerns that CMS' proposal created a requirement that plans must rely on a prior eligibility verification from another plan for purposes of enrollment in a C–SNP. The commenter preferred to conduct its own eligibility verification to ensure it has accurate and current information about beneficiaries.

Response: We believe the commenter misunderstood the proposal as we did not propose to require and currently do not require C–SNPs to rely on a prior verification of eligibility information from a previous plan. The opposite is the case. Under the rule we are finalizing and our current policy, C–SNPs cannot use a previous plan's chronic condition verification for the purpose of verifying an applicant's eligibility into their plan. Each C–SNP must conduct its own verification that the applicant has a qualifying severe or disabling chronic condition as outlined in § 422.52(f)(1).

Comment: A commenter suggested making the proposed changes effective no sooner than the 2026 plan year to provide sufficient time to implement the operational changes which they deemed as significant.

Response: We decline the suggestion to make the effective date later because the proposal is codifying longstanding guidance and plans should currently be performing these activities in compliance with our sub-regulatory guidance. To the extent that we are finalizing changes compared to our current guidance (for example, the expansion of the type of provider that can furnish the verification), we do not believe that these changes will add burden or make the process for verifying eligibility for new enrollees more difficult. The provisions we are finalizing at § 422.52(f) regarding eligibility verification for C–SNP enrollees are applicable with coverage beginning January 1, 2025.

Comment: A commenter believed that the PQAT is a duplicative assessment and adds unnecessary reporting burden since plans already request and document similar information as part of conducting a Health Risk Assessment (HRA) after enrollment.

Response: We agree that the HRA requirements under § 422.101(f)(1)(i) and the PQAT requirements being finalized under § 422.52(f)(1)(ii)(A)(1) may appear to collect similar health information. While there may be some similarities between the HRA and PQAT processes, the HRA is more specific in the categories of information collection (psychosocial, functional, etc.) and the PQAT is more specific to the severe or disabling chronic condition(s) the MA organization is required to verify prior to enrollment into a C–SNP. These tools serve different purposes, are not interchangeable, and are not duplicative, even if there is potential crossover in some of the information that is captured. We note that the PQAT is one of two ways to verify C–SNP eligibility prior to enrollment and that its use is optional.

Comment: A commenter noted that many C–SNP applicants are not new to an MA plan, but they are instead transferring from a non-SNP plan offered by the same MA organization with the same provider network. The MA organization may already have medical professionals (such as nurse practitioners and physician assistants) working with the member on ongoing condition management through clinical programs available from the non-SNP and clinical program staff may already be coordinating with the member's primary care provider or other physicians. The commenter stated that requiring the member's physician to once again validate to the MA organization that the member has the qualifying condition for enrollment in the C–SNP seems unnecessary and an inefficient use of the physician's (or physician's staff) time. The commenter requested that CMS continue to allow confirmations from a ''plan provider qualified to confirm the condition.''

Response: We believe that the review and sign-off by the applicant's current health care provider, who is already familiar with the MA organization's operational methods, will not add burden or create inefficiencies. The review by the applicant's current health care provider is a critical step in ensure program integrity of the C–SNP verification process. As discussed in a prior response to a public comment, we are finalizing § 422.52(f)(1) to permit the verification to be provided using the applicant's current health care provider, who is a physician (as defined in section 1861(r)(1) of the Act), physician assistant (as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.74(c) of this chapter), or a nurse practitioner (as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.75(b)(1)(i) and (ii) of this chapter) to confirm that the applicant has the qualifying condition(s); by including physician assistants and nurse practitioners who are also currently treating the applicant, we believe that we are sufficiently addressing concerns about burden on physicians. In addition, as finalized, pre-enrollment verification may be provided by the C–SNP contacting the treating health care provider directly or the treating health care provider's office; we believe that the treating health care provider's office would be able to use information in the applicant's records to provide sufficient information to verify that the applicant has the qualifying severe or disabling chronic condition in many if not all cases. Further, although paragraphs (f)(1)(ii)(B) and (f)(1)(iii) require the

enrollee's current health care provider to sign the PQAT as verification of the information used to establish eligibility, the C–SNP will have until the second month of enrollment to secure the signature as reflected in paragraphs (f)(1)(ii)(E) and (F), which we believe provides sufficient time post-enrollment to minimize the burden on the health care provider.

Comment: A commenter requested that in situations where an individual is disenrolled due to an inability to verify their eligibility, the deadline for disenrollment deadline be extended from 60 days to 90 days to align with the HRA completion deadline.

Response: We disagree that the standard is too restrictive as the proposed timeline is consistent with long-standing guidance in Chapter 16–B and C–SNPs have consistently shown the ability to meet this timeline. We also make the distinction that the verification process establishes the individual's eligibility, whereas the HRA completion assumes the applicant's eligibility and focuses on care coordination.

Comment: A commenter noted that under Special Supplemental Benefits for the Chronically Ill (SSBCI), plans can provide health-related and non-health-related benefits targeted to enrollees with C–SNP conditions in non-SNP plans, with significantly less documentation of an enrollee's condition than required for C–SNP enrollment. The commenter stated that requirements that place significantly higher barriers for C–SNP enrollment versus SSBCI eligibility can be detrimental to an individual seeking to switch to a C–SNP plan because they want more comprehensive case management and clinical support. Further, when validations are not received and individuals are disenrolled, the stress and disruption in care experienced by members can also exacerbate their health issues, which is the opposite of what they are seeking when they apply for the C–SNP. Limiting the diagnosis validation requests made to physicians for those members who are new to the MA plan or who are new to Medicare, would be a more effective use of time and resources for both the plan and providers, and would reduce the number of members who are disenrolled for administrative reasons. The commenter encouraged CMS to consider whether those differences support optimal outcomes for members with ongoing chronic conditions.

Response: We appreciate the comment. To the extent that an MA organization adopts a similar process for verifying eligibility for SSBCI under § 422.102(f)(4) as what is required by § 422.52(f)(1) as finalized here, it may be possible to rely on the verification by the individual applicant's/enrollee's health care provider or on the PQAT and subsequent confirmation for both purposes if the verification of eligibility for the C–SNP and for the SSBCI occur very close in time. However, § 422.102(f)(4) does not establish the same verification requirements as we are finalizing in § 422.52(f)(1), so it is not appropriate to develop a sweeping exception from either §§ 422.52(f)(1) or 422.102(f)(4). For more information on § 422.102(f) and SSBCI, we refer readers to section I.B.4 of this final rule. A non-SNP MA plan is a more generalized MA product that can offer SSBCI under § 422.102(f). CMS reviews whether an MA organization can deliver care under specific SNP regulations, including whether a plan can deliver care coordination and benefit arrangements for a specific chronic condition population. We believe it is critical to establish the specific processes of the C–SNP applicant verification to ensure the integrity of C–SNP plan operations.

Comment: A couple of commenters were concerned that the burden ultimately falls on the beneficiary to ensure that the provider responds to a plan's verification request in order to ensure they are able to enroll in their chosen plan. Because some providers will not submit the pre-enrollment attestation without an office visit, the proposed requirement could mean that a beneficiary that has recently seen their physician might need to visit their physician again solely for pre-enrollment verification purposes.

Response: We recognize that in some instances the applicant's health care provider could potentially ask the applicant to schedule an office visit before the health care provider will verify that the applicant has a qualifying severe or disabling chronic condition for the C–SNP. We believe that this is unlikely based on our knowledge of how this policy has played out historically and by the fact that the applicant's current health care provider's office will likely have information pertaining to the relevant medical history to verify the chronic condition.

Comment: A commenter noted that when considering pre-enrollment verification requirements, CMS must guard against providers who potentially may be incentivized to use C–SNP pre-enrollment verification as a tool in steering the beneficiary to a plan associated with the provider but may not be in the best interest of the beneficiary. The commenter stated that under the pre-enrollment verification process, it would be difficult to ensure that an enrollee's current treating physician will verify that an enrollee has a qualifying severe or disabling chronic condition in a timely manner if they know the enrollee is considering enrollment in a plan with which the provider does not contract.

Response: We appreciate the commenter's concern and acknowledge that such scenarios may occur. We believe that this is unlikely based on our knowledge of how this policy has played out historically.

After consideration of all public comments and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposal to add new paragraph (f)(1) to § 422.52 largely as proposed, but with modifications to specify that an applicant's current health care provider, who may be a physician, nurse practitioner or physician's assistant, provides the verification of the applicant's chronic condition. In addition, as described in our responses to public comments, we are finalizing revisions in paragraphs (f)(1)(i), (f)(1)(ii)(A)(4), (f)(1)(ii)(B) and (f)(1)(iii) to be consistent with the revisions in paragraph (f)(1) and to clarify the post-enrollment verification process when the C–SNP uses the PQAT.

E. I–SNP Network Adequacy

In accordance with § 422.116, CMS conducts evaluations of the adequacy of provider networks of all MA coordinated care plans to ensure access to covered benefits for enrollees. For MA coordinated care plans, which generally base coverage or cost sharing on whether the provider that furnishes services to an MA enrollee is in-network or out-of-network, these evaluations are particularly important. All MA special needs plans (SNP) are coordinated care plans and subject to the current requirements for network adequacy. Within the MA program, SNPs are classified into three distinct types: Chronic Care special needs plan (C–SNP), dual eligible special needs plan (D–SNP), and Institutional special needs plan (I–SNP). An I–SNP is a SNP that restricts enrollment to MA-eligible individuals who meet the definition of institutionalized and institutionalized-equivalent. One specific subtype of I–SNP is the facility-based I–SNP. Here, we use the term (''facility-based I–SNP'') to refer to an I–SNP that restricts enrollment to MA-eligible individuals who meet the definition of institutionalized; owns or contracts with at least one institution, specified in the

definition of institutionalized in § 422.2, for each county within the plan's county-based service area; and owns or has a contractual arrangement with each institutional facility serving enrollees in the plan. Historically, the I–SNP industry has stated that CMS's current network adequacy criteria under § 422.116 create challenges for facility-based I–SNPs because facility-based I–SNP enrollees access services and seek care in a different way than enrollees of other plan types.

In the December 2022 proposed rule, we explained in detail how I–SNPs restrict enrollment to MA-eligible individuals who are institutionalized or institutionalized-equivalent, as those terms are defined in § 422.2 and proposed new definitions for the different types of I–SNPs. As a result, the enrollees in I–SNPs are individuals who continuously reside in or are expected to continuously reside for 90 days or longer in one of the specified facilities listed in the definition of ''institutionalized'' at § 422.2 or individuals (''institutionalized-equivalent'') who are living in the community but require an institutional level of care. We refer readers to the December 2022 proposed rule (87 FR 79566 through 79568) and to section VIII.A of this final rule for a more detailed discussion of the eligibility requirements for I–SNPs and the final rule definitions for the different type of I–SNPs. See also Chapter 16b Section 20.3 of the Medicare Managed Care Manual.[207] Our use of the term ''facility-based I–SNP'' in this rule aligns with the definition of ''Facility-based Institutional special needs plan (FI–SNP)'' adopted in section VIII.A of this rule.

Per section 1859(f)(2) of the Act, I–SNPs restrict enrollment to MA-eligible individuals who, for 90 days or longer, have had or are expected to need the level of services provided in a long-term care (LTC) facility, which includes: a skilled nursing facility (SNF), a nursing facility (NF), an intermediate care facility for individuals with intellectual disabilities (ICF/IDD), an inpatient psychiatric hospital, a rehabilitation hospital, an LTC hospital, or a swing-bed hospital. See § 422.2 for the definition of ''institutionalized'' for the details of the types of facilities. Facility-based I–SNPs (FI–SNPs) serve a vulnerable cohort of Medicare beneficiaries with well over 95 percent of FI–SNP enrollees being eligible for both Medicare and Medicaid. Generally, FI–SNP enrollees reside either temporarily or permanently in an institution, therefore, these enrollees typically receive most of their health care services through or at the facility in which they reside, most often a SNF. As a result of the way that these enrollees receive covered services, CMS's established network adequacy time and distance standards under § 422.116 may not be a meaningful way to measure provider network adequacy for and ensure access to covered benefits for enrollees of this plan type. Time and distance standards are created using several factors, including pattern of care. In order to comply with the network evaluation requirements in § 422.116, a FI–SNP must contract with sufficient providers of the various specialties within the time and distance requirements specified in that regulation. The I–SNP industry has indicated through public comments and in prior correspondence to CMS that many FI–SNPs have difficulty contracting with providers outside their facilities, due to their model of care. This is because these providers know that enrollees of the I–SNP will not routinely seek care with these providers since they generally do not travel away from the facility for care.

The MA organizations offering and those that are interested in offering FI–SNPs have raised questions about whether our network standards are appropriate considering the nature of the FI–SNP coverage model. The residential nature of this model creates inherent differences in patterns of care for FI–SNP enrollees as compared to the prevailing patterns of community health care delivery in other MA plan types. For example, most residents of a facility receive their care from a provider at the facility rather than traveling to a provider outside the facility whereas individuals who live at home in the community will need to travel to a provider to receive health care services.

To address these concerns, CMS proposed to adopt a new exception for FI–SNP plans from the network evaluation requirements. This provision will apply only to FI–SNPs.

CMS adopted minimum access requirements for MA coordinated care plans (which include all SNPs) in § 422.112 and network evaluation criteria in § 422.116 as means to implement and ensure compliance with section 1852(d)(1)(A) of the Act, which permits MA plans to limit coverage to items and services furnished by or through a network of providers subject to specific exceptions (such as emergency medical services) and so long as the MA organization makes benefits available and accessible to their enrollees. Currently, § 422.116(f) allows an MA plan to request an exception to network adequacy criteria when both of the following occur: (1) certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file (that is, a cross-sectional database that includes information on provider and facility name, address, national provider identifier, and specialty type and is posted by state and specialty type); and (2) the MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care. In evaluating exception requests, CMS considers whether: (i) the current access to providers and facilities is different from the Health Service Delivery (HSD) reference file (as defined at 42 CFR 422.116(a)(4)(i)) and Provider Supply files for the year; (ii) there are other factors present, in accordance with *§ 422.112(a)(10)(v),* that demonstrate that network access is consistent with or better than the Traditional Medicare pattern of care; and (iii) the approval of the exception is in the best interests of beneficiaries.

CMS has provided examples of situations that meet the first requirement for an exception to be requested in sub-regulatory guidance, specifically the Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance.[208] The following examples of situations where providers or facilities are not available to contract with the MA plan do not account for the issues that are unique to FI–SNPs:

- Provider is no longer practicing (for example, deceased, retired),
- Provider does not contract with any organizations or contracts exclusively with another organization,
- Provider does not provide services at the office/facility address listed in the supply file,
- Provider does not provide services in the specialty type listed in the supply file,
- Provider has opted out of Medicare, or
- Provider is sanctioned and on the List of Excluded Individuals and Entities.

In addition, the use of Traditional Medicare telehealth providers or mobile providers and the specific patterns of care in a community that currently are

[207] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16b.pdf.*

[208] *https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidance08302022.pdf.*

the basis for an approval exception do not account for the provider network issues unique to FI–SNPs that we proposed to address in this rule. Therefore, we proposed to amend our network adequacy regulations at § 422.116(f) to establish an additional exception to the current CMS network adequacy requirements outlined in § 422.116 and we proposed that this exception be specific to FI–SNPs. As proposed and finalized, the revisions to § 422.116 provide that FI–SNPs will not be required to meet the current two prerequisites to request an exception from the network adequacy requirements in § 422.116 but FI–SNPs must meet alternate bases on which to request an exception.

With respect to the exceptions from the network adequacy process for FI–SNPs, CMS proposed to broaden the acceptable rationales for an exception from the requirements in § 422.116(b) through (e) for FI–SNPs. We proposed that a FI–SNP may request an exception from the network adequacy requirements in § 422.116 when one of two situations occurs. To add these proposed new rationales to § 422.116(f)(1), we proposed to reorganize the current regulation text; the two current requirements for an exception request will be moved to new paragraphs (f)(1)(i)(A) and (B) and the proposed new rationales for an exception request will be in new paragraphs (f)(1)(ii)(A) and (B). Next, we proposed additional considerations CMS will use when determining whether to grant an exception under § 422.116(f) that are specific to the additional acceptable rationales we proposed for an exception request. We proposed to add a new paragraph (f)(2)(iv) to specify the proposed new considerations that will apply to the new exceptions for FI–SNPs, which will be added to the existing considerations in § 422.116(f)(2).

This provision includes new bases on which only FI–SNPs may request an exception from the network adequacy requirements, additional considerations for CMS when deciding whether to approve an exception request from a facility-based I–SNP, and a new contract term for FI–SNPs that receive the exception from the § 422.116 network adequacy evaluation. Because we evaluate network adequacy and grant an exception at the contract level, this new exception is limited to contracts that include only FI–SNPs.

The first new basis on which we proposed a FI–SNP could request an exception from § 422.116(b) was that the FI–SNP is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in FI–SNPs receive care. For purposes of this first proposed new basis for an exception, the inability to contract means the MA organization offering the FI–SNP could not successfully negotiate and establish a contract with a provider, including individual providers and facilities. This new basis is broader than the existing condition for an exception that certain providers are unavailable for the MA plan (see current § 422.116(f)(1)(i), which we are redesignating to § 422.116(f)(1)(A) in this final rule). The non-interference provision at section 1854(a)(6) of the Act prohibits CMS from requiring any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services or require a particular price structure for payment under such a contract. As such, CMS cannot assume the role of arbitrating or judging the bona fides of contract negotiations between an MA organization and available providers or facilities. CMS does not regard an MA organization's inability to contract with a provider as a valid rationale for an exception from the network adequacy evaluation, but interested parties have indicated through public comments and in prior correspondence to CMS outside this particular rulemaking process that, historically, FI–SNPs have encountered significant struggles contracting with the necessary number of providers to meet CMS network adequacy standards due to their unique care model. In the proposed rule, we explained that we would add this new basis for an exception request to § 422.116(f)(1)(ii)(A). CMS also proposed that its decision whether to approve an exception for a FI–SNP on this specific basis (that the I–SNP is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in FI–SNPs receive care) will be based on whether the FI–SNP submits evidence of the inability to contract with certain specialty types required under § 422.116 due to the way enrollees in FI–SNPs receive care. For example, an organization could submit letters or emails to and from the providers' offices demonstrating that the providers were declining to contract with any FI–SNP. CMS proposed to add this requirement in a new paragraph (f)(2)(iv)(A). CMS will also consider the existing factors in addition to the new factors proposed here that are unique to the specific new exception proposed for FI–SNPs. In the proposed rule, we solicited comment on this proposed new rationale for an exception from the network adequacy requirements in § 422.116(b) through (e) and on the type of evidence we should consider in determining whether to grant an exception.

We also proposed a second basis on which a FI–SNP may request an exception from the network adequacy requirements in § 422.116(b) through (e) if:

(1) A FI–SNP provides sufficient and adequate access to basic benefits through additional telehealth benefits (in compliance with § 422.135 of this chapter) when using telehealth providers of the specialties listed in paragraph (d)(5) in place of in-person providers to fulfill network adequacy standards in paragraphs (b) through (e); and

(2) Substantial and credible evidence that sufficient and adequate access to basic benefits is provided to enrollees using additional telehealth benefits (in compliance with § 422.135 of this chapter) furnished by providers of the specialties listed in paragraph (d)(5) of this section and the FI–SNPs covers out-of-network services furnished by a provider in person when requested by the enrollee as provided in § 422.135(c)(1) and (2) of this chapter, with in-network cost sharing for the enrollee.

We believe it is appropriate to permit exceptions to the network evaluation standards in § 422.116(b) through (e) in these situations because enrollees in FI–SNPs do not generally travel to receive care, so the time and distance standards that apply to other plan types are not appropriate for I–SNP plans. As part of this proposal, we proposed to add to the factors that CMS will consider whether to approve the exception request a new factor specifically related to this type of exception.

Finally, we proposed new regulation text to ensure that the exception for FI–SNPs is used by and available only to FI–SNPs. We proposed a new paragraph (f)(3) at § 422.116 to require any MA organization that receives the exception provided for FI–SNPs to agree to offer only FI–SNPs on the contract that receives the exception. To support the provision outlined at § 422.116(f)(3), CMS also proposed to add, at § 422.504(a)(21), a new contract provision that MA organizations must not establish additional plans (or plan benefit packages, called PBPs) that are not facility-based I–SNPs to a contract that is within the scope of proposed § 422.116(f)(3). This will ensure MA organizations that have received the exception do not submit additional PBPs that are not FI–SNPs to their FI–SNP only contracts. CMS reviews

networks at the contract level which means if an MA organization were to add an MA plan (that is, a PBP) that is not a FI–SNP to a contract, the exception we proposed here will not be appropriate. We asked for comment on this aspect of our proposal and whether additional guardrails are necessary to ensure that the proposed new exception from network adequacy evaluations is limited to FI–SNPs consistent with our rationale for it.

Under our proposal, FI–SNPs will still be required to adhere to § 422.112 regarding access to covered benefits. For example, § 422.112(a)(1)(iii) requires an MA coordinated care plan to arrange for and cover any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs. Because all SNPs, including FI–SNPs, are coordinated care plans, this beneficiary protection applies to them. Similarly, the timeliness of access to care requirements newly adopted at § 422.112(a)(6)(i) will apply. We believe that our proposal, as specified in the proposed rule, appropriately balanced the need to ensure access to covered benefits for enrollees in FI–SNPs while recognizing the unique way this type of MA plan furnishes benefits and how enrollees generally receive services at the institution where the enrollee resides. Expanding this proposed new exception from the § 422.116 network adequacy requirements to other I–SNPs that enroll special needs individuals that reside in the community or other SNPs or MA plans that are not designed to furnish services to institutionalized special needs individuals will not be appropriate or serve the best interests of the Medicare program or Medicare beneficiaries.

Summaries of the comments we received on this proposal to amend § 422.116(f) and our responses to them follow.

Comment: Commenters overall were supportive of our efforts to broaden the bases of acceptable rationales for requesting an exception from the requirements in § 422.116 for facility-based I–SNPs. Commenters also expressed support for CMS strengthening its general oversight of I–SNPs to ensure people are receiving the care they need. Specifically, commenters supported the proposal's expanded access to telehealth care to ease beneficiary access to care. Also, commenters believe this proposal is well-positioned to ensure individuals receive necessary supports across the continuum of their care needs without having to experience the disruption of changing Medicare coverage types should there be a need for more extensive long-term care.

Response: CMS appreciates the support for our proposal, which we are finalizing, to establish two new exceptions from the network adequacy evaluations under § 422.116(b) through (e) for certain FI–SNPs, the factors and evidence CMS will consider in whether to grant the exceptions, and the new requirement that an MA organization that receives an exception for its FI–SNP(s) only offer FI–SNPs under the contract that receives the exception approval. CMS would like to thank all the commenters for their comments.

After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments, we are finalizing the revisions to § 422.116(f) as proposed.

F. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization (§§ 422.503, 422.504, 422.514, 422.530, and 423.38)

Dually eligible individuals face a complex range of enrollment options based on MA plan types (that is, HMOs, PPOs, private fee-for-service plans, MA special needs plans, etc.), enrollment eligibility, and plan performance, but which do not consider the enrollee's Medicaid choice. Further, many of the coverage options available to dually eligible individuals—even including many dual eligible special needs plans (D–SNP)—do not meaningfully integrate Medicare and Medicaid, chiefly because the parent organization of the D–SNP does not also provide the enrollee's Medicaid services. The current managed care enrollment and eligibility policies have resulted in a proliferation of such D–SNPs and leave dually eligible individuals susceptible to aggressive marketing tactics from agents and brokers throughout the year.

Over the last decade, we have taken numerous steps to improve the experiences and outcomes for dually eligible individuals through various forms of Medicare-Medicaid integrated care. Despite progress, there remain a significant number of enrollees who receive Medicare services through one managed care entity and Medicaid services through a different entity (misaligned enrollment), rather than from one organization delivering both Medicare and Medicaid services (aligned enrollment [209]). In the final rule titled Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid fee-for-service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS–4185–F) (hereinafter referred to as the April 2019 final rule), we expressed our belief that aligned enrollment, and especially exclusively aligned enrollment (when enrollment in a parent organization's D–SNP is limited to individuals with aligned enrollment), is a critical part of improving experiences and outcomes for dually eligible individuals.

Longer term, for dually eligible individuals who are in Medicare and Medicaid managed care, we believe that we should continue to drive toward increasing aligned enrollment until it is the normative, if not only, managed care enrollment scenario. Our proposals represented an incremental step toward increasing aligned enrollment, balancing our long-term policy vision with our interest in limiting disruption in the short term. For dually eligible individuals that elect MA plans, we are focused on increasing enrollment in integrated D–SNPs: fully integrated dual eligible special needs plans (FIDE SNPs),[210] highly integrated dual eligible special needs plans (HIDE SNPs),[211] and applicable integrated plans (AIPs).[212] These D–SNP types more meaningfully integrate Medicare and Medicaid services and administrative processes (such as unified appeals and grievances) than coordination-only D–SNPs [213] that are not also AIPs.

[209] 42 CFR 422.2 (definition of ''aligned enrollment'').

[210] Effective 2025, FIDE SNPs as defined in § 422.2 are required to have EAE and would therefore be AIPs by definition. To receive the FIDE designation, a D–SNP would be required to provide nearly all Medicaid services, including long-term services and supports, Medicaid behavioral health services, home health and DME.

[211] HIDE SNPs as defined in § 422.2 are required to cover long-term services and supports or behavioral health services but may have more Medicaid services carved out relative to plans with the FIDE designation. HIDE SNPs that also operate with EAE would meet the definition of an AIP, but there is no requirement for EAE for the HIDE designation.

[212] AIPs as defined in § 422.561 are D–SNPs with EAE, where the companion Medicaid MCO covers Medicaid benefits including primary care and acute care, Medicare cost-sharing, and at a minimum one of the following: home health services, medical supplies, equipment, and appliances (DME), or nursing facility services.

[213] Dual eligible special needs plans (D–SNPs) are defined at § 422.2. ''Coordination-only'' D–SNPs are D–SNPs that neither meet the FIDE SNP nor HIDE SNP definition at § 422.2 and for which there are no Federal requirements to cover any Medicaid

Continued

In the November 2023 proposed rule, we described interconnected proposals that would (1) replace the current quarterly special enrollment period (SEP) with a one-time-per month SEP for dually eligible individuals and other LIS eligible individuals to elect a standalone PDP, (2) create a new integrated care SEP to allow dually eligible individuals to elect an integrated D–SNP on a monthly basis, (3) limit enrollment in certain D–SNPs to those individuals who are also enrolled in an affiliated Medicaid managed care organization (MCO), and (4) limit the number of D–SNPs an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, can offer in the same service area as an affiliated Medicaid MCO in order to reduce ''choice overload'' of D–SNP options in certain markets. Affiliated Medicaid MCOs are Medicaid MCOs offered by the MA organization, the same parent organization, or another subsidiary of the parent organization. We noted that, in combination, our proposals would create more opportunities for dually eligible individuals to elect integrated D–SNPs, more opportunities to switch to Traditional Medicare, and fewer opportunities to enroll in MA–PD plans that do not integrate Medicare and Medicaid services. Table HC1 summarizes the combined effects of these proposals, then we describe each proposal in greater detail.

Table HF1: Enrollment scenarios under current rules and proposed amendment—individual perspective *(Note - table does not include other applicable SEPs)*

Scenarios for dually eligible individuals	Current rules under quarterly dual/LIS SEP	Proposed monthly dual/LIS SEP, integrated care SEP, and enrollment limitations for non-integrated MA-PD plans
Elect any MA plan during initial coverage election period (ICEP) or annual election period (AEP), or switch between any plans during MA open enrollment period (MA-OEP)	Permitted	Permitted, except individuals in Medicaid MCOs would not be able to select a misaligned D-SNP where applicable[214]
Elect Medicare fee-for-service (FFS) and standalone prescription drug plan (PDP), mid-year	One change permitted per quarter (except the last quarter)	Permitted each month
Elect an integrated D-SNP (FIDE SNP, HIDE SNP, or AIP) as eligible, mid-year		Permitted each month, but must be aligned enrollment
Elect a non-integrated D-SNP or other MA plan, mid-year		Not permitted
Scenarios for LIS individuals without Medicaid	**Current rules**	**As proposed**
Elect any MA plan during ICEP or AEP, or switches between any plans during MA-OEP	Permitted	Permitted
Elect Medicare FFS and standalone PDP, mid-year	One change permitted per quarter (except the last quarter)	Permitted each month
Elect an MA plan, mid-year		Not permitted

We proposed to create a new SEP and revise the dual/LIS SEP but otherwise did not change the remaining SEPs. To highlight the changes in our proposals without overly complicating this table, we did not reference the other SEPs.

benefits either directly or through an affiliated Medicaid managed care plan.

[214] We proposed that during AEP and other available enrollment periods, MA organizations would not be permitted to enroll dually eligible individuals into a D–SNP where such enrollment would not result in aligned enrollment with an affiliated Medicaid MCO offered in the same service area (that is, a Medicaid MCO offered by the MA organization, its parent organization, or another subsidiary of the parent organization).

1. Proposed Changes to the Special Enrollment Periods for Dually Eligible Individuals and Other LIS Eligible Individuals

Section 1860D–1(b)(3)(D) of the Act directs the Secretary to establish an SEP for full-benefit dually eligible individuals under Part D. The SEP, subsequently referred to as the continuous dual/LIS SEP, codified at § 423.38(c)(4), was later extended to all other subsidy-eligible beneficiaries by regulation. The continuous dual/LIS SEP allowed eligible beneficiaries to make Part D enrollment changes (that is, enroll in, disenroll from, or change Part D plans, including Medicare Advantage Prescription Drug (MA–PD) plans) throughout the year, unlike other Part D enrollees who generally may switch plans only during the AEP or via other applicable SEPs each year.

In the April 2018 final rule, we cited concerns with usage of the continuous dual/LIS SEP related to enrollees changing plans frequently, hindering care coordination efforts by D–SNPs; plans having less incentive to innovate and invest in serving high-cost enrollees who may disenroll at any time; and agents and brokers targeting dually eligible individuals due to their ability to make enrollment elections throughout the year (83 FR 16514). Ultimately, the April 2018 final rule amended the continuous dual/LIS SEP to allow usage 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).

The quarterly dual/LIS SEP reduced individuals moving from one Part D plan (including an MA–PD) to another Part D plan (including an MA–PD) as frequently. However, in the November 2023 proposed rule we discussed the ongoing concerns with the quarterly dual/LIS SEP:

- *Marketing.* We remain concerned about marketing opportunities, especially when they focus on dually eligible individuals who, as a group, have lower levels of education, health literacy, and access to resources that could help overcome sub-optimal coverage decisions. Because the quarterly dual/LIS SEP still allows the vast majority of dually eligible individuals to enroll in almost any MA–PD plan, they remain a target for marketing activities from all types of plans throughout the year.
- *Ability to enroll in integrated D–SNPs.* The quarterly dual/LIS SEP does not allow dually eligible individuals to enroll in integrated D–SNPs after those individuals have exhausted the opportunities allowed by the quarterly dual/LIS SEP.
- *Complexity for States.* The quarterly dual/LIS SEP has created some challenges related to aligning Medicare and Medicaid enrollment dates for dually eligible individuals seeking to enroll in integrated products. In the capitated financial alignment models of the Financial Alignment Initiative (FAI), we waived the quarterly dual/LIS SEP rules at State request to allow for monthly opportunities for individuals to enroll or disenroll. This alleviated the complexity of different Medicare and Medicaid enrollment periods and allows dually eligible individuals more opportunities to enroll in integrated products.
- *Complexity for enrollment counselors and individuals.* Enrollment counselors such as State Health Insurance Assistance Programs (SHIPs) and State ombudsman programs have also noted that the once-per-quarter rule is complicated and makes it difficult to determine the enrollment options available to dually eligible individuals.

To further protect Medicare beneficiaries, reduce complexity for States and enrollment counselors, and increasingly promote integrated care, we proposed two SEP changes. Section 1860D–1(b)(3)(D) of the Act requires the Secretary to establish SEPs for full-benefit dually eligible individuals, although it does not specify the frequency or mechanics of those SEPs. Further, section 1860D–1(b)(3)(C) of the Act grants the Secretary the authority to create SEPs for individuals who meet other exceptional circumstances.[215] Section 1859(f)(1) of the Act permits the Secretary to set forth regulations related to how MA organizations restrict the enrollment of individuals who are within one or more classes of special needs individuals. Section 1859(f)(6) establishes the authority to adopt a transition process to move dually eligible individuals out of SNPs when they are not eligible for the SNP. Section 1859(f)(8) of the Act also reflects an interest in and goal of furthering the integration of D–SNPs; the requirement for us to establish procedures for unified grievance and appeals processes and requirement, in section 1859(f)(8)(D), for a mandatory minimum level of integration illustrate how efforts to increase integration in implementing and adopting standards for the MA program further the goals of the program. Based on this, as outlined in detail in the November 2023 proposed rule (88 FR 78568 through 78569), we proposed to amend § 423.38(c)(4)(i) to replace the quarterly dual/LIS SEP with a simpler new dual/LIS SEP. The proposed dual/LIS SEP would allow dually eligible and other LIS-enrolled individuals to enroll once per month into any standalone prescription drug plan.

We noted that, functionally, the proposed revised dual/LIS SEP would mean that such individuals could, in any month, switch PDPs or leave their MA–PD for Traditional Medicare plus a standalone PDP (plans that only offer prescription drug coverage). However, as proposed, the dual/LIS SEP would no longer permit enrollment into MA–PD plans or changes between MA–PD plans, although such options would still be available where another election period permits.

In conjunction, based on the statutory authorities described above, we also proposed to create a new integrated care SEP at § 423.38(c)(35) for dually eligible individuals. This new integrated care SEP would allow enrollment in any month into FIDE SNPs, HIDE SNPs, and AIPs for those dually eligible individuals who meet the qualifications for such plans.

For dually eligible individuals, our two SEP proposals would allow a *monthly* election to:

- Leave an MA–PD plan for Traditional Medicare by enrolling in a standalone PDP,
- Switch between standalone PDPs, or
- Enroll in an integrated D–SNP such as a FIDE, HIDE, or AIP.

If an eligible individual attempts to use, or uses, both the monthly dual/LIS SEP and the integrated care SEP within the same month, the application date of whichever SEP is elected last in time is the SEP effectuated the first of the following month.

As a result of these proposals, dually eligible and other LIS-eligible individuals, like other Medicare beneficiaries, would be able to enroll into non-AIP coordination-only D–SNPs[216] or other MA plans only during the ICEP, AEP, or where another SEP permits. While the proposed changes constrain some enrollment options at certain times of the year, dually eligible individuals and other LIS-eligible individuals would never have fewer choices than people who are not dually or LIS eligible.

In the November 2023 proposed rule we stated our belief that the proposed SEP changes would create more opportunity for dually eligible or LIS individuals to leave MA–PD plans if

[216] Dual eligible special needs plans (D–SNPs) are defined at § 422.2. ''Coordination-only'' D–SNPs are D–SNPs that neither meet the FIDE SNP nor HIDE SNP definition at § 422.2 and are not required to cover any Medicaid benefits.

MA is not working well for them; reduce the incentive for most plans to deploy aggressive sales tactics targeted at dually eligible individuals outside of the AEP; increase transparency for Medicare beneficiaries and enrollment counselors; create more opportunities for enrollment into integrated D–SNPs; reduce the burden on States working to align Medicaid MCO and D–SNP enrollment; and strengthen incentives for MA sponsors to also compete for Medicaid managed care contracts.

We also noted some potential challenges of our proposal, including limiting dually eligible individuals' ability to change MA–PD plans outside of the AEP, MA–OEP, or other available SEPs in States with few or no integrated D–SNPs; less incentive for MA plans to innovate and invest in meeting the needs of high-cost dually eligible enrollees because such individuals can disenroll at any time; and dually eligible individuals changing between integrated care plans monthly, potentially hindering care coordination and case management efforts. In addition, since LIS individuals without Medicaid are ineligible for integrated D–SNPs, our proposal limits how the dual/LIS SEP can be used for these individuals compared to the current scope of the SEP.

Section 423.40(c) currently provides that the effective date of an enrollment change in Part D during a special enrollment period specified in § 423.38(c), including the existing SEP for dually eligible and other LIS-eligible individuals, will be the first day of the calendar month following the month in which the election is made, unless otherwise noted. In the November 2023 proposed rule, we requested comments on using flexibilities at section 1851(f)(4) of the Act and at § 423.38(c) to establish a Medicare enrollment effective date for the integrated care SEP at § 423.38(c)(35) that differs from the effective date in the current quarterly dual/LIS SEP to better align with Medicaid managed care enrollment cut-off dates, as some States do not enroll individuals on the first of the month following an enrollment request after a certain cut-off date and delay the effective date until the first of the following month.

2. Enrollment Limitations for Non-Integrated Medicare Advantage Plans

Aligned enrollment is a key feature of the FAI, PACE, and other long-standing integrated care programs such as the Massachusetts' Senior Care Options and Minnesota's Senior Health Options that started as demonstration programs that were precursors to D–SNPs. Individual States may also use their State Medicaid agency contracts (SMAC) to limit enrollment in a D–SNP to the enrollees in an affiliated Medicaid MCO. Further, we have adopted, as part of the definition in § 422.2, enrollment limits for FIDE SNPs that require, beginning January 1, 2025, FIDE SNPs to have exclusively aligned enrollment.

Separate from contracting with D–SNPs via SMACs, States have discretion in how they arrange their Medicaid managed care programs and may use Medicaid MCOs to cover a comprehensive scope of Medicaid benefits or use prepaid health plans to cover a smaller scope of Medicaid benefits.[217] Many States with Medicaid managed care programs select a limited number of Medicaid MCOs through a competitive procurement process.

In many service areas, dually eligible individuals face complicated enrollment policies, overwhelming marketing, and an increasingly complex array of plans purportedly designed especially for them but that do not offer meaningful Medicare and Medicaid integration due to service area and enrollment misalignment.

We noted in the November 2023 proposed rule that some States have utilized SMACs and selective contracting to limit the availability of D–SNPs in the State to those MA organizations that also have contracts with the State to cover Medicaid services. However, other D–SNP markets have grown without any limitations on non-integrated plans. In some markets, parent organizations of MA organizations have acquired multiple D–SNPs by purchasing smaller plans and have not consolidated the various plans, resulting in one parent organization operating multiple D–SNPs within a single State, often with overlapping service areas. For States that do not require parent organizations to consolidate their plans, multiple D–SNPs of this type may continue to operate indefinitely. This creates a market with a large number D–SNP options that often do not offer significantly different benefits or networks, which creates confusion for plan selection and could lead to individuals choosing unaligned Medicare and Medicaid plans.

We recognize that States have policy interests and goals that shape their Medicaid managed care programs, and our intent is to help further support States interested in implementing EAE. We have historically deferred to States to use SMACs to align Medicare and Medicaid plan offerings consistent with State policy priorities. However, as the number of dually eligible individuals with misaligned enrollment and sheer number of D–SNPs have grown, we noted in the November 2023 proposed rule that we now believe that Federal rulemaking is warranted to promote greater alignment of D–SNPs and Medicaid MCOs and to begin to simplify the array of choices.

We have authority, per section 1857(e)(1) of the Act, to add MA contract terms and conditions not inconsistent with the MA statute (that is, Part C of Title XVIII of the Act) as the Secretary may find necessary and appropriate. Given how section 1859(f)(8) of the Act reflects a goal of furthering the integration of D–SNPs and how our proposal is designed to reduce choice overload situations for dually eligible individuals while furthering opportunities for enrollment in integrated D–SNPs (that is, FIDE SNPs, HIDE SNPs, and AIPs), we believe that the standard in section 1857(e)(1) is met. Further, section 1854(a)(5) of the Act is clear that we are not obligated to accept any and every MA plan bid. Based on this, we proposed new regulations §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii).

At § 422.503(b)(8), we proposed to establish a new qualification for an MA organization (or new applicant to be an MA organization) to offer D–SNP(s) while at § 422.504(a)(20) we proposed to establish a new contract term for certain MA organizations. At § 422.514(h), we proposed to establish conditions for how certain MA organizations and D–SNPs may enroll dually eligible individuals and limit the number of D–SNPs that may be offered by certain MA organizations. Finally, at § 422.530(c)(4)(iii), we proposed to establish a new crosswalk exception to authorize MA organizations that are subject to these new enrollment limitations to crosswalk their enrollees to a single D–SNP to accomplish aligned enrollment.

Together, our proposals at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)(1) and (2) would require the following:

- Beginning in plan year 2027, when an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, also contracts with a State as a Medicaid MCO that enrolls dually eligible individuals in the same service area, D–SNPs offered by the MA organization, its parent organization, or

[217] See 42 CFR 438.2 for definitions of the terms managed care organization (MCO), prepaid ambulatory health plan, and prepaid inpatient health plan.

an entity that shares a parent organization with the MA organization, must limit new enrollment to individuals enrolled in (or in the process of enrolling in) the D–SNP's affiliated Medicaid MCO. This would apply when any part of the D–SNP service area(s) overlaps with any part of the Medicaid MCO service area, even if the two service areas do not perfectly align. Additionally, only one D–SNP may be offered by an MA organization, its parent organization, or another MA organization with the same parent organization in the same service area as the aligned Medicaid MCO. We would only enter into a contract with one D–SNP for full-benefit dually eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO (with limited exceptions as described below).

- Beginning in 2030, such D–SNPs must only enroll (or continue to enroll) individuals enrolled in (or in the process of enrolling in) the affiliated Medicaid MCO. Therefore, by 2030, integrated D–SNPs would be required to disenroll individuals who are not enrolled in both the D–SNP and Medicaid MCO offered under the same parent organization (that is, offered by the parent organization or any subsidiary), except that D–SNPs would still be able to use a period of deemed continued eligibility to retain enrollees who temporarily lost Medicaid coverage as described in § 422.52(d). This also means that where an enrollee is temporarily disenrolled from the affiliated Medicaid MCO but is expected to be re-enrolled in the affiliated Medicaid MCO within the period of deemed continued eligibility, the D–SNP would not be required to disenroll that enrollee during that period.

Consistent with how we believe MA organizations under the same parent organization share operational and administrative functions, we proposed to apply the regulations at the parent organization level.

To minimize enrollment disruption associated with achieving compliance with our other proposals, we proposed a corresponding new provision at § 422.530(c)(4)(iii) that would provide a new crosswalk [218] exception to allow one or more MA organizations that share a parent organization and offer D–SNPs subject to these proposed new limits to crosswalk enrollees (within the same parent organization and among consistent plan types) when the MA organization chooses to non-renew or consolidate its current D–SNPs to comply with the new rules in proposed §§ 422.504(a)(20) and 422.514(h). The proposed new crosswalk exception would explicitly permit moving enrollments across contracts held by MA organizations with the same parent organization; because we are not including any explicit exception from the rule in § 422.530(a)(2) prohibiting crosswalks to different plan types, the receiving D–SNP must be the same plan type as the D–SNP out of which the enrollees are crosswalked. We noted our expectation that MA organizations who offer D–SNPs would leverage § 422.530(c)(4)(iii)—as well as standard MA processes to add or remove service areas—to come into compliance with § 422.514(h).

In addition, we proposed to codify at § 422.514(h)(3) two exceptions to our new proposed requirements at § 422.514(h)(1) and (2) (the exceptions would carry over as part of the cross-references to compliance with § 422.514(h) in §§ 422.503(b)(8), 422.504(a)(20), and 422.530(c)(4)(iii)). In certain circumstances, State D–SNP policy may require the need for more than one D–SNP for full-benefit dually eligible individuals to operate in the same service area. Under § 422.514(h)(3)(i), we proposed to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, offering more than one D–SNP for full-benefit dually eligible individuals in the same service area. For example, where a SMAC limits enrollment for certain groups into certain D–SNPs (such as by age group), the MA organization may offer additional D–SNPs for different groups of full-benefit dually eligible individuals in the same service area accordingly. As proposed, the exception would only be available where the SMAC requires different eligibility groups for the different D–SNPs that are offered by the same MA organization, its parent organization, or another MA organization that shares the parent organization; this proposed exception would allow States the flexibility to design future integrated D–SNP programs with eligibility nuances should they so choose.

To minimize enrollee disruption, our second proposed exception would not prohibit an MA organization, its parent organization, or another MA organization that shares a parent organization with the MA organization, from continuing to operate both an HMO D–SNP and a PPO D–SNP in a State where the proposed new policy applies. To achieve the goals of the new regulation, including simplification of the D–SNP market and promotion of integrated care through aligned Medicare and Medicaid products, we proposed at § 422.514(h)(3)(ii) that the MA organization, its parent organization, or another MA organization that shares a parent organization with the MA organization may offer (or continue to offer) both the HMO and PPO D–SNPs only if they no longer accept new full-benefit dually eligible enrollees in the same service area as the D–SNP affected by the new regulations at §§ 422.504(a)(20) and 422.514(h). Under this proposal, the MA organization, its parent organization, and another MA organization that shares a parent organization with the MA organization may only accept new enrollment in one D–SNP for full-benefit dually eligible individuals in the same service area as an affiliated Medicaid MCO, and such new enrollment is limited to the full-benefit dually eligible individuals who are enrolled (or are enrolling) in the affiliated Medicaid MCO.

We also proposed at § 422.503(b)(8) that in service areas in which a D–SNP limits enrollment to individuals enrolled in (or in the process of enrolling in) an affiliated Medicaid MCO, the MA organization, its parent organization, or entities that share a parent organization with the MA organization may not newly offer another D–SNP for full-benefit dually eligible individuals, if it would result in noncompliance with § 422.514(h). Additionally, we proposed at § 422.504(a)(20) to establish a new contract term for MA organizations that offer D–SNPs to require compliance with the enrollment limits we are proposing to add to § 422.514(h).

Table HC2 summarizes enrollment scenarios to illustrate the combined effects of our proposed SEP changes and enrollment limitations. The term ''D–SNP's parent organization'' as used in the table includes the MA organization that offers the D–SNP, the MA organization's parent organization, and any other entity (MA organization or otherwise) that shares the parent organization with the MA organization that offers the D–SNP.

[218] A crosswalk is the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a contract between the MA organization and CMS. To crosswalk enrollee from one PBP to another is to change the enrollment from the first PBP to the second.

Table HF2: 2027 Scenarios for D-SNP enrollment under the proposed integrated care SEP and proposed enrollment limitations – plan perspective

Scenario	Who can enroll in the D-SNP?	When can such individuals enroll in the D-SNP?
D-SNP's parent organization has an affiliated Medicaid MCO that enrolls full-benefit dually eligible individuals in same service area	Only enrollees in the parent organization's companion Medicaid MCO who also meet eligibility requirements based on terms of that State's SMAC	Each month
D-SNP's parent organization does NOT have an affiliated Medicaid MCO that enrolls full-benefit dually eligible individuals in same service area	Any individuals who meet eligibility requirements based on terms of that State's SMAC	Only during ICEP, AEP, MA-OEP, or via an existing SEP

We noted that our proposals on enrollment limitations for non-integrated D–SNPs would apply based on an MA organization having an affiliated Medicaid MCO. However, we noted that we considered whether our proposals should apply where an MA organization has other affiliated Medicaid managed care plan options as well, including prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs). We expressed concern that applying our proposals to PIHPs and PAHPs could cause disruption without significantly furthering the goals of our proposals, but we solicited comments on the issue.

We noted that our proposals would require updates to the systems and supports designed to aid individuals in making Medicare choices. This includes MPF, HPMS, and other resources that help to outline available plan choices and is important where dually eligible individuals have choices that would vary based on the type of plan and time of year. We noted that we would welcome recommendations on how the choice architecture could best support the proposals or objectives described in the November 2023 proposed rule.

Overall, we noted our proposals at §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii) would increase the percentage of D–SNP enrollees in aligned enrollment, and—over time—exclusively aligned enrollment (EAE), increasing access to the comprehensive coordination of care, unified appeal processes across Medicare and Medicaid, continuation of Medicare services during an appeal, and integrated materials that come with enrollment in one or more of the various types of integrated D–SNPs; prompt MA organizations to consolidate PBPs down to a single PBP for full-benefit dually eligible individuals that is aligned with their Medicaid MCO that fully or partially overlaps the D–SNPs service area; reduce the number of D–SNP options and reduce choice overload and market complexity where parent organizations offer multiple D–SNP options in the same or overlapping service areas; remove some incentives for agents and brokers to target dually eligible individuals lessening the assistance needed from advocates and SHIP counselors to correct enrollment issues; and simplify provider billing and lower the risk of inappropriate billing.

While noting many benefits to our proposals, we acknowledged certain challenges:

- Our proposals would reduce the number of D–SNP options for Medicaid MCO enrollees in some States. It is plausible that some dually eligible individuals could benefit from the unique combinations of provider networks and supplemental benefits that could be possible only by enrolling in misaligned Medicare and Medicaid plans.
- Making plan choices clear under our proposals to dually eligible individuals, SHIP counselors and others would require changes to MPF, HPMS, and other CMS public materials explaining Medicare coverage options. Systems changes often present unknown challenges and a learning curve for users while they become accustomed to new updates.
- It also may seem that our proposal on limiting enrollment in D–SNPs offered by MA organizations with affiliated Medicaid MCOs, in isolation, would disadvantage parent organizations that choose to offer Medicaid MCOs as well as D–SNPs because such organizations would be limited in the number of D–SNP offerings and would be required to align their enrollment between D–SNP and MCO for full-benefit dually eligible individuals. However, our SEP proposals would have the opposite effect by permitting enrollment into integrated D–SNP options that cover both Medicare and Medicaid benefits using the new one-time-per month SEP. Therefore, we believe our proposals, in combination, would maintain a high level of competition and choice, even while imposing some new constraints.
- MA organizations that operate both D–SNPs and Medicaid MCOs might elect to participate in fewer competitive Medicaid procurements (or exit Medicaid managed care in ''any willing provider'' States) to be exempted from the proposed restrictions on plan enrollment and number of plan offerings. This could adversely affect competition and the minimum choice requirements in § 438.52 for Medicaid managed care programs. However, our SEP proposals would have the opposite effect, since only integrated D–SNPs could benefit from the new integrated care SEP, and overall, we believe our proposals, in combination, maintain strong incentives for organizations to compete for Medicaid managed care contracts.
- The enrollment and eligibility restrictions—without the offsetting proposed SEP changes—could incentivize sponsors to create D–SNP look-alikes or other types of MA plans

to build enrollment of dually eligible individuals without being subject to the enrollment limits and integration requirements associated with D–SNPs (although we plan to mitigate this risk with proposed revisions to § 422.514(d) and (e) in section VIII.G of the proposed rule). Finally, beginning in 2030, our proposal would no longer allow some enrollees to stay in their current D–SNPs, causing some enrollee disruption where the D–SNPs were unable to completely align their D–SNP and Medicaid MCO populations.

We received the following comments on this proposal and respond to them below:

Comment: Many commenters, including MedPAC and MACPAC, generally supported the proposals to increase the percentage of dually eligible individuals who receive Medicare and Medicaid services from the same organization. These commenters noted the proposals, taken together, would reduce administrative burden, support Medicaid agencies' ability to coordinate care, create more efficient program management, make it easier to navigate integrated care, and strengthen integrated care plans so that Medicare and Medicaid feel like one program. Some commenters stated the proposals would help to address marketing practices by MA organizations and agents and brokers that can be overwhelming and misleading, contributing to coverage decisions that do not meet enrollees' needs. A few commenters stated that the proposed changes may result in short-term disruptions to care but, in the long term, would significantly increase the percentage of dually eligible individuals receiving integrated care, which would likely result in improved care coordination, access to services, health outcomes, and enrollee experience. A commenter expressed support for the proposals, citing expanded access to integrated materials unified appeal processes across Medicare and Medicaid, and continued Medicare services during an appeal. A commenter also stated the proposals would improve the health care and social service needs of dually eligible individuals through the delivery of care and services that are coordinated through aligned enrollment in integrated Medicare and Medicaid plans. A commenter supported the proposal and noted navigating separate programs makes it extremely difficult for health care providers to deliver patient-centered care and challenging for individuals and their families to navigate care, appeal a coverage decision, or determine who to call for help.

Response: We appreciate the comments and support for increasing the percentage of dually eligible individuals in aligned enrollment. We agree with commenters that the proposal would reduce the volume of marketing activities, improve integration of Medicare and Medicaid services, and simplify navigation of complex programs for enrollees, their caregivers, and other groups supporting dually eligible individuals.

Comment: Many other commenters generally opposed the interconnected SEP and enrollment limitation proposals. A number of commenters stated they understand—and in some cases support—CMS's goal to improve integrated care for dually eligible individuals but believe CMS's proposals would lead to unintended consequences and overly burdensome requirements that could ultimately lead to fewer plans in some service areas, reducing MA plan competition and beneficiary choice. Some commenters stated the proposals would increase burden and complexity for States. Some commenters recommended CMS consider and mitigate any negative impacts on access prior to adopting policies that would limit the number of D–SNPs offered by MA organizations. A commenter also expressed general concern with the proposals and urged CMS to not move forward with finalizing the proposed changes.

Response: We acknowledge the commenters' perspectives on the proposals. As noted in the proposed rule (88 FR 78567), we believe our proposals represent an incremental step toward increasing aligned enrollment for dually eligible individuals who are in Medicare and Medicaid managed care, balancing our long-term policy vision with our interest in limiting disruption in the short term. We believe the combination of the SEP and enrollment limitation policies maintain strong incentives for organizations to compete for Medicaid managed care contracts while also reducing choice overload and incentives for agents and brokers that target dually eligible individuals. Further, we believe the opportunity to increase access to comprehensive coordination of care, unified appeal processes across Medicare and Medicaid, continuation of Medicare services during an appeal, and integrated materials outweighs any disadvantages in the shorter term.

Comment: Numerous commenters, including MedPAC and MACPAC, supported the proposals that would (1) replace the quarterly dual/LIS SEP with a monthly dual/LIS SEP that allows individuals enroll in Traditional Medicare and a PDP, and (2) create the new monthly integrated care SEP. A number of commenters stated the changes to the dual/LIS SEP would reduce aggressive marketing tactics from agents and brokers targeting dually eligible individuals and simplify counseling and messaging for the monthly SEP. Some commenters noted the SEPs give individuals freedom of choice because they are not locked into a plan for months that does not work for them. Other commenters stated the SEPs create less complexity for Medicaid agencies to navigate since the quarterly SEP posed challenges in aligning Medicare and Medicaid enrollment. A number of commenters noted the integrated care SEP would give enrollees the ability to enroll monthly into an integrated plan to access needed services and address complex chronic care needs. Some commenters stated only allowing movement into integrated plans would lessen agents' and brokers' ability to enroll dually eligible individuals into coordination-only D–SNPs that create fragmentation and disintegration.

Response: We thank the commenters for their support of the SEP-related proposals. We agree these changes will help to address aggressive marketing, simplify messaging for dually eligible individuals and choice counselors, reduce complexity for States, and overall increase the percentage of dually eligible managed care enrollees who are in FIDE SNPs, HIDE SNPs, and AIPs. We continue to believe that aligned enrollment, and especially exclusively aligned enrollment, is a critical part of improving experiences and outcomes for dually eligible individuals and will continue to drive toward increasing aligned enrollment until it is the normative, if not only, managed care enrollment scenario.

Comment: A number of commenters expressed concerns about the impact of the SEP proposals on partial-benefit dually eligible individuals and noted that partial-benefit dually eligible individuals would not be able to benefit from the integrated care SEP. Several commenters stated that partial-benefit dually eligible individuals experience similar health care needs as full-benefit dually eligible individuals and should have access to the same enrollment opportunities using SEPs. A commenter stated that partial-benefit dually eligible individuals may have greater health care needs since their health may worsen over time due to lack of State coverage and payment for necessary services and should have access to the same plan options.

A number of commenters indicated that partial-benefit dually eligible enrollees in MA plans and D–SNPs benefit from lower cost sharing, greater coordination of care and services, and access to supplemental benefits that are not available in the Traditional Medicare environment, plus disease management for those with chronic illnesses. A few of these commenters stated that although these enrollees do not have access to and thus do not require coordination of Medicaid services, they can nevertheless benefit from the model of care provided by coordination-only D–SNP plans, which are not present in traditional MA–PD plans or Traditional Medicare. Another commenter requested that CMS reconsider how CMS's SEP proposals may result in greater dislocation, reduced care management, increased marketing, and reduced opportunities for partial-benefit dually eligible and LIS individuals.

Some commenters urged CMS to either retain the quarterly dual/LIS SEP or create a corresponding SEP allowing partial-benefit dually eligible individuals to enroll in coordination-only D–SNPs. A commenter noted that a quarterly SEP for coordination-only D–SNP enrollment would ensure equity and parity between partial-benefit and full-benefit dually eligible individuals.

A few commenters expressed concern about the impact of CMS's SEP proposal on dually eligible individuals who are not Qualified Medicare Beneficiaries (QMBs). The commenter noted that if these individuals needed to change coverage outside of the standard enrollment periods, due to the lack of comprehensive Federal Medigap protections, they may not be eligible for a Medigap plan. Even if they were able to enroll, most Medigap plans have unaffordable premiums or out-of-pocket costs making enrollment in Traditional Medicare unattractive.

Response: We thank the commenters for their perspectives. We noted in the proposed rule (88 FR 78570) that our proposals at § 423.38(c)(4)(i) would allow partial-benefit dually eligible individuals and LIS eligible individuals the opportunity to disenroll from an MA–PD plan (to Traditional Medicare) in any month throughout the year and switch between standalone PDPs on a monthly basis. CMS regulations do not prohibit partial-benefit dually eligible individuals from enrolling in non-AIP HIDE SNPs; however, States may require more limited enrollment in HIDE SNPs via the SMAC.

We acknowledge the SEP proposals limit opportunities for partial-benefit dually eligible individuals and LIS eligible individuals to enroll in MA–PDs and coordination-only D–SNPs. Partial-benefit dually eligible individuals and LIS eligible individuals would still have the ability to make changes to their MA plan or non-integrated D–SNPs during the AEP, MA–OEP, or where another SEP permits.

With regard to retaining the quarterly dual/LIS SEP or creating a new SEP for partial-benefit dually eligible individuals to enroll in coordination-only D–SNPs, we direct the commenter's attention to the proposed rule (88 FR 78571), where we expressed our belief that the current managed care enrollment and eligibility policies have resulted in a proliferation of coordination-only D–SNPs and leave dually eligible individuals susceptible to aggressive marketing tactics from agents and brokers throughout the year. Adopting a new SEP for partial-benefit dually eligible individuals or extending the new integrated care SEP that we are adopting at § 423.38(c)(35) would not address that concern and would not further our goals of increasing aligned enrollment in integrated D–SNPs.

We recognize that non-QMB dually eligible individuals who enroll in Traditional Medicare may not be able to select a Medigap plan to cover cost-sharing, depending on the timing of that choice and State laws regarding Medigap enrollment. However, this is also true today, and we believe the benefits of the SEP proposals, including protecting Medicare enrollees from aggressive marketing tactics, reducing complexity for States and enrollment counselors, and promoting access to integrated care, outweigh the potential drawbacks.

Comment: Several commenters believed the integrated care SEP would only allow for enrollment in AIPs. A few commenters raised concerns about the potential for continued enrollment in misaligned plans. A commenter identified a State that is implementing default enrollment to increase alignment between Medicaid and Medicare but does not require HIDE SNPs to operate with exclusively aligned enrollment (EAE). The commenter further stated that the integrated care SEP would undermine current enrollment alignment, citing that it does not take into account Medicaid MCO enrollment and would give dually eligible individuals more opportunities to misalign their Medicare and Medicaid coverages. Another commenter urged CMS to consider a bar on new enrollments without concurrent alignment. The commenter recommended limiting the use of the integrated care SEP only when it would result in aligned enrollment with the Medicaid MCO.

Response: We share the concerns raised by commenters that, in certain instances, dually eligible individuals already enrolled in aligned plans could use the integrated care SEP as originally proposed at § 423.38(c)(35) to misalign their Medicare and Medicaid coverage. In States that do not require EAE, default enrollment mechanisms authorized under § 422.66(c)(2) can be used to enroll dually eligible individuals in a D–SNP that is affiliated with the Medicaid MCO in which the individual is enrolled for Medicaid coverage. However, without a State requiring D–SNPs to comply with EAE requirement as part of their SMAC, dually eligible individuals would theoretically be able to use the proposed integrated care SEP to elect a non-aligned HIDE SNP.

In the proposed rule (88 FR 78567), we discussed the primary goals of the proposals to drive toward increasing aligned enrollment for dually eligible individuals who are in Medicare and Medicaid managed care. The SEP polices we proposed and are finalizing are intended to create more opportunities for enrollment in integrated D–SNPs so that dually eligible individuals can experience plans that more meaningfully integrate Medicare and Medicaid services. While the integrated care SEP, as proposed, would create more opportunities to elect integrated D–SNPs, it could potentially also allow opportunities to misalign enrollment to persist in limited situations, which is contrary to our policy goals or intent for this new SEP.

After considering the comments received, we are finalizing the integrated care SEP with a narrower scope so that dually eligible individuals may use the SEP to enroll in a FIDE SNP, HIDE SNP, or AIP if they are enrolled in or in the process of enrolling in the sponsor's affiliated Medicaid managed care plan. We are finalizing § 423.38(c)(35) largely as proposed but with a modification that the SEP is available only to facilitate aligned enrollment, as that term is defined in § 422.2. As a result of this limitation, this SEP will effectively be limited to full-benefit dually eligible individuals because ''aligned enrollment'' is defined by reference to full-benefit dual eligibility. Adding this limitation to the integrated care SEP creates less opportunity for full-benefit dually eligible individuals to misalign their Medicare and Medicaid plans. Because FIDE SNPs (starting in 2025) and AIPs feature exclusively aligned enrollment, the effect of this change from our

original proposal is specific to HIDE SNPs. Relative to our original proposal, the same range of plans can enroll people using the finalized SEP, but it can be used in fewer circumstances and only by full-benefit dually eligible individuals: the integrated care SEP may be used only when it achieves aligned enrollment.

Comment: A few commenters expressed their belief that a monthly SEP would result in more marketing toward dually eligible individuals and would allow brokers to potentially take advantage of prospective enrollees.

Response: We appreciate the perspective raised by commenters but disagree that the monthly SEP, in combination with our other proposals, would result in more marketing toward dually eligible individuals or would allow brokers to potentially take advantage of prospective enrollees. As we noted in the proposed rule (88 FR 78570), we believe the proposals would remove some incentives both for MA–PD plans to deploy aggressive sales tactics targeted at dually eligible individuals outside of the AEP and for agents and brokers to target dually eligible individuals (especially among employed or captive agents affiliated with plans that do not offer integrated D–SNPs). Based on our review of 2023 plans, approximately 5 percent of the plans that can currently enroll dually eligible individuals using the quarterly dual/LIS SEP would be available as options for full-benefit dually eligible individuals using the proposed new monthly integrated care SEP at § 423.38(c)(35).

Comment: A few commenters expressed concern that the proposed monthly integrated care SEP could negatively impact an MA organization's Star Ratings, stating that allowing dually eligible individuals to make enrollment decisions on a monthly basis would be disruptive and impact quality outcomes, making it more difficult for plans to maintain or improve Star Ratings. A commenter further stated that where State Medicaid managed care programs require minimum Star Ratings of D–SNPs with affiliated Medicaid MCOs, the monthly integrated care SEP could result in non-compliance with that standard and jeopardize their ability to provide Medicaid coverage. Another commenter suggested that if CMS finalizes the monthly integrated care SEP proposal, CMS should make changes to the *Members Choosing to Leave the Plan* measure to exclude individuals who disenroll under the monthly SEP to move into a plan with a higher level of integration or from one D–SNP type to another, given the enrollment change is driven by something other than dissatisfaction with the plan, similar to the current exclusion for individuals enrolling in an employer group plan. Another commenter suggested that the SEP proposals, if finalized, could result in an increase in complaints by dually eligible individuals due to a lack of understanding of the changes to the SEPs and encouraged CMS to consider updating its practices around the Complaint Tracking Module (CTM) for disenrollments accordingly (see section III.O of the final rule for a discussion on codification of complaints resolution timelines and other requirements related to CTMs).

Response: We appreciate the commenters' perspective on this issue. We do not currently have evidence to suggest allowing full-benefit dually eligible individuals the opportunity to enroll into integrated D–SNPs in any month would negatively impact Star Ratings; in fact, we have reason to believe that the totality of the SEP proposals may actually benefit integrated D–SNPs on Star Ratings, including the *Members Choosing to Leave the Plan* measure. In 2023, a study published in *Health Affairs* noted that nearly one-third of dually eligible individuals in ''D–SNP look-alike plans,'' which the authors defined as MA plans that are marketed toward and primarily enroll dually eligible individuals but are not subject to Federal regulations requiring coordination with Medicaid, were previously enrolled in integrated care programs.[219] Such look-alike plans would no longer be able to accept enrollments from beneficiaries using the dual/LIS SEP at § 423.38(c)(4)(i) with our proposed and finalized changes. The dual/LIS SEP at § 423.38(c)(4)(i) would dramatically reduce the total array of options available outside of the AEP while the integrated care SEP at § 423.38(c)(35) allows enrollment by full-benefit dually eligible individuals into integrated D–SNPs, which together may improve integrated D–SNP performance on measures such as *Members Choosing to Leave the Plan.* Further, in the CY 2025 Advance Notice, we discussed a non-substantive update to that measure to exclude any enrollment into a plan designated as an AIP from the numerator of this measure, which could address the concerns if finalized; under the non-substantive update, CMS would treat a change in enrollment to an AIP from a non-integrated MA plan as an involuntary disenrollment.[220] We are committed to monitoring the impact of these policy changes and to considering necessary changes in the future as appropriate.

Comment: Numerous commenters stated the SEP proposals would increase movement in plans that could undermine care coordination and continuity of care. Some commenters expressed concern that D–SNPs would not be able to set up effective models of care if individuals could switch plans monthly. A few commenters stated changing plans monthly could lead to a delay in care if enrollees have to change providers or ask for new referrals for specialists or medications. A commenter stated that using a monthly SEP could cause disruption for dually eligible individuals if they are already receiving ongoing services such as home health, particularly if the new plan does not have the same provider network. A commenter noted that the SEPs would limit plans' ability to address social determinants of health (SDoH). Another commenter stated allowing individuals to change plans monthly creates less effective medication therapy management (MTM) programs.

Response: We thank commenters for their feedback and agree that coordination of care is an important element of integrated care plans. While we acknowledge changing plans monthly could impact coordination of care, we believe the benefits of reduced agent and broker marketing, improved transparency for enrollment counselors and individuals, and increased access to integration of Medicare and Medicaid benefits and administration outweigh the downsides. In addition, for individuals that are receiving an ongoing course of treatment and make an enrollment change, the April 2023 final rule (88 FR 22206) amended § 422.112(b)(8)(i)(B) to require MA organizations offering coordinated care plans, including D–SNPs, to have prior authorization policies that provide for a minimum 90-day transition period for any ongoing course(s) of treatment even if the course of treatment was for a service that commenced with an out-of-

[219] Ma Y., Frakt A., Roberts, E., Johnston K., Phelan J., and Figueroa J. Rapid Enrollment Growth in 'Look-Alike' Dual-Eligible Special Needs Plans: A Threat to Integrated Care. Health Affairs July 2023 [cited February 2024] *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00103.*

[220] Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies, p127–128. CMS explained that there are two exceptions to this: (1) If the plan in the old contract is also an Applicable Integrated Plan, then the enrollment is not excluded from the numerator; and (2) Any switch between D–SNPs in Florida is not excluded because all D–SNPs in Florida are directly capitated by the State for Medicaid services and therefore already provide aligned Medicare and Medicaid coverage.

network provider. We do not expect the volume of transitions to increase based on this rulemaking, and noted in the proposed rule (88 FR 78570), that approximately 5 percent of the MA–PD plans that can currently enroll dually eligible individuals using the quarterly dual/LIS SEP would be available as options for full-benefit dually eligible individuals using the once per month integrated care SEP.

As discussed in the proposed rule (88 FR 78570), we believe the integrated care SEP at § 423.38(c)(35) will create more opportunities for full-benefit dually eligible individuals to enroll in integrated plans, promoting coordination of Medicare and Medicaid services from the same organization. This includes plans addressing enrollees' SDoH needs and ensuring effective MTM programs are in place. In addition, we noted in the proposed rule (88 FR 78570) that the dual/LIS SEP at § 423.38(c)(4)(i) allows dually eligible individuals to disenroll from their MA–PD plan if MA is not working well for them. This would allow individuals to access providers that accept Medicare FFS that may not be in the MA plan's network, including providers that may be able to better address SDoH needs. We also note that dually eligible individuals leaving MA–PDs for Traditional Medicare and a PDP would still have access to an MTM program as this is a requirement of Part D plans at § 423.153(d). We do not anticipate the SEP changes will lead to dually eligible individuals making continuous changes to their enrollment or a major increase in SEP usage overall.

We will continue to monitor dual/LIS SEP usage as it transitions to monthly once again and can revisit in future policy making if issues arise.

Comment: Some commenters recommended the integrated care SEP be limited to allow dually eligible individuals in Traditional Medicare or MA–PDs to enroll in integrated D–SNPs but not permit switching between integrated D–SNPs on a monthly basis. Other commenters suggested allowing monthly enrollment into FIDE SNPs, HIDE SNPs, and AIPs but only allowing disenrollment during the AEP and MA–OEP to reduce changes between plans. A commenter supported the integrated care SEP but was concerned it created opportunities for providers to influence individuals' Medicare enrollment choices and recommended permitting dually eligible individuals to enroll into integrated care plans once per month but not allow disenrollments from an integrated care plan to Traditional Medicare.

Response: We thank commenters for the recommendations. We acknowledge the concern that a monthly SEP can disrupt coordination of care. While we acknowledge that there is a risk that full-benefit dually eligible individuals in integrated care plans could use the new integrated care SEP to switch monthly, we think the likelihood is low and the benefits (reduced marketing, improved transparency, and greater access to integrated care) outweigh potential risks.

We will continue to monitor dual/LIS SEP usage as it transitions to once per month again and can revisit in future policy making if issues arise.

Comment: Several commenters recommended limiting use of the integrated care SEP to only allow enrollment into integrated plans with quality ratings that are equal to or higher than the enrollee's current plan. Another commenter suggested only allowing use of the integrated care SEP to enroll in a FIDE SNP, HIDE SNP, or AIP with a Star Rating of four or greater.

Response: We appreciate the recommendations from commenters regarding the importance of high-quality integrated care plans. While we understand commenters' concerns, we do not currently prevent Medicare beneficiaries from enrolling in plans that do not have a quality rating equal to or higher than their current plan's rating when making new enrollment elections. Star Ratings are important indicators of plan performance, but other factors—such as supplemental benefits or participation of certain providers in-network—may make a 4-Star plan a better option for someone currently in a 4.5-Star plan. We do not intend to impose this limitation on the integrated care SEP.

Individuals wishing to enroll in a plan with 5 Stars will continue to have access to the 5-Star SEP at § 423.38(c)(20).

Comment: Other commenters suggested there may be countervailing incentives between the goal of increased integration and CMS's proposal to allow dually eligible individuals to move from an MA plan to Traditional Medicare and change between standalone Part D plans on a monthly basis. A few of these commenters noted that the proposal contradicts the goal of managing the care of an underserved and needy population. A commenter stated that MA plans, regardless of D–SNP integration status, provide a level of coordination that would be lost if enrollees reverted to Traditional Medicare. A commenter stated that potential changes in benefits, personalized care plans, providers, and care coordinators could lead to greater enrollee confusion, treatment errors, and care transition failures resulting in worsening health outcomes. The commenter stated that the core value proposition of integrated D–SNP coverage is the improved and seamless coordination of their Medicare and Medicaid benefits by a single insurer and believed monthly SEPs would damage the aligned enrollment in integrated plans that CMS is trying to accomplish because changes between plans or to Traditional Medicare undermine coordination of care. Another commenter opined that permitting dually eligible individuals to disenroll from MA plans in any month increases opportunities for adverse selection in Traditional Medicare and favorable selection in MA, especially if individuals are disenrolling from MA when they develop complex health needs. The commenter continued that such selection issues could further distort payments to MA plans and increase overall Medicare spending.

Response: We appreciate the commenters' perspectives on this issue. As we discussed in the proposed rule (88 FR 78567), we believe that aligned enrollment and especially exclusively aligned enrollment is a critical part of improving experiences and outcomes for dually eligible individuals because it allows States and plans to achieve greater levels of integration in the provision and coverage of benefits and plan administration for enrollees. Further, in the longer term, we believe that dually eligible individuals who are in Medicare and Medicaid managed care should receive services through the same organization and therefore our proposed and finalized SEPs are designed to incentivize enrollments into integrated D–SNPs to facilitate aligned enrollment as defined in § 422.2 while maintaining an SEP for LIS-eligible and dually eligible individuals to change their Part D coverage.

We acknowledge that under our proposals dually eligible individuals would have more opportunities to enroll in Traditional Medicare compared to opportunities to change enrollment to non-D–SNP MA–PDs and non-integrated D–SNPs. As we noted in the proposed rule (88 FR 78570), the SEP proposal at § 423.38(c)(4)(i) could mean that MA plans have marginally less incentive to innovate and invest in meeting the needs of high-cost dually eligible enrollees when these enrollees may disenroll at any time, thus exacerbating the phenomenon of higher-cost dually eligible individuals disenrolling from MA. However, we believe the benefits of the SEP proposals

outweigh the potential downsides, and we project in section XI of the final rule that our SEP and enrollment limitation policies will result in over $2 billion in Medicare savings over the ten-year projection period. We will continue to monitor dual/LIS SEP usage and can consider future policy options if issues arise.

Comment: Some commenters expressed concern that the SEP proposals may increase burden on States and plans. Several commenters noted the monthly SEPs would be administratively challenging for State Medicaid agencies to operationalize, putting further strain on States that already have limited capacity and budgetary challenges. Others noted a monthly SEP could lead to increased misalignment between Medicare and Medicaid plans because of monthly SEP usage or differences in enrollment effective dates for Medicare and Medicaid causing States to do extra work to continuously align enrollment into Medicaid managed care plans whenever enrollees change between D–SNPs. A few commenters stated the monthly SEPs could increase administrative costs on MA organizations having to track and manage enrollment that is changing monthly, including issuing ID cards, mailing materials, and the like.

Response: We appreciate the commenters' perspectives on this issue. While commenters stated the monthly SEPs would increase State burden, we noted in the proposed rule (88 FR 78570) our perspective that changing the SEPs to monthly would *reduce* burden on States as they work to align Medicaid MCO enrollment to D–SNP enrollment. We still believe this to be the case, even if it is not currently true for all States. This is particularly important for States transitioning their FAI demonstrations to integrated D–SNPs, all of which operated with monthly opportunities to change enrollment after requesting that CMS waive the quarterly dual/LIS SEP when it was initially established. We will continue to support States in their integration efforts by providing technical assistance, including education and support in implementing provisions of this final rule.

We acknowledge the concerns raised on enrollment effective date challenges and MA organizations having to manage a changing enrollment monthly. However, we do not anticipate the SEP changes, in combination with other policies finalized in this rulemaking, will cause a major increase in SEP usage, because, based on our review of 2023 information, only approximately 5 percent of the MA–PD plans that can currently enroll dually eligible individuals using the quarterly dual/LIS SEP would be available as options for full-benefit dually eligible individuals using the proposed new monthly integrated care SEP (88 FR 78750). Therefore, we do not believe our finalized changes will worsen existing challenges States and plans face around misaligned Medicare and Medicaid enrollment effective dates.

We will continue to monitor dual/LIS SEP usage and can consider future policy making if issues arise.

Comment: Some commenters raised concerns about the potential for increased provider burden as a result of the SEP proposals. A commenter noted, for example, that there are data lags in providers being notified of changes in payer source and coverage information, and more frequent changes in enrollment could result in delays to access to care for individuals and additional billing challenges for providers. A commenter further stated that frequent changes disrupt continuity of care, leading to administrative challenges like new referrals and authorizations, and an increase in administrative tasks like tracking eligibility and billing adding additional costs to providers. Commenters urged CMS to ensure accurate and timely information is available to providers so operations are not disrupted by frequent insurance changes.

Response: Changes in coverage often come with some administrative challenges for enrollees, providers, and health plans. As proposed, our policies would allow some people to change coverage more times per year than our rules permit today. However, our proposals also limit options for changing coverage in other situations, such that we do not expect an increase in total changes in coverage. Furthermore, one way in which we allow more coverage changes per year—changes among PDPs for people in Traditional Medicare—generally does not trigger any changes in provider networks as they would if they were changes from one MA–PD plan to another. The providers seen by dually eligible individuals and LIS-eligible individuals are likely to be enrolled in Medicare and Medicaid; in the unlikely situation that an individual receives treatment from an MA plan network provider that is not enrolled in Medicare, the ability to transition to another healthcare provider that is enrolled in Medicare is significantly easier than identifying a provider in a different MA plan network. Therefore, we are not persuaded by the argument that the SEP proposals would result in significantly more plan changes leading to increased provider burden. As noted in the proposed rule (88 FR 78750) and in previous responses, a relatively small percentage (approximately 5 percent) of the MA–PD plans would be available as options for dually eligible individuals using the proposed new monthly integrated care SEP. As a result, we do not believe that monthly changes would increase under the new SEPs. We also believe that the SEP proposals in combination with those proposed at §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii) would simplify provider billing and lower the risk of inappropriate billing, because more enrollees would be in D–SNPs with aligned enrollment, which generally means that providers would submit one bill to one organization, rather than (a) billing a D–SNP for Medicare covered services and the Medicaid plan (or State) for the Medicare cost sharing amount, or (b) having to determine which plan should be the primary payer for services covered in both programs, such as home health or medical equipment.

Comment: Many commenters were concerned that the new SEP proposals would result in confusion among Medicare beneficiaries and allow agents and brokers to continue using aggressive marketing and sales tactics to push optional or supplemental benefits instead of core coverage and/or incentivize them to sign up as many individuals as possible to increase commissions. Another commenter indicated the proposals would lead to greater choice overload and suboptimal coverage decisions. Another commenter stated that the ability to change plans monthly may generate more confusion as to what coverage is available and what providers they can and cannot see for specialized services. Commenters noted that dually eligible individuals often do not understand that a prior authorization does not move with them if they change carriers.

Response: We acknowledge the concerns raised by these commenters; increasing dually eligible individuals' understanding of available coverage options and limiting the use of aggressive marketing tactics by agents and brokers are among the primary goals of these proposals. However, we do not agree that the SEP proposals would create additional confusion and choice overload relative to the status quo. As we noted in the proposed rule (88 FR 78570), we believe the SEP proposals would reduce the incentive for plans to deploy aggressive sales tactics targeted at dually eligible individuals outside of

the AEP and would increase transparency for Medicare beneficiaries and enrollment counselors on opportunities to change plans. We are committed to exploring updates to the systems and supports designed to aid individuals in making Medicare choices in conjunction with the final rule. Finally, with respect to commenters' concerns about prior authorizations, we note that the April 2023 final rule (88 FR 22206) amended § 422.112(b)(8)(i)(B) to require MA organizations offering coordinated care plans to have prior authorization policies that provide for a minimum 90-day transition period for any ongoing course(s) of treatment for new enrollees even if the course of treatment was for a service that commenced with an out-of-network provider. While this does not fully guarantee coverage of services authorized through prior authorization by another plan, it does provide some protection against repetitive prior authorization processes as a result of a change to a new MA (or MA–PD) plan.

Comment: Several commenters recommended CMS consider exceptions or modifications to the SEP proposals to allow enrollment into additional MA–PDs outside of the AEP or MA–OEP. A few commenters noted dually eligible individuals should be able to choose between any MA plan during a Medicaid MCO open enrollment period, when a Medicare enrollee is newly eligible for Medicaid, and in States that do not have any Medicaid managed care or carve dually eligible individuals out of Medicaid managed care. Some commenters suggested maintaining the quarterly dual/LIS SEP in States that do not have D–SNPs or integrated D–SNPs so that individuals can enroll in other types of MA–PDs and have continued access to supplemental benefits and coordination of care and services. A commenter suggested keeping the quarterly SEP but allowing two changes during the quarter of Medicaid renewal to allow dually eligible individuals an additional opportunity to algin their Medicare and Medicaid coverage. A commenter suggested allowing dually eligible individuals to elect any MA–PD plan that is offered by an integrated delivery system or maintains a provider network in which the majority of physicians do not accept, or serve very few, Traditional Medicare enrollees. A commenter also requested that CMS consider applying the SEP changes on a State-by-State basis to take into account unique situations for States where enrollees would be adversely limited in choice and access.

Response: We appreciate commenters' suggestions to modify the SEP proposals. While we acknowledge that States may have their own enrollment policies and election periods, we believe the benefits of the SEP proposals, including the opportunity to protect Medicare enrollees from aggressive marketing tactics, reduce complexity for States and enrollment counselors, and promote access to integrated care, outweigh the potential drawbacks. Further, dually eligible individuals would still have the ability to make changes to their MA plan or non-integrated D–SNPs during the AEP, MA–OEP, or where another SEP permits. For example, dually eligible individuals that have a change in their Medicaid status—including newly gaining Medicaid eligibility—continue to have access to an SEP at § 423.38(c)(9).

We recognize dually eligible individuals will not be able to use the integrated care SEP in States that currently do not have Medicaid managed care plans, carve dually eligible individuals out of Medicaid managed care, or do not have integrated D–SNPs (that is, do not have Medicaid MCOs that are affiliated with D–SNPs or opportunities for aligned enrollment). Allowing exceptions to the proposed SEPs for certain plans or on a State-by-State basis would increase complexity for dually eligible individuals and enrollment counselors in understanding eligibility for the SEP and pose challenges for CMS to monitor usage.

Comment: Some commenters recommended that CMS monitor and publicly report SEP utilization. A commenter recommended that CMS create a transparent, accessible central data source on SEP usage and availability that would be available to SHIPs, State ombudsman programs, and State Medicaid agencies to support administration and oversight of SEP usage by MA plans. The commenter opined that making such data available would improve transparency for parties that support Medicare beneficiaries and dually eligible individuals to understand their Medicare enrollment options and increase visibility into potentially aggressive or misleading marketing behaviors, including targeting by D–SNP look-alikes. A commenter urged CMS to monitor SEP utilization patterns to ensure that plans are not dissuading individuals from staying enrolled and that there are no other issues that may be causing an individual to switch plans or leave MA. Another commenter encouraged CMS to collect monthly SEP utilization data and publicly report it at least annually. A commenter advised CMS to closely monitor for unintended effects on D–SNP enrollees who make multiple plan switches within a year. Citing potential challenges associated with the CMS SEP proposal in States with few or no integrated D–SNPs, a commenter requested that CMS conduct and release an analysis of the proposal's impact on States and individuals on a State-by-State basis.

Response: We thank commenters for their perspectives on this issue. In the proposed rule (88 FR 78569), we discussed concerns with the quarterly dual/LIS SEP creating complexity for SHIP and State ombudsman programs as they do not have access a central data source to determine if someone has already used the quarterly dual/LIS SEP, making it difficult to determine what enrollment options are truly available to dually eligible individuals. Changing the SEP to allow once-per-month usage will reduce complexity for enrollment counselors and individuals. In addition, if both the dual/LIS SEP and integrated care SEP are used in the same month, the application date of whichever SEP was elected last will be the enrollment effectuated the first of the following month.

We are considering making updates to systems and supports, including MPF and HPMS, that help individuals make Medicare choices. One of the considerations is how to show plans available to individuals along with options that align with their Medicaid enrollment.

We will work with States on implementing the policies finalized in this rule and will continue to monitor all aspects and consider future updates as appropriate.

Comment: Many commenters expressed significant concerns about limiting enrollment outside of the AEP to Traditional Medicare and PDPs. A few commenters suggested a revision to the dual/LIS SEP proposal so that dually eligible and LIS eligible individuals who use the SEP to disenroll from an MA–PD and enroll in Traditional Medicare and a PDP would have the ability to return to their former MA–PD within 90 days if they are dissatisfied with their choice.

Response: We appreciate the suggestion to allow individuals to return to their MA–PD plan within 90 days of disenrollment, but we are declining to incorporate it into the final rule. We believe incorporating a change like this could increase complexity for enrollment counselors, plans, and CMS to determine when someone was eligible to go back to their MA–PD plan and cause an increase in churn and disruption with individuals making frequent enrollment changes. However,

individuals may re-enroll where another SEP allows, such as for 5-Star plans. In addition, under current rules, dually eligible individuals can re-enroll into their former MA–PD plan or otherwise make a different plan selection during the AEP, MA–OEP, or where another SEP permits.

We acknowledge that the SEP changes will limit enrollment opportunities in MA–PDs and non-integrated D–SNPs during certain times of the year. We believe the benefits of the SEP proposals will do more to protect Medicare enrollees from aggressive marketing tactics, reduce complexity for States and enrollment counselors, and promote access to integrated care.

Comment: A few commenters raised concerns regarding the integrated care SEP and how it would apply in Oregon where some D–SNPs have a unique ownership model with Coordinated Care Organizations (CCO) to provide Medicaid managed care services. The D–SNPs aligned with some CCOs are not considered HIDE SNPs because they are not owned or controlled by the same parent organization as the CCO. The commenters noted many dually eligible individuals would not be able to use the integrated care SEP to enroll in the coordination-only D–SNPs aligned with a CCO. Another commenter suggested allowing dually eligible individuals in Oregon the ability to use the integrated care SEP to enroll in coordination-only D–SNPs that are aligned with a CCO or for CMS to expand the definition of AIP to include coordination-only D–SNPs within a CCO.

Response: We thank the commenters for the additional information and acknowledge that some States have unique Medicaid managed care arrangements. We recognized in the proposed rule (88 FR 78570) there would be some challenges in States with few or no integrated D–SNPs because the lack of FIDE SNPs, HIDE SNPs, and AIPs would limit dually eligible individuals' ability to change their MA–PD plan outside of the AEP, MA–OEP, or as other SEPs permit. We believe the benefits of the SEP proposals nationwide outweigh the potential drawbacks, including that in some States the integrated care SEP we are finalizing at § 423.38(c)(35) may not be fully accessible, in order to protect Medicare enrollees from aggressive marketing tactics, reduce complexity for States and enrollment counselors, and promote access to integrated care.

Expanding the definition of HIDE SNP is beyond the scope of this current rulemaking, and we believe that changes of the type recommended by the commenter should be carefully considered and subject to notice and an opportunity for comment by other interested parties, but we will consider the Oregon example for potential future rulemaking.

Comment: Many commenters requested clarification on current SEPs available to dually eligible individuals. Several commenters requested confirmation that the PACE SEP in Part D would still be available for individuals wishing to enroll in or disenroll from a PACE organization. A commenter also noted that PACE participants have been targeted in recent years by some MA–PD plans and D–SNPs encouraging them to disenroll from PACE and requested confirmation the PACE SEP would still be available for beneficiaries to re-enroll in PACE in these situations.

A commenter opposed the SEP changes and requested an exclusion for people who reside in institutions as their needs change frequently, as do the providers who see them. Another commenter suggested keeping the quarterly dual/LIS SEP but allowing individuals to use an SEP if they receive inaccurate information about a plan prior to enrollment or an agent enrolls them without their knowledge. Another commenter requested CMS confirm that D–SNPs with a 5-Star Rating will still be able to enroll individuals using the 5-Star SEP. Finally, a commenter supported the dual/LIS SEP and integrated care SEP and appreciated that CMS noted in the proposal that access to other SEPs will not change.

Response: We appreciate the commenters' request for clarity on the continued availability of current SEPs. We proposed to change the current dual/LIS SEP at § 423.38(c)(4)(i) but otherwise did not propose changes to the existing SEPs specifically mentioned by the commenters and that are available in the Part D program outlined in § 423.38(c). The PACE SEP for Part D enrollees at § 423.38(c)(14) will continue to be available for individuals wishing to enroll in or disenroll from a PACE organization. The institutional SEP at § 423.38(c)(15) will continue to be available when an individual moves into, resides in, or moves out of an institution. The exceptional circumstances SEP at § 423.38(c)(36) will continue to be available when a plan or agent of the plan materially misrepresents information to entice enrollment. The 5-Star SEP at § 423.38(c)(20) will continue to be available for individuals to use once per contract year to enroll in a plan with a Star Rating of 5 Stars. (Corresponding MA SEPs and open enrollment periods for each of these examples are at § 422.62(b)(7), (a)(4), (b)(3)(ii), and (b)(15) respectively.)

We appreciate the commenters' support for the SEP proposals and confirm that our decision to finalize these proposed revisions to the existing dual/LIS SEP and to adopt a new integrated care SEP will not affect the ability of individuals to access other applicable SEPs provided in CMS regulations.

Comment: A commenter questioned whether the proposed dual/LIS SEP changes would limit access for dually eligible and LIS eligible individuals since it would limit enrollment outside of the ICEP or AEP to standalone PDPs. The commenter, citing broader changes to Part D, expressed concern about many plans losing LIS benchmark status in 2025, leaving few PDPs (or only one PDP) per county qualifying as an LIS benchmark plan. The commenter further noted that, if the number of LIS benchmark PDPs is small, our SEP proposals could significantly disrupt enrollee care and lead to negative health consequences for high-need LIS individuals who have limited options among plans that may not cover their prescription drugs or impose new utilization management requirements.

Response: We thank the commenter for their perspective on this issue. While we acknowledge the commenter's concerns, we believe protecting Medicare enrollees from aggressive marketing tactics and reducing complexity for States and enrollment counselors outweigh the potential downsides. Our proposed improvements to the Part D risk adjustment model in the CY 2025 Advance Notice [221] would improve payment accuracy for Part D plans, including those that disproportionately serve enrollees with LIS, and we believe this will help foster a competitive market of PDPs. We will continue to monitor the availability of LIS benchmark PDPs over time. Further, dually eligible individuals would still be able to make changes to their MA plan or non-integrated D–SNPs during the AEP, MA–OEP, or where another SEP permits.

Comment: A few commenters raised concerns about the impact of the SEPs on access to providers and services. Other commenters noted that many dually eligible individuals need to change plans due to a change or loss in provider participation during the year or due to a change in need for a service

[221] Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

that not all plans may cover and would use the quarterly dual/LIS SEP to make midyear changes in enrollment. They further stated that in some service areas there may be a limited number of certain types of providers, resulting in in long waiting lists for individuals; as such, the proposed dual/LIS SEP would limit the ability to change plans outside of the AEP and could result in a lack of access to adequate care.

Response: We acknowledge the commenters' concerns and agree that continuity of care and mitigating disruption associated with plan changes is important for dually eligible individuals. However, we are not persuaded that the SEP proposals themselves increase the risk for service or provider disruptions compared to what is currently in place.

Comment: Some commenters responded to our solicitation in the proposed rule for comments on whether to use our flexibilities at section 1851(f)(4) of the Act (as cross-referenced at section 1860D–1(b)(1)(B)(iv) of the Act) and at § 423.40(c) to establish a Medicare enrollment effective date for the proposed integrated care SEP at § 423.38(c)(35) that differs from the effective date in the current quarterly dual/LIS SEP at § 423.38(c)(4). A few commenters supported the SEP changes but encouraged CMS not to make further adjustments to enrollment effective dates. One commenter acknowledged the real confusion misaligned enrollment dates present but believed the obstacles do not outweigh the benefits of current policy. The commenter believed that harm from misaligned enrollment dates today is mitigated by the fact that most individuals make their enrollment choices prior to the Medicaid cut-off dates, and suggested CMS work with States, SHIPs, D–SNPs, agents and brokers, and State enrollment vendors (including enrollment brokers that meet the requirements at section 1903(b)(4) of the Act and § 438.810) to clearly convey effective enrollment dates. Another commenter supported changes to the enrollment effective dates, noting it would more effectively support exclusively aligned enrollment. The commenter asked if States may direct specifics of enrollment date alignment via SMAC contracts. Another commenter recommended aligning enrollment dates between Medicare and Medicaid when feasible, while another commenter noted it may be additionally burdensome for States to align Medicaid enrollment effective dates with Medicare under a monthly SEP. Another commenter noted that misaligned enrollment effective dates between Medicare and Medicaid cause delays for enrollees in accessing LTSS but acknowledged that aligning start dates would be difficult to achieve. The commenter suggested CMS work with States, enrollment brokers, and plans to clearly convey effective enrollment dates so States can make Medicaid cut-off dates closer to Medicare enrollment effective dates.

Response: We thank the commenters for their thoughts on the option to use our statutory authority at section 1851(f)(4) of the Act (as cross-referenced at section 1860D–1(b)(1)(B)(iv) of the Act) to establish a different enrollment effective date for the proposed integrated care SEP at § 423.38(c)(35). Upon further consideration, we have decided that, as of now, we will not establish a Medicare enrollment effective date for the proposed integrated care SEP at § 423.38(c)(35) that differs from the effective date in the current quarterly dual/LIS SEP at § 423.38(c)(4). We will continue to work with States, D–SNPs, SHIPs, and other parties to strengthen communication to dually eligible individuals with respect to enrollment start dates of Medicare and Medicaid plans. Further, we note that such enrollment flexibilities may not be specified through the SMAC, as Federal regulation supersedes State flexibility in the SMAC, and as no such flexibility is adopted through Federal regulation, the option to change or delay Part D enrollment effective dates is not available to States through the SMAC.

Comment: One commenter noted the potential for increased complaints—including marketing misrepresentation complaints—in the HPMS Complaint Tracking Module (CTM) under the SEP proposals. The commenter noted it is possible dually eligible individuals will disenroll from an MA–PD plan, change their minds after enrolling in the new Part D plan before the next available open enrollment period, and subsequently open a CTM with their current integrated D–SNP in order to receive an SEP to disenroll (enrollees who open a marketing misrepresentation CTM against a plan may receive an SEP to disenroll if they received misleading or incorrect information leading them to enroll in a new plan). The commenter contends this creates a loophole to our SEP policy such that dually eligible enrollees can elect a non-integrated plan outside the AEP and, therefore, the commenter requests that CMS update the CTM to ensure only valid complaints result in a marketing misrepresentation SEP.

Response: We thank the commenter for raising the potential increases to CTMs. We appreciate the concern this commenter raises, and we will monitor whether the proposed SEPs lead to increased complaints to D–SNPs in the CTM to determine whether we need to make further adjustments to the CTM in response. However, we do not agree that marketing misrepresentation CTMs—a narrow but important protection for enrollees who receive misleading or incorrect information causing them to make an enrollment change—create a loophole to our SEP proposals sufficiently large enough to undermine their intent. Indeed, the vast majority of MA and Part D enrollees do not qualify for the dual/LIS SEP. Therefore, if marketing misrepresentation CTMs are as manipulable as the commenter suggests, we likely would be experiencing such manipulation on a widespread basis currently among non-dually eligible individuals. However, we do not believe this to be the current reality.

Comment: Many commenters offered support for the D–SNP enrollment limitation proposals at §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii). Commenters appreciated CMS's efforts to align enrollment between integrated D–SNPs and Medicaid MCOs, and to limit the number of D–SNP offerings per service area where a D–SNP, its parent organization, or a related MA organization under the same parent organization offers a Medicaid MCO. Commenters noted that integrated models that operate with exclusively aligned enrollment are better equipped to ensure true integration for full-benefit dually eligible individuals. Some of these commenters also appreciated the phased approached offered in the proposed rule. Additional commenters noted that the proposal to limit the number of D–SNPs offered by a parent organization would simplify plan options, reduce confusion for individuals, make it easier for States to track enrollment, and perform oversight and quality improvement with their plans. Commenters noted a reduction in D–SNPs would also reduce harmful marketing practices. Other commenters expressed appreciation for the proposed requirement that parent organizations only offer one D–SNP in a service area where the parent organization also offers a Medicaid MCO, as it would simplify options counseling to individuals, improve provider billing, and reduce barriers to Medicaid covered services like LTSS, dental, and transportation.

Response: We thank the commenters for the support. We similarly believe our proposals would increase the percentage of D–SNP enrollees who are in aligned

arrangements, reduce the number of D–SNP options overall and mitigate choice overload, remove some incentives for agents and brokers to target dually eligible individuals, simplify provider billing and lower the risk of inappropriate billing, and promote integrated care and the benefits it affords, like improved care coordination, integrated materials, and unified appeals and grievance processes.

Comment: Numerous commenters supported the proposal at § 422.514(h)(1)(i) intended to reduce choice overload and create more clear and meaningful plan options for dually eligible individuals. One commenter noted this policy would simplify plan options, reduce confusion for individuals, and make it easier for States to track enrollment, coordinate care, and perform quality improvement with their plans. Another commenter noted the removal of duplicative plans from the market would increase the likelihood that an individual will select a D–SNP. Another commenter felt that multiple plans operated by the same company is not only confusing for individuals dually eligible for Medicare and Medicaid, but also are very difficult for care coordinators assisting those individuals. Another commenter supported the limitation and noted that while this would limit dually eligible individuals' choice of plans, individuals currently struggle with the number of choices and often lack the resources to discern amongst numerous coverage options. They further stated that limiting the number of plans with meaningful differences would incentivize companies to build up their D–SNPs' networks and benefits and make it easier for individuals to make an enrollment choice.

Response: We thank the commenters for their support. We agree that the proposals would simplify D–SNP options, reduce confusion among dually eligible individuals and the options counselors that support them, and generally make plan choices more meaningful for dually eligible individuals, their families, advocates, and enrollment counselors. We similarly agree that a reduction in the overall number of D–SNP options will incentivize MA sponsors to invest in their integrated D–SNPs across markets.

Comment: Numerous commenters opposed the enrollment limitation proposals. Several of these commenters acknowledged or agreed with CMS's efforts to facilitate better alignment of enrollment between Medicare and Medicaid and simplify Medicare options for dually eligible individuals but had concerns with the details of the proposals. Many commenters were concerned about the potential of the proposal to limit the number of D–SNPs offered by the same parent organization in a given service area to negatively impact individual choice. A commenter expressed particular concern regarding the effects of this policy in States that have D–SNPs and Medicaid managed care, but no current requirements for EAE. The commenter believed that, unless CMS's intent is that all MA organizations must offer an affiliated Medicaid MCO and move to EAE, narrowing choices would adversely limit dually eligible individuals' choices, and by 2030 would limit the number of supplemental benefits offered by D–SNPs. Another commenter asked that CMS assess impact on SMACs and whether D–SNP relationships are positively or negatively impacted. Finally, another commenter noted that plans offer multiple PBPs to allow them to tailor benefits for a particular population, and the proposal would remove a plan's ability to do so.

Response: We thank the commenters for their perspective. We acknowledge that the enrollment limitations—both as proposed and as finalized at § 422.514(h) in this rule—may reduce the number of available D–SNP options for dually eligible individuals. As noted in the proposed rule (88 FR 78575), this is by design and a way to address the choice overload faced by dually eligible individuals, their families, and enrollment counselors. We clarify that these policies only apply to an MA organization where it, its parent organization (as defined in § 422.2), or any entity that shares a parent organization with an MA organization also contract with a State as a Medicaid MCO that enrolls full-benefit dually eligible individuals in the same service area (that is, in a service area that overlaps in full or in part with the service area of the MA organization's D–SNP(s)). In applying the enrollment limitations in § 422.514(h), we will follow corporate ownership to the highest level, rather than looking only to the immediate owner of an MA organization or other, related entity, consistent with the definition of parent organization as meaning the entity that is not a subsidiary of any other legal entity. MA organizations that offer D–SNPs where the MA organization, its parent organization or any entity that shares a parent organization with the MA organization do not offer an MCO are unaffected by the new proposals; such MA organizations may continue to offer coordination-only D–SNPs. Further, even after this final rule takes effect, dually eligible individuals will continue to have more Medicare coverage choices (including Traditional Medicare with a Part D plan, MA–PDs, SNPs, and PACE) relative to their Medicare-only peers.

As noted in the proposed rule (88 FR 78575), we believe the enrollment limitations will have the greatest impact in States that have Medicaid managed care but do not have EAE requirements already, as MA organizations operating D–SNPs in those States will likely choose to consolidate their PBPs down to a single PBP for full-benefit dually eligible individuals that is aligned with their affiliated Medicaid MCO (that is, the MCO that is offered by the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization) that fully or partially overlaps the D–SNPs service area. We will work closely with States in the event they wish to adjust their State Medicaid agency contracts to require EAE as a result of these policies.

We acknowledge this final rule will limit an MA organization's ability to offer multiple PBPs with tailored benefits, unless one of the exceptions we are finalizing applies. (We discuss the exceptions in detail in response to other public comments later in this section.) We also recognize that plan sponsors offering D–SNPs may also choose to adjust their supplemental benefit offerings as a result of these policies, though we do not believe operating fewer plans to be more administratively burdensome relative to offering many plans. We will monitor the policies' impact to D–SNP supplemental benefits.

Finally, we note we are finalizing § 422.514(h)(1) with a technical modification to correct the terminology to use the term ''full-benefit dual eligible individual(s)'' instead of the more general ''dually eligible individuals'' to match the cross-reference to § 423.772.

Comment: A number of commenters suggested that the enrollment limitations could create barriers for dually eligible individuals in States where they are not required to be in or are explicitly carved out from Medicaid managed care. For example, in New York, only dually eligible individuals with significant long-term care needs are required to enroll in Medicaid managed care, with the majority of dually eligible individuals remaining in Medicaid fee-for-service (FFS). These commenters noted that D–SNPs that also contract with States as Medicaid MCOs can currently enroll individuals

in Medicaid FFS but, under the proposals, those D–SNPs would not be able to enroll these individuals beginning in 2027 and would be required to disenroll them as of 2030. Commenters indicated that these individuals are better served in D–SNPs where they receive coordination of their Medicare and FFS Medicaid benefits. The commenters offered several suggestions for how CMS should address these concerns: (a) limiting the proposal to States that require mandatory enrollment for dually eligible individuals, including those who do not receive long-term care services, (b) implementing a limited exception process for States that would allow MA organizations with an affiliated Medicaid MCO to offer at least one D–SNP PBP that is not exclusively aligned and that can enroll dually eligible individuals who maintain FFS Medicaid coverage and (c) phasing in the proposal over time. Another commenter asked CMS to clarify whether dually eligible individuals in States with voluntary Medicaid managed care would be disenrolled from coordination-only D–SNPs beginning in 2027.

Response: We appreciate the commenters' perspectives but continue to believe that the policy we proposed is appropriate and a practicable means to achieve our goals of furthering integrated coverage for individuals who are dually eligible for Medicare and Medicaid. Applying the D–SNP enrollment limitations to only States that require mandatory enrollment for dually eligible individuals, while not something we explicitly considered in the proposed rule, has some potential drawbacks and we do not think it would further our policy goals as well as proposed § 422.514(h). This alternative would narrow the number of States in which these policies would apply, thus reducing the extent to which we would achieve the benefits described in the proposed rule. It would also raise potential complexity in States where certain subpopulations of dually eligible individuals are mandatorily enrolled, but others are not. Allowing each MA organization with an affiliated Medicaid MCO to offer at least one D–SNP that is not exclusively aligned with its affiliated Medicaid MCO for the purpose of enrolling dually eligible individuals who are enrolled Medicaid FFS would similarly reduce the extent to which we would achieve the benefits described in the proposed rule, create more additional operational complexity for States and CMS to administer and monitor, and would likely be more complicated to explain from a beneficiary communications and messaging perspective compared to the current proposal. Finally, we believe the phase-in outlined in the proposed rule provides ample time for transition; our proposal, which we are finalizing, limits new enrollment to individuals enrolled in both D–SNP and affiliated Medicaid MCO offered under the same parent organization starting in 2027 and then disenrolling those enrollees who do not have aligned enrollment in the D–SNP's affiliated Medicaid MCO in 2030. From the time of issuance of this final rule in 2024, there are two bid cycles and contract years (2025 and 2026) during which D–SNPs with affiliated Medicaid MCOs may prepare for the first phase of enrollment limitations. We decline to incorporate these suggestions in the final rule.

Comment: A commenter stated that the enrollment limitation proposals would seem to have the perverse effect of penalizing MA plans that are aligned with an MCO, while MA plans that are not aligned with an MCO may enroll any dually eligible individual. They further stated that there would be individuals enrolled in Medicaid MCOs that are not eligible for integrated care and requested that CMS clarify the definition of a ''Medicaid contract'' so it refers to only an integrated plan contract since CHIP, TANF, foster care, and other unrelated benefits offered under Medicaid should not be considered contracts for this purpose.

Response: We thank the commenter for their perspective and suggestion. As we described in the proposed rule (88 FR 78575) it may seem that our proposal on limiting enrollment in D–SNPs offered by MA organizations with affiliated Medicaid MCOs, in isolation, would disadvantage parent organizations that choose to offer Medicaid MCOs as well as D–SNPs because such organizations would be limited in the number of D–SNP offerings and would be required to align their enrollment between D–SNP and MCO for full-benefit dually eligible individuals. However, our SEP proposals were designed to have the opposite effect by permitting enrollment into integrated D–SNP options that cover both Medicare and Medicaid benefits using the new one-time-per month SEP while removing the option to use the dual/LIS SEP to enroll into MA–PDs—including coordination-only D–SNPs. The integrated care SEP would incentivize MA organizations to offer integrated D–SNPs as a means to take advantage of the monthly integrated care SEP that is available to full-benefit dually eligible individuals to facilitate aligned enrollment (that is, for these individuals to enroll only into integrated D–SNPs that are affiliated the Medicaid MCO in which the individual also enrolls).

While the proposals at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)(1) and (2) apply (and therefore limit the ability of an MA organization to offer multiple D–SNPs) when an MA organization, its parent organization, or an entity that shares a parent organization also contracts with a State as a Medicaid MCO, the limitation in these regulations applies only when the affiliated Medicaid MCO enrolls dually eligible individuals. Medicaid MCOs that solely enroll other Medicaid populations will not be impacted by this rule. We proposed that dually eligible individuals for purposes of this provision means ''dually eligible individuals as defined in § 423.772,'' but in retrospect realized that we should have used the term ''full-benefit dual eligible individuals'' as defined in § 423.772. Therefore, we have revised § 422.514(h)(1) to clarify that this provision applies only when a Medicaid MCO enrolls full-benefit dual eligible individuals as defined in § 423.772. We have made similar edits to § 422.514(h)(3)(i) and (ii) to specify that we are referring to full-benefit dual eligible individuals as defined in § 423.772. These clarifying edits to the regulatory text have no impact to the enrollment limitations as originally proposed or finalized in this rulemaking at § 422.514(h).

We acknowledge that some Medicaid MCOs may enroll full-benefit dually eligible individuals even when certain Medicaid services, such as long-term supports and services, are carved out. In such scenarios, the rules we are finalizing here will apply, facilitating better access for full-benefit dually eligible individuals to care coordination, unified appeals processes across Medicare and Medicaid, continuation of Medicare services during an appeal, and integrated materials that come from aligned enrollment, even if some Medicaid benefits are carved-out. As such, we decline to incorporate these suggestions in the final rule.

Comment: A few commenters expressed concern regarding the impact of our enrollment limitation proposals on partial-benefit dually eligible individuals. They acknowledged that some States permit integrated D–SNPs to enroll both full-benefit and partial-benefit dually eligible individuals; in such cases, our proposal would mean that the full-benefit enrollees are also enrolled in the D–SNP's related

Medicaid MCO while the partial-benefit dually eligible individuals are enrolled only in the D–SNP. These commenters were concerned that partial-benefit dually eligible individuals may experience disruption if they are no longer able to stay in D–SNPs affected by § 422.514(h) after 2030.

Response: We thank the commenters for raising this issue and would like to clarify the impact of the new regulations proposed at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)(1) and 422.514(h)(2) for partial-benefit dually eligible individuals. We proposed at § 422.514(h)(1)(i) that, beginning in 2027, an MA organization, its parent organization, or any entity sharing a parent organization with the MA organization that also contracts with a State as a Medicaid MCO may only offer one D–SNP for full-benefit dually eligible individuals. Functionally this means that an MA organization can continue to offer one or more D–SNPs for partial-benefit dually eligible individuals when it meets all other applicable requirements (including having a SMAC) even if the MA organization, its parent organization, or another entity (or entities) that share a parent organization with the MA organization offers an affiliated Medicaid MCO in the same service area. While proposed §§ 422.514(h)(1)(ii) and 422.514(h)(2) go on to limit enrollment in the D–SNP to individuals enrolled in, or in the process of enrolling in the Medicaid MCO, the MA organization that offers the D–SNP for full-benefit dually eligible individuals is not prohibited by § 422.514(h)(1)(i), (h)(1)(ii), or (h)(2) from offering additional D–SNPs solely for partial-benefit dually eligible individuals. We illustrate the differential impact on D–SNPs serving partial-benefit dually eligible individuals in the hypothetical example provided in Tables HC3 and HC4 in the proposed rule (88 FR 78574) where we noted that MA Organization Gamma could convert HIDE D–SNP Gamma 001 to coordination-only D–SNP Gamma 001 and keep that plan open for partial-benefit dually eligible individuals.

Comment: A few commenters suggested that CMS provide more information on how our proposals would impact States that have Medicaid managed care programs that only cover a subset of Medicaid services, such as long-term services and supports (these are often called partially capitated Medicaid managed care programs). A commenter further expressed concern that the requirement for MA organizations to limit D–SNP enrollment to only those individuals also enrolled in the affiliated Medicaid MCO may adversely impact individuals in specific States, particularly those that also have partially capitated Medicaid programs, such as New York. The commenter recommended that CMS explicitly clarify partially capitated models as another affiliated Medicaid managed care plan option or allow flexibility for State Medicaid agencies to determine Medicaid plan types that should be aligned with D–SNPs. Another commenter requested CMS clarify whether the exception proposed at § 422.514(h)(3)(i) extends to situations in which full-benefit dually eligible individuals are only enrolled in Medicaid managed care plans if they receive LTSS.

Response: We thank the commenters for raising the issue of partially capitated Medicaid managed care programs. As we noted in the proposed rule (88 FR 78574), while the enrollment limitations proposals for non-integrated D–SNPs would apply based on an MA organization having an affiliated Medicaid MCO, we were considering whether they should also apply where an MA organization has other affiliated Medicaid managed care plan options as well, including prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs). We described how some States use PIHPs or PAHPs to deliver specific categories of Medicaid-covered services, like behavioral health, or a single benefit, such as non-emergency medical transportation, using a single contractor. As we noted in the proposed rule, to the extent the enrollment limitation provisions incentivize an organization to end its Medicaid managed care contracts rather than offer D–SNPs that are subject to the new limitations, that incentive would be stronger for a PIHP or PAHP than an MCO. We continue to believe that applying these proposals to PIHPs and PAHPs could create incentives that are disruptive yet do not significantly further the goals of our proposals. As a result, we do not intend to extend the enrollment limitation policies in § 422.514(h)(1) and (2) beyond Medicaid MCOs or beyond D–SNPs that enroll full-benefit dually eligible individuals. This would mean that an MA organization offering a D–SNP in the same area that it, its parent organization, or an entity (or entities) that share a parent organization with the MA organization contracts with the State only as a PIHP or PAHP would not be subject to the enrollment limitations at §§ 422.503(b)(8), 422.504(a)(20), or 422.514(h). (We direct readers to § 438.4 for definitions of the terms PIHP and PAHP; these types of Medicaid managed care plans cover less comprehensive benefits than Medicaid MCOs.)

We acknowledge, however, that there may be situations where a State Medicaid agency operates multiple Medicaid managed care programs that enroll full-benefit dually eligible individuals. For example, New York currently operates a fully integrated care program using Medicaid MCOs, plus a separate partially capitated program through which the State pays Medicaid capitation to PIHPs to cover long-term services and supports and ancillary benefits but not primary or acute care. If the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization has a Medicaid MCO contract with the State, the provisions at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)(1)(i) would apply in this example to limit the MA organization's ability to offer D–SNPs in that State to full-benefit dual eligible individuals. However, the exception proposed and finalized at § 422.514(h)(3)(i) would allow the MA organization in this example to offer one D–SNP for full-benefit dually eligible individuals affiliated with the Medicaid MCO and a second D–SNP for full-benefit dually eligible individuals affiliated with the partially capitated PIHP *if* the State requires this arrangement in the SMAC.

Proposed § 422.514(h)(3)(i) established State flexibility to use the SMAC to ''limit enrollment [into D–SNPs] for certain groups'' based on ''age group or other criteria.'' However, upon reviewing comments, we believe the proposed exception at § 422.514(h)(3)(i) was insufficiently clear and warrants clarification for scenarios like those in New York. Therefore we are revising § 422.514(h)(3)(i) to clarify that we will allow an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, to offer more than one D–SNP for full-benefit dually eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO only when a SMAC requires it in order to *differentiate enrollment* into D–SNPs either (i) by age group or (ii) *to align enrollment in each D–SNP with the eligibility criteria or benefit design used in the State's Medicaid managed care program(s).* We believe this revised text better explains our intent for the exception at paragraph (h)(3)(i). As described in the proposed rule (88 FR 78572), this exception allows for States that currently have different integrated D–SNP programs based on age or Medicaid managed program design to continue to operate

these programs and allows States the flexibility to design future integrated D–SNPs with State-specific nuances as to D–SNP eligibility and/or benefit design should the State choose. In the New York context, for example, § 422.514(h)(3)(i) as finalized would give the State the ability to allow an MA organization with which it contracts as both a Medicaid MCO and as a Managed Long Term Care Plan (MLTCP) (the name for NY's PIHP-based program), to operate more than one D–SNP for full-benefit dually eligible individuals in the same service area—one affiliated with the Medicaid MCO and another with the MLTCP—as long as the State specifies this in the SMAC.

Comment: A few commenters expressed concern regarding the potential impact of the enrollment limitation proposals in rural areas. A commenter noted that network adequacy requirements make it challenging for health plans to offer D–SNPs in rural communities. The commenter further stated that Medicaid managed care is not always available in rural areas and was unsure how the proposed rules would impact the coordination-only D–SNPs that may operate there. A commenter also suggested that CMS should do more to ensure that rural communities have improved access to D–SNPs.

Response: We appreciate the perspectives of the commenters and agree that it can be challenging for States and plans to implement managed care in rural communities. Depending on the State, the enrollment limitation proposals may not be applicable or may have a limited impact, particularly in rural areas where both Medicaid and Medicare managed care may be limited. The proposals at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h) apply only when an MA organization, its parent organization, or an entity that that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO that enrolls full-benefit dually eligible individuals in the same service area. Coordination-only D–SNPs offered by an MA organization that does have an affiliated Medicaid MCO would not be prevented by the rules we are finalizing at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)—in rural communities or other locations—from continuing to operate as they do today.

Other policies designed to improve access to D–SNPs in rural communities are beyond the scope of this current rulemaking, but we will consider exploring opportunities for potential future rulemaking.

Comment: Some commenters expressed concern about the impact of the proposals that limit the number of D–SNPs available in a service area on plan competition and availability. A commenter cautioned CMS against implementing overly burdensome integration requirements that could ultimately lead to fewer plans in a particular service area, reducing competition and innovation. A few commenters questioned whether proposals that limit the number of D–SNPs available in a service area could force high-performing D–SNPs and/or those with expertise in specialized areas such as MLTSS and behavioral health out of State markets. Commenters further noted that there are plans that serve the dually eligible population through D–SNPs that have not historically served the Medicaid managed care population and that most State Medicaid managed care procurements do not evaluate the quality of available D–SNPs in the State, resulting in a situation where 4- or 5-Star plans are prohibited from offering a D–SNP without a Medicaid managed care contract even when those plans have a higher quality rating than D–SNPs or MA plans offered by entities that also offer Medicaid MCOs. The commenter further stated that higher rated D–SNPs typically offer more robust supplemental benefits, including those designed to address health-related social needs. Another commenter similarly suggested that the proposals could result in lower-quality Medicaid plans gaining new D–SNP enrollees. Another commenter suggested that increased market consolidation related to Medicaid procurements could eliminate coordination-only D–SNPs that can serve as pathways to integration for States and offer care coordination for partial-benefit and full-benefit dually eligible individuals who do not meet criteria for enrollment in integrated Medicaid MCOs. A commenter further stated the impact of the proposals would likely vary depending on whether the markets and procurements drive more competition for Medicaid contracts or drive less competition for Medicaid contracts if it becomes easier to be a coordination-only D–SNP in certain markets. They went on to state that larger organizations already offering D–SNPs may have more capacity to respond to a State Medicaid MCO request for proposals (that is, a procurement solicitation) compared to smaller organizations and that States may favor plans with whom they have existing relationships. Another commenter was concerned that the proposals would incentivize States to further limit the number of D–SNPs or other integrated plans with which they contract, either through procurements requiring statewide coverage or other criteria that may make it less possible for smaller and/or local/regional plans to participate, particularly in rural communities. They further state that, in accordance with the July 2021 Executive Order on Promoting Competition in the American Economy (#14036), CMS should evaluate whether these proposals will preserve ''a fair, open and competitive marketplace.''

Response: We appreciate the comments on the potential impact of our proposals on plan competition. We noted in the proposed rule (88 FR 78575) the theoretical possibility that MA organizations that operate both D–SNPs and Medicaid MCOs might elect to participate in fewer competitive Medicaid procurements (or exit Medicaid managed care in ''any willing provider'' States), to be exempted from the proposed restrictions on D–SNP enrollment and on the number of D–SNP offerings permitted in the MA program, which could adversely affect competition and the minimum choice requirements in § 438.52 for Medicaid managed care programs. However, our SEP proposals would have the opposite effect, since only integrated D–SNPs could benefit from the new integrated care SEP, and we believe our proposals, in combination, maintain strong incentives for organizations to compete for Medicaid managed care contracts. Nothing in our proposals or this final rule fundamentally changes the opportunity to compete for State Medicaid managed care contracts or the annual opportunity to apply for an MA contract. While national organizations have certain advantages, our observation has been that many of the organizations that have successfully created fully integrated D–SNPs with EAE—the types of plans relatively advantaged by the policies we are adopting in § 422.514(h) and with the SEPs—are local organizations with community roots. As such, we do not believe this rulemaking will result in excessive consolidation or anticompetitive outcomes. Nonetheless, we will monitor the market over time to ensure it sustains a fair, open and competitive marketplace.

We do not expect our policies, as proposed or as finalized, to drive out high-performing D–SNPs or Medicaid MCOs with specialized experience. While §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii), as finalized in this rule, in combination are intended to result in a reduction in the number of D–SNP options overall, we

are not persuaded that it would necessarily result in loss of high-performing D–SNPs or Medicaid MCOs with specialized experience. MA organizations that have an affiliated MCO and that offer multiple D–SNPs available to full-benefit dually eligible individuals in the same area will have some flexibility in choosing how to consolidate its D–SNPs under this final rule. We believe that this final rule offers significant incentives to ensure high-performing MA and Medicaid managed care plans continue. States that operate specialized Medicaid managed care programs focusing on MLTSS or behavioral health, for example, may be able to utilize the exception at § 422.514(h)(3)(i) to allow more than one D–SNP to be available in the State for full-benefit dually eligible individuals in the same service area by including in the State's SMAC with the MA organization that each D–SNP align enrollment with the eligibility criteria and/or benefit design used in the State's Medicaid managed care program(s). In finalizing our proposal at § 422.514(h) (with modifications discussed throughout this section of the final rule), we are clarifying that the final regulation applies based on an MA organization having an affiliated Medicaid MCO in the same service area; it would not apply to other affiliated Medicaid managed care plan options such as prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) which States use to deliver specific categories of Medicaid-covered services, like behavioral health, or a single benefit, such as non-emergency medical transportation (see further discussion in the proposed rule at 88 FR 78574). As a result, we believe the risk of specialized plans leaving the market is low.

As noted in the proposed rule (88 FR 78751), States have discretion in how they structure their Medicaid managed care programs. This includes whether and how they select Medicaid MCOs to participate in such programs, whether that is through competitive procurements or an ''any willing provider'' approach. As noted in prior response, under our proposals an MA organization, its parent organization or any entity that shares a parent organization with the MA organization that also contracts with a State as a Medicaid MCO could continue to offer one or more D–SNPs for partial-benefit dually eligible individuals.

Overall, we agree with commenters who stated that the impact will vary based on the market. As noted in the proposed rule (88 FR 78575), we believe the impact of these final policies will be concentrated in those States that have Medicaid MCOs but do not have EAE requirements already. We acknowledge that this rulemaking may impact organization decisions about whether and how to participate in certain markets but believe that, on the whole, the policies we are finalizing in this section of the final rule will better serve the dually eligible individuals by furthering opportunities for these individuals to enroll in integrated plans.

Comment: A commenter noted that the enrollment limitation proposals could lead to more D–SNP-only contracts, which may result in lower Star Ratings than other contract structures. The commenter further requested CMS consider the impacts of more D–SNP-only contracts on the Star Ratings program, noting that should D–SNP-only contracts have lower Star Ratings, D–SNPs would have less funds to invest in supplemental benefits that address important health related social needs.

Response: We appreciate the commenter's perspective and agree that the proposals could potentially lead to more States requiring D–SNP-only contracts after 2030, as aligned enrollment and service areas for D–SNPs with affiliated Medicaid MCOs would be Federally required, allowing States to receive the benefits of D–SNP-only contracts. For example, § 422.107(e) provides that States with D–SNP-only MA contracts may have HPMS access for oversight and information sharing, greater transparency on Star Ratings specific to D–SNP enrollees in their State, and increased transparency on health care spending. With regard to concerns that D–SNP-only contracts may result in lower Star Ratings than other MA contracts, we direct the commenter's attention to the April 2023 final rule (87 FR 27765 through 27766) where we addressed similar issues. While we understand the concern that D–SNP-only contracts are rated in comparison to MA contracts that may have few or no dually eligible enrollees, the Star Ratings methodology addresses accuracy of measurement by case-mix adjusting some individual measures in accordance with measure specifications and applying CAI for other measures that are not case-mix adjusted to ensure that factors outside a contract's control are not captured in Star Ratings. In addition, beginning with the 2027 Star Ratings, the HEI reward will be added to incentivize and reward relatively high performance among enrollees with specified SRFs including LIS/DE and disability among contracts, like D–SNP-only contracts, that serve relatively high percentages of these enrollees.

Comment: A commenter requested that CMS assess whether the proposed enrollment limitations for non-integrated D–SNPs could lead to more D–SNP look-alikes as MA organizations try to avoid application of § 422.514(h) and, if so, inquired about the strategies CMS would employ to mitigate such a risk. Another commenter noted that increasing requirements on D–SNPs and States before D–SNP look-alikes are addressed may promote enrollment into less integrated plan options.

Response: We appreciate the commenters' perspectives but do not expect our proposed limitations on enrollment into non-SNP MA plans to increase the number of D–SNP look-alikes. As we stated in the proposed rule (88 FR 78575), under our proposals MA organizations that have multiple D–SNP PBPs available to full-benefit dually eligible individuals and that also have affiliated Medicaid MCOs in the same service area (that is, MCOs offered by the MA organization, its parent organization, or an entity that shares the same parent organization) would likely choose to consolidate their D–SNP PBPs down to a single D–SNP that is aligned with their Medicaid MCO that fully or partially overlaps the D–SNP service area and therefore available to full-benefit dual eligible individuals. Such MA organizations could operate non-AIP coordination-only D–SNPs both for service areas where the MA organization does not have an affiliated Medicaid MCO and for partial-benefit dually eligible individuals. Thus, we expect robust availability of D–SNP options for dually eligible individuals, including partial-benefit dually eligible individuals, to remain and not lead to establishment of additional D–SNP look-alikes. In addition, we proposed (and are finalizing in this rule) a reduction in the threshold for identifying and phasing out D–SNP look-alikes (see section VIII.J). As the final rule is implemented over the transition periods and deadlines specified in § 422.514, we will monitor the D–SNP landscape and enrollment transitions and consider future rulemaking as needed.

Comment: A few commenters urged CMS to monitor the impacts of this rule over time. Several commenters suggested CMS examine the impact of these proposals on individuals and availability of viable plan options over time. A commenter specifically suggested including whether the quality of D–SNPs is impacted positively or negatively by these proposals. Another commenter suggested CMS monitor the

impacts of the changes on the availability of Medicaid managed care plans to better understand if the enrollment limitations encourage, or potentially discourage MA sponsors from applying to offer aligned Medicaid plans, creating an unintended effect on access to or choice among Medicaid managed care plans and by extension, aligned integrated plans. Another commenter asked CMS to monitor trends associated with the SEP proposals to ensure there are no adverse impacts on dually eligible individuals.

Response: We appreciate these comments underscoring the importance of monitoring the impact our rulemaking has on Medicare and Medicaid managed care plans. We agree and will pay close attention to the impact on sponsors as well as States and, most importantly, on dually eligible individuals.

Comment: Several commenters highlighted the potential impact of proposals to limit the number of and align enrollment in D–SNPs in certain service areas on State Medicaid policy. A few commenters expressed concern with what they characterized as the one-size-fits-all and/or top-down approach taken in these proposals and indicated that States need both direction and flexibility to innovate in a way that is appropriate to State-specific landscapes. Another commenter requested CMS consider how these proposals would impact ongoing State efforts to advance integration. Another commenter similarly noted that State autonomy in program design is a cornerstone of the Medicaid program and that aspects of the proposal may not account for the unique structure of certain Medicaid programs, including dually eligible individuals crossing multiple eligibility categories, State choice in benefit inclusion, voluntary vs. mandatory Medicaid managed care, and State procurement timelines. A few commenters acknowledged that States may not be aware of or planning ahead for how current State procurements may impact or be impacted by proposed new requirements for aligned enrollment applicable beginning 2027 and 2030, particularly when Medicaid procurement timelines do not align with MA service area expansion and bid filing timelines. The commenter further expressed concern that the proposed changes could result in unanticipated disruptions where States are making progress toward integration, including those States moving from the Financial Alignment Initiative to D–SNP models.

Response: We appreciate these perspectives. We agree that States have policy interests and goals that shape their unique Medicaid managed care programs; as noted in the proposed rule (88 FR 78571), our intent is to help further support States in their integration efforts while also addressing the significant recent growth in both the number of D–SNPs and the number of dually eligible individuals with misaligned enrollment. We believe the opportunities to reduce choice overload and market complexity where parent organizations offer multiple D–SNP options in the same service area and to provide a truly integrated experience for a greater number of dually eligible individuals by requiring plans to align enrollment outweigh incremental constraints on State flexibility. We also again note the exception to accommodate State policy choices, described in § 422.514(h)(3)(i). We are in close communication with the States planning to transition from the FAI to integrated D–SNPs and will continue to work closely with all States directly and through the Integrated Care Resource Center to provide technical assistance and support for States.

Comment: A number of commenters acknowledged limited capacity and resources at the State level to support integration efforts for dually eligible individuals. Some commenters were concerned that the increasing complexity of Federal regulations, including these proposals, could lead to greater State burden, while others, including MACPAC, recommended CMS offer more technical assistance and educational opportunities to support States, particularly those with limited expertise with Medicare and/or expertise with enrolling dually eligible individuals in managed care. Examples from these commenters included for CMS to work with States to share best practices for building infrastructure needed to facilitate alignment and to facilitate engagement between States, CMS, health plans, and other stakeholders to ensure a seamless transition. Another commenter expressed concern that the proposals combined with limited Medicare expertise among States could dissuade States from pursuing managed LTSS programs as part of the Medicaid programs in the future. Another commenter suggested CMS provide targeted resources to Medicaid agencies that would allow for systems upgrades to implement exclusively aligned enrollment. Another commenter suggested that a portion of the $2 billion CMS estimates in savings from these proposals could be allocated to support States including technical assistance, staffing, and modernization of systems to support integration. A commenter similarly noted that States need investments, both up front and through shared savings models, to invest in staff and systems changes necessary to integrated care.

Response: We appreciate and agree with the comments highlighting the need to support State Medicaid agencies in their efforts to integrate care for dually eligible individuals. We will continue to engage with States to promote integration, including through implementation of this final rule. Our technical assistance vendor, the Integrated Care Resource Center,[222] also provides a range of written and live resources targeted to State Medicaid staff, such as sample contract language for State Medicaid agency contracts with D–SNPs, tip sheets describing exclusively aligned enrollment and other operational processes that support Medicare and Medicaid integration, educational materials and webinars about D–SNPs and highlighting State strategies for integrating Medicare and Medicaid, and one-on-one and small group technical assistance.

Comment: Numerous commenters highlighted the impact of the enrollment limitation proposals on coordination-only D–SNPs. Several commenters noted that the proposals do not impact D–SNPs that do not also, directly or through an affiliated organization, contract with a State as a Medicaid MCO. These commenters expressed concern that this would afford unintegrated D–SNPs more flexibility than integrated D–SNPs, undermining CMS's goal to increase enrollment in integrated D–SNPs and may promote the proliferation of coordination-only D–SNPs. Many of these commenters encouraged CMS to extend the proposal to non-integrated D–SNPs by limiting the number of coordination-only D–SNPs offered by the same parent organization operating in the same service area. A commenter suggested that the enrollment limitation proposals could create churn between unaligned and aligned D–SNPs. Another commenter suggested CMS take steps to reduce the availability of non-integrated D–SNPs, particularly in service areas where integrated D–SNPs are available, by requiring that non-integrated D–SNPs only enroll people who are not enrolled in a Medicaid MCO. Another commenter expressed support for discontinuing coordination-only D–SNPs in 2027. In contrast, another commenter noted the role coordination-only D–SNPs play in providing a starting point for States on which to

[222] *http://www.integratedcareresourcecenter.com.*

build integrated care programs. They further requested CMS require States to support coordination-only D–SNPs as an option for partial-benefit dually eligible individuals as a condition of application of these requirements in order to ensure access for partial-benefit dually eligible individuals and to enable enrollment in coordination-only D–SNPs throughout the transition.

Response: We appreciate the commenters' perspectives. We clarify that we did not propose to eliminate coordination-only D–SNPs in 2027. As we described in the proposed rule (88 FR 78575), it may seem that our proposal on limiting enrollment in D–SNPs offered by MA organizations with affiliated Medicaid MCOs, in isolation, would disadvantage parent organizations that choose to offer Medicaid MCOs as well as D–SNPs because such organizations would be limited in the number of D–SNP offerings and would be required to align their enrollment between D–SNP and MCO for full-benefit dually eligible individuals. However, our SEP proposals would have the opposite effect by permitting enrollment into integrated D–SNP options that cover both Medicare and Medicaid benefits using the new integrated care SEP. Therefore, we believe our proposals, in combination, would maintain a high level of competition and choice, even while imposing some new constraints. While we thank the commenters for the suggestions on limiting the availability of unintegrated D–SNPs, we believe that they are beyond the scope of this current rulemaking and that such policies should be subject to advance notice and an opportunity to comment by all interested parties before we implement such changes. Finally, as noted in other comment responses, our proposals still would allow for parent organizations with an affiliated Medicaid MCO to continue offering (or newly offer) coordination-only D–SNPs for partial-benefit dually eligible individuals.

Comment: Some commenters expressed support for the exception to the D–SNP enrollment limitation proposed at § 422.514(h)(3)(i). Several of the commenters stated that the proposed exception preserves Medicaid agencies' ability to design D–SNP programs to meet specific populations' needs and requested CMS preserve this administrative flexibility. Another commenter agreed but cautioned this exception should be limited in scope. The commenter also recommend CMS consider adding another exception related to partial-benefit dually eligible enrollees.

Response: We thank the commenters for the support. We believe the exception at § 422.514(h)(3)(i), with the changes discussed in our responses to prior comments in this section, allows for States that currently have multiple integrated D–SNP programs based on age or benefit design in their Medicaid managed care programs to continue to operate these programs and allows States the flexibility to design future population-specific integrated D–SNP programs should they so choose. We agree that the exception should be limited in scope while allowing for this continued State flexibility.

We acknowledge commenters' concerns about the applicability to partial-benefit dually eligible individuals and, as addressed in a previous response, we reiterate that the limitations proposed and finalized at §§ 422.514(h)(1)(ii) and 422.514(h)(2) are specific to enrollment of full-benefit dually eligible individuals and D–SNPs that are open to enrollment by full-benefit dually eligible individuals. An MA organization can continue to offer one or more D–SNPs for partial-benefit dually eligible individuals when it has a SMAC and meets all other applicable requirements even if the MA organization, its parent organization, or another entity (or entities) that share a parent organization with the MA organization offer an affiliated Medicaid MCO in the same service area. Therefore, we do not believe that an additional exception to the enrollment limitations in § 422.514(h)(1) and (2) is necessary to ensure D–SNP enrollment opportunities for partial-benefit dually eligible individuals.

Comment: Several commenters raised questions regarding the timing of the proposals to increase the percentage of dually eligible individuals in aligned plans for Medicare and Medicaid (that is, when the D–SNP limitations will first apply). A few commenters recommended that provisions to limit D–SNP enrollment be implemented before the proposed date of 2027, while several commenters requested that implementation of these provisions, and specifically the proposed SEPs, be delayed. Another commenter indicated that it was unclear when the proposed changes would go into effect.

Response: We thank the commenters for their questions and suggestions regarding the timing of the proposals related to increasing aligned enrollment for dually eligible individuals. As finalized, the SEP policies in §§ 423.34(c)(4)(i) and (c)(35) will be applicable for enrollments that take effect on or after January 1, 2025, while the D–SNP limitation policies will apply as follows:

- The restriction on an MA organization offering more than one D–SNP for full-benefit dual eligible individuals in the same area where the MA organization has an affiliated Medicaid MCO will apply to contract years beginning on and after January 1, 2027 under § 422.514(h)(1)(i) (see also §§ 422.503(b)(8) and 422.504(a)(20), which require compliance with § 422.514(h)).
- The limit on new enrollment in a D–SNP offered by an MA organization with an affiliated Medicaid MCO in the same service area to individuals who are enrolled in or in the process of enrolling in the affiliated Medicaid MCO will apply to contract years beginning on and after January 1, 2027 under § 422.514(h)(1)(ii) (see also §§ 422.503(b)(8) and 422.504(a)(20), which require compliance with § 422.514(h)). This provision will apply to new enrollments and will not require the D–SNP to disenroll previously enrolled individuals (whether partial-benefit dually eligible individuals or full-benefit dually enrolled individuals) who are not also enrolled in the affiliated MCO.
- The limit on enrollment and continued enrollment or coverage for a D–SNP that is subject to § 422.514(h)(1) to only full-benefit dual eligible individuals who are also enrolled in or in the process of enrolling in the affiliated Medicaid MCO will apply to contract years beginning on and after January 1, 2030 under § 422.514(h)(2) (see also §§ 422.503(b)(8) and 422.504(a)(20), which require compliance with § 422.514(h)). This provision will require the D–SNP to disenroll individuals who do not meet the enrollment limitation requirements beginning January 1, 2030.
- The exceptions in § 422.514(h)(3) will apply on the same schedule as the new limitations and restrictions in § 422.514(h)(1) and (2).

We believe these timelines give CMS, States, and MA organizations an appropriate amount of time to make necessary policy and operational updates.

Comment: Many commenters raised operational concerns on, or provided suggestions for, our proposed enrollment limitations. Several commenters requested that CMS confirm the applicability of the proposals to integrated D–SNPs in ''direct capitation arrangements.'' One commenter suggested that in 2027, the alignment proposal would require States to change their processes and would require CMS to create a new process

that links D–SNPs with their affiliated Medicaid MCOs in order to implement the new enrollment limitations. Another commenter raised concerns with respect to State Medicaid auto-assignment processes, stating that dually eligible individuals could find themselves enrolled in a Medicaid plan and a D–SNP from the same organization without making any choice under our proposal. Another commenter expressed concern about the States transitioning the Financial Alignment Initiative (FAI) to D–SNPs in 2026, suggesting those States will be aligning enrollment based on the organization that provides Medicare coverage. The commenter requested that we adjust the timing of the implementation of the proposals to better align with the sunsetting of the FAI demonstrations. Finally, a commenter expressed concerns with the proposed § 422.514(h)(2) based on the commenter's belief that the rule would require certain individuals to be disenrolled both from their D–SNP and Medicaid MCO in 2030 and requested that CMS provide more clarity that D–SNP deeming would occur before a disenrollment.

Response: We thank the commenters for their questions and suggestions. First, we clarify that § 422.514(h), both as originally proposed and as finalized, applies to MA organizations that offer a D–SNP and where the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO and receives capitation payments from the State. This would include what a commenter referred to as ''direct capitation arrangements.''

We also clarify that we did not propose (and are not finalizing) any changes to the process or mechanism for how a dually eligible individual may elect a D–SNP. There is no passive enrollment of individuals into MA plans—including D–SNPs—aside from what is described at § 422.60(g). We did not propose (and are not finalizing) changes to default enrollment provisions or any other passive enrollment provisions for D–SNPs. In addition, we did not propose (and are not finalizing) any changes to the regulation at § 438.54 governing the enrollment process States must use for their Medicaid managed care plans (which may include passive and/or default enrollment procedures).

We clarify that our enrollment limitations at § 422.514(h) apply to D–SNPs regardless of integration status—including HIDE, FIDE, and coordination-only D–SNPs—so long as that D–SNP has an affiliated Medicaid MCO that serves full-benefit dually eligible enrollees in the same service areas as the D–SNP. We acknowledge that the policy will likely mostly apply to D–SNPs with HIDE and FIDE designations, but there are also examples of coordination-only D–SNPs achieving AIP status despite Medicaid benefit carve-outs, as is the case in California. See § 422.561, paragraph (2)(ii).

We understand commenters' concerns with respect to the potential need for States to change operations in reaction to the new D–SNP enrollment restrictions proposal, but we believe the requirements are broad enough that they may accommodate a variety of operational strategies for aligning enrollment between D–SNPs and Medicaid MCOs. For example, we do not believe changes to Medicaid auto-assignment processes will be uniformly required. However, because alignment of new enrollments is not required under § 422.514(h) until 2027 and full alignment is not required until 2030, we believe there is adequate lead time for States and D–SNPs to consider implications of the proposals and adjust operations as needed.

We acknowledge commenters' concerns with respect to the regulation's impact in 2030, when D–SNPs impacted by § 422.514(h) will only be permitted to cover enrollees who are full-benefit dually eligible individuals and enrolled in an affiliated Medicaid MCO. We clarify that there is no requirement that an unaligned enrollee be disenrolled *from a Medicaid MCO* in either 2027 or 2030 as a result of these proposals. The required disenrollment would be *from the D–SNP,* beginning January 1, 2030. In a scenario where a full-benefit dually eligible individual has unaligned enrollment (meaning enrollment in a Medicaid managed care plan other than the Medicaid MCO that is affiliated with the D–SNP), the D–SNP would be required to disenroll the individual, who would remain enrolled in the unaffiliated (unaligned) Medicaid managed care plan, subject to the enrollment rules for the State's Medicaid program. The D–SNP disenrollment must comply with existing rules on disenrollment due to a loss of eligibility. We anticipate D–SNPs will work to align as many enrollees in their affiliated Medicaid MCOs as soon as possible in advance of 2030 but acknowledge that the subsequent disenrollment of unaligned enrollees from the *D–SNP* may be disruptive. We believe the long-term benefits of these provisions—which will increase the number of enrollees in aligned Medicare and Medicaid plans—outweigh the potential disruptions the proposals may cause.

We also note that § 422.514(h) permits D–SNPs to implement periods of deemed continued eligibility to retain enrollees who temporarily lose Medicaid coverage as described in § 422.52(d). These deeming periods are optional unless a State directs a D–SNP to offer a minimum deeming period (which must not exceed 6 months) in the SMAC contract.

We appreciate the comments about States actively working to transition their FAI demonstrations to integrated D–SNPs in 2026. We are working closely with each of these States to keep as many Medicare-Medicaid Plan enrollees as possible connected with integrated care in 2026. Many of these States are currently working on operational processes for exclusively aligned enrollment for their new integrated D–SNP programs, and we do not expect that State operational choices for this program will conflict with any provisions at § 422.514(h). We do not agree that adjustments to the timeline of the D–SNP enrollment restrictions policy are necessary to effectively transition the demonstrations to integrated D–SNPs in 2026.

Comment: Another commenter supported CMS's goal to align D–SNPs with Medicaid MCOs for greater integration but expressed concerns that the rulemaking may negatively affect enrollees if the service areas or provider networks of the Medicare and Medicaid plans are not fully congruent and strongly urged CMS to require full network alignment and transparency before considering a plan to be integrated.

Response: We appreciate the comment. While we agree that completely aligned service areas may provide better transparency to enrollees and options counselors, we clarify that—aside from the service area alignment requirement for FIDE SNP and HIDE SNP designations for 2025 as articulated in the definitions in § 422.2—there is no current requirement nor are we finalizing any requirement that parent organizations offering D–SNPs adjust their service areas to exactly match the service areas of the affiliated Medicaid MCOs. Neither our enrollment limitation proposals nor the enrollment limitation policies we are finalizing have any direct impact on current Medicare or Medicaid network requirements. Nonetheless, we will monitor implementation and assess opportunities to further improve enrollee experiences.

Comment: Numerous commenters raised questions on the operations of

aligning enrollment in Medicare and Medicaid coverage under proposed §§ 422.514(h)(1)(ii) and 422.514(h)(2). A few commenters asked CMS to clarify how these proposals would be implemented in States where exclusively aligned enrollment (EAE) is already in place. In some of these States, dually eligible individuals elect AIP D–SNPs and the State matches the aligned Medicaid plan to the D–SNP; commenters asked CMS to clarify whether that arrangement would remain acceptable under the proposed rule, or if CMS was proposing that the Medicaid MCO be the ''lead'' plan. A few other commenters asked if CMS would use passive enrollment authority to align dually eligible individuals into integrated D–SNPs as a result of this policy. Finally, another commenter requested CMS allow States to implement Medicaid plan enrollment policies, including matching policies, that allow for disenrollment or switching Medicaid plans when a dually eligible individual is electing to enroll in a D–SNP. The commenter also requested that CMS clarify whether D–SNPs could outreach to and encourage unaligned enrollees to enroll in that organization's aligned Medicaid MCO.

Response: We thank the commenters for the questions on the operational impacts of the proposals at §§ 422.514(h)(1)(ii) and 422.514(h)(2). We clarify that we are not requiring that the Medicaid MCO be the ''lead'' plan for the purposes of operationalizing aligned enrollment or EAE, and we believe the requirements as proposed are broad enough that they may accommodate a variety of operational strategies for aligning enrollment between D–SNPs and Medicaid MCOs. Our intent is to strive toward aligned enrollment in D–SNPs—particularly in States that have Medicaid managed care but no EAE requirements—without significantly disrupting current State policies, operations, and program design. This rule does not amend or revise the Medicaid managed care enrollment and disenrollment requirements in §§ 438.54 and 438.56, so the existing flexibilities States have for their Medicaid managed care programs are undisturbed.

With respect to States that have already implemented EAE by ''matching'' Medicaid managed care plan enrollment to an enrollee's D–SNP selection, we confirm that this approach is compatible with the policies proposed and finalized at §§ 422.514(h)(1)(ii) and 422.514(h)(2). For States that have yet to implement EAE but wish to set up systems and operations that would allow their D–SNPs to operate with EAE, we are committed to collaborate on finding feasible operational processes that work best for them, with the aim of being as flexible as possible with the least disruption for dually eligible individuals.

We confirm there is no passive enrollment of individuals into MA plans—including D–SNPs—aside from what is described at § 422.60(g). We did not propose (nor are we finalizing) changes to default enrollment provisions at § 422.66(c) or any other passive provisions in conjunction with our proposals.

Finally, we confirm that no Medicare regulations prohibit D–SNPs from outreach to their current unaligned enrollees. However, there may be additional restrictions to this type of outreach regarding enrollment in a Medicaid managed care plan in State statute, regulations, or SMAC provisions.

Comment: A few commenters raised concerns about the applicability of the enrollment limitations policies on unique Medicaid managed care programs like in Oregon and Puerto Rico. A few commenters raised Oregon's CCOs that consist of a partnership of payers, providers, and community organizations that work at the community level with a community-based governance structure to provide coordinated health care for Oregon Medicaid enrollees. The commenter noted that this model does not currently allow the State to adopt integrated D–SNPs in all circumstances, because in some cases the CCO that holds the Medicaid contract is not under the same parent organization as the D–SNP, which is required for a D–SNP to achieve HIDE or FIDE status. Commenters suggested that CCOs currently provide the level of coordination and integration that CMS is seeking to encourage under this proposed rule and asked CMS to apply the enrollment limitations policy at the CCO level in Oregon. Another commenter questioned whether the proposal that requires an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization to only offer one D–SNP for full-benefit dually eligible individuals in a service area would impact the Medicare Platino program in Puerto Rico. The commenter notes this program has four MA organizations contracted, and these organizations typically offer six D–SNP options each.

Response: We appreciate comments with respect to the applicability of the policy in unique markets like Oregon and Puerto Rico. It is our understanding that most D–SNPs in Oregon already qualify as HIDE SNPs, however we acknowledge there are regulatory barriers for some Oregon D–SNPs to achieve greater integration statuses as defined by CMS and as such cannot be considered affiliated with a Medicaid MCO for the purposes of the proposed requirements at §§ 422.514(h)(1)(ii) and 422.514(h)(2). We will consider future rulemaking to take into account unique organizational structures that may hinder integration efforts as in the case of Oregon.

We understand that Puerto Rico directly contracts with 26 AIP HIDE SNPs, operated by four parent organizations for 2024, with a great deal of service area overlap between these D–SNPs. As is the case in the Platino program, wherever an MA organization that offers a D–SNP, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid MCO for full-benefit dually eligible individuals and receives capitation payments from the State, we consider the D–SNP and Medicaid MCO to be ''affiliated'' under § 422.514(h). MA organizations that offer multiple D–SNPs participating in the Platino program in Puerto Rico will be required to only offer one D–SNP starting in 2027 for full-benefit dually eligible individuals in a service area where the MA organizations, their parent organizations, and entities that share parent organizations with the MA organizations also offer an affiliated Medicaid MCO unless those D–SNPs meet the exception proposed at § 422.514(h)(3)(i). We acknowledge that MA organizations operating in Puerto Rico may choose to consolidate D–SNPs in order to comply with § 422.514(h) and are finalizing the proposed crosswalk exception at § 422.530(c)(4)(iii) to minimize enrollee disruption in connection with such contract consolidations.

Comment: A few commenters raised concerns about the proposed enrollment limitations resulting in negative impacts to the provider community. One commenter urged CMS to explore further how the proposals around integration affect physician and provider communities, specifically providers that serve a significant number of dually eligible individuals. The commenter noted that if there are changes in an individual's enrollment in and alignment with their Medicare and Medicaid benefits, their provider could also change and potentially disrupt continuity of care if that provider does

not have a relationship both with the MCO and the MA plan.

Response: We thank the commenters for their perspectives, but we believe that—because they are designed to increase the percentage of dually eligible enrollees who receive their Medicare and Medicaid benefits through the same organization—the enrollment limitations will ultimately simplify provider billing and lower the risk of inappropriate billing of dually eligible individuals which alleviates provider burden. We will continue to work with health plans, States, and the provider community to ensure providers have timely and accurate eligibility and enrollment information, which we acknowledge is crucial to providing effective and accurate care delivery and coverage for dually eligible individuals.

Comment: A number of commenters expressed support for, or provided questions about, the crosswalk exception proposed at § 422.530(c)(4)(iii) for MA organizations affected by the policies at §§ 422.514(h) and 422.504(a)(20). A few commenters noted the crosswalk exception would help maintain continuity and minimize confusion for enrollees. One commenter requested clarification regarding whether MA organizations can leverage the exception to crosswalk enrollees from a HIDE SNP to a FIDE SNP. The commenter also recommended CMS provide clarifications on the crosswalk methodology and criteria, including if enrollees can only be crosswalked from the affiliated Medicaid plan or if enrollees from another organization's Medicaid plan could also be crosswalked. Another commenter requested clarification regarding whether the crosswalk exception could be used to transition enrollees between D–SNPs that are ''cost-share protected and non-cost share protected.'' This commenter also requested CMS consider expanding the crosswalk flexibility to allow MA organizations to crosswalk enrollees—including full-benefit and partial-benefit dually eligible individuals—across different types of D–SNPs. Another commenter encouraged CMS to ease crosswalk opportunities to better capture the evolving needs of enrollees and State programs. The commenter recommended that CMS allow eligible enrollees from an existing unaligned D–SNP to be crosswalked to another existing unaligned D–SNP of the same plan type offered by the same parent organization but on a different contract to create additional interest from health plans to immediately reduce the volume of plan offerings, eliminating some marketplace confusion as States move along the path to integration.

Response: We appreciate the comments and requests for clarification on the proposed crosswalk exception. We clarify that the crosswalk exception at § 422.530(c)(4)(iii) will allow an MA organization, its parent organization, or an entity that shares a parent organization to crosswalk enrollees from one D–SNP to another across MA contracts, and not just plan benefit packages within a single MA contract, but only when the D–SNPs are being consolidated to a single D–SNP for a service area in order to comply with §§ 422.514(h) and 422.504(a)(20). We emphasize here that this crosswalk exception is about MA enrollment and will not change the Medicaid enrollment of any individual. The new crosswalks may be across contracts (that is, from one contract to another) and across related entities (that is, entities that share a parent organization) but must be of the same plan type; an MA organization may cross enrollees from one D–SNP PPO to another D–SNP PPO but may not crosswalk those enrollees to a D–SNP HMO under new § 422.530(c)(4)(iii). In addition, because this is a new crosswalk exception, the MA organization(s) involved in the crosswalk must request the crosswalk exception from CMS, which will review the request for compliance with the applicable regulation(s). The crosswalk exception is intended to promote continuity for enrollees when an organization consolidates D–SNP offerings in the same service area to comply with §§ 422.514(h) and 422.504(a)(20). If compliance with § 422.514(h) is not the basis for the crosswalk and the MA organization is not consolidating D–SNPs as part of that compliance, it will not be within the scope of new § 422.530(c)(4)(iii). Further the new crosswalk exception is not available until coverage for 2027.

Provided that the preconditions for the crosswalk exception at § 422.530(c)(4)(iii) are met, enrollees may be crosswalked from HIDE SNPs to FIDE SNPs, for example. We would not allow a D–SNP to crosswalk unaligned enrollees, or partial-benefit dually eligible enrollees, into a D–SNP required to operate with EAE, or into a D–SNP subject to the enrollment alignment requirements at § 422.514(h). Additionally, while plan types are taken into account for the purposes of enrollee crosswalks, plan benefit nuances like cost-sharing and supplemental benefits are not considered. Enrollees who are crosswalked into a D–SNP PBP with more cost-sharing responsibilities or different supplemental benefits than their prior D–SNP PBP would be notified of this change through the plan's Annual Notice of Change.

We note that all crosswalk and crosswalk exception requirements in § 422.530 still apply to MA organizations. We believe the new crosswalk exception and current crosswalk requirements offer sufficient flexibility and incentive for D–SNP sponsors to consolidate plan offerings and promote continuity for enrollees in D–SNP types that best meet their needs.

Comment: A few commenters opposed the proposal at § 422.514(h)(3)(ii), which states that an MA organization, its parent organization, or another MA organization that shares a parent organization with the MA organization may offer (or continue to offer) both an HMO and PPO D–SNP only if they no longer accept new enrollments from full-benefit dually eligible individuals in the same service area as the D–SNP affected by the new proposals at §§ 422.504(a)(20) and 422.514(h). The commenters note that the limitation does not consider product and service area differences that result from having two different D–SNP product types in the same State. Another commenter similarly argued that rural enrollees may need D–SNP PPO access as a result of provider scarcity and suggested that active travelers may value PPO coverage. Finally, another commenter believes that integration, care coordination, and financial alignment can occur even when an MA organization is operating both plan types in a service area, and that the policy unnecessarily limits enrollee plan choice and access to benefits.

Response: We thank the commenters for their perspectives. We recognize MA organizations may choose to adjust service areas as a result of this rulemaking and are not prohibited from providing PPO D–SNPs in more rural areas. As noted in the proposed rule (88 FR 78573), our goals include simplifying the D–SNP market for dually eligible individuals and promoting integrated care through aligned Medicare and Medicaid products. We believe § 422.514(h)(3)(ii), as finalized with clarifications, furthers longer term policy goals while minimizing enrollee disruption in the short term, particularly given that we are not changing the longstanding crosswalk limitations that prohibit enrollee crosswalks between plan types. An MA organization may encourage enrollees in its unaligned D–SNP to join the MA organization's integrated D–SNP and affiliated Medicaid MCO, as allowed in § 422.2264(b)(1) and

consistent with State marketing rules. To improve the clarity of the proposed exception at § 422.514(h)(3)(ii), we are revising the language to specify that if the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D–SNP(s) and PPO D–SNP(s), and one or more of the HMO D–SNPs is subject to § 422.514(h)(1), the PPO D–SNP(s) not subject to § 422.514(h)(1) may continue if they no longer accept new enrollment of full-benefit dual eligible individuals in the same service area as the plan (or plans) subject to § 422.514(h)(1). Likewise, if the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D–SNP(s) and PPO D–SNP(s), and one or more of the PPO D–SNPs is subject to § 422.514(h)(1), the HMO D–SNP(s) not subject to § 422.514(h)(1) may continue if they no longer accept new enrollment of full-benefit dual eligible individuals in the same service area as the plan (or plans) subject to § 422.514(h)(1).

Comment: A number of commenters recommended that CMS consider updates to MPF as part of implementing the SEP and enrollment limitation proposals. A few commenters encouraged CMS to develop a strategic communications plan for SEP changes affecting dually eligible individuals. The commenters suggested that CMS work with beneficiary advocates and consider how information is displayed on MPF and relayed through the Medicare call center(s) to make it easy to identify which plans are sufficiently integrated, both in general and for those using this SEP. Since the MA plan selections available during the SEP will differ significantly from open enrollment, other commenters suggested that CMS make updates to MPF that clearly delineate the integrated D–SNPs available based on the enrollee's service area, so they are easily recognizable for dually eligible individuals, caregivers, and SHIPs throughout the year. A commenter urged that CMS do more to convey the value and meaning of integrated D–SNP coverage options to ensure that potential enrollees do not feel they are being punished or limited by the narrower plan choice available when using the SEP but are getting an added benefit—the ability to enroll in a superior plan.

Related to the CMS's proposed enrollment limitations, a commenter noted the need for adding language to MPF explaining why individuals cannot choose a D–SNP listed on MPF, citing Medicare's history of ensuring choice in the Medicare program. Another commenter noted that the enrollment limitation on certain D–SNPs could result in increased confusion among individuals and enrollment counselors. Another commenter emphasized that if CMS adopts the proposal restricting FIDE SNPs to only enroll individuals enrolled in the affiliated Medicaid plan, it is critical for MPF to indicate which benefits are available through the affiliated Medicaid plans.

Response: We welcome the commenters' perspectives on the need for updates to MPF and other means of communication as we implement the SEP and enrollment limitations policies finalized in this rulemaking. As we noted in the proposed rule (88 FR 78574 through 78575), we will consider updates to the systems and supports designed to aid individuals in making Medicare choices. This will include MPF, 1–800–Medicare, HPMS, and other resources to help outline available choices to individuals, SHIP counselors, and others. We recognize such updates will be especially important where dually eligible individuals have choices that vary based on the type of plan and time of year and to clearly show only plans available to individuals along with MA plan options that align their MA coverage with their Medicaid enrollment. We plan to seek input from beneficiary advocates in these endeavors.

As we discuss further in section VIII.G of this final rule on our comment solicitation regarding improvements in MPF, for contract year 2025 we are working to add specific Medicaid-covered benefits to AIPs displayed on MPF.

Comment: A few commenters suggested CMS consider embarking on additional stakeholder engagement work prior to finalizing these proposals. A commenter recommended that CMS convene a diverse set of stakeholders, including consumer advocates and dually eligible individuals, States, and health plans, to minimize potential unintended consequences of the proposals, more robustly consider the unique experiences of Medicaid beneficiaries, and to fully account for the complexities of State Medicaid programs. Another commenter requested that CMS consult further with stakeholders regarding disenrollment processes for integrated plans since States may have different requirements than CMS and with which integrated plans must also align.

Response: We thank the commenters for their suggestion and appreciate the value of robust stakeholder engagement. As noted in the proposed rule (88 FR 78569 through 78571), the SEP and enrollment limitations proposals stemmed from feedback from States, advocacy organizations, health plans, and Medicare options counselors serving dually eligible individuals, among others. The proposals are also in line with previously suggested approaches from MedPAC. We will continue to collect feedback from stakeholders iteratively as we work alongside States and D–SNPs to implement these proposals and may consider future adjustments to the policies if unintended consequences arise.

Comment: Many commenters raised the need to provide technical assistance, funding, and/or sufficient time for training on the proposals to options counselors, SHIPs, and agents and brokers. Another commenter suggested CMS look for ways to enhance Medicare beneficiary education. Finally, a commenter raised the need for CMS to provide better education on the difference in FIDE SNPs and HIDE SNPs and how Medicaid programs cover cost sharing.

Response: We thank the commenters for their suggestions, and we agree it is important that dually eligible individuals understand their enrollment options. Options counselors as well as agents and brokers often play a critical role in assisting this population in making the critical health coverage choices. With respect to the SEP changes and education of SHIP counselors and agents and brokers, we believe that the proposals offer simplified choice options for dually eligible individuals throughout the calendar year, as there will no longer be a need to track quarterly SEP usage. We believe these changes increase transparency and reduce confusion for all parties. We are also considering updates to systems and supports designed to aid individuals in making Medicare choices, including Medicare Plan Finder. Additionally, we often conduct direct beneficiary research to improve our communication approaches with dually eligible individuals and plan to continue to do so in the future to help ensure information available to support individuals' choice of plans is accurate and understandable. We are committed to continuing to develop improved communication strategies and terminology that best resonates with this population as it relates to enrollment options and D–SNP benefits.

Comment: A few commenters stated there is a lack of data that shows integrated plans lead to better results for the populations they serve. A commenter cited a study from the JAMA Health Forum that examined the results

of several years of MA CAHPS surveys. When non-SNP plans were compared to FIDE SNPs, the study found that FIDE SNPs did not perform any better than coordination-only D–SNPs. The commenter also cited an additional study in JAMA Health Forum that compared outcomes between dually eligible enrollees in integrated plans to Traditional Medicare and did not find differences in the reduction of hospitalizations or improvements in care coordination and care management. The commenter indicated, citing these studies, the interconnected proposals would force dually eligible individuals into integrated D–SNPs that could cause harm to enrollees. They additionally cite a study from NORC on behalf of MACPAC where enrollees expressed greater satisfaction with coordination-only D–SNPs compared to those receiving higher levels of integration.

Another commenter acknowledged that the integrated model presents an opportunity for better outcomes and satisfaction but that isn't always the case. They cited MACPAC survey results conducted with enrollees in both integrated and coordination-only D–SNPs and found enrollees in ''highly integrated plans'' rated their plans slightly lower than those in the coordination-only D–SNPs and there were no meaningful differences between the experiences of dually eligible enrollees in plans with higher and lower levels of integration. The commenter added that there is a plethora of data to both support and refute integrated plans leading to better outcomes and without clear data, there can only be assumptions.

Response: We thank the commenters for their thoughts on the issue. While there is limited published research on the benefits of integrated care for dually eligible beneficiaries, we can point to published research from MedPAC, MACPAC, and other research bodies.[223] While some of this research states that evidence for integrated care is currently mixed, we noted in the proposed rule (88 FR 78567), we share MedPAC's belief ''that D–SNPs should have a high level of integration so they have the proper incentives to coordinate care across Medicare and Medicaid'' [224] and MACPAC's ''long-term vision is for all dually eligible beneficiaries to be enrolled in an integrated model.'' [225]

We look forward to more analysis on the experiences of dually eligible individuals and will continue to monitor the growing body of research, as well as continue to carry out our own monitoring, regarding integrated care so that dually eligible individuals have access to seamless, high quality health care.

Comment: A few commenters recommended CMS include an Ombudsman program in the proposal to help navigate the plan landscape for dually eligible individuals. A commenter requested additional flexibility and regulatory changes that would enable Medicaid services to be provided during a D–SNP's period of deemed continued eligibility. Another commenter noted that exclusively aligned enrollment does not address all organizational barriers and silos to system integration and care coordination. The commenter encouraged CMS to consider regulatory action that requires more substantial and meaningful changes to align Medicare and Medicaid to improve outcomes such as one joint health assessment, one personal care plan, one care coordinator, and one interdisciplinary care team across D–SNP and affiliated Medicaid MCO as well as total IT system integration. A commenter highlighted that State Medicaid programs differ, and CMS should establish guardrails and guidance, based on successful initiatives and best practices, to assist States in developing programs going forward. Another commenter was extremely concerned that CMS seems to be prioritizing private MCOs as the primary method of integrating care for dually eligible individuals.

A commenter cited MedPAC's 2013 report that noted I–SNPs perform better than other D–SNPs and other MA Plans on the majority of quality measures and had lower hospital re-admission rates that D–SNPs and C–SNPs. They recommend CMS consider I–SNPs when exploring opportunities for integration with a nursing facility population and provided several factors that could be attributed to I–SNPs achieving better outcomes compared to D–SNPs. Another commenter suggested CMS should enhance awareness of and access to PACE, which offers a truly integrated care option for dually eligible individuals. Another commenter encouraged States use LTSS accreditation programs to meet care coordination requirements for Medicare and Medicaid integration. A commenter recommended CMS implement process and outcome measures for D–SNP enrollee advisory committees (EAC), as increased transparency will help to ensure aspects of proposed regulations such as SSBCI and monthly SEPs have the impact they are intended to have. Another commenter expressed concern that there is a disparity in MA benchmark rates in Puerto Rico, as well as a lack of Medicare Savings Program and LIS benefits for dually eligible individuals in Puerto Rico.

Response: We appreciate the support from commenters who wish to further integrate Medicare and Medicaid benefits via integrated D–SNPs and note that CMS has made progress toward this goal in collaboration with State partners. We received a number of comments not strictly related to the proposals in the proposed rule. We acknowledge and appreciate the suggestions of commenters to include an Ombudsman program in our proposal, make additional regulatory changes around deemed continued eligibility when an individual loses Medicaid, incorporate additional ways to integrate care other than EAE, establish programs based on best practices, and implement process and outcome measures for D–SNP EACs. We also understand that I–SNPs play an important part for individuals receiving care in an institutional setting, the importance of PACE programs for individuals, and the role played by LTSS accreditation programs to meet care coordination requirements for Medicare and Medicaid integration. We recognize that there are lower MA benchmark rates in Puerto Rico and a lack of Medicare Savings Program and LIS benefits for dually eligible individuals. In addition, we acknowledge this final rule focuses largely on improving alignment for dually eligible individuals in Medicare and Medicaid managed care, but we point the commenter to the dual/LIS SEP (88 FR 78569) that allows dually eligible individuals to make a one-time per month election to leave an MA–PD for Traditional Medicare and a PDP. We truly appreciate all of these recommendations; however, these comments are outside the scope of this rulemaking. We will consider exploring opportunities for potential future

[223] See for example: MACPAC. 2020. *Evaluations of Integrated Care Models for Dually Eligible Beneficiaries: Key Findings and Research Gaps. https://www.macpac.gov/wp-content/uploads/2019/07/Evaluations-of-Integrated-Care-Models-for-Dually-Eligible-Beneficiaries-Key-Findings-and-Research-Gaps.pdf;* Anderson, W.Z. Feng, and S. Long. 2016 *Minnesota Managed Care Longitudinal Data Analysis.* Report to Office of Disability, Aging, and Long-Term Care Policy, Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//146501/MNmclda.pdf.*

[224] MedPAC response to Congressional request for information on dual-eligible beneficiaries, page 2, January 13, 2023.

[225] MACPAC response to proposed rule on policy and technical changes to Medicare Advantage and Medicare Part D for contract year 2024 (CMS–4201–P), page 1, February 13, 2023.

rulemaking to address some of these issues.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed amendment at § 423.38(c)(4) on the dual/LIS SEP.

We are finalizing with modifications our proposed amendment at § 423.38(c)(35) to add a new integrated care SEP; based on the comments we received we are narrowing the scope so that the SEP is available only to facilitate aligned enrollment as defined at § 422.2 (this limitation is reflected in a new paragraph at § 423.38(c)(35)(ii)) and clarifying in § 423.38(c)(35)(i) that the SEP is available only for full-benefit dually eligible individuals. Table HC3 summarizes the combined effects of the final SEP proposals.

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Table HF3: Enrollment scenarios under current rules and those finalized in this rulemaking—individual perspective *(Note-table does not include other applicable SEPs)*

Scenarios for dually eligible individuals	Current rules under quarterly dual/LIS SEP	Finalized monthly dual/LIS SEP, integrated care SEP, and enrollment limitations for non-integrated MA-PD plans
Elect any MA plan during initial coverage election period (ICEP) or annual election period (AEP), or switch between any plans during MA open enrollment period (MA-OEP)	Permitted	Permitted, except full-benefit dually eligible individuals in Medicaid MCOs would not be able to select a misaligned D-SNP where applicable[226]
Elect Medicare fee-for-service (FFS) and standalone prescription drug plan (PDP), mid-year	One change permitted per quarter (except the last quarter)	Permitted each month for all LIS eligible individuals and dually eligible individuals
Elect an integrated D-SNP (FIDE SNP, HIDE SNP, or AIP) as eligible, mid-year		Permitted each month for full-benefit dually eligible individuals and available only to facilitate aligned enrollment
Elect a non-integrated D-SNP or other MA plan, mid-year		Not permitted
Scenarios for LIS individuals without Medicaid	**Current rules**	**As finalized**
Elect any MA plan during ICEP or AEP, or switches between any plans during MA-OEP	Permitted	Permitted
Elect Medicare FFS and standalone PDP, mid-year	One change permitted per quarter (except the last quarter)	Permitted each month
Elect an MA plan, mid-year		Not permitted

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We are also finalizing without modification our proposed amendments at §§ 422.503(b)(8), 422.504(a)(20), and 422.530(c)(4)(iii) related to how MA organizations offer and enroll eligible individuals into D–SNPs. We are finalizing § 422.514(h)(1) with a modification to correct the terminology to use the term ''full-benefit dual eligible individual(s)'' where necessary. We are finalizing § 422.514(h)(2) with a modification to clarify that any D–SNP(s) subject to enrollment limitations in § 422.514(h)(1) may only enroll (or continue coverage of people already enrolled) individuals also enrolled in (or in the process of enrolling in) the Medicaid MCO beginning in 2030. We are finalizing with modifications our proposed amendment at § 422.514(h)(3)(i) to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization,

[226] During AEP and other available enrollment periods, MA organizations would not be permitted to enroll dually eligible individuals into a D–SNP where such enrollment would not result in aligned enrollment with an affiliated Medicaid MCO offered in the same service area (that is, a Medicaid MCO offered by the MA organization, its parent organization, or another subsidiary of the parent organization).

to offer more than one D–SNP for full-benefit dual eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO only when a SMAC requires it in order to differentiate enrollment into D–SNPs by age group or to align enrollment in each D–SNP with the eligibility criteria or benefit design used in the State's Medicaid managed care program(s). We are also finalizing with technical modifications our proposed amendment at § 422.514(h)(3)(ii) to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization that offers both HMO D–SNP(s) and PPO D–SNP(s) to continue to offer both the HMO and PPO D–SNPs only if the D–SNP(s) not subject to the enrollment limitations at § 422.514(h)(1) no longer accepts new full-benefit dual eligible enrollment in the same service area as the D–SNP affected by the new regulations at §§ 422.504(a)(20) and 422.514(h).

G. Comment Solicitation: Medicare Plan Finder and Information on Certain Integrated D–SNPs

Medicare Plan Finder (MPF) is an online searchable tool located on the Medicare.gov website that allows individuals to compare options for enrolling in MA or Part D plans. Medicare beneficiaries can also enroll in a plan using MPF. Each year, we work to improve its functionality by implementing enhancements to MPF. We solicited comment to inform our intent to improve MPF functionality in the future to make it easier for dually eligible MPF users to assess MA plans that cover their full array of Medicare and Medicaid benefits.

In the November 2023 proposed rule, we described at 88 FR 78576 how MPF displays benefits offered by MA and Part D plans, only displaying benefits that are included in the MA plan benefit package (PBP) (that is, Medicare Parts A and B benefits, Part D coverage, approved Medicare supplemental benefits, and Value Based Insurance Design (VBID)/Uniform Flexibility (UF)/ Supplemental Benefits for Chronically Ill (SSBCI)). For most MPF users, this represents the totality of their coverage.

We noted that for applicable integrated plans (AIPs), as defined at § 422.561, D–SNP enrollment is limited to those individuals who also receive Medicaid benefits through the D–SNP or an affiliated Medicaid managed care organization (MCO) under the same parent organization. For these D–SNPs, the benefits listed in MPF accurately reflect those covered by Medicare but do not reflect all the benefits available to all enrollees in the D–SNP.

We provided an example that in most States, all dually eligible individuals who qualify to enroll in an AIP would have access to Medicaid-covered non-emergency medical transportation (NEMT). However, MPF currently only displays NEMT as a covered benefit for any MA plan if it is also covered as an MA supplemental benefit. As such, all other things equal, an MA plan that offers NEMT as an MA supplemental benefit appears in MPF to have more generous coverage than an AIP that does not cover NEMT as an MA supplemental benefit but does cover it under the affiliated Medicaid MCO contract.

We noted in the proposed rule that information about only Medicare benefits covered by MA plans available to the individual, although accurate, may not provide as much information to dually eligible MPF users as would be beneficial, since the combination of available Medicare and Medicaid benefits available through some integrated D–SNPs may be greater than the Medicare benefits reflected in MPF. It may also create a perverse incentive for D–SNPs to offer certain types of supplemental benefits for Medicare marketing purposes even when the same services are already available to all enrollees in the plan through Medicaid.

We described our belief that there is an opportunity to better inform dually eligible MPF users. For AIPs, we noted that we were considering adding a limited number of specific Medicaid-covered benefits (for example, dental, NEMT, certain types of home and community-based services, or others) to MPF when those services are available to enrollees through the D–SNP or the affiliated Medicaid MCO. We indicated that we would limit this functionality to AIPs, because in such plans all enrollees—by definition—receive Medicaid benefits through the AIP.

We noted that we would not include in the MPF display any Medicaid benefits that are available but only through a separate carve-out. Consider, for example, a State in which NEMT is available to dually eligible individuals but through a Statewide vendor separate from the AIP. In this instance, displaying NEMT in MPF would accurately represent that all D–SNP enrollees have coverage for NEMT in Medicaid, but it would not accurately characterize the D–SNP's role (or the role of the affiliated Medicaid MCO offered by D–SNP parent organization) in delivering the service.

We continue to consider whether to indicate which services are Medicare supplemental benefits and which are Medicaid, weighing whether the additional information would be worth the added complexity.

We noted at 88 FR 78576 that displaying Medicaid benefits in MPF, even with the limitations described above, would present new operational challenges for CMS. We have not historically captured the necessary information for AIPs or other D–SNPs in a systematic manner to populate MPF with information about Medicaid benefits covered by D–SNPs, although we could potentially capture the necessary information by providing a mechanism for States or D–SNPs to report it to us annually using HPMS. We solicited comment on the practicality and means for accomplishing this. We also expressed interest in stakeholders submitting comments about any features from the My Care My Choice website at *https://mycaremychoice.org/en* that are particularly helpful for individuals in understanding and making plan choices.

Such enhancements to MPF would not require rulemaking. We solicited comments on the concepts described above to inform our decision about whether and how to implement changes to MPF along these lines.

We are not responding to each specific comment submitted on this comment solicitation, but we appreciate all the comments and interest on this topic. We will continue to take all concerns, comments, and suggestions into account as we work to address and develop policies on these topics and may reach out to commenters for further discussion. We provide a high-level summary of comments submitted regarding key topics raised by commenters.

Comment: Numerous commenters expressed support for improving MPF functionality for dually eligible MPF users, specifically by displaying Medicaid benefits on MPF. A few commenters recommended that CMS not exclude in the MPF display any Medicaid benefits that are available but only through a separate carve-out. A commenter requested that information added to the MPF for AIPs also include benefits available through Medicaid fee-for-service, such as dental. Another commenter agreed with CMS excluding carved-out Medicaid benefits from MPF.

Response: We appreciate the widespread support we received from commenters related to the concept of adding specific Medicaid-covered benefits to integrated D–SNPs displayed on MPF when those services are available to enrollees through the D–SNP or an affiliated Medicaid MCO. We are working on this for contract year

2025 and intend to include a limited number of specific Medicaid covered benefits on MPF when those services are available to enrollees through the D–SNP or the affiliated Medicaid MCO. We continue to improve functionality in MPF for dually eligible individuals, appreciate all the commenters' perspectives on improving their experience, and will consider them as we discuss future updates.

We also appreciate the commenters sharing their concerns about not displaying on MPF any carved out Medicaid benefits and including Medicaid FFS benefits. We will consider these suggestions as we discuss future updates to further enhance MPF functionality.

Comment: Several commenters expressed concern about the accuracy of the Medicaid benefit data and the ability to update it off-cycle. Some commenters also provided suggestions on the process for collecting the Medicaid benefits data. A commenter suggested that CMS consider developing, maintaining, and updating a list of Medicaid benefits covered by Medicaid MCOs in each State from State Medicaid agencies.

Response: We appreciate the commenters for sharing their concerns. Starting for contract year 2025, we plan to collect the Medicaid benefit data from the States using HPMS and will work with the States to verify its accuracy. In late summer each year, we provide two opportunities for MA plans to preview their upcoming contract year drug pricing and plan benefits prior to the data going live on MPF in October. We expect these to be opportunities to ensure accuracy of the Medicaid benefit data. We agree with the need to ensure the Medicaid benefit information is accurate and will consider the commenters concerns when implementing this process.

Comment: Several commenters believed that it was necessary to distinguish between Medicare supplemental and Medicaid benefits while a few did not. A commenter believed that dually eligible beneficiaries probably do not distinguish between the benefits they receive under Medicare and Medicaid.

Response: We appreciate the commenters sharing their perspectives. We will take the comments into consideration when weighing whether this additional information to distinguish whether benefits are covered under Medicare versus Medicaid is worth the added complexity.

Comment: Several commenters provided positive feedback on the My Care My Choice website saying that it was user-friendly and clearly conveyed complex information. A commenter did provide feedback from a study their organization conducted that indicated the tool was not being heavily used in the three focus group States and that the information it contained could be obtained through other resources.

Response: We appreciate commenters taking the time to provide feedback on their experiences with the My Care My Choice website and will consider the feedback as we discuss future updates to further enhance MPF's functionality.

Comment: Commenters also recommended:

- Updating the search and filtering options/functionality in MPF to prioritize D–SNPs over non-D–SNP MA plans when displayed on MPF.
- That the level of integration for D–SNPs be designated, defined, and/or prioritized for dually eligible users when using MPF to search for plans.
- Adding the ability for users to select more than one option on the ''Help with your costs'' MPF web page and concern that the results page still displayed Part B premiums for which dually eligible users may not be responsible.
- Providing definitions or explanations of terms and/or using more simplified language in general on MPF and specifically when describing D–SNPs and integrated plans.
- That MPF include functionality for more information about cost sharing and protections for dually eligible beneficiaries, for example by including the State Pharmaceutical Assistance Program in MPF.
- Including information about provider networks, Medicaid eligibility for D–SNPs, home and community-based alternatives like PACE.
- Displaying SHIP and/or state Medicaid agency contact information.

Response: We appreciate the commenters for sharing their perspectives. We will consider them as we discuss future updates to further enhance MPF's functionality.

H. Comment Solicitation: State Enrollment Vendors and Enrollment in Integrated D–SNPs

We, along with our State partners, have worked to create integrated care options for dually eligible individuals. When individuals choose to enroll, we want the enrollment process to be easy to navigate. Unfortunately, there remain technical challenges that can impede the ease of enrollment in integrated D–SNPs, including misalignment of Medicare and Medicaid enrollment processes, start dates, and related operational challenges for States and plans, as well as potentially confusing non-integrated enrollee communication materials.

In the November 2023 proposed rule, we described at 88 FR 78576 how, in the FAI, CMS delegated eligibility and enrollment functions for Medicare-Medicaid Plans (MMPs) to States by waiving regulations at 42 CFR 422, Subpart B, and how many States have leveraged their State Medicaid enrollment vendors (including enrollment brokers subject to the limitations in section 1903(b)(4) of the Act) to operationalize enrollment, eligibility, or both. The proposed rule outlined the multiple purposes State enrollment vendors serve within the FAI, including effectuating Medicare and Medicaid enrollment simultaneously, serving as an unbiased source of information, and reducing the risk of real or perceived conflicts of interest when plans initiate enrollment directly.

We also described how, outside of the FAI, dually eligible individuals elect MA plans, including D–SNPs, by enrolling directly with the plan, or through agents or brokers, or via 1–800-Medicare and the Medicare Online Enrollment Center. We noted how this creates special challenges for D–SNPs that have exclusively aligned enrollment (EAE) with affiliated Medicaid MCOs because these D–SNPs then need to separately coordinate enrollment of the dually eligible individual into the D–SNP's affiliated Medicaid MCO. We described how some States have expressed interest in leveraging State enrollment vendors, including enrollment brokers as described in section 1903(b)(4) of the Act, to effectuate EAE for integrated D–SNPs and their affiliated Medicaid MCOs.

We noted that we are assessing ways to promote enrollment in integrated D–SNPs, work toward an integrated D–SNP enrollment process that is operationally practical for CMS and States, create alignment—to the extent feasible—between Medicare and Medicaid managed care enrollment start and end dates, protect beneficiaries from abusive enrollment practices, and streamline beneficiary messaging and communication related to enrollment.

1. Current Opportunity for Use of State Enrollment Vendors for Enrollment in Integrated D–SNPs

In the proposed rule, we described at 88 FR 78577 how States can utilize Medicaid enrollment vendors for enrollment in integrated D–SNPs through requirements in the SMAC required by § 422.107. We use the term ''enrollment vendor'' as meaning

enrollment brokers that meet the requirements at section 1903(b)(4) of the Act and § 438.810. We noted that States may thus require D–SNPs to contract directly with the State's enrollment vendor to verify D–SNP eligibility and effectuate D–SNP enrollment transactions. We noted that while these contracts could govern the respective obligations of the broker and the D–SNP, they would have to be uniform for all D–SNPs in the State, and noted that in order to avoid a violation of section 1903(b)(4) of the Act and §§ 438.71(c)(2) and 438.810 regarding a broker having a financial interest in a provider or managed care plan in the State, the State (instead of the plan) would have to compensate its enrollment broker for performing these functions. We also noted how D–SNPs would still be subject to existing regulations at § 422.504(i), maintaining ultimate responsibility for adhering to and complying with all terms and conditions of their contract with CMS.

We described how States can implement, and require of D–SNPs, specific messaging directing dually eligible individuals to take enrollment actions via the State's enrollment vendor only, and how States could choose which functions to direct the D–SNPs to contract with the enrollment vendor for via the SMAC. We also described the process States could require of D–SNPs to verify eligibility and effectuate enrollment. We noted how requiring D–SNPs to contract with a State's enrollment vendor for enrollment and eligibility functions could create a simpler, streamlined enrollment experience for dually eligible individuals and may reduce the risk of misaligned Medicare and Medicaid enrollment. We described how, as in the FAI demonstrations, the State's enrollment vendor would need to implement Medicare managed care eligibility and enrollment policies. We also noted how, like the FAI demonstrations, States can prohibit D–SNPs, via SMACs, from using agents and brokers to perform the activities described in §§ 422.2274 and 423.2274.

We solicited comment on the feasibility of requiring integrated D–SNPs to contract with State enrollment brokers, as well as any specific concerns about States implementing it. We also solicited feedback on any concerns we should consider with States requiring (using the SMAC) D–SNPs to route enrollment through the State enrollment vendor, as well as whether there are any Federal regulations, other than or in addition to the limitations on enrollment brokers under section 1903(b)(4) and §§ 438.71(c) and 438.810, that interested parties view as an impediment to this option.

We are not responding to each specific comment submitted on this comment solicitation, but we appreciate all the comments and interest on this topic. We will continue to take all concerns, comments, and suggestions into account as we work to address and develop policies on these topics and may reach out to commenters for further discussion. We provide a high-level summary of comments submitted on a few key topics, including those we believe require clarification.

Comment: Several commenters expressed concern with requiring integrated D–SNPs to contract with State enrollment vendors and believed that CMS was proposing a Federal requirement to do so. A commenter stated that requiring D–SNPs to contract directly with State enrollment vendors would add administrative burden for plans, vendors, and enrollees and recommended that CMS not pursue this requirement. Another commenter expressed a belief that this proposal would restrict independent brokers from enrolling beneficiaries in D–SNPs. Another commenter encouraged caution and robust oversight if CMS decides to permit States to use enrollment vendors to enroll individuals dually eligible into D–SNPs.

Response: We clarify that we did not propose any new policy to impose a Federal requirement for D–SNPs to contract directly with State enrollment vendors. Rather, in the November 2023 proposed rule, we sought input on the feasibility of existing opportunities for States to require, through their SMACs, that D–SNPs contract with the State's enrollment vendors.

Comment: A number of commenters expressed support for the idea of States requiring D–SNPs to contract with State enrollment vendors for enrollment in integrated D–SNPs. Several commenters believed this approach could better align enrollment between a D–SNP and an affiliated Medicaid managed care plan and reduce the potential for misalignment. Some commenters emphasized that such an approach would require robust oversight, monitoring, and training for State enrollment vendors. A commenter recommended that CMS provide technical assistance to States to ensure vendors receive education on working with dually eligible individuals. Other commenters suggested that additional resources be invested in State Health Insurance Assistance Programs (SHIPs) as an alternative to requiring D–SNPs to contract with State enrollment vendors. A commenter noted that SHIPs are uniquely positioned to help dually eligible individuals understand their enrollment choices, and recommended CMS require SHIP contact information be included on all plan outreach to beneficiaries. Another commenter suggested that CMS work with States to create State-specific Medicare information.

Response: We thank the commenters for their support and feedback on this approach. These comments will help inform our work with State partners to promote enrollment in integrated care.

2. Medicaid Managed Care Enrollment Cut-Off Dates

The proposed rule described a challenge of applying FAI enrollment processes outside the demonstration context: alignment of Medicaid and Medicare managed care enrollment start and end dates. Sections 1851(f)(2) and 1860D–1(b)(1)(B)(iv) of the Social Security Act, and regulations codified at §§ 422.68 and 423.40(c) respectively, generally require that Medicare enrollments become effective on the first day of the first calendar month following the date on which the election or change is made, although section 1851(f)(4) of the Act and §§ 422.68(d) and 423.40(c) allow CMS flexibility to determine the effective dates for enrollments that occur in the context of special enrollment periods. Medicaid managed care regulations at § 438.54 do not specify the timelines or deadlines by which any enrollment must be effective.

We described how some States have cut-off dates after which enrollment in a Medicaid managed care plan is not effectuated until the first calendar day of the next month after the following month. If a dually eligible individual is trying to enroll in an integrated D–SNP at the end of a month in a State with a Medicaid managed care enrollment cut-off date, there could be a monthlong lag between their Medicare managed care effective date and Medicaid managed care effective date. We noted how the lag in start dates between Medicare and Medicaid services for an integrated D–SNP can be confusing to enrollees, operationally challenging for integrated plans, and difficult to describe in plan materials.

We noted our interest in learning more about reasons for implementing Medicaid managed care enrollment cut-off dates and the barriers, as well as potential solutions, to aligning Medicare and Medicaid managed care enrollment start and end dates. We solicited comment from interested parties, including States, D–SNPs, and Medicaid managed care plans, about their specific operational challenges related to

potential changes to Medicaid cut-off dates to align them with the Medicare start date. We also solicited comment on States' reasons for having a specific Medicaid managed care enrollment cut-off date in place.

We solicited comments on challenges individuals face when trying to enroll in integrated D–SNPs, as well as potential concerns stakeholders would have about CMS using flexibilities at section 1860D–1(b)(1)(B)(iv) of the Act and § 423.40(c) to determine effective dates for Medicare enrollments that occur in the context of our proposed special enrollment period for integrated care. We solicited comment on operational or systems barriers for States and Medicaid managed care plans to align disenrollment dates with Medicare. In addition to the above topics, we also solicited feedback on what type of technical assistance related to effectuating MA plan and D–SNP enrollment and eligibility processes would be helpful to States, what concerns should we consider about potential abusive enrollment practices, and on States' current requirements and policies related to agents and brokers. Finally, we solicited comments on whether other aspects of the integrated enrollment and disenrollment processes in FAI should apply to D–SNPs.

Comment: Several commenters believed that States have Medicaid managed care enrollment cut-off dates because of operational barriers. A commenter believed that cut-off dates allow for efficient planning and resource allocation, ensuring States can effectively manage and process a high volume of enrollments within a designated period. Some commenters expressed support for the idea of aligning Medicare and Medicaid enrollment effective dates, pointing out the challenges created by misaligned enrollment between D–SNPs and Medicaid managed care plans. However, most of these commenters cautioned that an approach would create substantial implementation challenges, including the need for system updates and training, as well as the potential for beneficiary confusion. Other commenters opposed the idea of aligning enrollment effective dates. A commenter did not believe this approach was feasible and believed it could harm consumers. Another commenter believed that if Medicare enrollment effective dates were aligned with Medicaid effective dates only in the context of AIPs, the commenter would be concerned about the added complexity this would create for organizations that operate additional D–SNP types (like coordination-only D–SNPs) alongside the AIPs. The commenter noted that having different enrollment effective dates for a subset of dually eligible individuals could also make it difficult for individuals to move seamlessly between D–SNP types when there are changes in eligibility.

Response: We thank the commenters for their input on these topics. While we are not responding to all specific comments submitted in response to this comment solicitation, we appreciate all of the comments and interest on these topics. These comments will inform our collaboration with States on D–SNP integration, and we will take them into consideration for potential future rulemaking.

I. Clarification of Restrictions on New Enrollment Into D–SNPs via State Medicaid Agency Contracts (SMACs) (§§ 422.52 and 422.60)

To elect a specialized MA plan for special needs individuals as defined at § 422.2 (special needs plans or SNPs), an individual must meet the eligibility requirements for the specific type of SNP in which the individual wishes to enroll. At § 422.52(b), we define the eligibility requirements for individuals to enroll in a SNP. These eligibility requirements indicate that an individual must meet the regulatory definition of a special needs individual at § 422.2, meet the eligibility requirements for the specific SNP they elect to enroll in, and be eligible to elect an MA plan under § 422.50. For D–SNPs, we also require at § 422.107(c)(2) that the categories and criteria for eligibility for dually eligible individuals to enroll in the SNP be included in the SMAC between the State and the D–SNP. D–SNPs must restrict enrollment eligibility categories or criteria consistent with the SMAC.

Currently, numerous States add eligibility categories and criteria to their SMACs that restrict new D–SNP enrollment to prioritize and promote integrated care. For example, some States only allow D–SNPs to enroll full-benefit dually eligible individuals. Other States only allow D–SNPs to enroll individuals who are also in an affiliated Medicaid managed care plan, creating exclusively aligned enrollment. State restrictions serve an important purpose in maximizing the number of dually eligible individuals who receive coordinated services through the same organization for both Medicare and Medicaid; minimizing disruption for enrollees currently served by existing D–SNPs; and allowing for the creation of D–SNP benefit packages that are tailored to certain subsets of dually eligible individuals.

State limitation of D–SNP enrollment to certain populations has been a feature throughout the history of D–SNPs. Nonetheless, we proposed regulatory amendments to further clarify our regulations.

We proposed to revise § 422.52(b)(2) to be explicit that to be eligible to elect a D–SNP, an individual must also meet any additional eligibility requirements established in the SMAC. We also proposed to revise § 422.60(a)(1) and add § 422.60(a)(3) to be more explicit that MA organizations may restrict enrollment in alignment with § 422.52(b)(2). Neither proposal is intended to change our longstanding policy. We do not expect any new burden associated with these proposed changes because States are already including eligibility categories and criteria in their SMACs and we are reviewing those accordingly.

We received the following comments on this proposal and respond to them below:

Comment: Several commenters expressed support for our proposed revisions at §§ 422.52(b)(2) and 422.60(a)(1). In outlining their support, a commenter requested that CMS be cognizant of State Medicaid procurement practices, timeframes, and underlying State regulations and noted that compliance with new Federal requirements may take time given reprocurement timeframes, contract amendment processes, and State regulatory policies that may need to be updated. A commenter indicated that describing the intersection with Medicaid coverage and State Medicaid requirements in MA rulemaking is an important step toward improved clarity and alignment for integrated programs. In supporting CMS's proposed clarifications, another commenter encouraged CMS to better educate States on MA enrollment requirements to avoid the inclusion of enrollment restrictions within the SMAC that would put a D–SNP at odds with MA enrollment requirements. This commenter noted that many States have shared their limited expertise and capacity to manage complex D–SNP policies and additional technical assistance and education are needed.

Another commenter noted that it did not object to CMS's proposal to make explicit that, to be eligible to elect a D–SNP, an individual must also meet any additional eligibility requirements established in the SMAC.

Response: We appreciate the commenters' support for our proposed clarifications. CMS provides technical assistance to States on enrollment related topics, including through the

Integrated Care Resource Center (see *https://www.integratedcareresourcecenter.com/*), and we will consider these comments as our technical assistance approaches evolve.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing without modification our proposed amendment at § 422.52(b)(2) to be explicit that, to be eligible to elect a D–SNP, an individual must also meet any additional eligibility requirements established in the SMAC. We are also finalizing without modification our proposed amendment to § 422.60(a)(1) and addition at § 422.60(a)(3) to be more explicit that MA organizations may restrict enrollment in alignment with § 422.52(b)(2).

J. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes (§ 422.514)

In the final rule titled Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program which appeared in the **Federal Register** on June 2, 2020 (*85 FR 33796*) (hereinafter referred to as the June 2020 final rule), we finalized the contracting limitations for D–SNP look-alikes at § 422.514(d) and the associated authority and procedures for transitioning enrollees from a D–SNP look-alike at § 422.514(e). For plan year 2022 [227] and subsequent years, as provided in § 422.514(d)(1), CMS does not enter into a contract for a new non-SNP MA plan that projects, in its bid submitted under § 422.254, that 80 percent or more of the plan's total enrollment are enrollees entitled to medical assistance under a State plan under Title XIX. For plan year 2023 and subsequent years, as provided in § 422.514(d)(2), CMS will not renew a contract with a non-SNP MA plan that has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a State plan under Title XIX, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

We established these contract limitations to address the proliferation and growth of D–SNP look-alikes, which raised concerns related to effective implementation of requirements for D–SNPs established by section 1859 of the Act (including amendments made by the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275) and the Bipartisan Budget Act of 2018 (Pub. L. 115–123)). We adopted the regulation to ensure full implementation of requirements for D–SNPs, such as contracts with State Medicaid agencies, a minimum integration of Medicare and Medicaid benefits, care coordination through health risk assessments (HRAs), and evidence-based models of care. In addition, we noted how limiting these D–SNP look-alikes would address beneficiary confusion stemming from potentially misleading marketing practices by brokers and agents that market D–SNP look-alikes to dually eligible individuals. For a more detailed discussion of D–SNP look-alikes and their impact on the implementation of D–SNP Medicare and Medicaid integration, we direct readers to the June 2020 final rule (85 FR 33805 through 33820) and the proposed rule titled Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (85 FR 9018 through 9021) (also known as the February 2020 proposed rule).

In the April 2023 final rule, we finalized amendments to close unforeseen loopholes in the scope of the regulation adopted to prohibit D–SNP look-alikes. Specifically, we finalized language at § 422.514(g) to apply the prohibitions on contracting with D–SNP look-alikes to individual segments of an MA plan. We also finalized language at § 422.514(d)(1) to apply the D–SNP look-alike contracting limitation to both new and existing (that is, renewing) MA plans that are not SNPs and submit bids with projected enrollment of 80 percent or more enrollees of the plan's total enrollment that are dually eligible for Medicare and Medicaid.

1. Reducing Threshold for Contract Limitation on D–SNP Look-Alikes

Our contracting limitations at § 422.514(d) mean that we do not contract with non-SNP MA plans that have enrollment consisting of 80 percent or more of enrollees who are entitled to Medicaid. We set the threshold at 80 percent or higher based on a 2019 MedPAC analysis that showed the proportion of dually eligible individuals in most geographic areas did not exceed the 80-percent threshold; [228] at that time, no MA plan service area had more than 50 percent dually eligible beneficiaries, and therefore dually eligible enrollment of 80 percent or greater would not be the result of any plan that had not intended to achieve high enrollment of dually eligible individuals (85 FR 33812). The 80-percent threshold also captured almost three-quarters of the non-SNP MA plans with more than 50 percent dually eligible enrollees (85 FR 33812).

In the June 2020 final rule, we stated that we would monitor for potential gaming after implementation of the final rule by reviewing plan enrollment data and consider future rulemaking as needed (85 FR 33812).

In response to our proposals to close unforeseen D–SNP look-alike loopholes in the April 2023 final rule, some commenters again recommended we lower the threshold to less than 80 percent (88 FR 22131). A few commenters recommended we lower the threshold below 80 percent without recommending a specific percentage, and other commenters recommended we lower the threshold to 50 percent. The commenters suggested that lowering the threshold further would promote integrated care and minimize beneficiary confusion. As one of these commenters, MACPAC noted that it ''remains concerned that while CMS's focus on plans where 80 percent or more of all enrollees are dually eligible addresses the most egregious instances, there could still be a real risk of growth in non-SNP MA plans falling below the 80-percent threshold and thus continuing to detract from Federal and State efforts to integrate care.'' We analyzed the percentage of non-SNP MA plans' dually eligible enrollment as a percentage of total enrollment from plan years 2017 through 2023. Our analysis shows that the number of non-SNP MA plans with high levels of dually eligible individuals has grown substantially.

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[227] We amended § 422.514(d)(1) in the April 2023 final rule, so the regulation text now refers to plan year 2024 and subsequent years; however, the regulation was in effect, with the reference to 2022 and subsequent years, as described here.

[228] See June 2019 MedPAC Report to Congress, Chapter 12 at *https://www.medpac.gov/wp-content/uploads/impart_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.*

TABLE HJ1: TOTAL NUMBER OF NON-SNPS BY DUALLY ELIGIBLE INDIVIDUALS AS PERCENT OF TOTAL ENROLLMENT AND YEAR

Year	Total Number of Non-SNP MA Plans with 50-60% Dually Eligible Individuals	Total Number of Non-SNP MA Plans with 60-70% Dually Eligible Individuals	Total Number of Non-SNP MA Plans with 70-80% Dually Eligible Individuals	Total Number of Non-SNP MA Plans with 50-80% Dually Eligible Individuals
2017	9	4	2	15
2018	13	6	5	24
2019	16	19	17	52
2020	30	18	17	65
2021	33	25	19	77
2022	58	35	26	119
2023	58	40	30	128
Percent growth from 2017 to 2023	544%	900%	1,400%	753%

Source: CMS analysis of Integrated Data Repository (IDR) data for January of each respective year. Analysis conducted in April 2023.

TABLE HJ2: TOTAL ENROLLMENT IN NON-SNP MA PLANS BY PERCENT OF DUALLY ELIGIBLE INDIVIDUALS ENROLLED AND YEAR

Year	Total Enrollees in Non-SNP MA Plans with 50-60% Dually Eligible Individuals	Total Enrollees in Non-SNP MA Plans with 60-70% Dually Eligible Individuals	Total Enrollees in Non-SNP MA Plans with 70-80% Dually Eligible Individuals	Total Enrollees in Non-SNP MA Plans with 50-80% Dually Eligible Individuals
2017	48,505	4,900	319	53,724
2018	49,367	4,180	3,737	57,284
2019	16,442	12,816	22,196	51,454
2020	85,320	24,281	28,019	137,620
2021	98,214	45,480	32,419	176,113
2022	137,380	70,348	35,313	243,041
2023	105,534	92,100	53,334	250,968
Percent growth from 2017 to 2023	118%	1,780%	16,619%	367%

Source: CMS analysis of Integrated Data Repository (IDR) data for January of each respective year. Analysis conducted in April 2023. This Table 2 reflects updates since the version of this table published in the November 2023 proposed rule, which only counted dually eligible enrollees in 2017 through 2022.

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The rate of growth from 2017 to 2023 in the number of non-SNP MA plans with 50 to 60 percent (544 percent increase), 60 to 70 percent (900 percent), and 70 to 80 percent dually eligible individuals as a percent of total enrollment (1,400 percent) [229] exceeded the rate of enrollment growth for all MA–PD plans (109 percent) over the same period of time.[230] The increased growth in non-SNP MA plans with dually eligible individuals between 50

[229] CMS analysis of Integrated Data Repository (IDR) data for January of each respective year. Analysis conducted in April 2023, as shown in Table 1.

[230] CMS data from the Contract Year 2021 and 2023 Landscape Plan shows the total number of MA–PD plans in 2017 was 2,332 and the total number of MA–PD plans in 2023 is 4,875.

and 80 percent of total enrollment suggests to us that MA organizations are offering plans for dually eligible individuals but circumventing rules for D–SNPs, including requirements from the Bipartisan Budget Act of 2018, and detracting from Federal and State efforts to better integrate Medicare and Medicaid benefits. This growth in enrollment in these non-SNP plans is likely also drawing enrollment from integrated care D–SNPs and similar integrated programs. Recent analysis found that almost one-third of dually eligible individuals newly enrolled in D–SNP look-alikes were previously enrolled in fully integrated dual eligible SNPs (FIDE SNPs), other D–SNPs, PACE plans, or MMPs.[231]

We also conducted analysis with 2023 data mimicking MedPAC's 2019 analysis showing the share of dually eligible individuals enrolled in non-SNP MA plans against the share of beneficiaries in a plan service area who are dually eligible individuals.[232] MedPAC's analysis showed that in most MA markets, the share of beneficiaries in a plan service area who are dually eligible was clustered in the 10 to 25 percent range and in no county exceeded 50 percent. Their analysis showed that dually eligible individuals generally represented 30 percent or less of non-SNP MA plans' total enrollment. MedPAC's analysis informed our decision to set the threshold for dually eligible enrollment at 80 percent of a non-SNP MA plan's enrollment because it far exceeded the share of dually eligible individuals in any given market (by 30 percentage points or more) at that point in time and, therefore, would not be the result for any plan that had not intended to achieve high dually eligible enrollment. Similar to the earlier MedPAC analysis, our analysis of 2023 data shows the share of beneficiaries in a plan service area who are dually eligible is clustered in the 10 to 30 percent range and does not exceed 49 percent except in one county (at 56 percent).[233] Also like MedPAC, we found that for most non-SNP MA plans, dually eligible individuals generally represent 30 percent or less of the plan's total enrollment. However, whereas MedPAC found 13 non-SNP MA plans with dually eligible enrollment between 50 percent and 80 percent for 2017,[234] we found 128 non-SNP MA plans with enrollment in that range for 2023.[235]

To address the substantial growth in non-SNP MA plans with disproportionately high enrollment of dually eligible individuals, we proposed lowering the D–SNP look-alike threshold from 80 percent to 60 percent incrementally over a two-year period. We proposed to lower the threshold for dually eligible enrollment to 60 percent of a non-SNP MA plan's enrollment because it exceeds the share of dually eligible individuals in any given MA plan service area currently and, therefore, would not be the result for any plan that simply reflected the concentration of dually eligible enrollees in its service area.

We proposed a limitation on non-SNP MA plans with 70 or greater percent dually eligible individuals for contract year 2025. For contract year 2026, we proposed to reduce the threshold from 70 percent to 60 percent or greater dually eligible enrollment as a share of total enrollment. This incremental approach would minimize disruptions to dually eligible individuals and allow MA organizations and CMS to operationalize these transitions over a two-year period. As discussed in more detail below, we would maintain processes to minimize disruption for the enrollees in plans affected by this proposed change.

Based on 2023 data, we stated in the November 2023 proposed rule that we expect the lower threshold would impact 30 non-SNP MA plans with dually eligible individuals representing 70 to 80 percent of total enrollment and 40 non-SNP MA plans with dually eligible individuals representing 60 to 70 percent of total enrollment. Some of the plans that could be affected by our proposal are offered in States (that is, California, Massachusetts, Minnesota) that limit contracting to integrated D–SNPs, such as FIDE SNPs and AIPs. Based on 2023 plan data, 12 non-SNP MA plans in California, Massachusetts, and Minnesota have shares of dually eligible enrollment between 60 and 80 percent. These States have chosen to limit their markets to certain D–SNPs to integrate Medicare and Medicaid for dually eligible individuals. Lowering the D–SNP look-alike contracting limitation to 60 percent will help to simplify choices for dually eligible individuals in these States and promote Medicare and Medicaid integration objectives.

We proposed revisions to the rule on dually eligible enrollment at § 422.514(d)(1) to apply the lower thresholds to new and existing non-SNP MA plan bids. Specifically, we proposed amending paragraph (d)(1)(ii) such that CMS would not enter into or renew a contract for a new or existing non-SNP MA plan that projects enrollment in its bid of 80 percent or more dually eligible individuals for plan year 2024 (as is already the case under current regulations); 70 percent or more dually eligible individuals for plan year 2025; and 60 percent or more dually eligible individuals for plan year 2026 and subsequent years. Consistent with our current practice, we would apply the proposed changes at § 422.514(d)(1)(ii) to all bids for the next plan year, including any bids for non-SNP MA plans projected to exceed the threshold even if the actual enrollment for the current plan year is under the threshold at § 422.514(d)(1).

Similarly, we proposed revisions to paragraph (d)(2) to apply the lower thresholds to non-SNP MA plan enrollment. Specifically, we proposed to amend paragraph (d)(2)(ii) to state that we will not renew a contract with a non-SNP MA plan that has actual enrollment, using January enrollment of the current year, in which dually eligible individuals constitute 80 percent or more dually eligible individuals for plan year 2024 (as is already the case under current regulations); 70 percent or more dually eligible individuals for plan year 2025; or 60 percent or more dually eligible individuals for plan year 2026 or subsequent years. In operationalizing these proposed changes, for example, we would use January 2024 enrollment data to identify non-SNP MA plans that exceed the proposed 70-percent threshold, for purposes of determining whether to renew contracts with these plans for plan year 2025. We would use January 2025 enrollment data to identify non-SNP MA plans that exceed the proposed 60-percent threshold for purposes of determining whether to renew contracts with these plans for plan year 2026. Consistent with existing rules, we would not apply the contracting limitation in § 422.514(d)(2) to any non-SNP MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals.

[231] Ma, Y., Frakt, A., Roberts, E., Johnston, K., Phelan, J., and Figueroa, J. ''Rapid Enrollment Growth In 'Look-Alike' Dual-Eligible Special Needs Plans: A Threat To Integrated Care'' *Health Affairs* (July 2023) 919–927. Retrieved from *https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00193.*

[232] See June 2019 MedPAC Report to Congress, Chapter 12 at *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.*

[233] CMS analysis of 2023 non-SNP MA plan data in the IDR. Analysis conducted in April 2023, as shown in Table 1.

[234] June 2019 MedPAC Report to Congress, Chapter 12, calculated from Table 12–9 at *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.*

[235] CMS analysis of 2023 non-SNP MA plan data in the IDR. Analysis conducted in April 2023, as shown in Table 1.

We solicited comments on whether an alternative to reduce the threshold to 50 percent is more appropriate to protect against plans circumventing the requirements for D–SNPs while enrolling a disproportionate number of dually eligible individuals.

2. Amending Transition Processes and Procedures for D–SNP Look-Alikes

Section 422.514(e) establishes parameters for transitioning individuals who are enrolled in a D–SNP look-alike to another MA–PD plan (or plans) offered by the MA organization to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. Under the existing processes and procedures, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in proposed paragraph (d)(2) could transition enrollees into another MA–PD plan (or plans) offered by the same MA organization, as long as any such MA–PD plan meets certain proposed criteria. This transition process allows MA enrollees to be transitioned at the end of the year from one MA plan offered by an MA organization to another MA–PD plan (or plans) without having to complete an election form or otherwise indicate their enrollment choice as typically required, but it also permits the enrollee to make an affirmative choice for another MA plan or standalone Part D plan of his or her choosing during the annual election period (AEP) preceding the year for which the transition is effective. Consistent with our description of the transition process in the June 2020 final rule (85 FR 33816), if a transitioned enrollee elects to enroll in a different plan during the AEP, enrollment in the plan the enrollee selected would take precedence over the plan into which the MA organization transitioned the enrollee. Transitioned enrollees would also have additional opportunities to select another plan through the Medicare Advantage Open Enrollment Period described in § 422.62(a)(3) from January 1 through March 31. Affected individuals may also qualify for a SEP, depending on the circumstances.

Existing provisions at paragraphs (e)(1)(i) through (iv) outline specific criteria for any MA plan to receive enrollment through this transition process to ensure that enrollees receive coverage under their new MA plan that is similarly affordable as the plan that would not be permitted for the next year. At existing paragraph (e)(1)(i), we allow a non-renewing D–SNP look-alike to transition that plan's enrollment to another non-SNP plan (or plans) only if the resulting total enrollment in each of the MA plans receiving enrollment consists of less than the threshold established in paragraph (d)(2)(ii) (now, 80 percent but with the proposed amendment, this would refer to the scheduled change in the threshold). SNPs receiving transitioned enrollment are not subject to this proposed limit on dually eligible individual enrollment. Under existing paragraph (e)(1)(ii), we require that any plan receiving transitioned enrollment be an MA–PD plan as defined in § 422.2. Under existing paragraph (e)(1)(iii), any MA plan receiving transitioned enrollment from a D–SNP look-alike is required to have a combined Part C and D beneficiary premium of $0 after application of the premium subsidy for full subsidy eligible individuals described at § 423.780(a). Finally, paragraph (e)(1)(iv) requires that the receiving plan be of the same plan type (for example, HMO or PPO) of the D–SNP look-alike out of which enrollees are transitioned.

At existing paragraph (e)(2)(ii), the current transition process requires MA organizations to describe changes to MA–PD benefits and provide information about the MA–PD plan into which the individual is enrolled in the ANOC that the MA organization must send, consistent with § 422.111(a), (d), and (e) and § 422.2267(e)(3). Consistent with § 422.111(d)(2), enrollees receive this ANOC describing the change in plan enrollment and any differences in plan enrollment at least 15 days prior to the first day of the AEP.

At existing paragraph (e)(4), the regulation addresses situations where the prohibition on contracting or renewing a D–SNP look alike is applied and the D–SNP look alike is terminated. In such situations where an MA organization does not transition some or all current enrollees from a D–SNP look-alike to one or more of the MA organization's other plans as provided in proposed paragraph (e)(1), the MA organization is required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2).

This transition process is conceptually similar to ''crosswalk exception'' procedures at § 422.530(c). However, in contrast to the crosswalk exceptions, our transition process at § 422.514(e) permits transition across contracts and across MA organizations under the same parent organization, as well as from non-SNP plans to SNPs.

We proposed to apply the existing transition processes and procedures at § 422.514(e) to non-SNP MA plans that meet the proposed D–SNP look-alike contracting limitation of 70 percent or more dually eligible individuals effective plan year 2025 and 60 percent or more dually eligible individuals effective plan year 2026. Consistent with the initial years of implementation of the D–SNP look-alike contract limitations with the 80-percent threshold, maintaining these transition processes and procedures will help to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. However, for plan year 2027 and subsequent years, we proposed to limit the § 422.514(e) transition processes and procedures to D–SNP look-alikes transitioning dually eligible enrollees into D–SNPs. Based on our experience with D–SNP look-alike transitions effective plan year 2023, the vast majority of enrollees are transitioned to other MA–PDs under the same parent organization as the D–SNP look-alike. Based on our review of D–SNP look-alike transition plans thus far, we expect the experience for transitions effective plan year 2024 to follow a similar pattern. We proposed this new limitation on the transition process at new paragraph (e)(1)(v).

MA organizations can utilize other CMS processes to transition D–SNP look-alike enrollees to non-D–SNPs. For a more detailed discussion of these other CMS processes, we direct readers to the November 2023 proposed rule (88 FR 78582 through 78583).

While multiple options exist for MA organizations to transition D–SNP look-alike enrollees to other non-SNP MA plans, these pathways are not available for moving enrollees from D–SNP look-alikes to D–SNPs. Consistent with the November 2023 proposed rule, we believe it is appropriate to limit the transition process in § 422.514(e) since although other options remain available to transition enrollees from the D–SNP look-alike, MA organizations do not have other options to transition D–SNP look-alike enrollees into D–SNPs, and movement into D–SNPs encourages enrollment in integrated plans. Furthermore, we are concerned that if D–SNP look-alikes continue to be allowed to transition enrollees into non-D–SNPs indefinitely, there is little incentive for MA organizations to avoid non-compliance with the D–SNP look-alike thresholds. Thus, for plan year 2027 and subsequent years, we proposed to add new paragraph § 422.514(e)(1)(v) to limit the existing D–SNP look-alike transition pathway to MA organizations with D–SNP look-alikes transitioning enrollees into D–SNPs.

We are solicited comment on an alternative to our proposal that would

eliminate the 70-percent threshold applying for plan year 2025 but would involve additional conditions and changes related to the transition authority Specifically, this alternative would:

- Apply the 60-percent threshold beginning in plan year 2026;
- Permit use of the transition authority into non-SNP MA plans (as currently permitted under § 422.514(e)) for plan year 2025; and
- Limit use of transition authority under § 422.514(e) to transition D–SNP look-alike enrollees into D–SNPs for plan year 2026 and beyond.

Relative to our proposal, this alternative would give plans with dually eligible individual enrollment between 70 and 80 percent of total enrollment (based on January 2024 enrollment data) one additional year to apply for a new D–SNP or service area expansion to an existing D–SNP, such that these plans could transition enrollees into a D–SNP for plan year 2026. The alternative would balance the additional year using the existing 80-percent enrollment threshold to identify prohibited D–SNP look-alikes with an earlier limitation on the § 422.514(e) transition authority to enrollees transitioning into non-SNPs. We solicited comment on whether this alternative is a better balance of the goals of our policy to prohibit circumvention of the requirements for D–SNPs and to encourage and incentivize enrollment in integrated care plans. Among the factors we that stated that we would consider in adopting the alternative instead of our proposal is the extent to which plans with between 70 and 80 percent dually eligible enrollment in plan year 2024 expect to be able to establish a D–SNP in the same service area as the D–SNP look-alike if given an additional year (that is, 2026) to transition enrollees.

We also proposed a technical edit at § 422.514(e)(1)(i) to make the term ''specialized MA plan for special needs individuals'' lowercase, consistent with the definition of D–SNPs at § 422.2.

We received the following comments on this proposal and respond to them below:

Comment: Numerous commenters, including MACPAC and MedPAC, supported the proposal overall to lower the threshold used to identify D–SNP look-alikes to 70 percent dually eligible individuals for plan year 2025 and 60 percent dually eligible individuals for plan year 2026 and subsequent years and limit the D–SNP look-alike transition pathway to D–SNPs starting in plan year 2027.

A number of commenters emphasized the importance of dually eligible individuals having access to integrated care and that the D–SNP look-alikes interfere with those efforts. MedPAC referenced their June 2018 and June 2019 reports that discussed D–SNP look-alikes and expressed concern that D–SNP look-alikes undermine efforts to develop integrated plans for dually eligible individuals by encouraging them to enroll instead in plans that provide many of the same extra benefits as D–SNPs but do not integrate Medicaid coverage. MACPAC articulated that D–SNP look-alikes act at cross purposes to State and Federal efforts to integrate care by drawing dually eligible individuals away from integrated products and avoiding the additional requirements that D–SNPs must meet. Other commenters conveyed similar points in favor of CMS's proposal; D–SNP look-alikes work against the promotion of Medicare and Medicaid integration for dually eligible individuals, thus inhibiting improvements in coordination of care and attracting dually eligible individuals away from coordinated plan options. Other commenters supported the CMS proposal because it would further incentivize the enrollment of dually eligible individuals into D–SNPs, which are specifically designed for the population. A commenter did not believe that D–SNP look-alikes were a widespread phenomenon across regions but characterized them as substantial barriers to coordination of care for individuals in those regions where they exist. Another commenter stated that D–SNP look-alikes place responsibility on an enrollee to navigate two separate delivery systems.

In outlining their support for CMS's proposal, a number of commenters noted that D–SNP look-alikes are designed to attract dually eligible individuals but are not subject to the same requirements as a D–SNP, such as the model of care, coordination of Medicare and Medicaid benefits, and requirements for enrollee advisory input, designed specifically for dually eligible individuals. A commenter indicated that the contracting standards for D–SNP look-alikes should be consistent with the requirements for D–SNPs.

A number of commenters based their support for the CMS proposal on the expectation that it would simplify choices for dually eligible individuals and reduce aggressive marketing of D–SNP look-alikes. A commenter stated that D–SNP look-alikes introduce another layer of complexity and confusion for dually eligible individuals when selecting their plans, while not providing the coordination necessary for their enrollees to navigate Medicare and Medicaid programs. Other commenters noted that the proposed additional contract limitations for D–SNP look-alikes would ultimately help reduce confusion over plan offerings. Another commenter shared anecdotal evidence that marketing of D–SNP look-alikes, especially in nursing facilities, is confusing to potential enrollees. The commenter noted that D–SNP look-alikes may use aggressive marketing tactics and have zero-premium plans with many supplemental benefits, and thus these plans can look like a good deal to individuals. A few commenters stated that dually eligible individuals are often the least informed about their health insurance and that MA organizations exploit these individuals with D–SNP look-alikes when they would qualify for a D–SNP, which provides more comprehensive coverage. In advocating its support for the CMS proposal, another commenter indicated it had assisted dually eligible individuals who were targeted by D–SNP look-alikes, many of whom experienced complications related to Medicaid payment and crossover billing issues. A commenter advocated that third-party marketing agencies should be banned from marketing to dually eligible individuals and State Medicaid programs should prohibit using the enrollee list from different products for sales and outreach within the same company.

Other commenters shared CMS's concerns regarding the rapid growth of non-SNP MA plans with high levels of dually eligible individuals. Referencing their review of MA bid data for 2020, MACPAC noted that enrollment in non-SNP MA plans with more than 50 percent projected dually eligible enrollment grew by 23.4 percent from 2019 to 2020, but enrollment in D–SNPs grew by 13.9 percent over the same period. MACPAC expressed concern that enrollment growth in D–SNP look-alikes exceeded that of D–SNPs because many States rely on D–SNPs aligned with Medicaid managed care plans to integrate care for dually eligible individuals. Another commenter suggested that CMS's proposal is an essential step toward directly addressing concerns over the substantial growth in non-SNP MA plans with disproportionately high enrollment of dually eligible individuals. Another commenter indicated MA plans have continued to target dually eligible individuals by retaining enrollment just below 80 percent dually eligible enrollment.

A commenter indicated that CMS's phased approach would provide plans a

helpful ramp to carefully plan enrollee transitions. In addition, the commenter indicated that reducing the D–SNP look-alike threshold all at once could disrupt the marketplace and impact beneficiary coverage, which should be avoided.

Response: We appreciate the widespread support we received for our proposal to lower the D–SNP look-alike threshold over two years to 60 percent and to limit the D–SNP look-alike transition pathway to D–SNPs. Our proposal builds on the policies finalized in the June 2020 final rule to limit entering into or renewing contracts with non-SNP MA plans with high percentages of dually eligible enrollees and addresses the substantial growth in non-SNP MA plans with disproportionately high enrollment of dually eligible individuals. We believe the lower thresholds and restriction on D–SNP look-alike transitions under § 422.514(e) that we are finalizing in this rule will enable us to more effectively implement Medicare-Medicaid integration requirements under the BBA of 2018 along with other State and Federal requirements. Our proposal will support full implementation of requirements for D–SNPs, such as contracts with State Medicaid agencies, a minimum integration of Medicare and Medicaid benefits, care coordination through HRAs, and evidence-based models of care. We agree with the commenters that our proposal will simplify beneficiary choices, reduce beneficiary confusion stemming from potentially misleading marketing practices by brokers and agents that market D–SNP look-alikes to dually eligible individuals, and further promote enrollment in integrated care plans.

Comment: Numerous commenters supported the CMS proposal to lower the threshold and recommended that CMS lower the D–SNP look-alike threshold further below the proposed threshold of 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years.

A number of commenters suggested lowering the D–SNP look-alike threshold to 50 percent. A few commenters emphasized that a 50-percent threshold would be a more effective threshold for deterring MA plans from soliciting dually eligible individuals into non-SNP MA plans and ensure plans are not designed to target dually eligible individuals and circumvent statutory requirements for D–SNPs. Another commenter recommended the D–SNP look-alike threshold be lowered in subsequent years to 50 percent, with further reductions considered as the plan landscape and D–SNP integration continue to shift. Another commenter opined that any plan where more than 50 percent of the enrollment is comprised of people who are dually eligible should be subject to the same additional requirements and oversight as D–SNPs to protect enrollees. In referencing a recent study,[236] a commenter noted that there were more dually eligible individuals enrolled in the non-SNP MA plans where 50 percent or more of enrollees are dually eligible than there were enrolled in FIDE SNPs in 2020, and county level availability of non-SNP MA plans where 50 percent or more of enrollees are dually eligible also increased dramatically, from just 75 counties (fewer than 3 percent of U.S. counties) in 2013 to 1,318 counties (more than 40 percent of U.S. counties) in 2020. The commenter suggested that these data support lowering the D–SNP look-alike threshold to 50 percent. Citing prior MedPAC analysis, MACPAC explained that it considers D–SNP look-alikes to be plans where more than 50 percent of enrollees are dually eligible.[237]

Several commenters suggested lowering the threshold to 40 percent. A commenter suggested that CMS lower the D–SNP look-alike threshold to 50 percent in plan year 2025 and 40 percent in plan year 2026 and subsequent years, noting that the lower thresholds would make it more difficult for an MA organization to create a PBP that could undermine Medicare-Medicaid integration. A commenter recommended that CMS reduce the D–SNP look-alike threshold to 40 percent by 2026, emphasizing that the establishment of D–SNP look-alikes does not appear to be unintentional because these plans are often in areas where their ratios of enrollees do not mirror the general population ratio and many of D–SNP look-alike enrollees were previously enrolled in integrated D–SNPs. The commenter further supported a reduction to 40 percent since D–SNP look-alike growth has continued despite CMS' previous efforts to curtail the growth in D–SNP look-alikes, and these plans seem to just come under the threshold CMS sets. Another commenter requested that CMS consider lowering the threshold to 40 percent by 2030.

A few other commenters recommended that CMS consider D–SNP look-alike thresholds below 70 percent in plan year 2025 and 60 percent in plan year 2026 and subsequent years but did not specify a percentage.

A commenter specifically noted that it did not support lowering the D–SNP look-alike threshold to 50 percent since plans at or near 50 percent dually eligible enrollment may reflect the distribution of eligibility in the service area which is outside of MA organization's control. The commenter emphasized that the plan may appeal to both dually and non-dually eligible individuals equally, indicating the plan is not intentionally designed to attract dually eligible enrollees while circumventing D–SNP requirements.

Response: We appreciate the commenters' perspectives and acknowledge the substantial growth in the number of non-SNP MA plans with dually eligible individuals comprising 50 to 60 percent of total enrollment. Similar to the earlier MedPAC analysis, our analysis of 2023 data shows the share of individuals in a plan service area who are dually eligible is clustered in the 10 to 30 percent range and does not exceed 49 percent except in one county (at 56 percent). However, we proposed to lower the threshold for dually eligible enrollment to 60 percent of a non-SNP MA plan's enrollment for plan year 2026 and subsequent years because 60 percent exceeds the share of dually eligible individuals in any given MA plan service area currently and, therefore, would not be the result for any plan that simply reflected the concentration of dually eligible individuals in its service area. For these reasons, we are finalizing our proposal to lower the D–SNP look-alike threshold at § 422.514(d) to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years, as proposed. We will continue to monitor non-SNP MA plans below the 60-percent threshold for potential gaming after implementation of the final rule and consider future rulemaking, as needed.

Comment: Other commenters expressed general opposition to the CMS proposal to lower the D–SNP look-alike threshold from 80 percent to 60 percent over a two-year period and, for plan year 2027 and subsequent years, limit the § 422.514(e) transition processes and procedures to D–SNP look-alikes transitioning dually eligible

[236] Ma, Y., Frakt, A., Roberts, E., Johnston, K., Phelan, J., and Figueroa, J. ''Rapid Enrollment Growth In 'Look-Alike' Dual-Eligible Special Needs Plans: A Threat To Integrated Care'', *Health Affairs* (July 2023) 919–927. Retrieved from *https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00103.*

[237] See June 2020 MACPAC Report to Congress on Medicaid and CHIP, Chapter 2 at *https://www.macpac.gov/publication/chapter-2-integrating-care-for-dually-eligible-beneficiaries-policy-issues-and-options* June 2019 MedPAC Report to Congress, Chapter 12 at *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.*

enrollees into D–SNPs. Some of these commenters noted that certain States do not contract with D–SNPs that enroll partial-benefit dually eligible individuals, which could reduce plan choices and benefits available to these beneficiaries. A commenter highlighted that many States have an inadequate number of SNPs in rural areas. A commenter noted that partial-benefit dually eligible individuals have similar levels of medical and social needs as full-benefit dually eligible individuals but are not being given the same level of support in navigating their health care choices. A few of these commenters indicated that partial-benefit dually eligible beneficiaries would either need to enroll in a different MA plan or enroll in Traditional Medicare, where they would not receive care coordination or valuable supplemental benefits. A commenter identified Arizona and Illinois as States where partial-benefit dually eligible individuals would need to enroll in products that are often designed to be attractive to those aging into the Medicare program and have fewer clinical and/or socioeconomic needs. This commenter raised concern that partial-benefit dually eligible beneficiaries could receive lower overall benefits, as rebates that would have been used to offer them lower Medicare Part C cost sharing or improved supplemental benefits would instead be directed to Part D drug cost-sharing reductions that are duplicative with their Part D Extra Help to attract enough non-dually eligible individuals to enroll in the non-SNP MA plan. Another commenter stated that Massachusetts and New Jersey are States that limit D–SNP enrollment to full-benefit dually eligible individuals and non-SNP MA plans would be further incentivized not to enroll partial-benefit dually eligible individuals if the threshold were lowered. That commenter recommended that CMS work with Congress to mandate such States to require their D–SNPs to have a separate PBP for partial-benefit dually eligible individuals as Pennsylvania and Virginia have done. A commenter recommended that CMS consider additional enrollment options for partial-benefit dually eligible individuals, such as modifications to the proposed monthly SEP. Another commenter indicated that the CMS proposal would force plans to avoid enrolling select categories of dually eligible individuals in their non-SNP MA plans where no D–SNPs are available and could create a vacuum where some dually eligible individuals no longer receive the benefits of MA, including the defined cost-sharing amounts, D–SNP model of care, and supplemental benefits designed to support SDOH.

Response: We appreciate the commenters' perspectives but do not find them to be sufficiently persuasive to change our position.

We agree that partial-benefit dually eligible individuals can benefit from enrollment in D–SNPs. As we stated in the June 2020 final rule (85 FR 33811 through 33812), partial-benefit dually eligible individuals benefit from the requirements that SNPs, including D–SNPs, have a MOC that addresses enrollees' needs and perform periodic HRAs precisely because these individuals have greater social, functional, and health needs than non-dually eligible Medicare beneficiaries. States, through their contracts with D–SNPs, can enhance these care coordination requirements, including for partial-benefit dually eligible individuals. Second, QMBs without full Medicaid benefits, who constitute roughly half of partial-benefit dually eligible individuals nationally, can benefit when D–SNPs, or the Medicaid managed care plans offered under the same parent company in which these individuals are enrolled, pay providers for Medicare cost sharing under a capitation agreement with the State. Such direct and seamless payment of cost sharing can result in an improved experience for providers serving these individuals, which itself may improve access to care for beneficiaries.

Of course, partial-benefit dually eligible individuals cannot benefit from these features of the D–SNP program if the State Medicaid agency contract with the D–SNP (that is, the SMAC) excludes these individuals from enrollment, and we recognize that some States using managed care as a platform for integration exclude partial-benefit dually eligible individuals from D–SNPs and other managed care plans. While some States are using the D–SNP platform for integration only to allow full-benefit dually eligible individuals to enroll in D–SNPs, others allow partial-benefit dually eligible individuals to enroll in separate D–SNP plan benefit packages.

Based on 2024 plan data, D–SNPs are widely available with 547 coordination-only D–SNP PBPs offered across 39 States,[238] and 457 of these coordination-only D–SNPs allow enrollment of partial-benefit dually eligible individuals.[239] In 2021, 54 percent of dually eligible beneficiaries were enrolled in a D–SNP and the majority were enrolled in coordination-only-SNPs.[240] The number of States with D–SNPs limited to partial-benefit dually eligible individuals has grown over recent years. For contract year 2024, D–SNPs that only enroll partial-benefit dually eligible individuals existed in 19 States and the District of Columbia, which is up from 11 States and the District of Columbia for contract year 2023.[241] We continue to think, as we conveyed in the May 2020 final rule (85 FR 33812), that allowing D–SNP look-alikes to continue to enroll partial-benefit dually eligible individuals with no limit would discourage States from taking this approach. As we stated in the June 2020 final rule (85 FR 33809), section 164(c)(4) of MIPPA does not in any way obligate States to contract with a D–SNP; therefore, CMS does not have the authority to mandate States to contract with D–SNPs, and States have significant control over the availability of D–SNPs. We will continue to work with States to identify ways to integrate Medicare and Medicaid benefits in a way that best serves the States' dually eligible population.

As discussed in the November 2023 proposed rule (88 FR 78600), most of the non-SNP MA plans with dually eligible enrollment between 60 percent and 80 percent of total enrollment have a D–SNP within the same service area or nearly the same service area as the non-SNP MA plans, providing a potential opportunity for transitioning D–SNP look-alike enrollees. We reviewed a sample of the 70 non-SNP MA plans with dually eligible individuals representing 60 to 79.9 percent of total enrollment (based on January 2023 enrollment data). While some of these non-SNP MA plans have services areas composed of a majority of Counties with Extreme Access Considerations, rural, and or/micro counties, most of the enrollment in the

[238] Integration Status for Contract Year 2024 D–SNPs available at: *https://www.cms.gov/medicaid-chip/medicare-coordination/qualified-beneficiary-program/d-snps-integration-unified-appeals-grievance-requirements.*

[239] CMS analysis of contract year 2024 SMACs.

[240] MedPAC, State Medicaid Agency Contracts: Interviews with Key Stakeholders, January 25, 2024. Slides available at *https://www.macpac.gov/wp-content/uploads/2024/01/04_January-Slides_State-Medicaid-Agency-Contracts-SMACs_-Interviews-with-Key-Stakeholders.pdf.*

[241] States with partial-benefit only D–SNPs in CY 2024: Alabama, Connecticut, District of Columbia, Delaware, Florida, Georgia, Iowa, Idaho, Indiana, Kentucky, Maryland, Michigan, Mississippi, North Carolina, New York, Ohio, Tennessee, Virginia, Washington, and Wisconsin. States with partial-benefit only D–SNPs in CY 2023: Connecticut, District of Columbia, Delaware, Florida, Idaho, Michigan, Mississippi, New York, Ohio, Virginia, Washington, and Wisconsin.

sample we reviewed was is concentrated in urban areas.[242]

While coordination-only D–SNPs are widely available, we acknowledge they are not available in every market and there is potential that lowering the D–SNP look-alike threshold will result in some enrollees, including partial-benefit dually eligible individuals, not being able to transition into a D–SNP. Based on our experience with D–SNP look-alike transitions effective plan years 2023 and 2024 through MA organizations using the transition authority at § 422.514(e) or the crosswalk authority at § 422.530, in situations where the MA organization is not able to transition D–SNP look-alike enrollees into a D–SNP, the vast majority of enrollees transitioned to other MA–PDs under the same parent organization as the D–SNP look-alike.

Comment: A commenter suggested that CMS's proposal might eliminate competition in the MA program for established D–SNPs and raised concern that these established D–SNPs might delay or avoid offering some additional benefits and instead increase provider payment or health plan profit margins.

Response: We acknowledge the commenter's concern. The D–SNP and MA markets remain robust. Plan bidding signaled strong interest in the D–SNP market for CY 2024, with the number of D–SNPs increasing by approximately 8 percent. Additionally, plans projected in their bids that MA enrollment overall is expected to grow over 7 percent, with D–SNPs enrollment expected to grow by approximately 13 percent.[243] Given that D–SNP look-alikes represent a relatively small share of MA–PDs overall, we do not expect our proposal to reduce the D–SNP look-alike threshold to 60 percent over two years and limit the D–SNP look-alike threshold pathway to D–SNPs starting in plan year 2027 to have a substantial impact on the competitiveness of the MA program.

Comment: Numerous commenters, but far fewer than the number of commenters expressing strong support for CMS's proposal, suggested that CMS exclude partial-benefit dually eligible individuals when calculating the percent threshold at § 422.514(d). A few of these commenters stated that only full-benefit dually eligible individuals benefit from enrollment in a FIDE SNP or HIDE SNP available in their county of residence and emphasized that since FIDE SNPs and HIDE SNPs generally are not an enrollment option for partial-benefit dually eligible individuals, the threshold should exclude partial-benefit dually eligible enrollees. Some commenters noted that D–SNPs serving partial-benefit dually eligible individuals are less widely available, and some States do not contract with coordination-only D–SNPs at all, limiting beneficiary choice and meaningful access to benefits.

Recognizing that some States choose not to contract with D–SNPs enrolling partial-benefit dually eligible individuals, a few commenters suggested that CMS not count partial-benefit dually eligible individuals toward the threshold in States that exclude partial-benefit dually eligible individuals from enrolling in D–SNPs. A commenter indicated that some States, like Massachusetts, limit D–SNP enrollment to full-benefit dually eligible enrollment, which restricts Medicare options to Traditional Medicare and regular MA plans. MA plans designed to support low-income Medicare beneficiaries by offering zero-dollar premiums and supplemental benefits that support functional and social needs risk meeting or exceeding the D–SNP look-alike threshold.

A commenter found CMS's proposal unclear regarding which enrollees—full-benefit dually eligible individuals, partial-benefit dually eligible individuals, and/or LIS eligible individuals—would count toward the D–SNP look-alike threshold under the proposed rule and recommended that only full-benefit dually eligible individuals be counted.

A commenter urged CMS to exclude partial-benefit dually eligible individuals who are not QMBs from the calculation of the D–SNP look-alike threshold since these beneficiaries do not qualify for full Medicaid benefits. The commenter believed that CMS's proposal, if applied strictly and rapidly, could stifle health plan efforts to create plans for the partial-benefit dually eligible individuals who are not QMBs.

Response: We welcome the commenters' perspectives, but we do not find them to be persuasive enough to outweigh other considerations that motivated our proposal.

Coordination-only D–SNPs are widely available with 547 such plans offered across 39 States in contract year 2024.[244] Of these 547 coordination-only D–SNPs, 457 enroll partial-benefit dually eligible individuals.[245] Also, 19 States contract with D–SNPs that limit enrollment of partial-benefit dually eligible individuals in contract year 2024. Partial-benefit dually eligible individuals are enrolling in these plans in high volume.

We recognize that some of the MA plans that could be affected by our proposal to lower the D–SNP look-alike threshold are offered in States that do not contract with D–SNPs that enroll partial-benefit dually eligible individuals. Such States include Arizona, California, Idaho, Massachusetts, Minnesota, and New Jersey. Based on January 2023 enrollment data, only ten of the 70 non-SNP MA plans with 60 to 79.9 percent dually eligible enrollment exist in States that only contract with D–SNPs that enroll full-benefit dually eligible individuals. These include five non-SNP MA plans in Arizona, three non-SNP MA plans in Massachusetts, and one non-SNP MA plan each in Idaho and Minnesota. These data indicate that partial-benefit dually eligible individuals are not congregating in non-SNP MA plans at high rates and do not suggest a need to remove partial-benefit dually eligible individuals from the D–SNP look-alike threshold calculation. We will monitor enrollment of partial-benefit dually eligible individuals, especially in service areas where they are not eligible for D–SNPs, to gauge whether enrollment of partial-benefit dually eligible individuals is causing non-SNP MA plans to cross the D–SNP look-alike threshold.

We acknowledge that the benefits provided under a D–SNP look-alike can be helpful to partial-benefit dually eligible individuals who do not have a D–SNP available to them. As articulated in the June 2020 final rule (85 FR 33805 through 33806), in contrast to non-SNP MA plans, D–SNPs and D–SNP look-alikes allocate a lower percentage of MA rebate dollars received under the bidding process at § 422.266 to reducing Medicare cost sharing and a higher percentage of rebate dollars to supplemental medical benefits such as dental, hearing, and vision services. However, because most dually eligible individuals are QMBs who are not required to pay Medicare cost sharing under sections 1848(g)(3) and 1866(a)(1)(A) of the Act, we believe they are not dissuaded from enrolling in these non-D–SNPs by the relatively higher cost sharing. A similar dynamic

[242] CMS analysis of January 2023 enrollment data and 2023 Individual Plan Service Area Data retrieved from HPMS.

[243] CMS, 2025 Medicare Advantage and Part D Advance Notice Fact Sheet, January 31, 2024. Retrieved from: *https://www.cms.gov/newsroom/fact-sheets/2025-medicare-advantage-and-part-d-advance-notice-fact-sheet.*

[244] Integration Status for Contract Year 2024 D–SNPs available at: *https://www.cms.gov/medicaid-chip/medicare-coordination/qualified-beneficiary-program/d-snps-integration-unified-appeals-grievance-requirements.*

[245] CMS analysis of contract year 2024 SMACs.

exists for Part D premiums and high deductibles, both of which are covered by the Part D low-income subsidy that dually eligible individuals receive. We believe that such benefit designs are unattractive for Medicare beneficiaries who are not dually eligible individuals because they would need to cover these costs out-of-pocket. Despite the similarities with D–SNPs in terms of level of dually eligible enrollment and benefits and cost-sharing design, D–SNP look-alikes are regulated as non-SNP MA plans and are not subject to the Federal regulatory and State contracting requirements applicable to D–SNPs.

As we outlined earlier in this section and in the November 2023 proposed rule, the rate of growth in non-SNP MA plans with 60 to 70 percent and 70 to 80 percent dually eligible individuals as a percent of total enrollment exceeded the rate of enrollment growth for all MA–PD plans over the same period of time. The increased growth in non-SNP MA plans with such levels of dually eligible individuals suggests to us that MA organizations are offering plans for dually eligible individuals but circumventing rules for D–SNPs, including requirements from the Bipartisan Budget Act of 2018, and detracting from Federal and State efforts to better integrate Medicare and Medicaid benefits. This growth in enrollment in these non-SNP plans is likely also drawing enrollment from integrated care D–SNPs and similar integrated programs.[246]

Removing partial-benefit dually eligible individuals from the D–SNP look-alike threshold calculation would render our existing D–SNP look-alike policy less effective. For contract year 2023, only two of the 12 non-SNP MA plans that met the 80 percent threshold calculated based on all dually eligible individuals would have been identified as D–SNP look-alikes under the 80 percent threshold calculated with only full-benefit dually eligible individuals. For contract year 2022, 31 of the 47 non-SNP MA plans that met the 80 percent threshold calculated based on all dually eligible individuals would have been identified as D–SNP look-alikes under the 80 percent threshold calculated with only full-benefit dually eligible individuals. Of these 31 plans, 26 were in California, which has very few partial-benefit dually eligible individuals. Of the estimated 70 non-SNP MA plans with dually eligible enrollment of 60 percent to 79.9 percent that would be affected by our proposal, only 10 of those plans have full-benefit dually eligible individuals comprising 60 to 79.9 percent of their total enrollment. Changing the D–SNP look-alike threshold calculation to only include full-benefit dually eligible individuals would allow 60 of these non-SNP MA plans to continue, reducing the ability of CMS and States to meaningfully implement the BBA of 2018 requirements.

Consistent with our position articulated in the June 2020 final rule (85 FR 33811), our proposed regulatory language uses the terminology from section 1859(f) of the Act and in § 422.2 to define the population of special needs individuals that D–SNPs may exclusively enroll. This language includes both full- and partial-benefit dually eligible individuals. Exclusion of partial-benefit dually eligible individuals from the threshold would allow any MA organization to design a benefit package and target enrollment for an MA plan that exclusively enrolled partial-benefit dually eligible individuals. Section 1859 of the Act, however, only allows D–SNPs to exclusively enroll dually eligible individuals.

We appreciate the commenters' suggestions for CMS to encourage States to contract with D–SNPs that enroll partial-benefit dually eligible individuals. We reiterate that section 164(c)(4) of MIPPA does not in any way obligate States to contract with a D–SNP; therefore, CMS does not have the authority to mandate States to contract with D–SNPs, and States have significant control over the availability of D–SNPs in their State using the SMAC. Nonetheless, the number of partial-benefit-only D–SNPs is increasing, and we will provide technical assistance to States interested in developing SMACs for such plans.

Comment: A commenter requested that CMS consider setting different dually eligible enrollment thresholds for full-benefit and partial-benefit dually eligible enrollees. The commenter suggested such thresholds could be consistent nationwide for both groups, a threshold determined by the percentage of full-benefit and partial-benefit dually eligible beneficiaries in a State, or a threshold that accounts for whether partial-benefit dually eligible beneficiaries can enroll in D–SNPs in the State. The commenter advised that this would allow CMS to set a lower threshold for full-benefit dually eligible beneficiaries and encourage their enrollment into integrated D–SNPs while allowing a higher percentage of partial-benefit dually eligible beneficiaries to remain enrolled in their plan. Another commenter recommended that CMS remove from the calculation of the percent threshold at § 422.514(d) any dual eligibility category for which D–SNPs are not available in the service area. The commenter indicated that as the D–SNP landscape becomes more complicated, the threshold calculation should incorporate additional nuances to avoid penalizing non-SNP MA plans for enrolling dually eligible individuals when there are not suitable D–SNP options available for every eligibility type.

Response: We appreciate the suggestions although we are not incorporating them into the final regulation. For the reasons articulated elsewhere in this section in response to comments suggesting that we limit the D–SNP look-alike calculation to full-benefit dually eligible individuals, we are retaining the current approach of using both full-benefit and partial-benefit dually eligible individuals in determining which non-SNP MA plans meet the D–SNP look-alike threshold at § 422.514(d). The other suggested approach would require CMS to calculate D–SNP look-alike thresholds specific to each county given the type of D–SNPs offered, and which dually eligible individuals they enroll could differ from one county to another within a State. In addition to the reasons articulated in response to comments recommending that we limit the D–SNP look-alike threshold calculation to full-benefit dually eligible individuals, we believe it would be challenging for CMS to operationalize a policy that requires county-specific D–SNP look-alike threshold. We also believe a more complicated D–SNP look-alike threshold would require data analysis that could be less transparent and more challenging for MA organizations to replicate in making their business decisions about plan consolidations and bids.

Comment: A commenter requested that CMS consider changing the D–SNP look-alike definition in future rulemaking, noting that the current definition is overly broad and captures MA plans that are not intentionally enrolling large percentages of dually eligible individuals. The commenter opined that the high dually eligible enrollment in these plans is often due to the lack of plan options in an area, especially for partial-benefit dually eligible individuals for whom these plans provide robust benefits that they would not receive in Traditional Medicare. The commenter

[246] Ma, Y., Fakt, A., Roberts, E., Johnston, K., Phelan, J., and Figueroa, J. ''Rapid Enrollment Growth In 'Look-Alike' Dual-Eligible Special Needs Plans: A Threat To Integrated Care'', *Health Affairs* (July 2023) 919–927. Retrieved from *https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00103.*

recommended that CMS consider updating the definition of D–SNP look-alikes to plans that exceed the dually eligible enrollment threshold and have a Part D basic premium set under the low-income premium subsidy amount as their only premium because such plans are structured to attract dually eligible individuals and draw them away from D–SNPs.

Another commenter suggested that defining D–SNP look-alikes solely based on the percentage of dually eligible enrollees promotes continued evasion, even after lowering the D–SNP look-alike threshold to 60 percent. As an example, that commenter indicated that MA organizations could increase the number of PBPs within a contract while enrolling slightly lower percentages of dually eligible individuals in each. To address this concern, the commenter suggested that CMS consider: 1) the D–SNP look-alike threshold is met when dually eligible individual penetration rates exceed the designated threshold at either the contract number or at the PBP level; and 2) revise the definition of D–SNP look-alikes to be plans that exceed—or that exceed by a certain amount—the average dually eligible individual penetration rate across non-SNP MA plans in each State. The comment provides the example that as of September 2023, approximately 14 percent of Massachusetts non-SNP MA enrollment came from full-benefit dually eligible individuals. A threshold set at even twice this Statewide penetration rate would fall significantly below the 60-percent threshold CMS proposed for 2026. The commenter explained that since markets MA plan markets vary widely across the country, establishing a range based on Statewide averages for dually eligible individual penetration in non-SNP MA plans would more accurately identify outlier plans. The commenter suggested another alternative which would tie the D–SNP look-alike threshold to the percent of Medicare beneficiaries who are full-benefit dually eligible individuals in each State. The commenter noted that in Massachusetts, 25 percent of Medicare beneficiaries are full-benefit dually eligible individuals, and, of these, 15 percent of Massachusetts' full-benefit dually eligible individuals were enrolled in a non-SNP MA plan in September 2023.

Response: We thank the commenters for sharing these ideas but we are not incorporating them into the final regulation.

As we stated earlier in this section, D–SNPs and D–SNP look-alikes allocate a lower percentage of MA rebate dollars received under the bidding process at § 422.266 to reducing Medicare cost sharing and a higher percentage of rebate dollars to supplemental medical benefits such as dental, hearing, and vision services. Because most dually eligible individuals are QMBs who are not required to pay Medicare cost sharing under sections 1848(g)(3) and 1866(a)(1)(A) of the Act, or other full-benefit dually eligible individuals who are protected under 42 CFR 422.504(g)(1)(iii) from paying any in-network cost sharing when the State is responsible for paying such amounts, we believe they are not dissuaded from enrolling in these non-D–SNPs by the relatively higher cost sharing. A similar dynamic exists for Part D premiums and high deductibles, both of which are covered by the Part D low-income subsidy that dually eligible individuals receive. We believe that such benefit designs are unattractive for Medicare beneficiaries who are not dually eligible individuals because they would need to cover these costs out-of-pocket. Thus, we do not believe that adding an additional criterion to the D–SNP look-alike definition of having a Part D basic premium set under the low-income premium subsidy amount as their only premium would be helpful or necessary in identifying D–SNP look-alikes.

While we appreciate the commenter's suggestion to revise the D–SNP look-alike threshold based on contract, PBP, and State dually eligible individual penetration rates, we believe it would be challenging for CMS to operationalize a D–SNP look-alike threshold that requires different dually eligible individual penetration rate across non-SNP MA plans in each State. As articulated earlier in this section, we believe a more complicated D–SNP look-alike threshold would require data analysis that could be less transparent and more challenging for MA organizations to replicate in making their business decisions about plan consolidations and bids.

Comment: A few commenters recommended that CMS encourage States to allow D–SNPs that enroll partial-benefit dually eligible individuals and educate States on the benefits of D–SNPs for partial-benefit dually eligible individuals, especially if CMS does not exclude partial-benefit dually eligible individuals from the D–SNP look-alike threshold at § 422.514(d). A commenter emphasized that, while partial-benefit dually eligible individuals are ineligible for most Medicaid services, these individuals have similar clinical, functional, and social needs as full-benefit dually eligible individuals and can benefit from access to stronger care management models available in D–SNPs.

Response: We appreciate the comments. As we have articulated in the June 2020 final rule (85 FR 33811 through 33812), we agree that partial-benefit dually eligible individuals can benefit from D–SNPs. First, partial-benefit dually eligible individuals benefit from the requirements that SNPs, including D–SNPs, have a MOC that addresses enrollees' needs and perform periodic HRAs precisely because these individuals have greater social, functional, and health needs. States, through their contracts with D–SNPs, can enhance these care coordination requirements, including for partial-benefit dually eligible individuals. Second, QMBs without full Medicaid benefits, who constitute roughly half of partial-benefit dually eligible individuals nationally, can benefit when D–SNPs, or the Medicaid managed care plans offered under the same parent company in which these individuals are enrolled, pay providers for Medicare cost sharing under a capitation agreement with the State. Such direct and seamless payment of cost sharing can result in an improved experience for providers serving these individuals, which itself may improve access to care for beneficiaries.

We emphasize that nothing about the proposals would discourage States from contracting with D–SNPs that enroll partial-benefit dually eligible individuals. Section 164(c)(4) of MIPPA does not in any way obligate States to contract with a D–SNP; therefore, CMS does not have the authority to mandate States to contract with D–SNPs, and States have significant control over the availability of D–SNPs. Nonetheless, we will continue to provide technical assistance to States interested in establishing SMACs with D–SNPs that serve partial-benefit dually eligible individuals.

Comment: A commenter suggested that CMS increase the number of enrollees permitted in the exemption under the current rules that a non-SNP MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals.

Response: The commenter is correct that the current requirements at § 422.514(d)(2)(ii) exempt any non-SNP MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals at the time of such determination based on January enrollment. We explained in the June 2020 final rule (85 FR 33813) that an appropriate comparison for D–SNP look-alikes is the minimum enrollment threshold for low enrollment SNPs,

which is 100 enrollees for plans in existence for three or more years; CMS applies this threshold and other considerations to identify MA plans that are not viable independent plan options to terminate the plans under § 422.510(a)(4)(xv).[247] We codified a minimum enrollment standard of 200 in § 422.514 to allow some additional flexibility for initial enrollment patterns that may not be representative of the longer term enrollment pattern for the plan. Once the initial enrollment period has passed or the number of enrollees during that first year of operation exceeds 200 enrollees, we continue to believe the enrollment profile accurately reflects whether or not the plan was design to exclusively enroll dually eligible individuals. We are not making any changes in response to this comment.

Comment: A commenter did not notice any limitation on the number of D–SNP look-alikes in a service area. Based on that observation, the commenter opined that MA organizations could offer more than one non-SNP MA plan in a service area and manage the level of dually eligible enrollment among these multiple plans such that none of them meets the D–SNP look-alike threshold, circumventing the policies to protect dually eligible individuals. This commenter recommended that CMS add additional language to limit MA plans in service areas where there are D–SNP options available, in service areas where D–SNPs are not an option, or in States where there are no D–SNPs, allowing dually eligible individuals to access supplemental benefits. Another commenter advocated that CMS provide States with the authority to prevent any MA organization from having D–SNP look-alikes, regardless of whether an MA organization offers D–SNPs in that State. A commenter recommended that the proposal should not apply in States that do not contract with D–SNPs and make that statement clearly in the rule.

Response: We appreciate the comments. We confirm that there is no current limitation on the number of non-SNP MA plans allowed in a service area. We will monitor the implementation of this final rule for unintended consequences or potential gaming by MA organizations.

As we stated in the November 2023 proposed rule (88 FR 78580 through 78581) and earlier in this section, the rate of growth from 2017 to 2023 in the number of non-SNP MA plans below the 80-percent D–SNP look-alike threshold substantially exceeded the rate of enrollment growth for all MA–PD plans over the same period of time. The increased growth in non-SNP MA plans with dually eligible individuals between 50 and 80 percent of total enrollment suggests to us that MA organizations are offering plans for dually eligible individuals but circumventing rules for D–SNPs. As a result, we are finalizing, as proposed, a reduction in the D–SNP look-alike threshold at § 422.514(d) to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years.

We clarify that the existing contracting limitations on D–SNP look-alikes at § 422.514(d) only apply in any State where there is a D–SNP or any other plan authorized by CMS to exclusively enroll individuals entitled to Medicaid, such as an MMP. This remains true despite the changes we are finalizing to the D–SNP look-alike threshold.

Comment: A commenter proposed that CMS limit further reductions to the D–SNP look-alike threshold calculation to States and counties where there exist at least eight integrated D–SNP offerings. The commenter explained that this approach would enhance choice and ensure States issue SMACs to qualified entities.

Response: We appreciate the importance of beneficiaries having enrollment options. As discussed in the November 2023 proposed rule (88 FR 78600), most of the non-SNP MA plans with dually eligible enrollment between 60 percent and 80 percent of total enrollment have a D–SNP within the same (or nearly the same) service area as the non-SNP MA plans, providing a potential opportunity for transitioning D–SNP look-alike enrollees. We also discussed earlier in this section that D–SNPs are widely available. Thus, we do not think it is necessary to limit further reductions in the D–SNP look-alike threshold to States and counties where there exist at least eight integrated D–SNP offerings.

Comment: A few commenters specifically signaled their support for the proposal to limit transition options available to identified D–SNP look-alikes. A commenter noted that eliminating the option to transition enrollees into traditional MA plans would immediately reduce incentives to transfer dually eligible individuals into an MA plan that in future years may reach the D–SNP look-alike threshold. A commenter expressed support for the proposal to limit the transition options, as the current scheme of allowing transition into non-D–SNPs does not provide any incentive for MA organizations to eliminate D–SNP look-alikes. Another commenter welcomed allowing D–SNP look-alike transitions only to D–SNPs since it would be a pathway of opportunity for partial-benefit dually eligible enrollment into coordination-only D–SNPs and bolster coordination-only D–SNPs as a conduit and platform for increased integration efforts with States.

Response: We appreciate the widespread support we received to limit transition options available to identified D–SNP look-alikes. We believe this amendment will support our goal to encourage the enrollment of dually eligible individuals into integrated plans. We acknowledge that not all States contract with D–SNPs that serve partial-benefit dually eligible individuals, and partial-benefit dually eligible individuals would not be eligible to transition to non-D–SNPs under the § 422.514(e) transition pathway starting with coverage for plan year 2027. In those situations, MA organizations can continue to utilize CMS crosswalk and crosswalk exception processes at § 422.530 provided all requirements for a crosswalk or crosswalk exception are met. The provisions we are finalizing at § 422.514(d) and (e) do not change the existing crosswalk processes.

Comment: Many commenters discussed their concerns about transitions of D–SNP look-alike enrollees into other plans. A few commenters noted that these transitions could cause potential disruptions in continuity of care among enrollees. Other commenters recommended that CMS continue the existing transition authority into non-SNP MA plans. Several commenters suggested that CMS continue to make existing crosswalk exceptions available to transition dually eligible individuals from D–SNP look-alikes into D–SNPs. In support of this approach, a commenter stated that CMS has regulations in place via the bid submissions process whereby plan crosswalking and consolidation does not negatively affect beneficiaries. Another commenter encouraged CMS to continue to permit the use of existing transition authority into non-SNP MA plans for plan years 2025 and 2026 to minimize beneficiary disruptions. That

[247] CMS has consistently used the 100 enrollee threshold for several years to identify low enrollment plans for termination under § 422.510(a)(4)(xv); see HPMS memo dated April 14, 2023, ''Final Contract Year (CY) 2024 Standards for Part C Benefits, Bid Review, and Evaluation,'' p. 4 (available online at *https://www.cms.gov/https/editcmsgov/research-statistics-data-and-systems/computer-data-and-systems/hpms/hpms-memos/hpms-memos-wk-2-april-10-14*) and Final CY 2020 Call Letter, available online at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

commenter stated that delaying the proposed change to limit transitions of D–SNP look-alike enrollees into only D–SNPs until plan year 2027 and beyond would grant MA organizations additional time to adjust to these changes and preserve beneficiary choice during that process, minimizing disruption for dually eligible enrollees that affirmatively selected their existing MA plans to meet their provider network and benefit preferences.

Response: We thank the commenters for their perspectives. We agree with the commenters that it is important to monitor for any gaps in coverage that may occur as enrollees are transitioned or crosswalked out of D–SNP look-alikes. The current process at § 422.514(e) allows D–SNP look-alikes to transition enrollees into an MA plan or plans meeting certain criteria within the same parent organization to promote continuity of care. Under our proposal and § 422.514(e) as finalized with the amendments we proposed, we continue these policies through plan year 2026, which will help provide continuity of care for individuals who are required to transition from D–SNP look-alikes under the initial years of implementing the lower thresholds. Based on our experience with D–SNP look-alike transitions effective plan years 2023 and 2024, MA organizations transition the vast majority of D–SNP look-alike enrollees into other MA–PDs under the same parent organization as the D–SNP look-alike, and the vast majority of the plans receiving these D–SNP look-alike enrollees are non-SNP MA plans. Thus, we do not expect limiting the § 422.514(e) transition pathway to D–SNPs beginning in 2027 to negatively affect the ability of MA organizations to transition D–SNP look-alike enrollees. Also, as we discussed in the November 2023 proposed rule (88 FR 78582 through 78583), MA organizations can continue to utilize CMS crosswalk and crosswalk exception processes at § 422.530 provided all requirements for a crosswalk or crosswalk exception are met. The provisions we are finalizing at § 422.514(d) and (e) do not change the existing crosswalk processes.

As we explained in the November 2023 proposed rule (88 FR 78583), while multiple options exist for MA organizations to transition D–SNP look-alike enrollees to other non-SNP MA plans, these pathways are not available for moving enrollees from D–SNP look-alikes to D–SNPs. We believe it is appropriate to limit the transition process in § 422.514(e) to D–SNPs since MA organizations do not have other options to transition D–SNP look-alike enrollees into D–SNPs and movement into D–SNPs encourages enrollment in integrated plans. We are also concerned that if D–SNP look-alikes continue to be allowed to transition enrollees into non-D–SNPs indefinitely under § 422.514(e), there is little incentive for MA organizations to avoid non-compliance with the D–SNP look-alike thresholds. Thus, for plan year 2027 and subsequent years, we are finalizing our proposal to add new paragraph § 422.514(e)(1)(v) to limit the existing D–SNP look-alike transition pathway to MA organizations with D–SNP look-alikes transitioning enrollees into D–SNPs.

Comment: A commenter noted that the plan crosswalk examples outlined by CMS in the November 2023 proposed rule require the transition of all plan enrollees into a single plan or segments of a single plan and do not permit enrollees to be crosswalked to separate PBPs based on Medicaid eligibility, which could result in enrollee disruption. The commenter inquired whether CMS intended for MA organizations to use the transition process at § 422.514(e) concurrently with crosswalks permitted at § 422.530, and, if so, requested that CMS update the regulatory text accordingly and provide detailed implementation instructions through sub-regulatory guidance. Another commenter requested that CMS consider some specific transition options. These options included allowing dually eligible enrollees from the D–SNP look-alike to transition to another plan but allow non-dually eligible enrollees to remain in the D–SNP look-alike; allowing dually eligible enrollees who qualify for a C–SNP to transition to a C–SNP; and allowing dually eligible enrollees from the D–SNP look-alike to transition into D–SNPs and/or default to Traditional Medicare. Another commenter recommended that CMS consider allowing D–SNP look-alikes to convert into ''all dually eligible plans'' and crosswalk any non-dually eligible enrollees into other MA plans. A commenter also encouraged CMS to automatically approve crosswalk exceptions that were previously approved by CMS as part of the D–SNP look-alike transition proposal process.

Response: We welcome the comments and appreciate the opportunity to clarify our proposal. Under our proposal, MA organizations with non-SNP MA plans meeting the 70 percent D–SNP look-alike threshold for plan year 2025 or 60 percent D–SNP look-alike threshold for plan year 2026 can use the existing D–SNP look-alike transition process at § 422.514(e), which allows transition of D–SNP look-alike enrollees to one or more MA plans, including a D–SNP, C–SNP, or I–SNP, if they meet eligibility criteria. This approach allows the D–SNP look-alikes meeting the lower threshold in the first years of implementation to transition enrollees under the existing D–SNP look-alike transition pathway at § 422.514(e) for 2026.

Our proposal limits the transition pathway to D–SNP look-alike enrollees transitioning into D–SNPs in plan year 2027 and future years. Thus, MA organizations have time to execute SMACs for new D–SNPs in service areas where they anticipate their non-SNP MA plans may meet or exceed the revised D–SNP look-alike threshold at § 422.514(d). For D–SNP look-alike transitions in plan year 2027 and subsequent years, MA organizations could use the revised § 422.514(e) transition pathway to move eligible D–SNP look-alike enrollees into a D–SNP, and any remaining D–SNP look-alike enrollees would default into Traditional Medicare. Alternatively, MA organizations can continue to utilize CMS crosswalk and crosswalk exception processes at § 422.530 provided all requirements for a crosswalk or crosswalk exception are met. The provisions we are finalizing at § 422.514(d) and (e) do not change the existing crosswalk or crosswalk exception processes. We clarify that MA organizations cannot use the § 422.514(e) transition pathway concurrently with a crosswalk or crosswalk exception pathway at § 422.530.

Under the existing requirements at § 422.514(d)(2), we do not renew a contract with a D–SNP look-alike that meets or exceeds the 80-percent threshold. Thus, D–SNP look-alikes cannot retain any enrollment in the D–SNP look-alike. As we explained in the June 2020 and April 2023 final rules (85 FR 33812 and 88 FR 22130, respectively), where an MA plan is one of several offered under a single MA contract and the MA organization does not voluntarily non-renew the D–SNP look-alike, we will sever the D–SNP look-alike from the overall contract using our authority under § 422.503(e) to sever a specific MA plan from a contract and terminate the deemed contract for the D–SNP look-alike. This policy will remain in effect upon finalizing our proposals to reduce the D–SNP look-alike threshold to 60 percent over two years and limit the D–SNP look-alike transition process to D–SNPs starting in plan year 2027.

Under the existing provision at § 422.514(e), MA organizations can transition D–SNP look-alike enrollees into C–SNPs. The revisions we are

finalizing at § 422.514(e)(1)(v) will—for plan year 2027 and subsequent years—limit the existing D–SNP look-alike transition pathway to MA organizations with D–SNP look-alikes transitioning enrollees into D–SNPs. Thus, for plan year 2027 and subsequent years, MA organizations will not be able to transition D–SNP look-alike enrollees into C–SNPs.

We clarify that none of the D–SNP look-alike transitions previously approved under § 422.514(e) were automatically approved or confer any automatic approvals by CMS for future transitions under § 422.514(e). CMS reviews all D–SNP look-alike transitions to ensure they meet the regulatory requirements.

Comment: A few commenters suggested an inconsistency in CMS's proposals to lower the D–SNP look-alike threshold and limit the D–SNP look-alike transition pathway at § 422.514(e) to D–SNPs starting in plan year 2027. These commenters believed that the calculation of the D–SNP look-alike threshold would include both full-benefit and partial-benefit dually eligible individuals whereas CMS's proposed revisions to the D–SNP look-alike transition process would limit that transition process to full-benefit dually eligible individuals.

Response: We appreciate the opportunity to clarify our proposal. The commenters are correct that we include both full-benefit and partial-benefit dually eligible individuals in the calculation of the D–SNP look-alike threshold at § 422.514(d) and will continue that policy in the reduction to that threshold that we are finalizing in this rule. We clarify that our proposed limitation at § 422.514(e) on the D–SNP look-alike transition process starting in plan year 2027 would permit transition of full-benefit and partial-benefit dually eligible individuals from a D–SNP look-alike into a D–SNP, if those individuals meet the eligibility criteria for the receiving D–SNP and all requirements at § 422.514(e).

Comment: Several commenters suggested that more information be provided to dually eligible individuals to help them understand their enrollment options. A commenter recommended informing individuals when they enroll in a non-integrated model where an integrated model exists. The commenter explained that these disclosures would shift the education burden from the individual, where it sits today, to entities providing the coverage. Another commenter advocated that CMS require outlier or all non-SNP MA plans to regularly send notices and information to their dually eligible enrollees about the State's integrated and coordinated care options, including integrated D–SNPs and PACE plans, and such information could be defined in a CMS template and/or provided by the State Medicaid agency. The commenter also encouraged that CMS clarify in regulation and/or in sub-regulatory marketing guidance that MA organizations offering both non-SNP and D–SNP products must clearly identify the specific contract numbers and PBPs contracted in each State as D–SNPs on plan websites and in marketing materials as well as clearly disclose the States in which their Medicare plans do not operate as D–SNPs.

Another commenter suggested that the ANOC language sent to dually eligible enrollees being transitioned into another MA plan should be plain and straightforward and include contact information for SHIPs.

Response: We appreciate recommendations for improved education on the availability and benefits of integrated products. Under the requirements at § 422.111(a)(2), an MA organization must disclose information specified in § 422.111(b), which includes service area, benefits, supplemental benefits, and other information, in a clear, accurate, and standardized form. This § 422.111(b) requirement applies to ANOCs. We also require that MA plans include the contact information for SHIPs in all ANOCs. We appreciate the other recommendations for improved education on the availability of integrated plans. We will consider ways to strengthen this information through future rulemaking and our current authority, such as by considering an update to the pre-enrollment checklist at § 422.2267(e)(4) to require that MA organizations inform enrollees about available integrated plan options.

Comment: A commenter requested information about the future of enrollees in D–SNP look-alikes and whether community-based organizations will maintain their service provision capabilities. The commenter expressed concern about the sustainability of the home health program if all providers became managed care organizations.

Response: We welcome the opportunity to respond to this comment. As we described earlier in this section, CMS will not renew a contract with a D–SNP look-alike, but that D–SNP look-alike can transition its enrollment to one or more MA plans using the D–SNP look-alike transition pathway at § 422.514(e) or crosswalk or crosswalk exception pathways at § 422.530, if requirements are met. MA plans, including D–SNPs, are widely available with 761 MA plan contracts with approximately 33 million total enrollees based on January 2024 data,[248] and we do not expect lowering the D–SNP look-alike threshold at § 422.514(d) and limiting the D–SNP look-alike transition pathway at § 422.514(e) to D–SNPs to have a substantial effect on the extent to which beneficiaries can enroll in MA or community-based organizations can contract with MA organizations.

Comment: A few commenters encouraged CMS to consider providing plans more time before implementing its proposal. A commenter noted that using January 2024 enrollment data to identify D–SNP look-alikes for plan year 2025 may be problematic for some plans given that CMS would not finalize the rule until later in 2024. This commenter recommended that CMS implement the proposed reduction in the D–SNP look-alike threshold starting with plan year 2026, consistent with the June 2020 final rule in which CMS finalized the D–SNP look-alike threshold to begin two years later in 2022. Other commenters acknowledged that plans must secure State Medicaid agency contracts to offer D–SNPs, which can take several years depending on the State legislative framework and procurement schedules. Another commenter suggested that CMS consider allocating an extra one or two years for plans that reduce cost sharing by material amounts for Medicare covered services and have made a good faith effort to avoid D–SNP look-alike status but might also provide benefits such as non-emergency transportation, Part D co-pay reductions, and benefits that assist with housing, utilities, and food that appeal to individuals receiving Part D LIS and dually eligible individuals. Another recommended that CMS consider adding one-to-two standard deviations to the D–SNP look-alike thresholds, in addition to providing one-or-two extra years, to give start-up plans time to make adjustments.

Response: We acknowledge the commenters' requests that we consider a delay in lowering the D–SNP look-alike threshold but we do not find them persuasive. MA organizations have had opportunities to work with States to execute SMACs for new D–SNPs. In finalizing the existing contracting limitation on D–SNP look-alikes in the June 2020 final rule, we delayed implementation of the contracting

[248] CMS Medicare Advantage, Cost, PACE, Demo, and Prescription Drug Plan Contract Report—Monthly Summary Report (Data as of January 2024) retrieved from *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/monthly/contract-summary-2024-01*.

limitation by one year from plan year 2022 to plan year 2023 but allowed MA organizations that volunteered to transition enrollees out of D–SNP look-alikes for plan years 2021 or 2022 to do so. Providing more time for implementation and application of the new contracting standard when it was first adopted was appropriate then to give MA organizations time to adjust. However, the D–SNP look-alike prohibition and contracting standard have been in place for several years at this point and MA organizations are familiar with it. We do not believe additional delay before implementing the lower threshold is necessary. Of the D–SNP look-alike enrollees that MA organizations voluntarily transitioned for plan years 2021 and 2022, more than 90 percent of these enrollees transitioned to D–SNPs. For D–SNP look-alikes that CMS would no longer contract with for plan years 2023 and 2024, MA organizations transitioned less than 30 percent of enrollees to D–SNPs, other SNPs, or MMPs. Despite having additional time to establish D–SNPs, these MA organizations did not establish new D–SNPs as the replacements for existing D–SNP look-alikes.

Since November 2023, MA organizations have been aware of our proposal to lower the D–SNP look-alike threshold to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years. We explained in the November 2023 proposed rule (88 FR 78581) that in operationalizing the proposed changes, we would use January 2024 enrollment data to identify non-SNP MA plans that exceed the proposed 70-percent threshold, for purposes of determining whether to renew contracts with these plans for plan year 2025. We articulated that we would use January 2025 enrollment data to identify non-SNP MA plans that exceed the proposed 60-percent threshold for purposes of determining whether to renew contracts with these plans for plan year 2026. Consistent with the existing rules, we will not apply the contracting limitation in § 422.514(d)(2) to any non-SNP MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals. Thus, MA organizations have had time to start working with State Medicaid agencies on SMACs, and they have additional time to continue to work with State Medicaid agencies after this rule is finalized and before contract year 2025 SMACs are due in July 2024.

With respect to new plans, the current requirements at § 422.514(d)(2)(ii) already exempt any non-SNP MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals at the time of such determination based on January enrollment. As stated earlier in this section, once this initial enrollment period has passed, we continue to believe the enrollment profile accurately reflects whether or not the plan was designed to attract enrollment of dually eligible individuals.

For these reasons, we are finalizing the reduction in the D–SNP look-alike threshold as proposed without delay in implementation.

Comment: Several commenters, who all supported the CMS proposal, recommended that CMS continue to analyze and monitor D–SNP look-alikes. MACPAC urged continued rigor and analysis around D–SNP look-alike plan growth. Citing its April 2020 comments on the February 2020 proposed rule, MACPAC expressed support for CMS's efforts to restrict D–SNP look-alikes and encouraged CMS to pay particular attention to the set of plans where dually eligible beneficiaries account for between 50 and 80 percent of total enrollment. MACPAC also suggested that CMS monitor growth in enrollment of dually eligible beneficiaries in other types of SNPs, including C–SNPs and I–SNPs, and identify any potential effects on integration efforts. A commenter emphasized the need for CMS to continue to monitor and address potential loopholes in prohibiting D–SNP look-alikes. A commenter advocated that CMS monitor plans' actions and provide public information on compliance and enforcement with the D–SNP look-alike regulations. Another commenter noted that States have invested time and resources to implement, operate, and monitor integrated care models to better serve dually eligible individuals, and allowing sponsors to circumvent D–SNP requirements and oversight wastes Federal and State resources and dilutes the effectiveness of this work. To that end, the commenter suggested that CMS further collaborate with States, including sharing oversight responsibilities of the MA market with State regulators and proactively publicizing how to report concerns about misleading and potentially exploitative marketing behavior by agents and brokers. A commenter requested that CMS apply stronger penalties for MA plans that States, SHIPs, ombudsman programs, or dually eligible individuals identify as potentially misleading or exploitative marketing behavior.

Response: We agree with the commenters' concerns. As we have done since codifying the D–SNP look-alike contract limitations at § 422.514(d) in the June 2020 final rule, we will continue to monitor for potential gaming, review plan enrollment data, and consider future rulemaking as needed. We shared a list of the D–SNP look-alikes identified for plan years 2022 and 2023 and will post lists for subsequent years under ''Information about D–SNP Look-Alikes'' on the CMS website.[249]

We encourage stakeholders to contact 1–800-Medicare to report concerns about marketing behavior. We appreciate the suggestion that CMS share oversight responsibilities of the MA market with State regulators, but that issue is beyond the scope of this rulemaking.

Comment: A commenter recommended that CMS add new data reporting requirements to assist in monitoring non-SNP MA plans. In particular, the commenter encouraged CMS to require non-SNP MA plans to provide administrative data and encounters to States for their dually eligible enrollees, which would help State Medicaid agencies. The commenter noted these data would also act as a counter incentive to MA organizations developing D–SNP look-alikes and targeting dually eligible individuals for enrollment to avoid D–SNP coordination and integration requirements. The commenter further suggested that CMS require MA organizations to consult with States on new applications and renewals for non-SNP MA plans that would exceed the monitoring threshold or that include benefit design that would likely be less attractive to non-dually eligible Medicare beneficiaries. Finally, the commenter advocated that CMS share detailed data with States on dually eligible enrollment in MA plans, including relative to total enrollment, to support State awareness and ability to monitor non-SNP MA plans.

Response: We appreciate the commenter's concerns and suggestions and will consider them for future action. The recommendation to require non-SNP MA plans to provide administrative data and encounter data directly to States would likely require additional rulemaking and is outside the scope of this proposal. Prior to implementation of new program-wide Part C reporting requirements (under OMB control number 0938–1054), we make them available to the public for review and comment in complying with

[249] *https://www.cms.gov/medicaid-chip/medicare-coordination/qualified-beneficiary-program/d-snps-integration-unified-appeals-grievance-requirements.*

the standard PRA process, which includes publication of 60- and 30-day **Federal Register** notices. We will also consider sharing additional data with States on dually eligible enrollment in MA plans. As stated earlier in this section, we currently post annual lists of D–SNP look-alikes online.

Comment: In submitting comments about CMS's D–SNP look-alike proposal, a commenter indicated that an MA plan's Star Rating may be negatively impacted if an enrollee stays with the same parent organization but elects to enroll in a D–SNP, which better serves the enrollees' needs than a non-SNP MA plan. This commenter suggested that CMS include flexibilities to establish exclusion criteria for the Star Ratings measure monitoring disenrollment from the MA plan to exclude enrollees from the disenrollment calculation if they enroll in the MA organization's FIDE SNP.

Response: We thank the commenter for raising this issue. As we state in section VIII.F. of this rulemaking, we do not currently have evidence to suggest allowing dually eligible individuals the opportunity to enroll into integrated D–SNPs in any month would negatively impact Star Ratings; in fact, we have reason to believe that the totality of the SEP proposals may actually benefit integrated D–SNPs, such as FIDE SNPs, on Star Ratings, including the Members Choosing to Leave the Plan measure. In 2023, a study published in *Health Affairs* noted that nearly one-third of dually eligible individuals in ''D–SNP look-alike plans,'' were previously enrolled in integrated care programs.[250] Such D–SNP look-alikes would no longer be able to accept enrollments using the dual/LIS SEP with the changes we are finalizing in this rulemaking. The revised duals/LIS SEP that we are finalizing in this rulemaking will dramatically reduce the total array of options available outside of the AEP while the integrated SEP that we are finalizing in this rulemaking will allow full-benefit dually eligible individuals to enroll in integrated D–SNPs, which together may improve integrated D–SNP performance on measures such as Members Choosing to Leave the Plan. Further, in the CY 2025 Advance Notice, we discussed a non-substantive update to that measure to exclude any enrollment into a plan designated as an AIP from the numerator of this measure, which could address the commenter's concerns here if that measure update is finalized; under the non-substantive update, CMS would treat a change in enrollment to an AIP, including FIDE SNPs, from a non-integrated MA plan as an involuntary disenrollment.

As we described in the June 2020 final rule (85 FR 33817), the specifications for the Members Choosing to Leave the Plan Star Rating measure allow individuals transitioned because of a PBP termination to be excluded from the calculation of this Star Rating measure. The vast majority of D–SNP look-alike enrollees transitioned into another MA plan or plans, including a D–SNP, will be identified in MARx as disenrollment reason code 09, termination of a contract (CMS-initiated), or disenrollment reason code 72, disenrollment due to a plan-submitted rollover. Neither disenrollment reason code 72 nor 09 are counted toward the calculation of the Members Choosing to Leave the Plan Star Rating measure. As described in the Collection of Information section of this rulemaking, based on our experience with D–SNP look-alike transitions through plan year 2024, we estimate that 14 percent of transitioned D–SNP look-alike enrollees would make a Medicare choice other than the MA plan into which they are transitioned. MARx will identify these transitions as disenrollment code 13, disenrollment because of enrollment into another plan, and these transactions will be counted toward the calculation of the Members Choosing to Leave the Plan Star Rating measure. Since the measure specifications do not penalize a plan for *involuntary disenrollment* that may be caused by this rulemaking, we do not believe a change to the Star Rating measure specifications is warranted.

Comment: A commenter expressed opposition to CMS's D–SNP look-alike proposals by citing potentially contradictory policies related to the enrollment of dually eligible individuals in MA plans, specifically the interaction between the current and proposed D–SNP look-alike policies and the Health Equity Index (HEI). The commenter noted that under the HEI, an MA contract may be eligible for an increase in its Star Rating if the contract performs well on a set of measures for enrollees with social risk factors (SRFs), and CMS identifies enrollees with SRFs as those who are (i) dually eligible individuals or receive the Part D LIS, or (ii) are eligible for Medicare due to a disability. The commenter explained that a contract is eligible for the maximum reward if enrollment of beneficiaries with SRFs is greater than the median across all contracts and opined that setting such a threshold would likely create an incentive for MA organizations to enroll more dually eligible individuals into MA–PDs. In contrast, CMS proposed to disenroll dually eligible individuals from a non-SNP MA plan with dually eligible enrollment of at least 60 percent of total enrollment.

Response: We appreciate the commenter raising this concern. We agree that there is potential for countervailing incentives between our proposal to lower the D–SNP look-alike threshold and the HEI calculation of enrollees with SRFs, which includes dually eligible individuals. However, we believe lowering the D–SNP look-alike threshold to 60 percent will not interfere with the HEI reward. In calculations of the HEI using data from the 2023 and 2024 Star Ratings that we released via HPMS in December 2023, the median percentage of dually eligible, LIS, and disabled enrollees was 41.8 percent. This median percent is well below the thresholds we are finalizing at § 422.514(d), even as it counts non-dually eligible individuals who do not count toward the look-alike threshold.

Comment: A few commenters requested clarity on the data CMS uses to calculate dually eligible individuals as a percent of total enrollment to determine which non-SNP MA plans are D–SNP look-alikes and the timing of this calculation. A commenter sought clarification on when CMS uses projected enrollment versus actual enrollment. Another commenter stated that the MMR that CMS uses to calculate the percent of dually eligible individuals does not always have the most up-to-date information, which may result in an incorrect calculation of dually eligible enrollment. The commenter encouraged CMS to consider using real-time State data to assess this percentage instead of relying solely on the MMR. A commenter noted that CMS reviewing the percentage of dually eligible enrollment as of January 1 of a plan year is challenging for new PBPs and instead recommended that CMS review the percentage at the time of bid submission using May or June enrollment percentages to allow plans the opportunity to account for both OEP and age-in enrollments.

Response: We thank the commenters for the opportunity to clarify the data we use to calculate the D–SNP look-alike threshold at § 422.514(d) and related timing. As outlined in existing requirements at § 422.514(d)(1), we do not enter into or renew a contract for a non-SNP MA plan that projects in its

[250] Ma, Y., Frakt, A., Roberts, E., Johnston, K., Phelan, J., and Figueroa, J. ''Rapid Enrollment Growth In 'Look-Alike' Dual-Eligible Special Needs Plans: A Threat To Integrated Care'', *Health Affairs* (July 2023) 919–927. Retrieved from *https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00103.*

bid under § 422.245 that 80 percent or more of the plan's total enrollment is comprised of dually eligible enrollees. Per § 422.514(d)(1)(ii), we use enrollment projections submitted by the MA organization as part of its bid to make that determination. To make these determinations, in June we review enrollment projections in bids submitted in June for the following plan year. For example, we reviewed enrollment projections in bids submitted in June 2023 for plan year 2024 to determine whether 80 percent or more of the plan's total projected enrollment is comprised of dually eligible enrollees. The proposal that we are finalizing in this rulemaking will lower the percent at § 422.514(d)(1)(ii) to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years. For example, we will review enrollment projections in bids submitted in June 2024 for plan year 2025 to determine whether 70 percent or more of the plan's total projected enrollment is comprised of dually eligible enrollees.

Per existing requirements at § 422.514(d)(2), we do not renew a contract for an MA plan that has *actual* enrollment consisting of 80 percent or more enrollees who are dually eligible, unless that MA plan has been active for less than one year and has enrollment of 200 or fewer individuals at the time of such determination. Per § 422.514(d)(2)(ii), we use January enrollment of the current year to make that determination. The proposal that we are finalizing in this rulemaking will lower the percent at § 422.514(d)(2)(ii) to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years but would continue to use *actual* enrollment as of January of the current year. For example, we will review January 2024 enrollment data to identify non-SNP MA plans that exceed the proposed 70-percent threshold, for purposes of determining whether to renew contracts with these plans for plan year 2025. We would use January 2025 enrollment data to identify non-SNP MA plans that exceed the proposed 60-percent threshold for purposes of determining whether to renew contracts with these plans for plan year 2026.

We currently obtain the January enrollment data through the February MMR, which reflects enrollment through early January. For example, we use the February 2024 MMR to reflect January 2024 enrollment in a non-SNP MA plan. We believe the MMR file accurately represents a plan's enrollment and includes necessary dually eligible status indicators. While we appreciate the suggestion to supplement the MMR data with real-time State data, we do not believe that the added benefit outweighs the operational complexity of obtaining such real-time data from States. We note that the MMR file is the data source that CMS currently uses to determine D–SNP look-alikes, but we may change the data source(s) as necessary to identify accurate and reliable information about January enrollment in plans. We will continue to assess the accuracy of the data we use to calculate the D–SNP look-alike threshold at § 422.514(d)(2)(ii), but we are not making any changes to the data or timing of these calculations in the final rule and are finalizing as proposed.

As discussed earlier in this section, we believe the exemption for an MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals (based on January enrollment data of the current year) provides a new plan sufficient start-up time before being subject to the contracting limitation at § 422.514(d)(2). We decline to change the timing for determining D–SNP look-alike status based on actual enrollment because we believe clarifying D–SNP look-alike status and use of the transition process may affect the ways in which MA organizations structure their plan benefit packages; making such determinations later in the year would make it impractical to complete the determinations and ensure plans' requests to use the transition process meet the requirements of § 422.514(e) before bids are due on the first Monday in June.

Comment: We only received a few comments on the alternative we described in the November 2023 proposed rule of eliminating the 70-percent threshold applying for plan year 2025 but would involve additional conditions and changes related to the transition authority. Specifically, this alternative would apply the 60-percent threshold beginning in plan year 2026; permit use of the transition authority into non-SNP MA plans (as currently permitted under § 422.514(e)) for plan year 2025; and limit use of transition authority under § 422.514(e) to transition D–SNP look-alike enrollees into D–SNPs for plan year 2026 and beyond. Some of these commenters opposed the alternative consistent with their opposition to CMS's proposal to lower the D–SNP look-alike threshold and revise the D–SNP look-alike transition process. A commenter welcomed the alternative providing plans an additional year to apply for new D–SNPs or service area expansions for existing D–SNPs. Another commenter believed the additional time provided by the alternative would be unnecessary because MA organizations have had the opportunity to apply for a D–SNP when they applied for a D–SNP look-alike and did not.

Response: We thank the commenters for responding to our request for comments on an alternative proposal. Our alternative proposal would delay lowering the D–SNP look-alike threshold by one year—to plan year 2026 rather than plan year 2025, as proposed—but would apply the 60-percent threshold starting with plan year 2026 rather than the 70-percent threshold. The alternative would also limit use of transition authority under § 422.514(e) to transition D–SNP look-alike enrollees into D–SNPs for plan year 2026 and beyond, which is one year earlier than our proposal.

Our reasons for not implementing the alternative are consistent with our reasons for not delaying implementation of our proposal. As we articulated earlier in this section, the D–SNP look-alike prohibition and contracting standard have been in place for several years at this point and MA organizations are familiar with it. We do not believe additional delay before implementing the lower threshold is necessary. We agree with the commenter about MA organizations having had time to apply for a D–SNP although—as discussed earlier in this section—we recognize that some States do not contract with D–SNPs that enroll partial-benefit dually eligible individuals. In our experience with implementation of the existing D–SNP look-alike prohibition and contracting standard, despite having additional time to establish D–SNPs MA organizations did not establish new D–SNPs as the replacements for existing D–SNP look-alikes. Since November 2023, MA organizations have been aware of our proposal to lower the D–SNP look-alike threshold to 70 percent for plan year 2025 and 60 percent for plan year 2026 and subsequent years. MA organizations have had time to start working with State Medicaid agencies on SMACs, and they have additional time to continue to work with State Medicaid agencies after this rule is finalized and before contract year 2025 SMACs are due in July 2024. We are not finalizing the alternative approach in this rulemaking.

Comment: A few commenters, while supportive of the changes proposed throughout the rule, noted that there is limited or mixed published research on whether or not enrollment in integrated care for dually eligible individuals leads to improved outcomes. A commenter expressed concern that the model of

integration may fall short of potential and fail to ultimately make meaningful change in health outcomes for enrollees.

Response: We appreciate the commenters' thoughts on the issue, and we look forward to more analysis on the experiences of dually eligible individuals. While there is limited published research on the benefits of integrated care for dually eligible beneficiaries, we find value in the published research that currently exists through MedPAC, MACPAC, and other research bodies. While many of these research papers note that evidence for integrated care is currently mixed, we share MedPAC's position of being ''supportive of integrated plans as a way to address the misaligned incentives between Medicare and Medicaid, improve care coordination, and improve outcomes for dual-eligible beneficiaries.'' [251] We will continue to monitor the growing body of research, as well as continue to carry out our own monitoring, regarding integrated care so that dually eligible individuals have access to seamless, high quality health care.

Comment: A commenter suggested that CMS consider excluding dually eligible individuals from enrolling in non-SNP MA plans, including by reassignment, when any of the Part C, Part D, or overall Star Ratings fall below average, which the commenter identified as 3.0. The commenter offered data specific to Massachusetts, citing that within the four non-SNP MA plans with the highest rates of dually eligible enrollment (as of February 2023), 69 percent of dually eligible individuals were enrolled in a plan that received 2024 Part C, Part D, and/or overall Star Ratings of 2.5 or less and 31 percent of dually eligible individuals were enrolled in a plan rated 4.0 or higher. To target additional monitoring or exclusion of non-SNP MA plans with stratified low Star Ratings for its dually eligible enrollees, the commenter urged CMS to review Star Rating data stratified by full-benefit dually eligible individuals versus other Medicare beneficiaries within non-SNP MA plans disproportionately serving dually eligible individuals.

Response: We thank the commenter for sharing these perspectives. The comments are outside the scope of this rulemaking, but we will consider them for future rulemaking.

Comment: A commenter recommended that CMS take steps to put C–SNPs into the category of D–SNP look-alikes. The commenter described C–SNPs as restrictive in the level of coordination and services they provide, which exemplifies C–SNPs acting more like D–SNP look-alikes than true SNPs.

Response: We appreciate the comment, but it is outside the scope of this rulemaking. As we stated in the June 2020 final rule (85 FR 33813), we excluded SNPs from evaluation against the prohibition on D–SNP look-alikes to allow for the predominant dually eligible enrollment that characterizes D–SNPs, I–SNPs, and some C–SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. Nonetheless, we will monitor enrollment in other types of SNPs to assess whether such plans are structured primarily to serve dually eligible enrollees without meeting D–SNP requirements.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing revisions to §§ 422.514(d)(1)(ii), 422.514(d)(2)(ii), and 422.514(e), as proposed.

K. For D–SNP PPOs, Limit Out-of-Network Cost Sharing (§ 422.100(o))

MA organizations offer a range of health plan options including Medicare savings account (MSA) plans, private fee-for-service (PFFS) plans, preferred provider organizations (PPOs), health maintenance organizations (HMOs) and health maintenance organizations with point of services benefits (HMO/POS). (See § 422.4.) The most common health plan options are HMOs and PPOs. HMOs generally require enrollees to use network providers. PPOs have a network of providers but also pay for services delivered by providers not contracted with the MA organization as a network provider. PPOs can be attractive to Medicare beneficiaries who want a broader choice of providers than would be available through an HMO or who have a specific preferred provider, like a psychiatrist, who is not in network. MA organizations offer PPOs that are open to all Medicare beneficiaries as well as D–SNP PPOs that enroll only individuals dually eligible for Medicare and Medicaid.[252]

We noted in the proposed rule that enrollment in D–SNP PPOs has increased in recent years, rising to approximately 925,000 enrollees as of May 2023, accounting for about 17 percent of total D–SNP enrollment. D–SNP PPO enrollment has increased by 38 percent from May 2022 to May 2023.[253] Four national MA sponsors account for over 98 percent of D–SNP PPO enrollment.[254]

Like PPOs offered primarily to Medicare beneficiaries not entitled to Medicaid benefits, D–SNP PPOs generally have higher cost sharing for out-of-network services than for the same services obtained from network providers. For non-D–SNP PPOs, the higher out-of-network cost sharing is meant to incentivize use of in-network providers. In D–SNP PPOs, however, the large majority of enrollees are protected from being billed for covered Medicare services delivered by Medicare providers, including out-of-network providers. Instead, when these enrollees access services, either State Medicaid agencies pay the cost sharing or, if State payment of cost sharing is limited by a Medicaid rate for the service that is lower than the amount the D–SNP paid the provider, the provider must forego receipt of the cost sharing amounts.

Those cost sharing amounts for out-of-network services in D–SNP PPOs are often significantly higher than the cost sharing for the same services under original Medicare, including for physician services, Part B prescription drugs, DME, home health, dialysis, and stays in SNFs, acute and psychiatric inpatient hospitals.

This higher cost sharing for out-of-network services in D–SNP PPOs raises several concerns. First, when State Medicaid agencies pay the cost sharing for out-of-network services, these levels of cost sharing raise costs for State Medicaid programs.

Second, certain dually eligible enrollees, specifically full-benefit dually eligible enrollees who are not Qualified Medicare Beneficiaries (QMBs), are liable for cost sharing if they go out of network to providers not enrolled in Medicaid, as services from these providers are not covered by Medicaid unless the provider is enrolled in Medicaid.

Third, the higher out-of-network cost sharing disadvantages out-of-network safety net providers serving D–SNP PPO enrollees in States where limits established by Medicaid rates for the service result in no State payment of cost sharing.[255] A more detailed

[251] MedPAC, Congressional Request for Information on Dual-Eligible Beneficiaries, January 13, 2023. Retrieved from: *https://www.medpac.gov/wp-content/uploads/2023/01/01132023_DualEligibles_RFI_MedPAC_Comment_SEC_v2.pdf.*

[252] There are currently no D–SNP PFFS plans. MSA plans are prohibited from enrolling dually eligible individuals. HMO/POS plans have 1,423,000 enrollees as of July 2023.

[253] D–SNP PPO enrollment was at approximately 668,000 as if May 2023.

[254] The four sponsors are UnitedHealth Group (69 percent of national D–SNP PPO enrollment), Humana (23 percent), Centene (4 percent), and Elevance (2 percent).

[255] For example, if the Medicare (or MA) rate for a service is $100, of which $20 is beneficiary coinsurance, and the Medicaid rate for the service

discussion of the impact of higher out-of-network cost sharing in D–SNP PPOs can be found in the November 2023 proposed rule beginning on page 88 FR 78584.

In addition to the potential impact of this cost sharing structure on States, safety net providers, and dually eligible individuals, we believe such higher cost sharing for out-of-network services may result in situations that are inconsistent with the policy goals underlying section 1852(a)(2) of the Act. Section 1852(a)(2)(A) of the Act describes how MA organizations can satisfy the requirement to cover Traditional Medicare services (that is, Part A and B benefits, with limited exceptions) under section 1852(a)(1)(A) when covered services are furnished by non-contracted (that is, out-of-network) providers. This statute provides that the MA organization has satisfied its coverage obligation for out-of-network services if the plan provides payment in an amount ''so that the sum of such payment and any cost sharing provided for under the plan is equal to at least the total dollar amount for payment for such items and services as would otherwise be authorized under parts A and B (including any balance billing permitted under such parts).''

For a non-D–SNP PPO, in which the majority of plan enrollees must pay plan cost sharing, the total dollar amount for a service paid at the Medicare rate will equal the total dollar amount under parts A and B, even if the cost sharing exceeds the cost sharing under Traditional Medicare.

For a D–SNP PPO, however, the vast majority of plan enrollees are not liable for cost sharing for out-of-network services, just as they are not liable for such cost sharing under Traditional Medicare.[256] Therefore, whenever State Medicaid limits on payment of Medicare cost sharing result in no payment of cost sharing or payment of only a portion of cost sharing, the total dollar amount of payment received by the out-of-network provider for these covered services is less than the provider would collect under Traditional Medicare whenever the plan out-of-network cost sharing exceeds the cost sharing for those services under Traditional Medicare.

This lesser net out-of-network provider payment in a D–SNP PPO undermines the balance of obligations and benefits among MA organizations and Medicare providers that the statute creates to regulate out-of-network payments and beneficiary access for the MA program. While section 1852(a)(2)(A) of the Act requires the total dollar amount to be at least as much as would be authorized under Traditional Medicare, Medicare providers are required by sections 1852(k)(1) and 1866(a)(1)(O) of the Act to accept such amounts as payment in full. When a D–SNP PPO imposes cost sharing greater than Traditional Medicare and that cost sharing is unpaid by the State and uncollectable from the beneficiary, the MA organization has, in effect, failed to fulfill the spirit of its side of this statutory scheme and the providers are in effect forced to accept less than they would receive under Traditional Medicare if they agree to treat the D–SNP PPO enrollee.

In a D–SNP PPO, therefore, we are concerned that the combination of these issues results in a situation frustrating the underlying intent of section 1852(a)(2)(A) of the Act because, for services furnished to many (if not all) enrollees in the D–SNP PPO, the out-of-network provider potentially receives a total payment that is less than the total payment available under Traditional Medicare. To address these concerns, we proposed new limits on out-of-network cost sharing under D–SNP PPOs. We have authority under section 1856(b)(1) of the Act to establish standards for MA organizations and MA plans to carry out the MA statute (that is, Part C of Title XVIII of the Act) in addition to authority, under section 1857(e)(1) of the Act, to adopt additional terms and conditions for MA contracts that are not inconsistent with the Part C statute and that are necessary and appropriate for the MA program. Further, CMS is not obligated to accept any and every bid from an MA organization and is authorized to negotiate MA bids under section 1854(a)(5)(C) and (a)(6)(B) of the Act. We proposed regulatory amendments that would establish minimum standards for D–SNP PPO plans that are consistent with and necessary and appropriate for the MA program to address our concerns.

We proposed at § 422.100(o)(1) that an MA organization offering a local PPO plan or regional PPO plan that is a dual eligible special needs plan (that is, a D–SNP) cap out-of-network cost sharing for professional services at the cost sharing limits for such services established at § 422.100(f)(6) when such services are delivered in network starting in 2026. The term ''professional services'' as used here means the same thing as it does in existing § 422.100(f)(6)(iii) and includes but is not limited to primary care services, physician specialist services, partial hospitalization, and rehabilitation services. Under this proposal, a D–SNP PPO with a catastrophic limit set at the mandatory MOOP limit in 2026 and subsequent years must have cost sharing for a visit with an out-of-network psychiatrist or other specialist (that is, cost sharing subject to paragraph (f)(6)(iii)) that is capped at 30 percent coinsurance. If the catastrophic limit is set at the intermediate MOOP limit in 2026 and subsequent years, the coinsurance cap would be set at 40 percent. If the catastrophic limit is set at the lower MOOP limit in 2026 and subsequent years, the coinsurance cap would be 50 percent. Under our proposal, the rules in § 422.100(f)(6) and (j)(1) about how we assess that copayments that are actuarially equivalent to coinsurance would apply to new § 422.100(o) as well.

Our proposal at § 422.100(o)(1) also would require that cost sharing for out-of-network acute and psychiatric inpatient services be limited by the cost sharing caps under § 422.100(f)(6) that now apply only to in-network benefits. Using the same methodology to calculate comparable FFS cost sharing in § 422.100(f)(6)(iv), the cost sharing limit for a D–SNP PPO with a catastrophic limit set at the mandatory MOOP limit could not exceed 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length-of-stay scenario in an out-of-network inpatient or psychiatric hospital. For catastrophic limits equivalent to the intermediate and lower MOOP amounts, higher cost sharing for out-of-network cost sharing for inpatient and psychiatric stays could be charged as described at § 422.100(f)(6)(iv)(D)(*2*) and (*3*), respectively.

We also proposed at § 422.100(o)(2), by cross-referencing § 422.100(j)(1), that cost sharing for out-of-network services under D–SNP PPOs be limited to the existing cost sharing limits now applicable to specific in-network services for all MA plans. For a more detailed discussion of these proposed limitations, which apply to chemotherapy/radiation services, Part B drugs, renal dialysis, SNF care, home

is $90, the State would only pay $10. If the Medicaid rate is $80 or lower, the State would make no payment. This is often referred to as the ''lesser of'' policy. Under the ''lesser of'' policy, a state caps its payment of Medicare cost-sharing at the Medicaid rate for a particular service.

[256] For more information on cost sharing protections applicable to dually eligible individuals, see: *https://www.cms.gov/medicare-medicaid-coordination/medicare-and-medicaid-coordination/medicare-medicaid-coordination-office/qmb.*

health and DME, please see 88 FR 78585.

For regional PPO D–SNPs, we proposed to exclude paragraph (j)(1)(i)(C)(*2*) and the last sentence of paragraph (j)(1)(i)(E) regarding overall actuarial equivalence requirements to avoid conflict with section 1852(a)(1)(B)(ii) of the Act.

We believe our proposed uniform application of out-of-network cost sharing limits for all PPO D–SNPs is the appropriate way to address our concerns about section 1852(a)(2)(A), the shifting of costs to States, the reduction in net payments to safety net providers, and the potential for excessive cost sharing for those dually eligible individuals, who, while low income, do not benefit from cost sharing protections out-of-network.

To provide the industry time to adjust to and for CMS to operationalize these new requirements, we proposed to implement these new limits starting for the 2026 plan year.

Currently, D–SNP PPOs already submit out-of-network benefits for a limited review to ensure that cost sharing does not exceed 50 percent of the costs (as required by § 422.100(f)(6)(i)) and in-network benefits for a review to ensure compliance with the cost sharing limits we propose to apply to out-of-network cost sharing. In the proposed rule (88 FR 78586), we stated that we do not believe this rule creates substantial information collection requirements. We received no comments on our burden estimates. In this final rule, we are finalizing, as proposed, that this rule does not create substantial information collection requirements.

In the proposed rule at 88 FR 78586, we discussed our burden estimate for this proposal, stating that we did not expect any new burden to be associated with these requirements. We did not receive any comments on burden estimates for this proposal and are finalizing the proposed burden estimates without change.

We received the following comments on this proposal and respond to them below:

Comment: Numerous commenters, including the vast majority who commented on this topic, supported our proposal to impose limits on the out-of-network cost sharing for Parts A and B benefits in the benefit packages offered by D–SNP PPOs.

Response: We thank the commenters for their support.

Comment: A few commenters asked CMS to require the new cost sharing limits for plan year 2025 rather than for the 2026 plan year, as we had proposed.

Response: We decline to accelerate the timetable for implementation of this proposal. The additional time is necessary for changes to bid review systems and industry training on bid submission to enable implementation of the proposed requirements.

Comment: Several commenters supported the alternative proposal we had considered: capping all D–SNP PPO out-of-network cost sharing to levels consistent with Traditional Medicare. Several other commenters warned that imposing such limits, which are stricter than those imposed for in-network services, could result in an increase in cost sharing levels for in-network services.

Response: We appreciate the comments on the alternative we had considered in the proposed rule. We share the concerns raised from a variety of commenters on the potential to lead to higher in-network cost sharing and decline at this time to finalize these more stringent limits on out-of-network cost sharing for D–SNP PPOs.

Comment: MedPAC expressed support for policy remedies to address the cost sharing issues described in the proposed rule. However, citing CMS's finding that the cost sharing imposed by D–SNP PPOs is often higher than Traditional Medicare for out-of-network services and similar to Traditional Medicare for in-network services, MedPAC questioned how such plans are meeting the requirement that aggregate cost sharing be actuarially equivalent to the cost sharing charged under Traditional Medicare. MedPAC encouraged CMS to provide additional detail about how actuarial equivalence is assessed and enforced for D–SNP PPOs, and to provide evidence that the benefit packages of D–SNP PPOs charging high out-of-network cost sharing are meeting actuarial equivalence standards. MedPAC encouraged CMS to clarify whether cost sharing for in-network services can be reasonably expected to increase under the rule for plans seeking to maintain their current actuarial value and whether such an outcome is an intended consequence of the proposed policy.

Response: CMS regulations at §§ 422.100(f)(5) and 422.101(d)(3) require that all MA PPO plans have a maximum out-of-pocket (MOOP) amount. Because of the level of flexibility in these MOOP and cost sharing limit requirements, an MA plan could comply with the MOOP limit requirements, have cost sharing that is more generous on certain highly-utilized Part A or B benefits, and have cost sharing for other benefits that is higher than cost sharing in Original Medicare to design a benefit package that is actuarially equivalent to Original Medicare without offering reductions in cost sharing for Part A and B benefits as a supplemental benefit. However, most MA plans do offer supplemental benefits in the form of reductions in cost sharing for services under Parts A and B compared to Original Medicare. We consider the effect of the MOOP in evaluating the plan benefit packages for Medicare Parts A and B benefits to ensure actuarial equivalence. Where the MA organization's decision as to which MOOP level to use in combination with the other cost sharing requirements for basic benefits causes the basic benefit (that is, the Part A and B benefit package) to be actuarially more generous than Traditional Medicare, we treat that excess value as a mandatory supplemental benefit. Where an MA organization has elected to use cost sharing that is exactly like Original Medicare—where there is not a MOOP limit—for all Part A and Part B benefits, the MA organization has not balanced the actuarial value of the MOOP against other cost sharing in the MA plan to achieve a plan design that is actuarially equivalent to Original Medicare without any supplemental benefits. Using higher cost sharing for out-of-network services may provide a means to balance the actuarial value of the MOOP limit without resulting in the MA plan offering supplemental benefits in the form of cost sharing reductions for Part A and B benefits. Because the enrollees in a D–SNP PPO are generally protected from the cost sharing, the competitive incentives for a D–SNP to elect to offer cost sharing reductions as a supplemental benefit is reduced or eliminated in favor of the D–SNP covering additional items and services, which dually eligible individuals are more likely to perceive as more beneficial and useful.

Mathematically, under our final rule, the plan sponsor could increase the in-network cost sharing while decreasing the out-of-network cost sharing and still meet the actuarial equivalence requirements. However, there is a business disincentive associated with this action. If the in-network cost sharing were to increase, this could lead to lower payments for their network providers and future difficulties establishing networks. Therefore, we do not expect our proposed regulation limiting out-of-network cost sharing for D–SNP PPOs to increase in-network cost sharing.

In addition, section 1852(a)(1)(B)(ii) of the Act provides that in applying the requirement that MA plans cover Traditional Medicare benefits with

actuarially equivalent cost sharing does not apply to out-of-network services covered by MA regional plans; therefore, in evaluating whether the plan design—and cost sharing—of an MA regional plan complies with section 1852(a)(1)(B) of the Act, we do not consider out-of-network cost sharing. This is also reflected in § 422.100(j)(2), which excludes the out-of-network benefits covered by a regional MA plan from the cost sharing evaluations specified in § 422.100(j)(2)(i).

Comment: A few commenters expressed concern that the proposal would eliminate D–SNP PPOs which provide access to covered benefits outside of the plan's network while a few other commenters urged CMS to use its authority not to allow any D–SNP PPOs.

Response: We do not believe the requirements for increased cost sharing will force D–SNP PPOs to exit the markets. We note that, compared to non-D–SNP PPOs and to non-PPO D–SNPs, D–SNP PPOs had higher financial margins in the bids submitted for both the 2023 and 2024 plan years. And our final rule will not result in major changes to benefit design or other features that would cause disruption in the market. Not allowing any D–SNP PPOs is beyond the scope of this rulemaking.

Comment: Several commenters requested that CMS monitor the impact of finalizing and implementing the proposal, including on access to other supplemental benefits and on in-network cost sharing under D–SNP PPOs.

Response: We thank the commenters for this suggestion and will continue to monitor the offerings of D–SNP PPOs.

Comment: We received a number of comments that were beyond the scope of this rulemaking. These include several requests from commenters for CMS to improve access to in-network services, including for DME, teaching hospitals, and home care. A few commenters noted that the lesser-of policies employed by State Medicaid agencies can impede access to services for dually eligible individuals and disadvantage the providers who serve them. Several commenters noted that the materials used by D–SNP PPOs should provide an accurate picture of the cost sharing enrollees will face out-of-network. A few commenters requested that the proposed out-of-network cost sharing limits for D–SNP PPOs be applied to non-D–SNP PPOs as well.

Response: We thank the commenters for this input and will take it into consideration in our ongoing oversight of the MA program.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed amendment at § 422.100(o)(1) that, starting in 2026, for an MA organization offering a local PPO plan or regional PPO plan, cost sharing for out-of-network services under D–SNP PPOs will be limited to the existing cost sharing limits now applicable to specific in-network services for all MA plans, as described in § 422.100(f)(6). We are also finalizing, with minor technical edits, our proposed amendment at § 422.100(o)(2) to limit out-of-network cost sharing to the cost sharing limits for such services established at § 422.100(j)(1) when such services are delivered in network by cross-referencing § 422.100(j)(1).

We also note that some of the public comments received for the provisions related to the integration of Medicare and Medicaid were outside of the scope of the proposed rule. These comments covered topics such as: opportunities for States to share in savings from integrated care and aligned enrollment; modernizing identification cards for dually eligible enrollees; impact of Medicare and Medicaid policies on rural areas; long term care pharmacy services for dually eligible enrollees eligible for institutional care; default enrollment; and private equity. We appreciate the input. However, as these comments are outside the scope of this rulemaking, they are not addressed in this final rule.

IX. Updates to Programs of All-Inclusive Care for the Elderly (PACE) Policy

A. PACE Past Performance (§§ 460.18 and 460.19)

Sections 1894(e)(4) and 1934(e)(4) of the Act establish CMS's authority to oversee the PACE program. To strengthen CMS's oversight of the PACE program, we proposed to amend the PACE regulation at § 460.18 (CMS evaluation of applications) to incorporate an evaluation of past performance into the review of applications submitted by PACE organizations that seek to offer a PACE program or expand an approved program by adding a geographic service area and/or PACE center site or sites. Our evaluation of past performance will be a criterion CMS will use to review a PACE organization's application. The addition of this evaluation criterion at § 460.18(c) will permit CMS to deny applications from PACE organizations based on the organization's past performance. We also proposed to establish at § 460.18(d) that CMS may deny a PACE application if the PACE organization's agreement was terminated by CMS or not renewed during the 38 months preceding the date the application was first submitted to CMS.

The performance history of an organization is an important criterion for CMS to consider when evaluating a PACE application because the past performance of an organization may be a valuable predictor of an organization's ability to effectively operate a new PACE program or expand an existing program. Organizations that have performed well are more likely to continue their high performance while organizations that have not performed well may have even greater difficulty meeting regulatory requirements when operating a new or expanded PACE program in addition to their existing PACE program. CMS believes that adding the consideration of an organization's past performance will guard against poor-performing organizations expanding their footprint and putting the health and safety of future PACE participants they enroll at risk. It is important for CMS to ensure that the legal entities with whom we hold program agreements can safely, effectively, and appropriately provide health care services and benefits to PACE participants, who are frail and elderly and among the most vulnerable Medicare beneficiaries.

In the Medicare Advantage (MA) and Part D programs, CMS considers an organization's past performance during the evaluation of its application. We modeled the proposed PACE past performance review regulations after the MA and Part D past performance review regulations at 42 CFR parts 422 and 423, using applicable evaluation criteria. We believe modeling the PACE past performance review criteria after the criteria that appear in the MA and Part D regulations is appropriate given that consideration of past performance has been a long-standing part of application reviews under the MA and Part D programs, resulting in the denial of initial and expansion applications of poorly performing organizations. As with its reviews of MA and Part D applications, CMS seeks through its review of PACE applications to identify poorly performing organizations and to prevent such organizations from entering into new agreements or expanding their service area in the program.

As explained in the proposed rule, we believe modeling past performance

reviews in PACE on past performance reviews in MA and Part D is appropriate since PACE organizations that provide Part D benefits are subject to the Part D regulations at 42 CFR part 423, except for those regulations CMS has waived in accordance with § 423.458(d). In addition, modeling after past performance reviews in MA and Part D reduces burden for PACE organizations by not having a different set of criteria for the non-Part D PACE benefits. In keeping with this requirement, our proposal would ensure that all entities that submit PACE applications would be subject to past performance reviews, the same as PACE entities that submit Part D applications.

In the January 2021 final rule (86 FR 5864), we established in regulation the methodology and criteria used to decide to deny an MA or Part D application based on prior contract performance (§§ 422.502(b) and 423.503(b)). We noted in the final rule that we may deny applications based on past contract performance in those instances where the level of previous noncompliance is such that granting additional MA or Part D business opportunities to the responsible organization would pose a high risk to the success and stability of the MA and Part D programs and their enrollees (86 FR 5999). In the January 2021 final rule and through subsequent rulemaking, we adopted the following factors as the basis for denying an MA or Part D application: (A) the organization was subject to an intermediate sanction; (B) the organization failed to maintain a fiscally sound operation; (C) the organization filed for bankruptcy or is under bankruptcy proceedings; (D) the organization had low Star Ratings for two or more consecutive years; or (E) the organization exceeded CMS's threshold for compliance actions (*see* 86 FR 6000 and 87 FR 27704). Each of these factors, on its own, represents significant noncompliance with an MA or Part D contract; therefore, the presence of any of these factors in an applicant's record during the past performance review period could allow CMS to deny its MA or Part D application.

In the December 2022 proposed rule, we proposed to apply a past performance methodology to entities that seek to offer a new PACE program or expand an existing program. We proposed to modify the PACE regulations at 42 CFR part 460 to permit CMS to consider an entity's past performance in determining whether to approve or deny a new application or an application to expand a current program. Our proposed methodology for taking into account past performance when evaluating PACE applications is similar to the methodology we use when deciding whether to deny MA and Part D applications based on past performance. As with our MA and Part D past performance reviews, the purpose of the proposed PACE past performance reviews is to prevent organizations from expanding their PACE operations in circumstances where the organization's past conduct indicates that allowing the organization to expand would pose a high risk to the success and stability of PACE and the welfare of PACE participants. Like MA organizations and Part D sponsors, PACE organizations that have been under sanction, failed to meet fiscal soundness requirements, or been issued compliance actions above a certain threshold have demonstrated that they have had significant failures in operating their program. Consistent with the past performance standards for MA and Part D and discussed in the December proposed rule beginning on page 79637, we proposed that CMS would have the authority to deny an initial or service area expansion (SAE) application based on the same factors (other than low Star Ratings) that serve as the basis for denying an MA or Part D application. We did not propose to include Star Ratings in the past performance reviews for PACE because we do not calculate these measures for PACE organizations.

We accept applications on designated quarterly submission dates from entities seeking to either establish a PACE program or expand an existing program. Like MA applications, and in accordance with § 460.18, CMS evaluates a PACE application based on information contained in the application itself, as well as information obtained by CMS (or the applicable State Administering Agency (SAA), which serves as the designated State agency for PACE), through on-site visits, or any other means. If an organization meets all application requirements, we approve the application.

We proposed to incorporate past performance reviews into the PACE application process to safeguard the program and ensure PACE participants are protected from the expansion of poorly performing organizations. The PACE program has seen significant growth in recent years, with increased numbers of both initial and expansion applications and steady increases in overall enrollment. This growth can be attributed in part to the statutory not-for-profit restriction no longer being applied beginning in May 2015, which allowed for-profit entities to operate PACE programs (see sections 1894(h) and 1934(h) of the Act).

From 2012 to 2013, Mathematica Policy Research, under contract with CMS, conducted a study to address the quality of and access to care for participants of for-profit PACE programs. Based on the 2012 Mathematica study and a prior study in 2008, HHS prepared and submitted the report to the Congress on May 19, 2015. Based on the findings in the report to Congress, we determined that under sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act, the requirement that a PACE program be a not-for profit entity would no longer apply after May 19, 2015 (the submission date of the report to Congress).

Prior to that change, only not-for-profit entities were eligible to offer PACE programs. At the end of calendar year 2016, a total of 121 approved PACE organizations were in operation, serving 37,584 predominantly dually eligible participants. In calendar year 2022, we received 35 initial applications and 29 expansion applications. As of August 2023, there were 154 PACE organizations serving 70,209 participants in 32 States and the District of Columbia.

PACE participants are some of the most vulnerable Medicare beneficiaries. To enroll in a PACE program, the SAA must determine that the beneficiary needs the level of care required under the State Medicaid plan for coverage of nursing facility services (§ 460.150(b)(2)). Beneficiaries who need this level of care are generally frail, may have multiple chronic conditions, and require extensive assistance with activities of daily living. The PACE organization is responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year (§ 460.98(a)). Each PACE organization must have a center, which PACE participants can visit weekly or even daily, based on each participant's needs and preferences. The PACE center must provide primary care services, nursing services, social services, restorative therapies (including physical therapy and occupational therapy), personal care and supportive services, nutritional counseling, recreational therapy, and meals (§ 460.98(c)).

As discussed in the proposed rule given the recent and anticipated future growth in PACE and the vulnerable populations that PACE organizations serve, we believe that the past performance of a PACE organization should be reviewed as part of the application process. Past performance evaluations ensure CMS only approves

initial PACE applications and applications for service area expansions from existing PACE organizations that have a strong and positive record of performance. The ability to deny initial PACE applications or service area expansion applications submitted by organizations that we determine are poor performers helps to ensure that the organizations with which we have an agreement will be able to provide health care services to beneficiaries in a high-quality manner.

The PACE application review process is unique, and we finalized rules with that process in mind. Per the regulations at § 460.20(a) and (c), upon receipt of a complete PACE application, CMS must: (1) approve the application; (2) deny the application; or (3) issue a request for additional information (RAI) in the event there are deficiencies. CMS's deadline for these actions is within 90 days of submission of an initial application or for a service area expansion (SAE) application that includes both a proposed geographic expansion and a new center site, or within 45 days of submission of an SAE application that includes either a proposed geographic expansion or a new center site. If CMS issues an RAI, the applicant must respond to the RAI only when ready and able to submit a complete response that addresses all deficiencies cited in the RAI, which includes a complete State readiness review (SRR) report, as applicable. If CMS issues an RAI, the first review clock ends and the second and final review clock does not begin until the applicant submits a complete RAI response, which starts the second and final 45- or 90-day review clock, as applicable. As part of the application process, the applicable SAA must conduct an SRR at the applicant's proposed PACE center site (if applicable) to ensure that the PACE center meets the State's regulatory requirements. Applicants are required to submit documentation of the completed SRR report to CMS for applications that include a new PACE center site (*see* § 460.12(b)(2)). Per application instructions, the SRR report is the only required document that may be uploaded after the initial application submission, in response to CMS's RAI. In our experience, a response to a RAI may take anywhere from a few weeks to more than a year to receive, often because of the renovation or construction of a center site, attainment of building permits, and/or the need for a readiness review to be completed. The MA and Part D past performance review currently has a 12-month look-back period which is defined as the most recent 12 months preceding the application deadline (*see* § 422.502(b) and 423.503(b)). Since MA and Part D applications are generally due in February of each year, this review period results in a 12-month look-back period that covers the previous March through February of the year the applications are due. We proposed to use a 12-month review period for PACE past performance, which is the same lookback period that applies to MA and Part D past performance reviews. Under our proposal, CMS would review an organization's past performance for the 12 months preceding the deadline established by CMS for the submission of PACE applications. We proposed that, if CMS sends a Request for Additional Information (RAI) to the organization, the 12-month look-back review period would apply upon receipt of the applicant's response to CMS's RAI. As explained in the proposed rule, a 12-month look-back period provides recent information on the operations of a PACE organization, which we believe is the best indicator of the PACE organization's current and future performance.

We proposed to specify at § 460.18(c)(1)(i) that CMS would evaluate the following components of an applicant organization's past performance, starting with the March 2025 quarterly application submission cycle: whether the organization was subject to an enrollment or payment sanction under § 460.42(a) or (b) for one or more of the violations specified in § 460.40, even if the reasons for the sanction have been corrected and the sanction has been lifted; whether the organization failed to maintain fiscal soundness; whether the organization has filed for or is under State bankruptcy proceedings; and whether the organization has exceeded CMS's proposed 13-point threshold for compliance actions with respect to the PACE program agreement. We proposed that, if any of those circumstances applies to the applicant organization, CMS may deny its initial or expansion application.

Specifically, we proposed at § 460.18(c)(1)(i)(A) to include the imposition of enrollment or payment sanctions under § 460.42 for one of the violations listed in § 460.40 as a reason for which we may deny a PACE application, as noted in the previous paragraph. Currently, § 460.42 authorizes CMS to impose a suspension of enrollment or payment if a PACE organization commits one or more of the violations listed in § 460.40. Violations in § 460.40 include the failure of the PACE organization to provide medically necessary services, discrimination in enrollment or disenrollment of individuals eligible to enroll in a PACE program based on health status or need for health services, and involuntary disenrollment of a PACE participant in violation of § 460.164. These violations are serious and egregious actions by the PACE organization. Organizations that have been sanctioned (enrollment or payment) based on their failure to comply with CMS's regulations have either admitted they failed to comply with PACE requirements or have appealed and a third party has upheld CMS's determination that the PACE organization failed to comply with requirements. Because of the egregiousness of the actions that led to the PACE organizations' sanctions, we do not believe these organizations should be permitted to enter into new agreements, add new PACE sites, or expand their service area until the PACE organization corrects the issues that resulted in the sanction and ensures that such issues are not likely to recur.

We proposed at § 460.18(c)(1)(i)(B) to include, as a basis for application denial, the failure to maintain a fiscally sound operation after the end of the trial period. For purposes of fiscal soundness, the trial period ends when CMS has reviewed independently audited annual financial statements covering three full 12-month financial reporting periods. The regulation at § 460.80(a) requires a PACE organization to have a fiscally sound operation. Under § 460.80(a)(1), a PACE organization must have a positive net worth as demonstrated by total assets greater than total unsubordinated liabilities. To monitor compliance with § 460.80(a)(1), we require PACE organizations to submit certified financial statements on a quarterly basis during the trial period, and annually thereafter, unless CMS or the SAA determines that the organization requires more frequent monitoring and oversight due to concerns about fiscal soundness, in which case the organization may be required to submit certified financial statements on a monthly or quarterly basis (or both) (§ 460.208). Fiscal soundness is a key factor in our evaluation of past performance because we have a responsibility to ensure the organizations that provide health care services to Medicare beneficiaries have sufficient funds to allow them to pay providers and otherwise maintain operations. The failure of an organization to have a positive net worth puts PACE participants in

jeopardy of not receiving necessary health care. In addition, organizations that are not fiscally sound may not be able to continue operations, causing the organization to close its PACE physical site, leaving PACE participants without PACE access to their PACE organization. Based on this, we believe it is in the best interest of the program to add failure to maintain a fiscally sound operation—specifically, failure to have a positive net worth as demonstrated by total assets greater than total unsubordinated liabilities—to the list of reasons CMS may deny a new application or an expansion application from a PACE organization.

We proposed to establish at § 460.18(c)(1)(i)(C) that CMS may deny the application of an organization that has filed for or is currently in State bankruptcy proceedings. Like an organization that lacks fiscal soundness, an organization that has filed for or currently is in State bankruptcy proceedings is at great risk of having insufficient funds to cover costs associated with administering a PACE program. In circumstances where an organization has filed for bankruptcy or is currently in State bankruptcy proceedings, the outcome often results in the closure of an organization's operations, putting beneficiaries at great risk. Examples of participants being at risk may include the inability to find adequate and timely care, lack of care coordination, loss of access to providers (especially primary care providers who are employed by the PACE organization), and loss of the social and emotional support the PACE organization provides to participants. Thus, permitting an organization to expand while under bankruptcy proceedings is not in the best interest of the PACE program, and as CMS is responsible for oversight of PACE, we believe it is appropriate for us to have the authority to deny an application from any organization that has filed for or is in State bankruptcy proceedings.

Finally, we proposed to establish at § 460.18(c)(1)(i)(D) that CMS may deny an initial application or an expansion application for a PACE organization that exceeds the proposed 13-point threshold with respect to CMS-issued compliance actions. We proposed to specify at new § 460.19(a) that CMS may take compliance actions as described at § 460.19(c) (discussed in this section of this rule) if CMS determines that a PACE organization has not complied with the terms of a current or prior PACE program agreement with CMS and an SAA. PACE organizations are required to adhere to requirements in sections 1894 and 1934 of the Act and at 42 CFR part 460. As proposed, § 460.19(a)(1) would provide that CMS may determine that a PACE organization is noncompliant with requirements if the PACE organization fails to meet set performance standards articulated in sections 1894 and 1934 of the Act, regulations at 42 CFR chapter IV, and guidance. In addition, we proposed to establish at § 460.19(a)(2) that if CMS has not previously articulated a measure for determining compliance, CMS may determine that a PACE organization is non-compliant if its performance in fulfilling requirements represents an outlier relative to the performance of other PACE organizations.

Currently, we issue three types of compliance actions: Notices of Non-Compliance (NONCs), Warning Letters (WLs), and Corrective Action Plans (CAPs).[257] These actions are our formal way of recording an organization's failure to comply with statutory and regulatory requirements as well as providing notice to the organization to correct its deficiencies or risk further compliance and/or enforcement actions. They also serve to document the problem and, in some instances, request details regarding how the organization intends to address the problem.

First, we proposed to specify that NONCs may be issued for any failure to comply with the requirements of the PACE organization's current or previously terminated program agreement. We typically use a NONC to document small or isolated compliance problems. NONCs represent the lowest level of compliance action issued by CMS. We typically issue NONCs for the least egregious failures, such as a first-time offense, a failure that affects only a small number or percentage of participants, or issues that have no participant impact. An example of a failure that would lead to an NONC would be a failure to upload marketing materials or incorrectly uploading these materials.

Second, we proposed to specify that a WL may be issued for a serious failure or continued failure to comply with the requirements of the PACE organization's current or previously terminated prior program agreement. WLs are typically issued as an intermediate level of compliance action and when discussing compliance actions on a continuum, would be issued for compliance issues that fall in terms of the level of their egregiousness between a NONC and a CAP. WLs are issued when an organization has already received a NONC and the problem continues to persist without correction, or they may be issued after a first offense when the offense concerns a larger or more concerning problem, such as failure to provide medically necessary services. Unlike NONCs, WLs contain language informing the PACE organization of the potential consequences to the organization should the non-compliant performance continue. An example of when a WL might be issued would be when, for example, a PACE organization has failed to have the full interdisciplinary team (IDT) involved in the review of participant care plans, which may result in participants not receiving necessary care. We might determine that the PACE organization's non-compliance in this regard warrants a higher level of compliance, such as a WL in place of a lower level of compliance. Our determination to issue a WL instead of a NONC, in this case, might be based on a review of factors, such as the type of care that was not received and the consequence of the care, not being properly provided, due to the PACE organization's failure to ensure that the IDT was reviewing all care plans.

Third, we proposed to specify that the last type of compliance action, the CAP, is the most serious type of compliance action and may be issued for particularly egregious or continued non-compliance. We may determine that the PACE organization has repeated, not corrected, or has a new deficiency which substantially impacts participants. In these types of scenarios, we require the PACE organization to implement a CAP. The CAPs contemplated here are not the same as corrective actions issued under § 460.194(a)(2). CAPs issued under § 460.194(a)(2) require PACE organizations to take action to correct deficiencies identified by CMS or the SAA through reviews and audits of the PACE organization (§ 460.194(a)(2)). We have a formal audit process, which separately identifies non-compliance. We issue CAPs under § 460.194(a)(2) resulting from finding of our reviews or audits. CMS routinely requests these CAPs and responses are submitted to CMS by PACE organizations as they address deficiencies identified during CMS reviews or audits. We expect to continue to request CAPs as necessary under § 460.194(a)(2) in response to deficiencies identified through reviews

[257] The CAPs we proposed to issue for purposes of compliance and take into account during past performance evaluations to determine whether to deny PACE organizations' applications would be separate and distinct from CAPs issued under § 460.194(a)(2), which are corrective action plans that are requested and received in the course of audits.

or audits; nothing about this rule would change that process.

Consistent with the past performance methodology applicable to MA, we proposed to assign points to each type of compliance action taken by CMS against PACE organizations. We then proposed to apply a compliance action threshold to determine if the PACE organization that submitted the application exceeds the threshold and should be denied. The following points would be assigned: CAP—6 points, WL—3 points, NONC—1 point. We will then sum the total of the points accrued by the applicant organization, and if the total meets or exceeds 13 points during the 12-month review period, we may deny the organization's new or expansion application on the basis of past performance.

With the addition of compliance actions as a basis for the denial of applications, we proposed to specify at new § 460.19(b) the factors we currently use to determine whether to issue a compliance action and the level of compliance action that should be issued.

At § 460.19(b)(1) through (6), we proposed to codify in regulation the factors CMS currently uses when determining whether and at what level of a compliance action should be issued. As discussed in the paragraphs that follow, we consider the following factors: the nature of the conduct; the degree of culpability of the PACE organization; the actual or potential adverse effect on participants, which resulted or could have resulted from the conduct of the PACE organization; the history of prior offenses by the PACE organization or PACE organization's contractors or subcontractors; whether the non-compliance was self-reported; and other factors which relate to the impact of the underlying non-compliance or to the PACE organization's inadequate oversight of the operations that contributed to the non-compliance.

We proposed to add § 460.19(b)(1) to establish that CMS considers the nature of the PACE organization's non-compliant conduct. The nature of the conduct is relevant to our determination of whether to issue a compliance action and the level of compliance action to take because failure to comply can range from an administrative issue to failure to provide necessary health care. Compliance issues that are less egregious in nature generally result in lower-level compliance actions.

We proposed to specify at § 460.19(b)(2) that CMS considers the degree of culpability of the PACE organization. This factor is relevant because the PACE organization's failure may have been avoided if the PACE organization had performed differently. For example, if the PACE organization failed to properly train or failed to hire properly trained staff to assist participants in activities of daily living, such as bathing, and a participant fell and injured themself in the shower, the PACE organization would be more culpable than if staff were properly trained and the participant still injured themself. The PACE organization has a responsibility to do everything possible to ensure the safety of the participants, and its failure, either intentional or unintentional (for example, lack of training, lack of oversight, lack of staff) would be a factor in our decision about the type of compliance action to take.

As proposed, § 460.19(b)(3) would provide that CMS considers the effects or potential effect of a PACE organization's conduct on PACE participants. This factor is relevant because a PACE organization's failure to comply may have very different effects (or potential effects) on PACE participants and may affect varying numbers of participants. For example, an organization's failure to timely arrange for primary care could affect many or all of the participants enrolled with that organization. However, an organization's failure to timely arrange for a very specific type of specialty care may affect only a few participants.

At § 460.19(b)(4), we proposed to specify that CMS considers the history of prior offenses of a PACE organization or its related entities. A PACE organization's (or its related entity's) failure to comply is relevant because the PACE organization should have ongoing processes in place to correct deficiencies as they occur and ensure that deficiencies are not likely to recur. As mentioned later in this section, organizations that have had recurrent compliance issues may be subject to a higher level of compliance action. For example, a PACE organization that failed to provide transportation for a period of time to participants one year ago may have received a NONC at that time. If the organization fails to correct this deficiency after first being cited with a NONC for the deficiency regarding the PACE organization's previous failure to provide transportation, we may escalate this continued failure to comply with CMS requirements by issuing a WL, based on the PACE organization's history and continued failure to correct the deficiency.

As proposed, § 460.19(b)(5) would provide that CMS considers whether an organization self-reported a compliance failure. A PACE organization that self-reports that the organization has found the deficiency, such as through an internal audit, generally indicates that the organization is actively engaged in identifying and correcting compliance issues, and likely has initiated the corrective action to address the deficiency prior to CMS being made aware of the matter. We do not consider issues to be self-reported if they are identified through specific requests made by CMS, the review of data CMS either has or has requested, complaints that have come into CMS through sources such as 1–800–Medicare, or complaints that CMS has asked the PACE organization to provide. If an organization has self-reported a compliance issue, we may decide to lower the level of non-compliance (for example, issuing a NONC instead of a WL) because of the organization's transparency with respect to the non-compliant behavior, since it is possible CMS would not have found the deficiency if not for the self-reporting. However, even if the organization did self-report the issue, CMS may decide against lowering the level of compliance action if, based on the factors identified previously, CMS determines that a higher-level compliance action is warranted.

Finally, we proposed to add § 460.19(b)(6) to provide that CMS considers the PACE organization's failure to adequately oversee its operations. For example, if an organization fails to properly pay claims, is aware of the issue, and fails to correct it (for example, by processing the claims accurately), or if the organization fails to do any monitoring or auditing of its own systems to ensure proper claims payment is occurring, CMS could take that into account in determining whether to issue a compliance action and, if so, the level of compliance action.

As previously mentioned, we proposed to establish at § 460.18(c)(1)(i)(D) that CMS would have authority to deny a new application or an expansion application if a PACE organization accumulates 13 or more compliance action points during the applicable proposed 12-month look-back period. This would be the equivalent of just over two CAPs. We believe an organization whose performance results in issuance of two CAPs and a NONC, or whose performance results in any combination of compliance actions that adds up to 13 points, should not be permitted to expand.

We proposed to specify at § 460.18(c)(1)(ii) that CMS could also

deny an application from an organization that does not hold a PACE program agreement at the time of the submission if the applicant's parent organization or another subsidiary of the same parent organization meets the past performance criteria for denial proposed in § 460.18(c)(1)(i). Specifically, if an initial applicant is a legal entity under a parent organization that has a PACE program agreement, or if there are other organizations under the same parent that have a PACE program agreement, and the parent's PACE application or the other related organizations' PACE applications would be denied based on any of the factors proposed in § 460.18(c)(1)(i), we would also deny the new entity's application based on the past performance of other members of its corporate family. It is likely that similar structures, policies, and procedures are used across legal entities that are part of the same parent organization, increasing the likelihood that any part of a parent organization that has at least one poorly performing legal entity may be at increased risk of poor performance. In addition, using other legal entities' performance when the new applicant has no history would also prevent organizations from manipulating our past performance methodology by establishing new legal entities and using those to submit PACE applications to avoid having CMS consider the troubled performance history of the parent organization or its subsidiaries when reviewing the new legal entity's PACE application.

It would be especially important, when we review a new application from a legal entity that does not have activity that would constitute the past performance of that legal entity, as a PACE organization, to consider information from the current or prior PACE program agreement(s) of the parent organization of the applicant, and from members of the same parent organization as the applicant. As noted in the proposed rule, we are seeing initial PACE applications more frequently that represent unique and distinct legal entities that are part of a broader parent organization. In the December 2022 proposed rule at page 79642, we described an instance in which we reviewed an initial PACE application for a new legal entity under a parent organization that already had created a number of separate and unique legal sub-entities. In that case, in accordance with § 460.18(a) and (b), we considered the known adverse audit findings of other legal entities that were under the same parent organization, and which resulted in formal enrollment sanctions for the other legal entities. In the review of the new legal entity's application, we determined that the new legal entity was under the same ''umbrella'' as the legal entities that had been sanctioned because many of the key members of the executive leadership team were served in similar roles for both the sanctioned entities and the new applicant. We denied the application due to the nature of the deficiencies that led to formal sanctions for the related organizations.

We also proposed one exception to this policy. Specifically, we proposed that a PACE organization that acquires an organization that would have an application denied based on any of the factors in § 460.18(c)(i) would have a 24 month ''grace'' period that would extend only to the acquiring parent organization. This means that the acquiring organization would still be able to enter into new agreements or expand its programs under other agreements for which there are no performance issues for 24 months following the acquisition. It is in the best interest of the PACE program to allow PACE organizations that are meeting our requirements to acquire poorly performing PACE organizations without being penalized based solely on that acquisition. As stated in § 460.18(c)(ii), this ''grace'' period would be limited to 24 months from the date of acquisition. We believe this 24-month grace period would give an acquiring PACE organization sufficient time to ''turn around'' a poorly performing organization.

Finally, we proposed to add a new paragraph § 460.18(d) to provide CMS the explicit authority to consider prior termination history as part of the evaluation of an initial PACE or expansion application. Specifically, we proposed that if CMS has terminated a PACE organization's program agreement under § 460.50(a), or did not renew the program agreement, and that termination or non-renewal took effect within the 38 months prior to the submission of an application by the PACE organization, we would be able to deny the PACE organization's application based on the applicant's substantial failure to comply with the requirements of the PACE program, even if the applicant satisfies all other application requirements. The 38-month period is consistent with the Part D regulations at 42 CFR part 423. Because PACE organizations that offer Part D are subject to 42 CFR part 423, we believe a 38-month period is appropriate. This ensures PACE applicants are not unduly burdened by having two different sets of past performance requirements, resulting in two different timeframes. CMS does not unilaterally terminate PACE organizations' program agreements without significant failures, which are often failures affecting the furnishing or quality of care provided to PACE participants. Furthermore, a PACE organization whose program agreement has been terminated may appeal. If the PACE organization chooses to appeal and the termination is subsequently upheld through the appeals process, the organization has been found to have committed an action or actions that are egregious enough to warrant a termination. If the organization does not appeal, then the organization is acknowledging our ability to terminate its PACE program agreement. Allowing organizations to re-enter the PACE program when they have failed to adequately implement a prior agreement would be contrary to ensuring that high-quality care is provided to PACE participants. However, we believe that an organization, after a 38-month period, may have improved its operations sufficiently for us to consider its submission of an initial application.

We solicited comments on these proposals. We appreciate stakeholders' input on the proposed changes and have provided comment summaries and our responses later in this section.

Comment: Several commenters supported the evaluation of PACE organizations' past performance in CMS's application review process. Commenters also supported our proposed 24-month grace period and expressed appreciation for CMS's transparency in publicly sharing the past performance methodology.

Response: We thank those supporting the evaluation of past performance during application reviews.

Comment: A few commenters questioned whether the corrective actions resulting from CMS's audits are included in the calculation of compliance points. Commenters were concerned that issues identified in audits would unfairly disadvantage those organizations that have been audited by CMS within the past twelve months as compared to organizations that were not audited by CMS.

Response: We clarify that the compliance action plans identified in § 460.19(c)(3) are separate from the corrective action requests resulting from audits, as identified in § 460.194, and are not considered as part of the past performance methodology. We explained in the proposed rule that the corrective action requests resulting from audits are considered routine and result from a process which CMS considers

separate and distinct from past performance. We updated the language § 460.18(c)(1)(D)(*1*)(*i*) to state that these corrective action requests resulting from audits, as identified in § 460.194, are not issued points used for past performance evaluation purposes.

Comment: A few commenters were concerned that the 13-point compliance point threshold would disproportionately affect larger organizations. They expressed concern that organizations that had many center sites, especially in different States, could incur a disproportionate number of points due to the size or geographic spread of the organization.

Response: We do not believe that the compliance point threshold would disproportionately affect larger organizations because past performance is determined at the legal entity level, not the parent organization level. PACE organizations are generally licensed under different legal entities in each State. The compliance action taken against a contract only impacts that contract's legal entity and does not impact any other legal entity held by that parent organization. This eliminates the concern of the commenters that compliance actions will disproportionately affect larger organizations. Moreover, regardless of the size of the PACE organization, CMS expects all PACE organizations to comply with established requirements. Therefore, we decline to adjust the proposed 13-point calculation to account for the size of an organization.

Comment: A commenter requested that CMS outline the process, protocols, and compliance thresholds that rise to the levels of a Notice of Non-Compliance, a Warning Letter, or a Request for a Corrective Action Plan.

Response: In the December 2022 proposed rule starting on page 79640, we outlined the factors CMS uses to determine whether to take a compliance action against a Medicare Advantage Organization and the level of compliance that is appropriate. The process CMS uses to determine whether to issue and how CMS issues a Notice of Non-Compliance, a Warning Letter, or a Request for a Corrective Action Plan to an organization is the same for regardless of the type of compliance taken. CMS considers the following list of factors when determining the level of compliance action to take as described in this list, and we note that we may consider additional factors not specifically listed here that address the impact of the non-compliance or the organization's inadequate oversight that contributed to the non-compliance: the nature of the conduct, the degree of culpability of the organization, the actual or potential adverse effect on enrollees which resulted or could have resulted from the conduct of the organization, the history of prior offenses by the organization, the organization's contractors or subcontractors, whether the non-compliance was self-reported, and other factors which relate to the impact of the underlying non-compliance or the organization's inadequate oversight of the operations that contributed to the non-compliance. Once we determine the level of compliance action to issue based on our criteria, we issue the action to the organization through a letter. As for compliance review protocols, as discussed in the December 2022 proposed rule, we base the review protocols on the specific issue being reviewed in accordance with the approach detailed therein, for example, the standard protocol for fiscal soundness is such that the organization either has a positive or negative net worth. However, the protocols for other issues such as, for example, the failure to ensure enrollment packets are provided timely to participants are subject to review and consideration in accordance with the factors set forth at § 460.19, such as how many participants are affected and the lack of timeliness with respect to when the enrollment packets were actually received by an enrollee. Compliance thresholds may also be dependent upon specific circumstances. As identified above, compliance actions are taken for fiscal soundness if the organization has a negative net worth. The level of compliance taken for untimely delivery of an enrollment packet would depend on the application of the factors outlined in our final regulation. We believe these criteria and processes are well-documented in the December 2022 proposed rule and do not believe additional elaboration is needed here.

Comment: One commenter disagreed with our proposal to have the authority to deny an application based on past performance when an organization was under sanction, even though the sanction was ultimately lifted prior to CMS receiving the application. The commenter suggested that denying an application after a sanction is lifted would inhibit the expansion of PACE into new States.

Response: We believe sanctions, even if lifted, should be a basis for denial if that sanction was in place at any time during the twelve-month look-back period. A sanction is issued for serious non-compliance and is in place until such time the issue is corrected and not likely to reoccur. Sanctions issued for these reasons, indicate the organization should continue to focus on compliance rather than expansion, even after the sanction is lifted. We believe the inclusion of sanctions that have been lifted within the twelve-month look-back period is an important protection for the PACE program and the participants of the PACE organization that was under sanction as well as being consistent with Part C and Part D Past Performance regulations. For these reasons, we are finalizing our proposal to establish as a basis for denying a PACE application that an organization was under sanction within the twelve-month look-back period, without modification.

Comment: A commenter stated that CMS should not start the look-back period until 2025, noting that it would be unfair to use compliance letters issued prior to January 1, 2025. The commenter suggested that CMS exclude the time of performance during the COVID–19 pandemic and the associated public health emergency. This commenter also stated that CMS should provide PACE organizations time to train and educate employees on compliance.

Response: We understand the commenters concern regarding the time for consideration of compliance letters. By waiting, we could be providing PACE organizations additional time to correct any issues that might result in a compliance action. However, organizations should be vigilant about complying with program rules, regardless of the timing of the start of the past performance methodology. If a PACE organization is complying with CMS rules, the start of the period of past performance is immaterial. The timing is only a concern for those organizations whose current non-compliance would result in CMS denying an application based on past performance. It is exactly those organizations that should not expand and providing them with an additional year to come into compliance with existing rules is not in the best interest of the program or participants. This is particularly important should PACE organizations that are out of compliance attempt to expand during any period in which the start date of our consideration of past performance is delayed.

With respect to the commenter's contention that we should delay the implementation to avoid issues that may have resulted from the COVID–19 Public Health Emergency, we disagree. The federal COVID–19 Public Health Emergency declaration ended May 11, 2023, and sufficient time has passed allowing PACE organizations an

opportunity to address and cure any issues resulting from the Public Health Emergency and return to a normal state of operations.

Finally, the commenter suggested waiting so PACE organizations had time to train and educate their employees regarding past performance criteria. CMS's past performance measures do not require training or educating employees. Any training or educating would concern adhering to CMS regulations, which employees should already be trained on and educated about. Past performance only looks back at the actions of the organization and does not require the organization to do anything differently.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the rule as proposed.

Comment: A commenter suggested we use a six-month look-back instead of a 12-month look-back. The commenter stated that a 12-month look-back effectively prohibits an organization from expanding for 24 months.

Response: We do not believe a six-month look back is appropriate for a few reasons. The 12-month look-back period aligns with the look-back period used in the MA and Part D past performance methodology, which has proven effective over a number of years. In addition to aligning with the MA and Part D past performance methodology, we believe a 12-month look-back period allows for CMS to obtain sufficient data to determine whether an organization is operating in such a manner that we would deny an application. We believe a six-month look-back period is an insufficient amount of time for CMS to evaluate an organization's performance. We believe a 12-month look-back period is necessary to ensure an organization can provide the required services in a compliant manner over the long term, and not only in a shortened timeframe.

As mentioned previously, we are working towards consistency within programs and across programs where applicable. PACE organizations are already subject to Part D regulations. Establishing a 6-month look-back period for PACE would be inconsistent with the 12-month look-back period in the Part D regulations.

For these reasons, we are finalizing as proposed.

Comment: A few commenters stated that some PACE organizations may have high-quality programs but are not fiscally solvent and that applications from these organizations should be approved. A commenter stated that a PACE organization, to meet fiscal soundness requirements for expansion, may decrease staff or services resulting in less care for participants.

Response: We do not agree with the commenter that CMS should look beyond an organization's negative net worth when reviewing past performance. While a PACE organization may be able to provide quality services in the absence of a positive net worth, such an entity should not expand its operations until it demonstrates it can meet our fiscal soundness requirements. If such an organization were to expand operations the organization would likely incur additional costs, possibly resulting in further deterioration of the organization's fiscal soundness. An organization with a decreasing net worth and potentially experiencing cash flow problems, may reduce services to participants or the number of providers to continue operating, neither of which would be a desired outcome. As previously noted, we believe an organization's past performance is an indicator of future performance. We believe a positive net worth is critical to ensuring the future success of a PACE organization.

Based on these reasons we are finalizing these requirements as proposed.

B. PACE Determining That a Substantially Incomplete Application Is a Nonapplication (§§ 460.12 and 460.20)

Sections 1894(e)(8) and 1934(e)(8) of the Act established CMS's authority regarding PACE provider application requirements. Based on this authority, we proposed to strengthen the PACE regulations at §§ 460.12(a) and (b) and 460.20(b), which pertain to application requirements, by further defining what constitutes a complete and valid application.

CMS accepts PACE applications from entities seeking to establish a PACE program (initial applicants) or to expand an existing PACE program's service area (including both expansion of a PACE program's geographic service area and/or the addition of a new PACE center), on designated quarterly submission dates.

To receive funds under Part D to provide prescription drug benefits, PACE organizations must qualify as Part D sponsors under § 423.502(c)(1) by submitting an application in the form and manner required by CMS. Therefore, as a matter of necessity, initial PACE applicants that provide the Part D benefit to eligible beneficiaries must submit a separate Part D application. Effective March 31, 2017, CMS requires organizations to submit all applications electronically via the Health Plan Management System (HPMS). The PACE application includes attestations and certain required documents to ensure compliance with established PACE regulations, including, but not limited to: policies and procedures related to enrollment, disenrollment, grievances and appeals; information regarding the legal entity and organizational structure; and State-based documents, including a State assurance document. The State assurance document is a template that includes standard statements regarding the State's roles and responsibilities and includes the physical address of the proposed PACE center, geographic service area, or both, as applicable, depending on the type of application. This document must be signed by an official within the applicable State Administering Agency (SAA) and the designated agency for the PACE program in the State in which the program will be located. The document confirms the State's support for the PACE application. It is imperative that the applicant demonstrate the State's support of the application because the State is an equal party to the PACE program agreement, which, once approved and finalized, establishes the 3-way contract between CMS, the State, and the PACE organization.

Section 460.12 sets forth the application requirements for an organization that wishes to qualify as a PACE organization, and for an active PACE organization that seeks to expand its geographic service area and/or add a new PACE center site. Paragraph (a) of § 460.12 states that an individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its approved service area and/or add a new center site must submit a complete application to CMS in the form and manner specified by CMS. Furthermore, § 460.12(b)(1) specifies that an entity's application to become a PACE organization must include an assurance from the SAA of the State in which the program is to be located indicating that the State considers the entity qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity. Similarly, an existing PACE organization's application to expand its service area and/or add a PACE center site must include an assurance from the SAA of the State in which the program is located, indicating that the State is willing to amend the signed PACE program agreement to

include the expanded service area and/or new center site (§ 460.12(b)(2)).

We indicated in the final rule titled ''Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)'', which appeared in the June 3, 2019 issue of the **Federal Register** (84 FR 25610) (hereinafter referred to as the June 2019 final rule) that an application received without the required State assurance document would not be considered a complete application and would, therefore, not be reviewed (see 84 FR 25615 and 25671).

Section 460.20(a) provides that within 90 days, or 45 days in the case of an application to expand a service area or add a PACE center, after an entity submits a complete application to CMS, CMS takes one of the following actions in the form and manner specified by CMS: (1) approves the application or (2) denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial. An application is considered complete only when CMS receives all information necessary to determine whether to approve or deny the application (§ 460.20(b)).

As part of annual training sessions and resources available at: *https://www.cms.gov/Medicare/Health-Plans/PACE/Overview,* CMS acknowledges and has stated that the State readiness review (SRR) of a center site, as applicable, is the only required application document that may not be available and submitted at the time of the initial application submission to CMS on the designated quarterly application submission date. The SRR is conducted at the applicant's PACE center by the State, and the accompanying report issued by the State certifies to the State and CMS that the PACE center satisfies all applicable local, State, and Federal requirements for operation. CMS has instructed PACE applicants to upload the SRR during the application process, including following the initial submission date if necessary, and when responding during the course of CMS's review to a CMS-initiated request for additional information from the applicant.

The application is not considered complete and valid without the required documentation from the applicable SAA that provides clear evidence of the State's support. However, in our experience, some PACE organizations submit a State assurance document that is not signed by the State, is provided after the designated submission date, or has changed the location of the proposed PACE center or included the corporate address as a placeholder. Should any of these aforementioned scenarios occur, CMS will instruct the applicant to withdraw the application.

In the December 2022 issue of the **Federal Register** (87 FR 79637) (hereinafter referred to as the December 2022 proposed rule), we proposed to treat any PACE application that does not include a signed and dated State assurance document, meaning a document with accurate service area information and the accurate physical address of the PACE center, as an incomplete and invalid application and therefore not subject to CMS review or consideration. Further, an application submitted without a valid State assurance document must be withdrawn from HPMS. These applicants must wait until the next quarterly submission date to submit the application with the State assurance document included. We proposed to add paragraph § 460.12(b)(3) to specify that any PACE application that does not include the proper State assurance documentation is considered incomplete and invalid and will be removed from HPMS.

In the June 2019 final rule, we amended § 460.12(a) by adding the phrase ''in the form and manner specified by CMS'' to describe the submission to CMS of a complete application, to allow for submission of applications and supporting information in formats other than paper, which was the required format at the time the proposed rule (84 FR 25671) was issued. We proposed to amend § 460.12(a), which states that an individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its approved service area (through a geographic service area expansion and/or addition of a new center site) must submit a complete application to CMS ''in the form and manner specified by CMS'' by adding a parenthetical with the words ''including timeframes for submission'' after ''manner,'' in order to make it clear that CMS will only accept applications that are submitted within the timeframes established by CMS.

In the December 2022 proposed rule, we proposed to establish at § 460.20(c) that any application that, upon submission, is determined to be incomplete under proposed § 460.12(b)(3) because it does not include a signed and dated State assurance document with accurate service area information and the physical address of the PACE center, as applicable, would be withdrawn by CMS, and the applicant would be notified accordingly. We proposed § 460.20(b)(1) to further specify that the applicant would not be entitled to a hearing if the application is withdrawn based on that determination. Without the necessary evidence of support for the application by the SAA, the application would not be valid, and therefore not subject to reconsideration. This is consistent with how CMS addresses MA or Part D applicants that submit substantially incomplete applications. Such applications are considered invalid applications and applicant organizations are not entitled to a hearing per § 422.660 or § 423.650.

Finally, we proposed to establish at § 460.12(a)(2) that an individual authorized to act for an entity that seeks to become a PACE organization (initial PACE applicant) is required to submit a separate Part D application that complies with the applicable requirements under 42 CFR part 423 Subpart K. This is consistent with our current practice, under which initial PACE applicants must submit a Part D application. By contrast, existing PACE organizations seeking to expand their service area are not required to submit a Part D application. Therefore, consistent with current practice, we did not propose to establish Part D application requirements for PACE organizations seeking to expand their existing service area. As stated in the proposed rule, we will continue our current practice of following the timeframes for PACE applications, including submission deadlines and review periods, for Part D applications associated with PACE applications—that is, we will continue to accept Part D applications from initial PACE applicants on a quarterly basis. We believe it is important to continue to align application and review and submission deadlines for PACE applicants to the extent practicable to promote consistency.

Consistent with current practice, we proposed to treat an initial PACE application that does not include responsive materials for one or more sections of its Part D application as substantially incomplete, and those applications would not be reviewed or subject to reconsideration. If the Part D application associated with an initial PACE application is deemed substantially incomplete, that would render the PACE application incomplete and therefore not subject to review or reconsideration.

Comment: A few commenters were not in support of the State assurance form being a requirement for a PACE application submission. They requested that PACE applicants be afforded an opportunity to amend the State assurance document after application submission.

Response: We appreciate the comments and understand the request. The State assurance document is a necessary part of the application because the document demonstrates that the State is supportive of the PACE application. Since the State is a party to the 3-way agreement that is signed once the application is approved, it is important that the information provided on the State assurance form is correct at the time of application submission.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposed requirements at §§ 460.12 and 460.20 to determine that a substantially incomplete PACE application without a State assurance document is a nonapplication. These provisions will strengthen the PACE regulations which pertain to application requirements, by further defining what constitutes a complete and valid application.

C. Personnel Medical Clearance (§§ 460.64 and 460.71)

Sections 1894(f)(4) and 1934(f)(4) of the Act grant CMS broad authority to issue regulations to ensure the health and safety of individuals enrolled in PACE. The PACE regulations at §§ 460.64 and 460.71 protect participants' health and safety by requiring PACE staff to be medically cleared of communicable diseases before engaging in direct participant contact.

In the 1999 PACE interim final rule (64 FR 66242), we added § 460.64, which sets forth certain personnel qualification requirements for PACE staff. When drafting these regulations, we reviewed the personnel requirements of other Medicare and Medicaid providers that serve populations similar to PACE participants (for example, home health agencies, nursing facilities, intermediate care facilities) (*Id.*). We also explained that in drafting these provisions we took a flexible approach that relied on State requirements as much as possible (*Id.*).

In the 2002 interim final rule, titled ''Medicare and Medicaid Programs; Programs of All-inclusive Care for the Elderly (PACE); Program Revisions,'' which appeared in the **Federal Register** October 1, 2002 (67 FR 61496), we added § 460.71, which sets forth oversight requirements for PACE employees and contractors with direct patient care responsibilities. We noted the importance of adding this new section due to the vulnerable frail population served by the PACE program and the increased opportunity for a PACE organization to contract out participant care services due to the amendment in the 2002 interim final rule which allowed PACE organizations to provide PACE center services through contractual arrangements (67 FR 61499). One of the new requirements that the 2002 interim final rule adopted was the requirement at § 460.71(b)(4) for PACE organizations to develop a program to ensure that all staff furnishing direct participant care services be ''free of communicable diseases.'' In the rule titled ''Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions,'' which appeared in the **Federal Register** on December 8, 2006 (71 FR 71243), herein after referred to as the 2006 PACE final rule, we amended § 460.64 to align with § 460.71(b)(4) by adding the requirement at § 460.64(a)(5) that employees and contractors with direct participant contact ''[b]e medically cleared for communicable diseases and have all vaccinations up-to-date before engaging in direct participant contact.'' In the June 2019 final rule, we amended the language in § 460.71(b)(4), which referred to staff being ''free of communicable disease'' so that it instead referred to staff being ''medically cleared for communicable disease,'' which is the phrasing used in § 460.64(a)(5) (84 FR 25636) to reduce confusion across PACE organizations.

The proposed rule at 87 FR 79643 discussed how we have seen as part of our audit and oversight activities that PACE organizations have an inconsistent approach to medical clearance. We further discussed how the COVID–19 pandemic impacted the population served by PACE and ''demonstrated a need for a more comprehensive approach to infectious disease management and prevention'' (*Id.*). We believe that the inconsistent approach to medical clearance that has been noted on audit has led to insufficient medical clearance, which places PACE participants at risk of exposure to communicable diseases. Therefore, we proposed to amend §§ 460.64 and 460.71 to require all PACE organizations to develop and implement a comprehensive medical clearance process with minimum conditions that CMS deems acceptable to meet the requirement of medical clearance and to better protect the frail and vulnerable population served by PACE.

We proposed several modifications to the requirement at § 460.64(a)(5). Currently, the language states that staff must ''be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact.'' First, we proposed to separate the requirement to be medically cleared for communicable diseases from the requirement to have all immunizations up to date. We believe these are two separate and distinct requirements, and each serves a unique and important purpose. Specifically, we proposed to create a new paragraph (a)(6) that would specify that each member of the PACE organization's staff (employee or contractor) who has direct contact with participants must have all immunizations up to date before engaging in direct participant contact. We proposed to include in paragraph (a)(6) language specifying that, at a minimum, vaccinations identified in § 460.74 must be up to date. As we discussed in the proposed rule at 87 FR 79644, CMS does not currently define what immunizations are included in the requirement that ''all immunizations are up to date.'' We considered defining all immunizations as including those recommended by the Advisory Committee on Immunizations Practices (ACIP) for health care workers, including when they are applicable based on individual criteria such as age or past infection. However, based on the PACE population we also considered limiting the required vaccinations for PACE staff with direct participant contact to the Flu vaccine, Measles, Mumps and Rubella (MMR); Varicella; Tetanus, Diphtheria, Pertussis (Tdap); and Hepatitis B. We solicited comment on whether any specific vaccinations other than the COVID–19 vaccination should be required for each member of a PACE organization's staff (employee or contractor) that has direct participant contact, with particular focus on commenters' views on vaccinations recommended by ACIP. We also solicited comment on whether we should use the ACIP list without modifications, or whether we should only require this subset of vaccines: Flu vaccine, Measles, Mumps and Rubella (MMR); Varicella; Tetanus, Diphtheria, Pertussis (Tdap); and Hepatitis B.

At § 460.64(a)(5), we proposed to require that each member of a PACE organization's staff (employee or contractor) who has direct participant contact be medically cleared of communicable diseases both before engaging in direct participant contact and on an annual basis. Requiring staff to be medically cleared of communicable diseases annually will ensure that medical clearance is not a one-time requirement, but rather an ongoing responsibility. We solicited comment on adding this annual

requirement into the medical clearance provision.

We also proposed adding requirements to define what would constitute an acceptable medical clearance process. As discussed in the proposed rule at 87 FR 79644, we considered many different provider types, including hospital systems, and what different States require for medical clearance. We also considered the PACE population, and its vulnerability to communicable diseases. Based on these factors, we proposed at § 460.64(a)(5)(i) to require that staff who engage in direct participant contact must be medically cleared for communicable diseases based on a physical examination performed by a licensed physician, nurse practitioner, or physician assistant acting within the scope of the practitioner's authority to practice. This exam could be done at the PACE center by the primary care provider already employed by the PACE organization; therefore, it would not be difficult to operationalize. We also proposed at § 460.64(a)(5)(ii) that as part of the initial physical examination, staff with direct participant contact must be determined to be free of active Tuberculosis (TB) disease. It is important for organizations to screen for TB because it is a deadly disease and baseline testing is recommended by the CDC for all health care professionals. We proposed to add ''initial'' into this regulation text, because annual TB testing is not recommended by the CDC unless a risk assessment is performed which indicates it is necessary.

However, we also understand that not all individuals who have direct participant contact have the same level of risk of having communicable diseases (through previous exposures) and requiring a physical examination may be overly burdensome. Therefore, we proposed that, as an alternative to medically clearing all staff with direct participant contact for communicable diseases based on a physical examination, the PACE organization could opt to conduct an individual risk assessment as allowed under proposed § 460.64(a)(5)(iii). If the results of the risk assessment indicate the individual does not require a physical examination in order to be medically cleared, then a physical examination would not be required.

We proposed at § 460.64(a)(5)(iii) to establish the minimum requirements that the PACE organization must satisfy if it chooses to conduct a risk assessment for medical clearance. First, we proposed to specify at § 460.64(a)(5)(iii)(A) that the PACE organization must develop and implement policies and procedures for conducting a risk assessment on each individual with direct participant contact based on accepted professional standards of care, for example, standards of care for screening influenza. While each organization should have the operational latitude to develop its own policies and procedures, consistent with these proposed requirements, to assess if an individual needs a physical examination, when drafting and implementing these policies and procedures, organizations should consider any applicable professional standards of care and/or any applicable State guidelines on medical clearance.

We proposed at § 460.64(a)(5)(iii)(B) to specify that the purpose of the risk assessment is to determine if, based on the assessment, a physical examination is necessary for an individual. As we discussed in the proposed rule at 87 FR 79645, we believe that the best practice for medical clearance is a physical examination by a physician, nurse practitioner, or physician assistant acting within the scope of their authority to practice. However, by allowing PACE organizations to conduct a risk assessment to determine if some individuals on a PACE organization's staff who engage in direct participant contact (employee or contractor) may not need a full physical exam would provide some administrative flexibility for organizations. We proposed at § 460.64(a)(5)(iii)(C) to establish a requirement that the results of the risk assessment be reviewed by a registered nurse, physician, nurse practitioner or physician assistant. We initially considered limiting these professions to primary care providers. However, we believe that because this risk assessment is used to screen staff to determine whether a physical exam is needed but is not itself a physical exam meant to diagnose an individual, it would be appropriate for a registered nurse to review those results and help triage staff that may need a more thorough exam. However, because registered nurses are not permitted to diagnose individuals, it would be inappropriate for a registered nurse to perform the physical examination.

Finally, we proposed to identify at § 460.64(a)(5)(iii)(D) the minimum requirements we would expect to be included in a PACE organization's risk assessment. First, we proposed to require that any risk assessment developed by a PACE organization would assess whether staff have been exposed to or have symptoms of the following diseases: COVID–19, Diphtheria, Influenza, Measles, Meningitis, Meningococcal Disease, Mumps, Pertussis, Pneumococcal Disease, Rubella, Streptococcal Infection, and Varicella Zoster Virus. We proposed to include the aforementioned diseases in the risk assessment because they are commonly reportable and transmissible via air or through droplets. In addition to the aforementioned specific diseases, we also proposed to include any other infectious disease noted as a potential threat to public health by the CDC in order to allow for situations such as the recent COVID–19 pandemic where a new communicable disease creates a situation that poses a threat to public health and is significant enough that the CDC notes the threat or determines that a threat exists and communicates that threat via an official mechanism such as the CDC's Health Alert Network mentioned above. We would expect in those situations for a PACE organization to update its risk assessment to include that new public threat in the screening process. As we discussed in the proposed rule at 87 FR 79645, we considered CDC's Health Alert Network, the agency's primary method of sharing cleared information about urgent public health incidents with public information officers; Federal, State, territorial, Tribal, and local public health practitioners; clinicians; and public health laboratories. It is likely that any threat to public health related to communicable diseases would be shared through this mechanism, but we solicited comment on whether this would be an appropriate source to consider, or whether there are other sources that CMS and PACE organizations should use. Because we recognize these sources may change over time, we were not inclined to add a specific source into regulation, but we solicited comment on that as well. We also proposed to require that a PACE organization's initial risk assessment must determine whether staff are free of active TB disease. We considered adding TB into the list of diseases in § 460.64(a)(5)(iii)(D)(1); however, we believe screening for this disease through a series of questions about exposure or symptomatology would not be sufficient to rule out this condition when conducting an initial evaluation of an individual. Although we proposed an alternative to requiring a physical examination for every employee or contractor with direct participant contact (that is, by allowing PACE organizations to conduct a risk assessment), we solicited comment on whether we should eliminate the risk assessment from this proposal and

require all staff who engage in direct participant contact (employee or contractor) to undergo a physical examination by a physician in order to be medically cleared. We discussed and accounted for the burden of updating the policies and procedures in the collection of information requirements section of the proposed rule.

As we previously discussed, the requirement for medical clearance with respect to communicable diseases resides both in §§ 460.64(a)(5) and 460.71(b)(4). In section § 460.71(b)(4), we proposed to amend the current language to state that all employees and contracted staff furnishing care directly to participants must be medically cleared for communicable diseases before engaging in direct participant contact and on an annual basis as required under § 460.64(a)(5). We also proposed to add language to a newly designated § 460.71(b)(5) to require all employees and contracted staff to have all immunizations up-to-date before engaging in direct participant contact. Under our proposal, current paragraphs (b)(5) and (b)(6) would be redesignated as paragraphs (b)(6) and (b)(7). As we stated in the proposed rule, we believe that modifying this provision as proposed would not increase the burden on PACE organizations as they are already required to ensure employees and contractors have all immunizations up-to-date (87 FR 79646).

We received the following comments related to this proposal:

Comment: Several commenters expressed concerns with the solicitation for comment related to vaccinations. These same commenters noted that requiring an expansive list of required immunizations would create a new federal floor for PACE that was unlike what any other Medicare provider was required to adhere to. These commenters were concerned that requiring specific vaccinations would impair PACE organizations' ability to hire and retain staff. A commenter stated that a PACE organization had lost 30 percent of its staff after the COVID–19 vaccination rule went into effect. Another commenter requested that CMS clarify if religious and medical exemptions would apply to the new vaccination requirements. Multiple commenters requested that, if CMS finalized a list of required vaccinations, CMS finalize the more targeted subset of vaccinations for which CMS solicited comment, specifically Hepatitis B virus, influenza, measles, rubella, and varicella. Lastly, a commenter asked CMS to clarify whether the up-to-date COVID–19 requirement referred to the primary series or if booster shots would be required.

Response: When we issued the proposed rule (87 FR 79452) on December 27, 2022, many Medicare and Medicaid providers and suppliers (including PACE organizations) were required to have policies and procedures in place for staff vaccination against COVID–19. However, on June 5, 2023, we issued a final rule ''Medicare and Medicaid Programs: Policy and Regulatory Changes to the Omnibus COVID–19 Health Care Staff Vaccination Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Diseases (ICFs-IID) To Provide COVID–19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID–19 Testing Requirements'' (88 FR 36485), hereinafter referred to as the ''LTC 2023 final rule.'' In that final rule, we cited, among other considerations, ''increased vaccine uptake, declining infection and death rates, decreasing severity of disease, increased instances of infection-induced immunity'' as reasons for withdrawing the provisions of the COVID–19 staff vaccination rule (88 FR 36488). Taking these considerations into account, we removed the requirement at § 460.74(d) for PACE employees and contractors to be up-to-date with COVID–19 vaccinations. In our proposed rule, we had proposed referencing the COVID–19 vaccination rule at § 460.74(d) as part of our new paragraph § 460.64(a)(6). Following the withdrawal of that rule, we are not finalizing the proposed reference to § 460.74(d) in §§ 460.64(a)(6) and 460.71(b)(5).

We thank commenters for their concerns regarding PACE organizations' ability to staff due to the COVID–19 vaccination rule as well as our solicitation for comment relating to requiring a specific set of immunizations in the proposed rule. As we stated in the LTC 2023 final rule, ''[S]taffing shortages peaked nationally during the Omicron wave, with nearly one in three facilities reporting a shortage in January 2022. Staffing shortage rates have fallen since then, and remained relatively stable through March 2022, even after the implementation of the staff vaccination IFC'' (88 FR 36495). Based on the data available, we disagree with commenters that implementing additional vaccination requirements would adversely impact PACE organizations' ability to staff. However, we understand the concerns expressed by commenters that requiring a specific list of vaccinations for PACE organizations would potentially hold PACE organizations to a different standard regarding vaccinations than other Medicare programs. While we are not finalizing a specific list of vaccination requirements, and instead will leave the language in § 460.64(a)(6) that ''all immunizations must be up to date'', we will continue to assess the need for vaccinations. We will consider moving forward with a vaccination requirement in the future if the need arises. We also encourage PACE organizations to consider resources such as the ACIP vaccination standards when determining which immunizations to require for their employees and/or contractors.

Comment: Several commenters expressed concerns with the proposed requirement that medical clearance be conducted on an annual basis, versus only being done at the time of hire. These commenters suggested that it was overly burdensome for PACE organizations, particularly smaller organizations, to have to re-clear staff on an annual basis. These commenters also indicated that this would place an undue burden on a PACE organizations' ability to contract with other health care providers who may not be currently required to medically clear staff on an annual basis.

Response: We agree with commenters that an annual physical screening requirement may be overly burdensome for some PACE organizations since the requirement could impact PACE organizations' ability to contract with other health care providers. Therefore, we are not finalizing the proposed requirement that the physical examination or risk assessment be conducted annually. Instead, we will maintain the current requirement that direct care personnel be medically cleared prior to having direct contact with participants.

Comment: Most commenters requested that CMS codify the risk assessment approach to medical clearance as an alternative to requiring a physical examination for every individual. Commenters indicated this alternative proposal would allow PACE organizations to retain some discretion to medically clear staff as well as to reduce burden on PACE organizations. A couple of commenters requested that CMS leave medical screening requirements up to individual States, while a couple of other commenters expressed concern that home health agencies in certain States are not required to undergo additional medical screenings. These commenters noted

that State medical screening requirements apply to all health care providers within each respective State, and that requiring only PACE organizations to follow stricter federal requirements by conducting a physical exam in all instances or requiring specific vaccinations would put PACE organizations at a disadvantage when competing for contracts with medical providers and/or facilities. Instead, most commenters wanted CMS to finalize the risk assessment approach without requiring the PACE organization to conduct a physical exam.

Response: We thank commenters for sharing their concerns. We understand why commenters requested that we finalize the risk assessment alternative to the proposal that a physical exam be completed on each individual that provides direct participant care. As we stated in the proposed rule, PACE organizations serve a vulnerable population, and we believe performing a physical exam prior to staff having direct contact with participants is a best practice to protect participants from infectious diseases (87 FR 79644). However, we understand that requiring a physical exam for every individual that a PACE organization may employ or contract with may be overly burdensome, and therefore we proposed the risk assessment as a way for PACE organizations to determine if a physical exam is necessary for all personnel (*Id.*).

We recognize the concern commenters expressed of additional medical screening requirements putting PACE organizations at a disadvantage in contract negotiations with medical providers and/or facilities, including home health agencies, and as we discussed in our earlier responses, we are not finalizing our proposed requirements for annual medical clearance or a specific list of required vaccinations. We believe our decision not to finalize the annual physical screening requirement or the specific vaccination list will alleviate contracting concerns; however, PACE organizations can also take into consideration the processes they already have in place to demonstrate compliance with individual State requirements when they develop the risk assessment tool. Therefore, we are finalizing the requirement for a physical examination of direct care personnel with the risk assessment as an alternative provided the risk assessment meets the minimum requirements set forth in the proposed rule.

Comment: Multiple commenters raised questions and concerns regarding whether allowing colleagues to conduct health screenings would violate HIPAA. A commenter requested that PACE organizations be allowed to conduct physical exams or outsource them as needed. Another commenter asked that risk assessments without red flags be allowed to be reviewed by non-clinical staff to free up the time of clinical staff. A commenter supported CMS's approved list of clinical staff who can perform the risk assessment and/or physical exam.

Response: We appreciate the commenters' concerns over potential HIPAA Privacy Rule violations; however, we believe they are misplaced. The HIPAA Privacy Rule does not apply to employment records held by a covered entity in its role as an employer. In our experience, there are many medical organizations and hospital systems that perform medical clearance on personnel without violating the HIPAA Privacy Rule. However, it should be noted that the language allowing PACE organizations to perform their own physical exams or risk assessments was in no way meant to force PACE organizations to do so. Our intent was to allow PACE organizations the option to perform medical clearances in house; however, there is nothing in our proposal that would prohibit a PACE organization from requiring direct care personnel to seek a physical examination from their primary care physician or from contracting with a primary care provider for the specific purpose of conducting medical clearance reviews. As we stated in the proposed rule, we do not believe that assessments conducted by unlicensed staff or self-assessments are sufficient to meet the requirement for medical clearance (87 FR 79643). We also considered different clinical staff to determine the appropriate professions to perform the physical exam versus the risk assessment (87 FR 79645). We determined that while a physical exam required a primary care provider, a registered nurse could screen staff through the risk assessment because it is not ''a physical exam meant to diagnose an individual'' (*Id.*) We believe it is outside the scope of authority of nonclinical staff to perform a physical exam or risk assessment. Therefore, we are finalizing the clinical staff members approved to perform a physical exam or risk assessment, as proposed.

Comment: A commenter stated that the communicable disease clearance is a ''snapshot in time'' and is ineffective due to the transient nature of communicable disease. Another commenter stated that the proposal was not evidence-based, specifically the requirement to screen annually for Tuberculosis, which is not recommended by the CDC.

Response: We thank commenters for their responses. While screening for medical clearance prior to individuals having direct participant contact does not ensure that participants will never be exposed to communicable diseases, we believe it is a minimum safeguard to ensure that PACE participants are protected to the extent possible. It is also a common practice in other health care settings to have a process to ensure new individuals coming into an organization have received some form of health screening to demonstrate that the individuals are free of communicable diseases. As we stated in an earlier response, we are not finalizing the requirement for a physical examination or risk assessment to be conducted on an annual basis.

After considering the comments, and for the reasons set forth in the proposed rule and our responses to comments, we are finalizing the proposed changes to §§ 460.64(a) and 460.71(b)(4) in part, with a modification to remove the requirement to conduct medical clearance on an annual basis. We are finalizing the proposed changes to §§ 460.64(a)(6) and 460.71(b)(5) in part, with a modification to remove the reference to § 460.74.

D. Timeframes for Coordinating Necessary Care (§ 460.98(b)(4) and (c))

As discussed in the December 2022 proposed rule, sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act specify that the PACE program provides comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE Protocol. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities. Additionally, sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act require that a PACE organization must provide participants access to all necessary covered items and services 24

hours per day, every day of the year. This includes the full range of services required under the PACE statute and regulations. Although the PACE regulations at 42 CFR part 460 have codified service delivery requirements established in the Act, they currently do not include specific timeframes for service delivery. Since the 1999 PACE interim final rule, in which CMS discussed the crucial role of timely comprehensive care and service delivery in maintaining participant functional status (64 FR 66251), we have continued to revisit the feasibility of implementing such timeframes in subsequent rulemaking (64 FR 66251, 71 FR 71292, 85 FR 9138, 86 FR 6034).

As discussed in the December 2022 proposed rule (87 FR 79648), previous rulemaking has highlighted the challenges of determining specific timeframes for delivering the varied and broad scope of services PACE organizations must provide to participants, which is further complicated by the many possible scenarios that are part of the multifaceted care needs of PACE participants. As required at the current § 460.98(b)(4), services must be provided as expeditiously as the participant's health condition requires. Determining how quickly a service must be provided would depend on more than the physical health of the participant, and PACE organizations must consider all aspects of the participant's condition, including their social, emotional, and medical needs when determining the provision of services. Although we continue to believe that a specific timeframe for service delivery would not be feasible, and that ultimately, a service delivery timeframe based on the needs of the participant's condition remains the best timeframe for service delivery, our monitoring and oversight efforts have demonstrated the need for additional participant protections regarding timely service delivery. For example, based on data collected through audits, in the past 4 years, over 80 percent of audited PACE organizations have been cited for a failure to provide services in a way that is necessary to meet participant needs.

In response to audit findings, in the December 2022 proposed rule (87 FR 79648), we proposed to strengthen participant protections and accountability for PACE organizations by amending the service delivery requirements at § 460.98 to establish maximum timeframes for arranging and scheduling IDT-approved services for PACE participants, allowing for certain exceptions. First, we proposed to amend § 460.98 by redesignating current paragraphs (c), (d), and (e) as paragraphs (d), (e), and (f), respectively. Next, we proposed to add a new paragraph (c) with the heading ''Timeframes for arranging and providing services'' and add 4 new subparagraphs. In addition, we proposed to move the requirement in current paragraph § 460.98(b)(4) to new paragraph (c)(4). We also proposed to redesignate paragraph (b)(5) as (b)(4).

Our proposal at the new section § 460.98(c) included four subparagraphs related to the timeframes for arranging and providing services. A ''service'' as defined in § 460.6 means all services that could be required under § 460.92, including items and drugs. We proposed at new § 460.98(c)(1) to require PACE organizations to arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after the primary care provider orders the medication. We explained that we consider the use of the words ''arrange and schedule'' to mean that the PACE organization has notified the participant's pharmacy or pharmacy service of the approved medication order and has provided all necessary information that would enable the pharmacy to fill the medication order and provide the participant with timely access to the medication. We explained that this timeframe would not require the medication to be delivered to the participant within those 24 hours, unless the participant's condition required delivery within that timeframe.

Next, we proposed to establish at new § 460.98(c)(2) the requirement that PACE organizations arrange or schedule the delivery of IDT-approved services, other than medications, as identified in the proposed § 460.98(c)(2)(i), as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the IDT or a member of the IDT first approves the service, except as identified in § 460.98(c)(3). This requirement pertains to all IDT-approved services other than medications. We would expect PACE organizations to take affirmative steps to make sure the approved service was set up, scheduled, or arranged within the proposed timeframe, which may include scheduling appointments and/or purchasing the item the IDT approved. As with the proposal at § 460.98(c)(1), we noted that the proposed maximum timeframe to arrange or schedule the delivery of IDT-approved services, as we proposed at § 460.98(c)(2), does not apply a specific timeframe to the provision of the service.

We solicited comment on alternative maximum timeframes for arranging or scheduling IDT-approved services, particularly timeframes within 5 to 10 (that is, 5, 6, 7, 8, 9, or 10) calendar days after the date the IDT or a member of the IDT first approves the service. Additionally, we invited comment on whether there are additional definitions of ''arrange or schedule'' that we should consider. We requested that such comments address how the alternative timeframes they recommended would ensure participant health and safety, especially if commenters advocate for a timeframe longer than 7 calendar days.

We proposed at § 460.98(c)(2)(i)(A) through (D) to define which services are included in the definition of IDT-approved services. We proposed to specify at § 460.98(c)(2)(i)(A) that IDT-approved services include services approved by the full IDT. These services would typically be the ones discussed and approved during IDT meetings. This would be any service other than a medication. We proposed to specify at § 460.98(c)(2)(i)(B) that IDT-approved services also include services approved by a member of the IDT. We believe this is important to emphasize to ensure that service determination requests that are immediately approved by a member of the IDT under § 460.121(e)(2) are subject to this new timeframe. We proposed at § 460.98(c)(2)(i)(C) that IDT-approved services include services ordered by a member of the IDT. We would consider an IDT member ordering a service as approving that service for purposes of proposed § 460.98(c)(2). We explained that, under our proposal at § 460.98(c)(2), the timeframe to arrange or schedule a service begins when the IDT or a member of the IDT first approves the service. Therefore, when any one of these approvals at § 460.98(c)(2)(i)(A) through (D) occurs, on that first instance, the timeframe would be initiated.

We proposed at new § 460.98(c)(3) to exclude routine or preventative services from the timeframe requirement in § 460.98(c)(2) when certain requirements are met. We understand that PACE organizations may not be able to schedule every service within 7 calendar days, especially when the service is a routine service and not needed until a much later time. To satisfy this exception, we proposed at § 460.98(c)(3)(i) through (iii) three requirements that would all need to be met in order for a PACE organization to be exempt from the timeframe in § 460.98(c)(2). First, we proposed at § 460.98(c)(3)(i) that the PACE organization must document that it was unable to schedule the appointment for the routine or preventative service due to circumstances beyond the control of

the PACE organization. Second, we proposed to establish at § 460.98(c)(3)(ii) that the PACE organization is exempt from the timeframe as long as the participant does not have a change in status that requires the service to be provided more quickly. Last, we proposed at § 460.98(c)(3)(iii) that the PACE organization may be excepted from the timeframes to arrange a service if the PACE organization provides the service as expeditiously as the participant's condition requires.

We proposed to redesignate § 460.98(b)(4) as § 460.98(c)(4) without further modification, except to add a new paragraph heading ''Providing approved services''. Thus, new § 460.98(c)(4) would maintain the requirement that PACE organizations provide services as expeditiously as the participant's health condition requires, taking into account the participant's medical physical, emotional, and social needs. Under redesignated § 460.98(c)(4), PACE organizations would continue to make determinations on how quickly to provide a service on a case-by-case basis, and we would expect PACE organizations to demonstrate that services were provided as expeditiously as the participant's medical, physical, emotional, and social needs require during monitoring efforts by CMS.

We estimated a one-time burden for PACE organizations to update their policies and procedures to reflect the proposed timeframes for arranging and providing services. We discuss and account for the one-time burden for their policies and procedures to reflect these proposed timeframes for arranging and scheduling services in the Collection of Information Requirements section.

In the paragraphs that follow, we summarize the comments received on the proposal at § 460.98(b)(4) and (c) and respond to those comments.

Comment: A few commenters recommended that CMS address how PACE organizations would satisfy the proposed requirements at § 460.98(c) to ''arrange and schedule'' services. Specifically, two commenters recommended that CMS define ''arrange and schedule'' such that PACE organizations would demonstrate they have arranged and scheduled services when they can provide documentation that a service authorization was acted upon to initiate scheduling. Another commenter recommended that CMS add language to define ''reasonable efforts'', a term not included in the proposed provision, to arrange and schedule services with providers external to a PACE organization, particularly specialty providers. The commenter expressed concern that PACE organizations may be unfairly penalized for providers' communication delays that impact when provider appointments can be scheduled.

Response: We explained and provided examples of the actions a PACE organization would have to take to arrange and schedule services within the maximum timeframes at § 460.98(c) in the December 2022 proposed rule (87 FR 79649). The proposed rule explained that, for purposes of the proposed requirement at § 460.98(c)(1), we consider ''arrange and schedule'' to mean that the PACE organization has notified the participant's pharmacy or pharmacy service of the approved medication order and has provided all necessary information for the pharmacy to fill the medication order and provide the participant with timely access to the medication (87 FR 79649). This timeframe would not require the medication to be delivered to the participant within those 24 hours, unless the participant's condition required delivery in that timeframe. For the proposed requirement at § 460.98(c)(2), we described the action that we would expect the PACE organization to take within the proposed 7-calendar day maximum timeframe to arrange or schedule IDT-approved services other than medication (87 FR 79649). Delivery of services would not need to occur within the proposed timeframe, unless the participant's condition required delivery within that timeframe. Instead, the PACE organization would be expected to take affirmative steps to make sure the approved service was set up, scheduled, or arranged within this timeframe, which may include scheduling appointments and/or purchasing the item the IDT approved (87 FR 79649). We also emphasized that, for our proposal at § 460.98(c)(2), the timeframe begins when the IDT or a member of the IDT first approves a service (87 FR 79650).

In the December 2022 proposed rule (87 FR 79649), we described some examples of how a PACE organization might comply with the requirement at § 460.98(c)(2). If the IDT approved increasing a participant's physical therapy frequency from two to three times per week, we would expect the PACE organization to conduct outreach to the participant's physical therapist or the physical therapist's administrative support to set up a third weekly appointment within the timeframe at § 460.98(c)(2). If the IDT determines that the participant should see an ophthalmologist, the PACE organization would be required to reach out to the ophthalmologist office to schedule the appointment within the timeframe at § 460.98(c)(2). We would not expect the delivery of the service (in this example, the actual appointment) to occur within the proposed timeframe, only that the PACE organization scheduled the appointment within that timeframe. Following the ophthalmologist appointment, if the IDT determines that eyeglasses were necessary upon review of the provider's recommendation, the PACE organization would then be required to arrange for the provision of the eyeglasses within the timeframes proposed at § 460.98(c)(2), which may include a purchase order for eyeglasses. During an audit or review, we would expect the PACE organization to have documentation to support compliance with the requirements in § 460.98(c). For example, a note that the appointment was scheduled or documentation that eyeglasses were purchased.

We believe that these explanations sufficiently establish how PACE organizations would comply with the proposed requirements at § 460.98(c), and do not believe codifying documentation standards or ''reasonable efforts'' at § 460.98(c) would enhance the provision's effectiveness. As per the current requirement at § 460.98(b)(4) (which we proposed to redesignate to § 460.98(c)(4)), PACE organizations must already document, track, and monitor the provision of services across all care settings. Since arranging and scheduling services are components of service delivery, we expect PACE organizations to maintain documentation of efforts to arrange and schedule services.

After consideration of the comments we received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.98(c) to establish timeframes for arranging and providing services without modification.

Comment: With respect to our proposal at § 460.98(c)(1) and regarding the required timeframes for arranging and scheduling the dispensing of medications, many commenters agreed that PACE organizations must arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires and supported CMS establishing maximum timeframes for arranging and scheduling the dispensing of medications. However, most commenters disagreed with CMS establishing one timeframe for all medications, and instead recommended establishing separate timeframes for arranging and scheduling

the dispensing of emergency medications and non-emergency medications. These commenters advocated for allowing a longer maximum timeframe for arranging and scheduling the dispensing of non-emergency medications, and a shorter timeframe for emergency medications. Most of these commenters supported allowing up to 24 hours to schedule and arrange the dispensing of emergency or urgently needed medications and recommended that PACE organizations be allowed up to 2 business days to schedule and arrange the dispensing of non-emergency medications. Many commenters expressed that a longer timeframe for arranging and scheduling the dispensing of non-emergency medications would allow better prioritization of arranging and scheduling the dispensing of emergency medications. A commenter proposed a 48-hour timeframe for the coordination of all medications without explaining the basis for their recommendation. Another commenter did not support CMS establishing maximum timeframes for arranging and scheduling the dispensing of medications.

Response: PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year as established at § 460.98(a). As a result, PACE organizations must meet participant needs on evenings, weekends, and holidays as expeditiously as the participant's condition requires. Therefore, we are not persuaded to lengthen the proposed timeframe to arrange and schedule the dispensing of medications on the basis of standard business hours. Furthermore, we emphasize that the timeframe requirement at § 460.98(c)(1) does not pertain to the provision of medications, only to scheduling and arranging the dispensing of medications, which can typically be facilitated electronically. As explained in the December 2022 proposed rule (87 FR 79649), for the purposes of § 460.98(c)(1), we consider the use of the words ''arrange and schedule'' to mean that the PACE organization has notified the participant's pharmacy or pharmacy service of the approved medication order and has provided all necessary information for the pharmacy to fill the medication order and provide the participant with timely access to the medication. However, PACE organizations must still provide services, including medications, as expeditiously as the participant's condition requires, as per the newly redesignated § 460.98(c)(4).

Additionally, we are not persuaded to implement two distinct maximum timeframes for arranging and scheduling the dispensing of emergency and non-emergency medications. We understand that PACE organizations prioritize the delivery of emergency and non-emergency provider medication orders differently, because participants must receive services as expeditiously as their condition requires, taking into account their medical, physical, social and emotional condition in accordance with § 460.98(c)(4). However, we disagree with creating a distinction in regulation for arranging and scheduling the dispensing of emergency versus non-emergency medications, because we believe doing so would be difficult and impractical. For example, a medication that may be emergent to one participant may not be emergent to another, depending on factors that may not be apparent without information specific to the individual participant's medical, physical, social, and emotional condition. We think it is a fair and reasonable expectation that all medications be arranged and scheduled with the pharmacy within 24 hours. As previously explained, the timeframe requirement at § 460.98(c)(1) pertains to arranging and scheduling the dispensing of medications, which is related to, but distinct from, the service delivery requirement at § 460.98(c)(4). Therefore, although PACE organizations must arrange and schedule the dispensing of a medication no later than 24 hours after a primary care provider orders the medication, PACE organizations may deliver or provide the medication to the participant at a later time, as long as the medication is provided to the participant as expeditiously as their condition requires. We also believe this requirement is more easily accomplished than commenters seem to think. The timeframe to arrange or schedule a medication begins when an IDT member first approves or orders the service. Therefore, when a primary care provider orders a medication, they can submit the order to the pharmacy at the same time and satisfy this requirement. Based on many of the electronic medical records we have seen during oversight efforts, we think many systems are set up to ensure this happens seamlessly.

After consideration of the comments received and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.98(c)(1) to require PACE organizations to arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after a primary care provider orders the medication, without modification.

Comment: A few commenters expressed concern and made recommendations in regard to establishing maximum timeframes for the provision of medications. A commenter opposed the proposal at § 460.98(c)(1) and expressed that providing all medications within 24 hours was likely to cause harm to participants. The commenter gave the example that some medications, especially medications meant to treat chronic conditions in the elderly, should be explained and delivered thoughtfully in order to avoid misuse. Other commenters expressed concern that factors outside of the PACE organization's control, for example, pharmacy benefit manager (PBM) issues and national medication shortages, may delay access to medications and impact the PACE organization's ability to provide medications within the proposed 24-hour timeframe for arranging and scheduling the dispensing of medications. Additionally, a commenter recommended a maximum timeframe of 48 hours for the delivery of all medications.

Response: We believe these commenters may have misunderstood that the proposed maximum timeframe at § 460.98(c)(1) would apply to scheduling and arranging the dispensing of medications, not the provision of the medications. As discussed in the preceding comment response, our intention with this proposal was not to impose a specific timeframe for the delivery of medication, but to establish a maximum timeframe for the PACE organization to arrange and schedule the dispensing of medications. Considering the wide range of medications provided in PACE and varying needs of participants, we do not believe a specific timeframe for the provision of services, including medications, is feasible at this time. We agree with commenters that the delivery of medication would be based on the needs of the participant. We expect PACE organizations to provide medications as expeditiously as the participant's condition requires, as per the redesignated § 460.98(c)(4). Additionally, if PBM issues like medication shortages could impact participant care, the PACE organization must have contingencies in place to ensure participants have timely access to all necessary medications.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to

comments, we are finalizing our proposal at § 460.98(c)(1) to require PACE organizations to arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after a primary care provider orders the medication, without modification.

Comment: While most commenters agreed with the premise of a maximum timeframe to arrange and schedule services other than medications, most of these commenters disagreed with our proposal that 7 calendar days was the appropriate timeframe to apply. Most commenters recommended we allow a maximum timeframe of up to 10 calendar days for arranging or scheduling these services.

These commenters made their maximum timeframe recommendation for services at § 460.98(c)(2) in consideration of potential delays in communication with provider offices. While a commenter cited general delays in communication from provider offices as another potential consideration for extending the maximum timeframe at § 460.98(c)(2), another commenter suggested that more time may be needed to coordinate scheduling appointments with providers whose offices may be closed on weekends and holidays. A commenter preferred a 10-calendar day maximum timeframe, in part, due to the time needed to coordinate with both the provider and participant based on provider availability and in consideration of participant preference. Additionally, some commenters suggested that the participant might not need certain services arranged or scheduled within the proposed timeframe to meet their care needs. One commenter did not specify a particular alternative maximum timeframe to arrange or schedule the delivery of all IDT-approved services other than medications. Rather, the commenter expressed that establishing a 7-calendar day maximum timeframe for scheduling or arranging specialty items such as power mobility devices and stair lifts would be challenging for the PACE organization to meet.

A few commenters expressed concerns with arranging and scheduling services with external providers, particularly specialists. A commenter that expressed this concern, suggested that delays in scheduling or arranging specialty services may not be within the PACE organization's control, and that ensuring compliance with the proposed requirements would be administratively burdensome and would divert resources from participant services. Another commenter recommended an exception to the proposed maximum timeframe and suggested up to 30 days for the PACE organization to schedule appointments with specialist providers.

Lastly, a commenter expressed that PACE organizations are unique with each participant requiring a personalized array of services, and that a single timeframe for service delivery could not meet all their needs.

Response: PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year as established at § 460.98(a). When we published the December 2022 proposed rule (87 FR 79650), we solicited comment on different maximum timeframes for arranging or scheduling the delivery of IDT-approved services, other than medications, and we specifically asked commenters that supported a longer timeframe than the proposed 7-calendar day maximum timeframe to include a rationale for how their alternative timeframe would ensure participant health and safety. While most commenters requested a longer timeframe, most commenters cited operational challenges for PACE organizations as the reason for a longer timeframe and did not address participant health and safety. However, during our oversight and monitoring efforts, we have not seen that the time and effort required to schedule services is a significant contributor to scheduling delays. Rather, we have observed that scheduling delays are often the result of a process breakdown after the primary care provider orders the service, which delays any attempts to schedule the service. For example, we have observed in numerous audits where a specialist service is ordered and the first documented attempt to schedule the appointment with the provider does not occur for weeks or months. We have not seen that PACE organizations expend significant effort making multiple unsuccessful attempts to schedule provider appointments to ensure the participant receives the service timely.

Since PACE organizations are required to provide services through employees or contractors (see § 460.70(a)), they should have mechanisms in place to ensure that they are able to quickly schedule or arrange services. As explained in the December 2022 proposed rule (87 FR 79649) and reiterated in this rule, to comply with the proposal at § 460.98(c)(2), PACE organizations must take affirmative steps to make sure the IDT-approved service was set up, scheduled, or arranged within the proposed timeframe, which may include scheduling appointments and/or purchasing the item the IDT approved. This requirement does not pertain to the provision of services, only to scheduling and arranging the service. However, PACE organizations must continue to provide services as expeditiously as the participant's condition requires in accordance with the current requirement at § 460.98(b)(4), which we proposed to be redesignated as § 460.98(c)(4).

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.98(c)(2) to require PACE organizations to arrange or schedule the delivery of IDT-approved services, other than medications, as identified in paragraph § 460.98(c)(2)(i), as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the IDT or member of the IDT first approves the service without modification.

Comment: Many commenters fully supported the proposed exception at § 460.98(c)(3) for routine or preventative services being excluded from the requirement in paragraph (c)(2).

Response: We thank the commenters for their support of our proposed criteria to exempt a PACE organization from the requirements at § 460.98(c) when certain conditions are met as proposed at § 460.98(c)(3)(i) through (iii).

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.98(c)(3) to exclude routine or preventive services from the requirements in § 460.98(c)(2) when requirements in § 460.98(c)(3)(i) through (iii) are met without modification.

E. Care Coordination (§ 460.102)

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act require PACE organizations to provide comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations, based upon those required under the PACE protocol. Sections 1894(b)(1)(A) and

1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities. Sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act require that a PACE organization must provide participants access to all necessary covered items and services 24 hours per day, every day of the year. Additionally, sections 1894(b)(1)(C) and 1934(b)(1)(C) of the Act specify that PACE organizations must provide services to participants through a comprehensive, multidisciplinary health and social services delivery system which integrates acute and long-term care services in accordance to regulations, and specify the covered items and services that will not be provided directly by the entity, and to arrange for delivery of those items and services through contracts meeting the requirements of regulations. We have codified requirements pertaining to the interdisciplinary team (IDT) at § 460.102.

As discussed in the December 2022 proposed rule, changes to § 460.102 are the result of years of assessing PACE organizations' compliance with care coordination requirements established by the Act and our conclusion that further specification of these care coordination requirements in regulation would benefit participants and improve PACE organizations' understanding of how to comply with these requirements. In the December 2022 proposed rule, we proposed strengthening § 460.102 to identify the IDT's specific care coordination responsibilities, introduced maximum timeframes for the IDT's review of all recommendations from hospitals, emergency departments, urgent care providers, other employees, and contractors, and reiterated the IDT's role in timely service delivery.

Although the PACE organization is ultimately responsible for providing comprehensive, multidisciplinary care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, the IDT has a critical role in enabling the PACE organization to meet these responsibilities. As established in the 1999 PACE interim final rule (64 FR 66248), the IDT, then referred to as the multidisciplinary team, must comprehensively assess and meet the individual needs of each participant. In addition, the IDT is responsible for the initial assessment, periodic reassessments, the plan of care, and coordinating 24-hour care delivery (64 FR 66249). Through monitoring and oversight activities, CMS has determined that further specification of IDT responsibilities is necessary to ensure appropriate compliance with the program requirements. While many IDTs appropriately apply the multidisciplinary approach to providing care, our monitoring efforts have shown that some organizations do not ensure the IDT is fully involved in coordination of care for participants across all care settings. We have also seen organizations interpret IDT responsibilities to coordinate care narrowly. For example, an IDT may order care, but then fail to ensure that the care has been provided in accordance with those orders and that the participant's needs were met.

In the December 2022 proposed rule we proposed several amendments to § 460.102(d)(1). First, we proposed to redesignate current paragraph (d)(1)(ii) as paragraph (d)(1)(iii), and to add a new paragraph (d)(1)(ii). We also proposed to add a new paragraph (d)(1)(iv). We proposed to modify § 460.102(d)(1) to specify that the IDT is responsible for all activities as described at § 460.102(d)(1)(i) through § 460.102(d)(1)(iv) for each participant. The addition of ''for each participant'' emphasizes that these responsibilities are not general requirements the IDT must fulfill, but rather specific responsibilities the IDT must fulfill for each participant. Since the inception of PACE, CMS has considered the IDT responsibilities to apply to all participants at the individual level. The 1999 PACE interim final rule (64 FR 66288) established basic requirements for the IDT at § 460.102(a), including that the IDT must comprehensively assess and meet the individual needs of each participant and that each participant be assigned an IDT at the PACE center that they attend.

We proposed to modify the requirement at § 460.102(d)(1)(i) to include only the IDT's responsibility for the initial assessment, periodic assessment, and plan of care and to relocate the requirement pertaining to the IDT's responsibility to coordinate 24-hour care delivery to new § 460.102(d)(ii). We believe the responsibility to coordinate 24-hour care delivery is a separate and distinct requirement from the requirements to conduct assessments and create or revise a plan of care. Additionally, we proposed to add a paragraph heading at § 460.102(d)(1)(i) to read ''Assessments and plan of care'' in order to reflect the proposed modified content of the paragraph. We proposed to move IDT coordination of care requirements from § 460.102(d)(1)(i) to new § 460.102(d)(1)(ii), because separating IDT coordination of care responsibilities at § 460.102(d)(1)(ii) from the assessment and care planning responsibilities at § 460.102(d)(1)(i) improves the provision's readability. We also proposed to modify the language of § 460.102(d)(1)(ii) and to add 5 paragraphs at § 460.102(d)(1)(ii)(A) through (E) to further specify what coordination of 24-hour care delivery involves by defining what actions we consider care coordination to include.

We proposed at new § 460.102(d)(1)(ii) to require that the IDT coordinate and implement 24-hour care delivery that meets participant needs across all care settings. We added language into this requirement about meeting the participant's needs across all care settings in order to clarify the scope of the IDT's care coordination for all participants, including, but not limited to, participants residing in long-term care facilities. We also added ''implementation'' into the requirement at § 460.102(d)(1)(ii) because we have seen through audits and monitoring efforts that PACE organizations are interpreting ''coordination'' narrowly, and they do not consider it to include all necessary components of care coordination, such as ensuring the implementation of care. For example, we have seen problems with medication orders being implemented inappropriately, wound care not being done in accordance with orders, and other necessary services not being provided to the participant.

We have received requests to explain the difference between the PACE organization's responsibility to furnish care, and the IDT's responsibility to coordinate care. As we discussed in the January 2021 final rule, PACE organizations are responsible for furnishing comprehensive services to PACE participants across all care settings, 24 hours a day, every day of the year (86 FR 6034, 86 FR 6036). The IDT, which consists of a subset of PACE organization's employees or contractors, is responsible for certain activities, such as coordinating care, which includes services that are furnished by the IDT as well as services furnished by other employees and contractors of the PACE organization. The proposed requirement at § 460.102(d)(1)(ii) for the IDT to coordinate and implement 24-hour care delivery that meets participant needs across all care settings aligns with this interpretation, as the IDT is not always responsible for directly furnishing or providing the care to participants, but it always maintains responsibility for coordinating care for participants.

As previously noted, we proposed adding 5 subparagraphs at

§ 460.102(d)(1)(ii)(A) through (E) that further specify IDT coordination responsibilities across all care settings. We proposed at § 460.102(d)(1)(ii)(A) that the IDT is responsible for ordering, approving, or authorizing all necessary care in order to clarify CMS expectations regarding one aspect of the IDT care coordination responsibilities. PACE is a program designed around the IDT being responsible for authorizing and ordering all care that is needed for PACE participants. In fact, contractors, including medical specialty providers, must agree to furnish only those services authorized by the PACE IDT at § 460.70(d)(5)(i). We believe the responsibilities at § 460.102(d)(1)(ii)(A) are important aspects of coordinating care that are inherent to the IDT's established and central role in care coordination.

We proposed at § 460.102(d)(1)(ii)(B) to establish that the IDT is responsible for communicating all necessary care and relevant instructions for care. As discussed in connection with proposed § 460.102(d)(1)(ii)(A), the IDT is already responsible for authorizing all care the participant receives; however, in order for the participant to actually receive the care, the IDT must communicate the orders and relevant instructions to the appropriate individuals. For example, while a PCP may order a specialist consult, it is often scheduling or administrative staff that are responsible for arranging the appointment. As a part of coordinating care, the IDT must ensure that it communicates the necessary care and instructions to those individuals that need to know, for example, the individuals who will schedule, arrange, or provide the care and services. In the December 2022 proposed rule (87 FR 79652), we contemplated adding further specificity in regulation about who those individuals may be, but we believe that it would encompass too many individuals for us to identify. For example, for a participant residing in a nursing facility, the IDT would need to ensure it communicated orders and instructions for care to the facility staff. For scheduling appointments, the IDT may need to communicate orders to administrative staff. We believe the IDT would be in the best position to identify the staff that need to know the information, and therefore we are leaving this regulatory provision broad.

We proposed to specify at § 460.102(d)(1)(ii)(C) that the IDT is responsible for ensuring care is implemented as it was ordered, approved, or authorized by the IDT. We have seen through oversight and monitoring efforts that while the IDT will order or authorize care, the team does not always follow through on ensuring that the care is provided in accordance with those orders. For example, a PCP may order wound care 3 times a week, but then the IDT will not follow through on ensuring that the wound care is done in accordance with those orders. As previously discussed, the 1999 PACE interim final rule (64 FR 66279) established the IDT as instrumental in controlling the delivery, quality, and continuity of care. Part of controlling the delivery and quality of care is ensuring that the care that is ordered, approved or authorized is actually provided.

We proposed at § 460.102(d)(1)(ii)(D) to establish that the IDT is responsible for monitoring and evaluating the participant's condition to ensure that the care provided is effective and meets the participant's needs. The IDT cannot appropriately coordinate 24-hour care delivery without also ensuring that it remains alert to the participant's condition by monitoring and evaluating the participant's condition. While the IDT is responsible for making sure that care is implemented in accordance with the approved or authorized orders, the IDT also remains responsible for ensuring the participant's needs are met through that care. For example, if the PCP orders wound care 2 times a week but the wound continues to worsen, the PCP should consider whether a new order is necessary in order to meet the participant's needs.

We proposed to specify at § 460.102(d)(1)(ii)(E) that the IDT is responsible for promptly modifying care when the IDT determines the participant's needs are not met in order to provide safe, appropriate, and effective care to the participant. The IDT's responsibilities for a participant do not end when care is authorized or ordered. As we stated in the 2006 PACE final rule (71 FR 71289), it is important for the IDT to monitor and respond to any changes in a participant's condition. Also, it is essential that the IDT respond promptly and modify care when it is determined that the participant's needs are not currently being met. For example, if the PCP writes an order for blood pressure medication but then notes during a later assessment that the medication is not working, we would expect the PCP and the IDT to consider alternative medications or treatments that might better meet the participant's needs.

We proposed to redesignate current § 460.102(d)(1)(ii) as § 460.102(d)(1)(iii) and add the title ''Documenting recommended services'' for improved readability. No further modifications were proposed for this provision. Then, we proposed to add § 460.102(d)(1)(iv) to require the IDT to review, assess, and act on recommendations from emergency or urgent care providers following participant discharge, and employees and contractors, including medical specialists, within maximum timeframes, as proposed in at § 460.102(d)(1)(iv)(A) through (C). As discussed earlier, the IDT is responsible for authorizing, approving and ordering all care, including care recommended from contracted providers. Through monitoring and oversight activities, we had identified instances where the IDT is not promptly reviewing recommendations from urgent and emergency care providers, as well as employees and contractors. Based on data collected during the 2021 audits, approximately 75 percent of audited PACE organizations were cited based on a failure to review and act on recommendations from specialists in a manner necessary to meet the needs of the participant. Delayed review of recommendations and action on recommendations can delay the provision of necessary care and services and can jeopardize participant health and safety. To address these concerns, we proposed timeframes for the IDT to review and act on recommendations from urgent and emergency care providers, as well as employees and contractors.

As we stated in the January 2021 final rule (86 FR 6132), we do not believe we could implement a specific timeframe for the provision of services, given the vast array of services that PACE organizations provide and variation in individual participant needs. However, we believe requiring the IDT to promptly act on recommendations from urgent and emergency care providers, as well as employees and contractors, creates accountability for expeditious service delivery while offering flexibility for wide ranges of services and variation in urgency. The timeframes we proposed at § 460.102(d)(1)(iv)(A) through (C) would be maximum timeframes within which the IDT must review, assess and determine whether service recommendations from urgent and emergency care providers, as well as employees and contractors, are necessary to meet the participant's medical, physical, social, or emotional needs, and if so, promptly arrange and furnish the service in accordance with the timeframes at § 460.98(c).

Per § 460.98(b)(4) (which we proposed to redesignate as § 460.98(c)(4)), PACE organizations must continue to provide services as expeditiously as the

participant's condition requires, taking into account the participant's medical, physical, social, and emotional needs. To meet the participant's needs, the IDT may need to review and act on recommendations sooner than the timeframes proposed in § 460.102(d)(1)(iv). Nothing in § 460.102(d)(1)(iv) would require the IDT to approve all recommendations; however, we would expect that the IDT review, assess, and act on the recommendation. That action would either be to make a determination to approve or provide the recommended service or make a determination to not approve or provide the recommended service. If the IDT makes a determination to approve or provide a service, it must arrange and schedule the service in accordance with § 460.98(c). If the IDT makes a determination not to approve or provide a service, we would expect the IDT to document the reason(s) for not approving or providing the recommended care or services in accordance with current § 460.102(d)(1)(ii), which, as previously noted, we proposed to redesignate as § 460.102(d)(1)(iii) and § 460.210(b).

We proposed at § 460.102(d)(1)(iv)(A) to establish that the appropriate member(s) of the IDT must review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs within 24 hours from the time of the participant's discharge. We considered multiple factors when proposing a 24-hour timeframe and expressed that we believed the 24-hour timeframe was necessary and reasonable due to the following considerations. First, the 24-hour timeframe would be limited to only those recommendations made by hospitals, emergency departments and urgent care providers, and it would not apply to recommendations made by other providers or more routine appointments. Second, we considered that PACE is responsible for the needs of the participant 24 hours a day, every day of the year. When a participant is discharged from one of these settings there may be recommendations made or care needed that cannot wait until the next business day. For example, a participant who is discharged from the hospital on a Saturday with a recommendation for antibiotics should not have to wait until Monday to have their prescription ordered or approved by the IDT. Third, we proposed to not require that the full IDT be involved in assessing and acting on these recommendations, but rather the appropriate member(s) of the team as determined by the IDT. We invited comment on alternative maximum timeframes for IDT review of all recommendations from hospitals, emergency departments, and urgent care providers and to make a determination on the recommendation's necessity. We requested commenters' perspectives on timeframes of 12 hours, 24 hours, 48 hours, and 72 hours from the time of the participant's discharge. We requested that such comments address how the commenter's preferred/recommended timeframe would ensure participant health and safety.

We proposed to require at § 460.102(d)(1)(iv)(B) that the appropriate member(s) of the IDT must review all recommendations from other employees and contractors and make a determination with respect to whether the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 5 calendar days from the date the recommendation was made. As discussed in the December 2022 proposed rule (87 FR 79653), we have seen through monitoring and audits where recommendations have not been considered or acted upon for significant periods of time, which has contributed to delays in the provision of necessary care. While we do not believe that all recommendations made by all types of employees and contractors need to be responded to as quickly as recommendations from hospitals, urgent care providers, or emergency departments, we do believe the IDT must act promptly to consider the recommendations made, and, when the IDT deems the recommended care necessary, it must authorize the recommended care. We explained that the proposed 5-day timeframe would represent the maximum amount of time a PACE organization would have to determine whether a recommended service is necessary, and that we would expect the IDT to consider the participant's condition in determining whether it is necessary to make a determination sooner than 5 calendar days after the recommendation is made.

Additionally, we proposed that the timeframe would begin when the recommendation is made, not when the recommendation is received by the IDT. We have seen through monitoring instances of PACE organizations not making initial requests for consult notes from a participant's appointment with a specialist until months after the appointment has taken place, and only learning at that time that a recommendation was made during the appointment. It is important that the PACE organization promptly act on recommendations, and it is our expectation that they develop processes with their employees and contractors to ensure the IDT is receiving recommendations in a manner that allows the IDT to determine the necessity of the recommended services within the proposed timeframe. We invited comment on alternative maximum timeframes for IDT review of all recommendations from other employees and contractors and to make a determination on the recommendation's necessity. We asked about commenters' perspectives on whether we should adopt a 3-calendar day timeframe, a 5-calendar day timeframe, a 7-calendar day timeframe, or a 10-calendar day timeframe. We requested that commenters address how the alternative timeframes would ensure participant health and safety.

In the December 2022 proposed rule (87 FR 79654), we emphasized that these recommendation review and necessity determination timeframes are maximum timeframes that the IDT and PACE organization should consider when reviewing recommendations. For some recommendations, such as an MRI to be done in 3 months, these timeframes would be sufficient to ensure that the service is approved and arranged before the service is needed. However, there are other recommendations made where it would not be appropriate for the IDT to take a full the full maximum timeframe to assess and act on a recommendation, and then arrange and schedule it. For example, if a cardiologist indicated that the participant needed an urgent coronary artery bypass graft, we would expect that the IDT and PACE organization act upon that information in a more expeditious manner.

Finally, we proposed to establish at § 460.102(d)(1)(iv)(C) that, if recommendations are authorized or approved by the IDT or a member of the IDT, the services must be promptly arranged and furnished in accordance with the timeframes at § 460.98(c).

As discussed in the December 2022 proposed rule, we are not scoring this provision in the Regulatory Impact Analysis section because the IDT is already required to comprehensively assess and meet the individual needs of each participant, including ensuring the participant's access to all necessary covered items and services 24 hours per day, every day of the year. We reiterate our belief that, by modifying this

provision, we would not be increasing burden on PACE organizations, as they already consider these items on a routine basis. We are also not scoring this provision in the Collection of Information section since all information impacts of this provision have already been accounted for under OMB control number 0938–0790 (CMS–R–244).

We summarize the comments received on the proposal at § 460.102 and provide our responses to those comments in this section of this rule.

Response to Comments

Comment: Some commenters expressed concern with the implementation of IDT care coordination responsibilities across all care settings as proposed in § 460.102(d)(1)(ii), and particularly in reference to IDT care coordination when participants reside in acute and long-term care facilities. Although most of the commenters that provided recommendations pertaining to § 460.102(d)(1)(ii) acknowledged that PACE organizations are responsible for overseeing participants' care at these facilities, they considered IDT involvement in daily care coordination activities for participants residing in care facilities to be functionally impractical and potentially harmful to participants. A few commenters thought that having the IDT order all necessary care for participants residing in care facilities could delay the provision of necessary care. In order to prevent delays in necessary care, a couple commenters recommended that the PACE organization delegate ordering care to care facility providers operating within their scope of practice. Another commenter suggested that the IDT does not have purview to order services provided by care facilities and recommended that the IDT take a consultative approach to overseeing care of participants staying in care facilities.

Another commenter noted different challenges with IDT involvement in daily care coordination at care facilities. These commenters remarked on the difficulty of ensuring daily communication between the IDT and the care facilities when care facilities experience operational issues, like staffing shortages, that may diminish their ability to promptly communicate with the IDT. The commenter asked CMS to provide guidance on how PACE organizations could strengthen care coordination with external healthcare facilities and suggested care coordination with the IDT be added into the contractual agreement between the PACE organization and care facility. This commenter also requested that CMS provide guidance on the types of documentation that would be needed to demonstrate that the IDT is meeting the care coordination requirements proposed at § 460.102(d)(1)(ii).

Response: The PACE program design is based on the IDT being responsible for authorizing and approving all care that is needed for PACE participants. Contractors, including medical specialty providers and contracted facilities, must agree to furnish only those services authorized by the IDT per § 460.70(d)(5)(i). Therefore, the IDT is currently required to authorize all participant care, regardless of the participant's care setting. PACE organizations may need to establish different coordination procedures and/or contract terms to ensure adequate communication with inpatient care facilities that meets the needs of participants. This does not mean that the PACE organization, or the PCP, needs to directly order all services for the participant that resides in acute and long-term care settings. While we know that some PACE organizations ensure that their PCP has privileges at contracted facilities (and therefore can order services directly), this is not always an option. While the PCP may not directly order all care, it does not absolve the IDT from ensuring that only approved or authorized care is provided. For example, even if a skilled nursing facility (SNF) PCP orders the participant's care, the IDT must authorize or approve the participant's care at the SNF.

As for documentation that demonstrates IDT compliance with the care coordination requirements proposed at § 460.102(d)(1)(ii) when a participant resides in a care facility, CMS expects to see documentation of communications with the facility that demonstrate the IDT's active monitoring and management of the participant's condition. This may include documentation from the admission of the participant, which includes all approved or ordered services (including medication) and ongoing documentation addressing any changes to the participant's care.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(ii) to require coordination and implementation of 24-hour care delivery that meets participant needs across all care settings without modification.

Comment: A commenter requested that CMS clarify the specific actions the IDT should take to ''act on'' recommendations as proposed in § 460.102(d)(1)(iv), which states that the interdisciplinary team must review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists.

Response: In the December 2022 proposed rule (87 FR 79653), after introducing at § 460.102(d)(1)(iv) the requirement that the IDT review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists, we explained the specific components of the requirement in § 460.102(d)(1)(iv)(A) through (C). In addition to the IDT reviewing all recommendations from emergency or urgent care providers, employees, and contractors, we proposed that the IDT would determine whether the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs and arrange and furnish necessary care in accordance with § 460.98(c). Therefore, for the purposes of § 460.102(d)(1)(iv), ''act on'' means, in addition to reviewing and assessing these recommendations, the IDT would decide whether it is appropriate to approve the service and ensure the provision of any approved services. If the IDT determines a recommended service is not necessary, they must document their rationale for not approving or providing the service in accordance with the redesignated § 460.102(d)(1)(iii) and § 460.210(b).

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(iv) to require the interdisciplinary team to review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists without modification.

Comment: A few commenters had concerns regarding the proposed requirement at § 460.102(d)(1)(iv) that the IDT review, assess, and act on recommendations from emergency or urgent care providers following participant discharge, and employees and contractors, including medical specialists, specifically with respect to the involvement of the full IDT in recommendation reviews. They believed that CMS was proposing to require that the full IDT be involved in reviewing and approving these recommendations, which they considered administratively burdensome without added benefit to participant outcomes, particularly in emergency situations.

Response: We disagree with the commenters' interpretation of this requirement. The proposed regulatory text supports flexibility in determining which IDT disciplines review, assess and act on recommendations. Although § 460.102(d)(1)(iv) proposed to require the IDT to review, assess, and act on recommendations from emergency or urgent care providers following participant discharge, § 460.102(d)(1)(iv) further specifies that, in the cases of § 460.102(d)(1)(iv)(A) and (B), ''The appropriate member(s) of the interdisciplinary team must review all recommendations.'' The proposed language at § 460.102(d)(1)(iv) is similar to the language in § 460.121(h)(1), which allows the IDT to determine the appropriate IDT member or members to conduct a reassessment in response to a service determination request. For the proposed § 460.102(d)(1)(iv)(C), the IDT or a member of the IDT may authorize and approve the recommended service, which then must be promptly arranged and furnished.

Additionally, as discussed in the December 2022 proposed rule (87 FR 79653), we reiterate that the IDT can determine the appropriate IDT disciplines for reviewing recommendations. We do not anticipate that the full IDT would need to be involved in all decisions relating to recommendations made by hospitals, emergency departments, or urgent care centers. More likely, 1 or 2 IDT members would be responsible for these recommendations, and we believe typically this would be the PCP. The PCP in PACE is typically the only individual that can order care given a state's scope of practice laws, and the PCP has the additional responsibility of ensuring they manage the participant's condition, including the use of specialists and inpatient care, as required per § 460.102(c)(2). The example we provided in the December 2022 proposed rule involved a post discharge recommendation for antibiotics. In this instance, the PCP may be the only IDT discipline needed in order to appropriately review, assess, and act on the medication request, since the PCP is responsible for ordering care and medications. We clarify that the IDT has flexibility to determine which IDT disciplines should review, assess, and act on employee and contractor recommendations as well, which may not involve the full IDT. However, we emphasize that PACE organizations are responsible for providing comprehensive, multidisciplinary care that meets the needs of each participant, and that the IDT should review recommendations with a multidisciplinary approach, as appropriate.

After consideration of the comments and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(iv) to require the interdisciplinary team to review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists without modification.

Comment: Most commenters recommended that CMS modify the proposed § 460.102(d)(1)(iv)(A) to extend the maximum timeframe for the IDT review of all recommendations from hospitals, emergency departments, and urgent care providers from 24 to 72 hours from the time of the participant's discharge. A few commenters recommended other maximum timeframes for IDT review of all recommendations from hospitals, emergency departments, and urgent care providers: 2 business days, 3 calendar days from the time the IDT was notified of the discharge, and 96 hours after documentation is included in the participant's medical record. One commenter did not recommend a maximum timeframe for IDT review of these recommendations but believed the proposed maximum timeframe to be unreasonable and shared the experience that it may be several days or weeks before the PACE organization receives emergency department recommendations. Another commenter was against imposing any timeframe for IDT review of recommendations from hospitals, emergency departments, and urgent care providers. These commenters advocated for more time to process these recommendations primarily due to concerns that hospitals, emergency departments, and urgent care providers tend to be providers external to the PACE organization for which the PACE organization has no purview. Additionally, some commenters noted that participants may not notify the PACE organization when they receive emergency or urgent care services. Thus, commenters expressed concern that PACE organizations may not be made aware of a participant's discharge or receive the recommendation from the external provider promptly enough for review of the recommendation within 24 hours from the time of the participant's discharge. The commenter that recommended a 2-business day maximum timeframe for the IDT review of these recommendations also recommended we keep long holiday weekends in mind when setting timeframes for recommendation reviews and that codifying a business day instead of a calendar day approach to the IDT recommendation review timeframe would give the PCP an opportunity to consider the information in the recommendation and develop a plan of care.

Several commenters interpreted the proposed maximum timeframe at § 460.102(d)(1)(iv)(A) to require the full IDT to be on-call to review all recommendations from hospitals, emergency departments, and urgent care providers on weekends. They expressed that having the full IDT present to review recommendations on weekends would impose unreasonable cost increases on the PACE organization, reduce IDT availability for participant care, and impact staff retention. Another commenter expressed general concern for requiring the IDT to review these recommendations within the proposed timeframe when the participant's discharge occurs on weekends.

Response: We carefully considered commenters' recommendations on lengthening the maximum timeframe to act on recommendations from hospitals, emergency rooms and urgent care providers. When we solicited comment on potentially lengthening the proposed timeframe of 24 hours, we asked commenters to indicate in their response how a longer timeframe would ensure participant health and safety. While commenters overwhelmingly requested a longer timeframe than 24 hours, all commenters indicated operational challenges as the basis for their recommendation and did not discuss how these longer timeframes would ensure participant health and safety. While we think there needs to be some consideration to operational challenges, our primary focus is on the participant and their needs. We are not persuaded to lengthen the timeframe to 72 hours or greater without some consideration of how the participants' needs would be addressed. However, we understand that sometimes, despite the PACE organizations' best efforts, 24 hours to act on recommendations may not be enough time. Therefore, we have modified the timeframe in which the appropriate member(s) of the IDT must review and determine the necessity of all recommended services from hospitals, emergency departments, and urgent care providers from our proposed 24 hours to 48 hours from the time of the participant's discharge as a compromise to the majority of commenters' preference for a 72-hour timeframe. We consider 48 hours to be a maximum timeframe, and therefore have also added language to take into

account the participant's condition, such that the finalized timeframe requirement is ''as expeditiously as the participant's health condition requires, but no later than 48 hours from the time of the participant's discharge.'' We believe the 48-hour timeframe would not negatively impact participant well-being, as we reiterate that the 48-hour timeframe is a maximum timeframe, and PACE organizations ultimately must both review the recommendation and provide any necessary services as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs, which may require the IDT to act sooner than the maximum 48-hour timeframe. Since PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, which includes weekends and holidays, we believe the 48-hour maximum timeframe provides an appropriate level of protection for participants and accountability for PACE organizations regarding the types of services typically recommended after a participant receives urgent or emergency care. Additionally, as discussed in our earlier response to commenters regarding the IDT involvement in recommendation reviews, the IDT has flexibility to determine which IDT disciplines should review, assess, and act on recommendations. We do not expect the full IDT's involvement in every recommendation review. The recommendation review may be conducted by 1 IDT member. However, we continue to emphasize the importance of a multidisciplinary approach to participant care.

After consideration of the comments received, and for the reasons outlined in our response to comments, we are modifying and finalizing our proposal at 460.102(d)(1)(iv)(A) to require that the appropriate member(s) of the interdisciplinary team review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 48 hours from the time of the participant's discharge.

Comment: A commenter requested clarification regarding how the IDT's recommendation review, as proposed at § 460.102(d)(1)(iv) should be documented, and more specifically asked whether the IDT review of recommendations could be conducted verbally, or whether the reviewing provider should document their review of the order.

Response: We interpret this commenter's question as asking about documentation expectations for recommendations the IDT receives and reviews orally. At a minimum, the IDT is responsible for documenting recommendations from employees and contractors into the medical record per § 460.210(b)(4). Once the recommendation is documented, the IDT may have oral conversations regarding the necessity of that recommendation. Not all of those discussions would need to be documented. However, we expect to see the result of that discussion documented to demonstrate that the IDT assessed and considered the recommendations. If a recommendation was approved, we expect to see some evidence or documentation that the service was approved/authorized or ordered. If the recommendation was not considered necessary (and therefore not approved), the IDT is responsible for documenting the rationale for that decision per redesignated §§ 460.102(d)(1)(iii) and 460.210(b)(5). Additionally, if the IDT approves or orders the recommended service, the PACE organization must document, track, and monitor the provision of the service as per the redesignated § 460.98(b)(4).

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(iv) to require the interdisciplinary team to review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists without modification.

Comment: Most commenters recommended that we modify § 460.102(d)(1)(iv)(B) to extend the maximum timeframe for the IDT to review and make determinations on all recommendations from other employees and contractors. We had initially proposed 5 calendar days from the date the recommendation was made as the maximum timeframe, and most commenters recommended a maximum timeframe of 10 calendar days. Commenters' primary justification for extending the timeframe centered on the concern that providers external to the PACE organization might not cooperate in providing all necessary information to the IDT in a timely manner, which they considered beyond the control of the PACE organization, and potentially a situation that may unfairly penalize PACE organizations. Many commenters mentioned that PACE organizations may experience delays in follow-ups from specialist providers, since provider offices are often closed on weekends and holidays. A commenter did not recommend a specific alternative maximum timeframe for IDT review of other employee and contractor recommendations but expressed that the proposed 5-calendar day maximum timeframe was unreasonable based on their experience that PACE organization may not receive specialist recommendations for up to 2 weeks after the date the provider made the recommendation. Another commenter recommended that CMS not impose any timeframe for IDT reviews of contractor recommendations. This commenter considered any review timeframe for contractor recommendations unreasonable and echoed other commenters' concerns that PACE organizations may be penalized for situations outside of their control, such as when contracted providers do not communicate or provide necessary documentation timely to the PACE organization. This commenter also suggested that IDT review of all contractor recommendations would increase IDT responsibilities to the point of negatively impacting the time they can devote to participant care. A commenter asked that we clarify what the starting point for the review timeframe would be and recommended that we base the timeframe on when the PACE organization receives the recommendation rather than the date the recommendation was made.

Response: After careful consideration of the comments, we have decided to modify the proposed § 460.102(d)(1)(iv)(B). Specifically, we have modified the maximum timeframe in which the appropriate member(s) of the IDT must review and make necessity determinations for all recommended services from other employees and contractors from the proposed 5 calendar days to 7 calendar days from the date the recommendation was made. As previously mentioned in the December 2022 proposed rule (87 FR 79653), most PACE organizations audited in 2021 received citations of non-compliance for failing to review and act on recommendations from specialists in a manner necessary to meet the needs of the participant. Most PACE organizations audited in 2022 and 2023 also received citations in this area. During our oversight and monitoring efforts, we have not observed that PACE organizations are routinely making multiple good faith attempts to receive

documentation, including recommendations, from specialist providers. Instead, we have seen numerous situations where PACE organizations make no attempt to obtain recommendations from specialists, and therefore are not aware of their recommendations until months later. The delayed receipt of specialist recommendations jeopardizes participant wellbeing by delaying necessary follow-up care and services. In consideration of our oversight and monitoring observations and commenter concerns, we believe the 7-calendar day timeframe is an appropriate compromise between the 5-calendar day timeframe we originally proposed and the 10-calendar day timeframe that the majority of commenters on this proposal preferred. We believe the 7-calendar day maximum timeframe offers additional flexibility to the IDT in terms of coordination with external providers, while continuing to prioritize participant wellbeing.

We continue to emphasize that the 7-calendar day timeframe is a maximum timeframe, and that the IDT must review all recommendations from other employees and contractors and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, which may require action sooner than 7 calendar days. Although we recognize there may be logistical challenges involved with external provider communications, PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and we decline to implement a timeframe that may result in a lower standard of care on the basis of communication delays by the contracted providers, as we expect PACE organizations to initiate communication and follow-up with external providers to ensure participants receive any necessary follow-on care and services. We also understand that some specialists may not provide written consult notes immediately following an appointment, but nothing would prevent the IDT from calling the specialist and documenting recommendations prior to receiving the complete consultation documentation. Additionally, as discussed in the December 2022 proposed rule, we reiterate that the § 460.102(d)(1)(iv)(B) timeframe begins the date the recommendation was made (87 FR 79654), not the date that the PACE organization or IDT receives the recommendation. In order to ensure participants receive the care they need, in the timeframe they need it, it is important that the timeframe begins when the recommendation is made, and that the PACE organization puts processes into place to get information relating to the recommendations quickly from providers.

After consideration of the comments received, and for the reasons outlined in our response to comments, we are modifying and finalizing our proposal at § 460.102(d)(1)(iv)(B) to require the appropriate member(s) of the interdisciplinary team to review all recommendations from other employees and contractors and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 7 calendar days from the date the recommendation was made.

Comment: A commenter suggested that we may have made an error when proposing at § 460.102(d)(1)(iv)(C) that services must be promptly arranged and furnished under § 460.98(c). The commenter did not believe the use of ''arrange and furnish'' was consistent with other sections in the proposed amendments to § 460.98, which specify maximum timeframes for arranging and scheduling services, but also that services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs.

Response: Although the proposed and now finalized § 460.98 addresses timeframes for arranging and scheduling services, the redesignated § 460.98(c)(4) also states that services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, social, and emotional needs. As discussed in the December 2022 proposed rule, the IDT must arrange (or schedule) the IDT-approved service within the maximum timeframes established at § 460.98(c)(1) and (2) and furnish the service as required by § 460.98(c)(4). (87 FR 79654).

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.102(d)(1)(iv)(C) to require that, if recommendations are authorized or approved by the interdisciplinary team or a member of the interdisciplinary team, the services must be promptly arranged and furnished under § 460.98(c) without modification.

F. Plan of Care (§ 460.106)

Sections 1894(a)(2)(B) and 1934(a)(2)(B) of the Act require that the PACE program provides comprehensive health care services to PACE participants in accordance with the PACE program agreement and regulations under those sections. Sections 1894(b) and 1934(b) of the Act set forth the scope of benefits and beneficiary safeguards under PACE. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act specify in part that PACE organizations must provide participants, at a minimum, all items and services covered under titles XVIII and XIX of the Act without any limitation or condition as to amount, duration, or scope, and all additional items and services specified in regulations based upon those required under the PACE protocol. Sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act also specify that, under a PACE program agreement, a PACE organization must furnish items and services to PACE participants directly or under contract with other entities.

In the 1999 PACE interim final rule (64 FR 66251), CMS developed requirements for participant plans of care based on the requirements in Part IV, section B of the original PACE Protocol. Those requirements were finalized in the 2006 PACE final rule (71 FR 71292).

In 2010, in response to questions from PACE organizations, CMS issued a subregulatory document titled, ''Care Planning Guidance for PACE Organizations.'' This care planning document provided detailed guidance for developing, implementing, monitoring, reevaluating, and revising plans of care. While this document stressed that care plans should be comprehensive and include the participants medical, physical, social, and emotional needs, it also noted that not all care received by the participant would need to be included in the care plan, and instead, could be tracked and documented through discipline specific progress notes.

Since that time, CMS has seen through oversight and monitoring efforts that participant care plans are often sparse and may not fully detail the care received by a participant. We have noted that organizations are relying heavily on providing and documenting care through discipline-specific progress notes, rather than through incorporation into a more comprehensive and formal plan of care.

In the June 2019 final rule (84 FR 25675), CMS added additional requirements around the development

of a comprehensive plan of care which included: a consolidation of discipline-specific initial assessments into a single plan of care for each participant within 30 days of the date of enrollment; documentation in the plan of care of the reasoning behind any IDT determination that certain services are not necessary to the care of a participant; and documentation in the plan of care that the participant was assessed for all services, even where a determination was made that certain services were unnecessary at the time.

In addition to the modifications at § 460.104(b), in the June 2019 final rule, CMS also amended § 460.106 in order to provide additional clarity with respect to the development and content of the plan of care process (84 FR 25646). Among other changes, CMS added requirements for PACE organizations to utilize the most appropriate interventions for each care need that advance the participant toward a measurable goal and outcome (§ 460.106(b)(3)); identify each intervention and how it will be implemented (§ 460.106(b)(4)); and identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes (§ 460.106(b)(5)).

Despite the addition of these requirements in the June 2019 final rule, we continue to find that PACE organizations are struggling with developing, implementing, monitoring, reevaluating, and revising plans of care. As we discussed in the proposed rule, we have seen through our oversight and monitoring process that robust initial care plans become more sparse over time due to the omission of care originally included in the plan of care which is instead handled through discipline-specific progress notes as the participant's enrollment continues (87 FR 79655). In the proposed rule, we acknowledged that documenting detailed information about participant care and services in discipline-specific progress notes is necessary and an accepted standard practice, but argued that practice should not be done in lieu of a comprehensive plan of care that addresses the participant's needs because it results in individual IDT members providing care in an isolated and individualized approach (*Id.*).

Since the June 2019 final rule became effective, CMS has completed 40 PACE audits and we have identified a failure to provide services or delays in providing services in 37 of the 40 audits conducted. Although this noncompliance cannot be directly attributed to a failure to consolidate information into a comprehensive plan of care, our audit findings suggests that the coordination and delivery of necessary services is a challenge for PACE organizations.

Finally, we discussed in the proposed rule how we have also seen on audit that participant and caregiver involvement in the care planning process tends to be minimal and primarily occurs after the development and/or revisions to the plan of care have been finalized and implemented by the IDT (*Id.*). In the 1999 PACE interim final rule (64 FR 66252), CMS specifically stated that plans of care must be developed, reviewed, and reevaluated in collaboration with the participants or caregivers. In the proposed rule, we stated that the purpose of participant/caregiver involvement is to ensure that they approve of the care plan and that participant concerns are addressed (87 FR 79656). Furthermore, in the 2006 PACE final rule (71 FR 71293), CMS reiterated that it is our expectation that the IDT will include the participant in the plan of care development when possible and include the participant's representative when it is not appropriate to include the participant or at the instruction of the participant.

As we discussed in the proposed rule, we believe it is prudent to implement additional requirements related to the minimum requirements for a participant's plan of care (*Id.*). The proposed rule included a discussion of our attempt to adopt language and requirements that are consistent with the long-term care facility regulation at § 483.21(b) when possible because these regulations require nursing homes to develop comprehensive and person-centered care plans that meet residents' needs. Since individuals who enroll in PACE must be deemed nursing home eligible, they have similar needs as those who receive services from nursing facilities (*Id.*).

First, we proposed to modify the requirement in § 460.106(a) to require that the members of the IDT specified in § 460.102(b) must develop, evaluate, and if necessary, revise a person-centered plan of care for each participant. As we discussed in the proposed rule, this is consistent with the requirement at § 460.104(b) that states that within 30 days of the date of enrollment, the IDT must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire IDT (87 FR 79656). Additionally, the IDT is required to reevaluate the plan of care on a semiannual basis at the current § 460.106(d); however, we proposed to remove that requirement as our proposal at § 460.106(a) would cover the role of the IDT in both the initial care plan development and also the subsequent reviews and reevaluations of the care plan. We also proposed to add language into § 460.106(a) that would require each plan of care to take into consideration the most current assessment findings and identify the services to be furnished to attain or maintain the participant's highest practicable level of well-being. The nursing home regulations require that care plans must describe ''the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being'' (§ 483.21(b)(1)(i)). This language should also apply to PACE care plans, since they serve the same nursing home eligible population.

Next, we proposed to add a new section, § 460.106(b), which would define the specific timeframes for developing, evaluating, and revising care plans. For initial care plans, we intend to maintain the requirement for the IDT to finalize the development of the initial plan of care within 30 calendar days of the participant's enrollment that is located at current § 460.106(a), but we propose to move this requirement to new section § 460.106(b)(1).

The regulation at § 460.106(d) currently requires the IDT to reevaluate the plan of care, including defined outcomes, and make changes as necessary on at least a semi-annual basis. The interpretation of the semiannual timeframe has posed issues for PACE organizations. We therefore proposed at § 460.106(b)(2) to require that the IDT must complete a reevaluation of, and if necessary, revisions to each participant's plan of care at least once every 180 calendar days. We believe that creating a strict timeframe of 180 days would be less ambiguous and easier for organizations to track.

We proposed at § 460.106(b)(3)(i) that the IDT must complete a reevaluation, and if necessary, revisions of the plan of care within 14 calendar days after the PACE organization determines, or should have determined, that there has been a change in the participant's health or psychosocial status or more expeditiously if the participant's condition requires. As we discussed in the proposed rule, the current requirement is that the IDT must conduct reassessments when a participant experiences a change in participant status and the IDT must also reevaluate the participant's plan of care (87 FR 79656). However, there is no timeframe for how quickly the IDT

members must conduct those reassessments or reevaluate the plan of care to determine if changes are needed. In the proposed rule, we argued that we believe that a 14-calendar day timeframe is appropriate since it will ensure the IDT is promptly acting on changes to the participant's status (*Id.*). We reviewed the long-term care requirements which state that a resident must receive a comprehensive assessment within 14 calendar days after the date the facility determines, or should have determined there was a significant change in status in the resident's condition and the facility must use the results of the assessments to develop, review, and revise the resident's plan of care (*Id.*) In the proposed rule, we argued this is an appropriate standard to apply in PACE as well due to the similarities between the populations (*Id.*). As discussed later in this section of this proposed rule, we also proposed to modify § 460.104(e) to emphasize that all required assessments must be completed prior to the plan of care being revised. Therefore, this 14-calendar day timeframe would include both the required assessments under § 460.104(d)(1) and the process of revising the plan of care under § 460.106.

We proposed to specify at § 460.106(b)(3)(i) that the 14-calendar day timeframe starts when the PACE organization determines, or should have determined, that a change in the participant's condition occurs. As we discussed in the proposed rule, if a participant experiences a change in status that triggers this reassessment and reevaluation of the care plan, the PACE organization should not be able to delay the timeframe by not recognizing the change in status for a period of time (87 FR 79657). We also proposed to define at § 460.106(b)(3)(i) what constitutes a change in status. As we discussed in the proposed rule, what constitutes a change in status has not been previously defined and we proposed to adopt in PACE the requirement applicable to nursing homes at § 483.20(b)(2)(ii), but with language tailored to be specific to PACE (*Id.*). Therefore, the proposed requirement would state that for purposes of this section, a ''change in participant status'' means a major decline or improvement in the participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant's health status, and requires IDT review or revision of the care plan, or both.

In conjunction with the proposed requirement that a PACE organization must reevaluate and, if necessary, revise the plan of care within 14 calendar days after a change in the participant's condition occurs, we proposed at § 460.106(b)(3)(ii) that if a participant is hospitalized within 14 calendar days of the change in participant status, the IDT must complete a reevaluation of, and if necessary, revisions to the plan of care as expeditiously as the participant's condition requires but no later than 14 calendar days after the date of discharge from the hospital. In the proposed rule, we recognized that when a participant is hospitalized, it is difficult for the IDT to assess the participant, and revise a plan of care, during the course of that hospitalization (87 FR 79657). We proposed that the timeframe for reevaluating the plan of care starts when the participant is discharged from the hospital. Despite this proposed exception, we reminded PACE organizations in the proposed rule that their responsibilities toward the participant do not end or stop when a participant is hospitalized, and the IDT should remain alert to pertinent information in all care settings under § 460.102(d)(2)(ii) (*Id.*).

We solicited comment on whether 14 calendar days is an appropriate timeframe to use or if 21 or 30 days would be more appropriate.

We proposed at § 460.106(c) to make certain modifications related to the content of a plan of care. As we discussed in the proposed rule, the current content of a plan of care is specified at § 460.106(b), which requires the care plan to include the care needed to meet the participant's medical, physical, emotional and social needs; identify measurable outcomes to be achieved; utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal; identify each intervention and how it will be implemented; and identify how each intervention will be evaluated to determine progress (87 FR 79657). We discussed in the proposed rule that we have seen as part of our audit and oversight activities where treatments for participants' medical conditions are included in discipline-specific notes, but not in the comprehensive care plan which has caused members of the IDT to be unaware of the treatments and recommendations the participant has received from other members of the IDT or outside contracted specialists (*Id.*). Additionally, we discussed how we have seen participants experience delays in receiving the recommended treatment or service, the treatment or service not being provided at all, and in some situations, duplicate orders for a service or treatment due to the IDT being unaware the service or treatment was previously provided (*Id.*). Therefore, in addition to proposing to move the content of plan of care requirements from § 460.106(b) to § 460.106(c), we proposed to add language to the section to create minimum requirements for what each plan of care must include. As we discussed in the proposed rule, we considered the regulations at § 483.21(b) which specify the requirements for a comprehensive plan of care (*Id.*). Additionally, § 483.21(b) references § 483.24 (Quality of Life), § 483.25 (Quality of Care), and § 483.40 (Behavior Health), so we considered those sections as well. Therefore, at § 460.106(c), we proposed modifying the language to state at a minimum, each plan of care must meet certain requirements, which would be set forth in the regulations at proposed § 460.106(c)(1)(i) through (xiii). At § 460.106(c)(1), we proposed to add language that requires PACE organizations to identify all of the participant's current medical, physical, emotional, and social needs, including all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring, and that at a minimum, the care plan must address specific factors we will discuss in the next paragraph. As we discussed in the proposed rule, care plans are currently required at § 460.106(b)(1) to include the care needed to meet the participant's medical, physical, emotional and social needs, as identified in the initial comprehensive assessment (*Id.*). However, we proposed to further specify that the plan of care should address all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring which is consistent with nursing home requirements. As explained in the proposed rule, our proposal related to chronic behavioral and psychiatric disorders is consistent with long-term care requirements in § 483.40, which require that each resident must receive and the facility must provide the necessary behavioral health care and services (87 FR 79657). We observed that the nursing home care plan requirements at § 483.21(b) reference the behavior health requirements at § 483.40. Therefore, we proposed that chronic behavioral and psychiatric disorders that require treatment or routine monitoring also be included in PACE plans of care.

We proposed to limit what diseases must be included in the plan of care to

those that are chronic and require treatment or routine monitoring. As we discussed in the proposed rule, when considering how organizations would define ''chronic'' we believe that most organizations would consider the guidance issued by the CDC, which defines chronic diseases as conditions that last 1 year or more, and require ongoing medical attention or limit activities of daily living or both (87 FR 79658). We also solicited comment on whether acute conditions should be included in the minimum content that a care plan must address.

We proposed to specify at § 460.106(c)(1)(i) that the PACE participant's plan of care must address the participant's vision needs. This is consistent with the long-term care provisions at §§ 483.20(b)(1)(v) and 483.25(a). As we discussed in the proposed rule, the age of the PACE population and the co-morbidities that may impact the population makes addressing a participant's vision an important part of the care plan (87 FR 79658). We similarly proposed at § 460.106(c)(1)(ii) that a PACE participant's plan of care must address the participant's hearing needs. This is consistent with the long-term care regulations at § 483.25(a). We proposed at § 460.106(c)(1)(iii) that a participant's plan of care must address the participant's dentition. This is consistent with the requirement at § 483.20(b)(1)(xi). We proposed at § 460.106(c)(1)(iv) that a plan of care must address the participant's skin integrity. This is consistent with the requirements at §§ 483.20(b)(1)(xii) and 483.25(b). We proposed at § 460.106(c)(1)(v) that the participant's plan of care must address the participant's mobility. This is consistent with the requirement at § 483.25(c). We proposed at § 460.106(c)(1)(vi) that the participant's plan of care must address the participant's physical functioning (including activities of daily living). This is consistent with the requirements at §§ 483.20(b)(1)(viii) and 483.24(b). We proposed at § 460.106(c)(1)(vii) that the plan of care must address the participant's pain management needs. This is consistent with the requirement at § 483.25(k).

As we discussed in the proposed rule, the next few proposed requirements deviate from the nursing home requirements and are tailored specifically to the PACE program (87 FR 79658). We proposed to require at § 460.106(c)(1)(viii) that the plan of care address the participant's nutrition, including access to meals that meet the participant's daily nutritional and special dietary needs. The proposed language is based on the long-term care regulations at §§ 483.20(b)(1)(xi), 483.24(b)(4), and 483.25(g), but it is tailored to be more specific to PACE. As we discussed in the proposed rule, PACE participants live in a variety of settings and the exact manner in which the organization meets the requirement may be different for each participant (*Id.*). For this reason, we proposed to include in § 460.106(c)(1)(viii) language that would specify that the plan of care address not only nutrition, but also how a participant accesses meals that meet their nutritional and special dietary needs.

We proposed at § 460.106(c)(1)(ix) to establish the requirement that the plan of care address the participant's ability to live safely in the community, including the safety of their home environment. As we discussed in the proposed rule, the proposal also deviates from the nursing home requirements, as the goal of PACE is to keep nursing home eligible individuals out of a facility and living in the community, and the IDT must assess the participant's environment and living situation for potential factors that may make it unsafe for the participant (87 FR 79658). As we noted in the 2006 PACE final rule (71 FR 71275), PACE organizations are at risk for all health care services the participant receives and, therefore, we expect PACE organizations will be involved in assuring the health and safety of participants at all times, including when they are at home. We proposed at § 460.106(c)(1)(x) that the plan of care must address the participant's home care needs. As we discussed in the proposed rule, this proposal would also deviate from nursing home guidance because, while nursing homes provide 24-hour care to residents living at the facility, PACE provides similar care through home care services (87 FR 79653). Therefore, we believe a participant's home care needs must be addressed through the plan of care. We proposed to establish at § 460.106(c)(1)(xi) that the participant's center attendance must be included in the plan of care. As we discussed in the proposed rule, center attendance is an integral part of the PACE program, and we believe it is appropriate to include it in a participant's plan of care (*Id.*). We proposed at § 460.106(c)(1)(xii) to require that a participant's transportation needs be incorporated into the plan of care. As we discussed in the proposed rule, transportation is an essential part of the PACE benefit, as often it is the PACE transportation that ensures participants have access to their necessary medical appointments and specialist visits (*Id.*). In addition, we proposed to require at § 460.106(c)(1)(xiii) that a participant's communication needs (including any identified language barriers) be incorporated into the plan of care. As we discussed in the proposed rule, for participants who are not English speaking, or have some other difficulty communicating, addressing and resolving these needs preemptively can mean the difference between quality of care and participants not receiving the care they need (*Id.*).

We solicited comment on all items identified in proposed § 460.106(c)(1) and whether they should be required content in a plan of care for PACE participants. We specifically requested comment on whether to include acute diseases and/or acute behavioral and psychiatric disorders in the plan of care as part of the minimum criteria. We also solicited comment on whether there is other content that is required to be in a nursing home care plan that should also be included in a PACE plan of care.

We proposed at § 460.106(c)(2) to require that the plan of care must identify each intervention (the care or service) needed to meet the participant's medical, physical, emotional, and social needs. As we discussed in the proposed rule, the PACE organization must also identify any service that will be provided to meet the participant's medical, physical, social, or emotional needs (87 FR 79659). We proposed to include at § 460.106(c)(2) an exception to the interventions that need to be included in the plan of care; specifically, proposed § 460.106(c)(2) would provide that the plan of care does not need to identify the medications needed to meet a participant's needs if a comprehensive list of medications is already documented elsewhere in the medical record. As we discussed in the proposed rule, we define services at § 460.6 to include medications because we strongly believe that medications are an important part of the PACE benefit and may be the most applicable service for a particular diagnosis or condition (*Id.*). However, we also understand that medications may change frequently, and are typically documented in the medical record in way that would allow the IDT to understand all current, pending and discontinued medications. While we did not propose to require that all medications be identified in the plan of care, we solicited comment on whether the plan of care should include a comprehensive list of active medications.

We proposed to redesignate current § 460.106(b)(3), which requires the care

plan to utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome, as § 460.106(c)(3).

We proposed at § 460.106(c)(4) to specify that the plan of care must identify how each service will be implemented, including a timeframe for implementation. The proposed rule noted that the IDT is already required to identify how each intervention will be implemented in § 460.106(b)(4); we proposed to modify the language to specify that as part of identifying how the intervention will be implemented, the PACE organization should specify a timeframe for that implementation (*Id.*). As part of the plan of care process, the IDT should determine the parameters of a service—specifically, how it will be provided to the participant in order to meet their needs.

We proposed at § 460.106(c)(5) to require that the plan of care must identify a measurable goal for each intervention. As we discussed in the proposed rule, the current care plan regulations require that the plan identify measurable outcomes (§ 460.106(b)(2)) and utilize appropriate interventions that advance the participant toward a measurable goal (§ 460.106(b)(3)) (87 FR 79659). We explained in the proposed rule that our proposal at § 460.106(c)(5) is consistent with the intention of the current requirement; however, we believe that it is important when identifying a service to also identify the measurable goal for that service (*Id.*).

We proposed at § 460.106(c)(6) to require that the care plan identify how the goal for each intervention will be evaluated to determine whether the intervention should be continued, discontinued, or modified. As we discussed in the proposed rule, the IDT is currently required at § 460.106(b)(5) to identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes (87 FR 79659). We explained in the proposed rule that our proposal is similar in intent, but would reduce ambiguity by specifying that the evaluation by the IDT should focus on determining whether the goal was met before deciding if the intervention needs to be continued, discontinued or modified (*Id.*). We further explained that if the participant met the goal, the IDT may decide to discontinue the service; however if the participant didn't meet the goal, the IDT may decide to modify or continue the intervention, and at that time, the IDT will need to determine both a new measurable goal and how that goal will be evaluated (*Id.*).

Finally, we proposed at § 460.106(c)(7) to require that the plan of care must identify the participant's preferences and goals of care. As we discussed in the proposed rule, it is important for the PACE organization to document the participant's goals and wishes for treatment and to consider them not only when developing and reevaluating the plan of care, but during implementation of the services that were added to the plan of care (87 FR 79659).

We proposed to move the requirements in § 460.106(c) to § 460.106(d) and make modifications to the existing requirements. We proposed to move the language in § 460.106(c)(1) to § 460.106(d)(1) and modify it to read that the IDT must continuously implement, coordinate, and monitor the plan of care, regardless of whether the services are furnished by PACE employees or contractors, across all care settings. As we discussed in the proposed rule, we have seen where PACE organizations met the minimum requirement of reassessing participants semiannually and updating the plan of care accordingly, but then took no further action with respect to the plan of care until the next semiannual assessment period (87 FR 79660). In the proposed rule, we reemphasized that the intent of the plan of care is to create a comprehensive, living document that is updated per the participant's current status at any given point (*Id.*). We proposed to include the language ''across all care settings,'' to reiterate the responsibilities of the IDT in ensuring that care is appropriately coordinated and furnished, regardless of where a participant resides.

We proposed to move the current requirements at § 460.106(c)(2) to § 460.106(d)(2) and to modify § 460.106(d)(2) to specify that the IDT must continuously evaluate and monitor the participant's medical, physical, emotional, and social needs, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the IDT and other employees or contractors. As we discussed in the proposed rule, the modification to change the language from ''participant's health and psychosocial status'' to ''participant's medical, physical, emotional, and social needs'' is intended to align more closely with the regulation on required services at § 460.92(b) (87 FR 79660).

We proposed to add § 460.106(d)(3) to state that all services must be arranged and provided in accordance with § 460.98(c). As we discussed in section VI.G. of the proposed rule, we have proposed additional criteria concerning the arranging and provision of services that are determined necessary by the IDT (87 FR 79648). We explained in the proposed rule that when a service is care planned, the IDT has determined that the service is necessary for the participant, and we would expect it to be arranged and provided in accordance with the rules governing other approved or necessary services (87 FR 79660).

As we discussed in the December 2022 proposed rule, although § 460.106(e) currently requires that the team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, we have seen as part of our audit and oversight activities where participants and/or caregivers are unaware of the contents of their plan of care or what services they should be receiving (87 FR 79660). We further discussed how we often see that the plan of care is finalized by the team and then provided or reviewed with the participant after the fact as a means of ''collaboration.'' (*Id.*) Therefore, we proposed to split the existing language into two new paragraphs § 460.106(e)(1) and (e)(2). We proposed at § 460.106(e)(1) that the IDT must develop, evaluate, and revise each plan of care in collaboration with the participant or caregiver, or both. We proposed to amend the language to refer to ''each'' plan of care in order to emphasize that this collaboration must be performed for every new plan of care, including the initial, semi-annual, and a revised plan of care as a result of a change in status. We also proposed at § 460.106(e)(2) that the IDT must review and discuss each plan of care with the participant and/or caregiver before the plan of care is completed to ensure that there is agreement with the plan of care and the participant's concerns are addressed.

As we discussed in the December 2022 proposed rule, we have seen organizations have insufficient documentation related to participant plans of care despite the current requirement that the team document the plan of care, and any changes made to it, in the participant's medical record (87 FR 79660). We further explained how we often see minimum documentation related to whether a participant has met the goals set at the last assessment and any changes in the participant's status, but no documentation of the conversations with the participant in the plan of care, including whether the participant disagreed with any part of the plan of care and whether those concerns were

addressed (*Id.*). Therefore, we proposed to modify the language in § 460.106(f) to state that the team must establish and implement a process to document and maintain records related to all requirements for the plan of care in the participant's medical record, and ensure that the most recent care plan is available to all employees and contractors within the organization as needed. As we discussed in the proposed rule, our proposal is consistent with the current requirement, but ensures that the PACE organization understands that it must document all care planning requirements (*Id.*). Therefore, we would expect to see documentation that the appropriate members of the IDT were involved in care planning in accordance with § 460.106(a), the IDT met the timeframes for finalizing care plans in § 460.106(b), that the care plans included all required content in § 460.106(c), that the IDT implemented and monitored the plan of care in accordance with § 460.106(d), and that the participant and caregiver were appropriately involved in the care planning process in accordance with § 460.106(e).

We also proposed certain modifications to § 460.104 to align with our proposed amendments to § 460.106. We proposed to remove most of the language currently in § 460.104(e) and add the requirement that when the IDT conducts semiannual or unscheduled reassessments, the IDT must reevaluate and, if necessary, revise the plan of care in accordance with § 460.106(c) following the completion of all required assessments. As we discussed in the proposed rule, we believe this will eliminate any unnecessary duplication and ensure there is no confusion as it relates to care plans (87 FR 79661).

As both the development of and updates to the care plan are a typical responsibility for the IDT, any burden associated with this would be incurred by persons in their normal course of business. Therefore, the burden associated with the development of and updates to the care plan are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities and is a usual and customary business practice.

We solicited comment on these proposals. A summary of the comments received and our responses follow.

Comment: Most commenters appreciated CMS's clarification of semi-annual by modifying the requirement to 180 days. Several commenters expressed concern over the change in requirement from a semi-annual re-evaluation of the plan of care to a re-evaluation at least every 180 days. Those commenters stated the requirement is overly burdensome because it will require PACE organizations to monitor and track the care plan precisely and notify the IDT when the next care plan is due. A commenter requested clarification of whether the 180-day timeline restarts every time the plan of care is reevaluated or if it is predicated on the participant's enrollment date. A commenter requested that the requirement be modified from 180 days to the last day of the 6th month following the last reevaluation of the plan of care because it would provide PACE organizations an entire month to focus on care planning rather than having to calculate the 180 days exactly. Another commenter pointed out that 180 days is just short of six months, and that CMS should change the requirement to 185 days to allow for a full six months between reevaluations for plans of care.

Response: We thank commenters for sharing their concerns regarding the 180-day timeline being overly burdensome. We believe that providing a clear standard will reduce the ambiguity of the semi-annual care plan requirement currently in regulation. We are not persuaded by the argument that tracking the care plan by 180 days is overly burdensome as PACE organizations are already required to track care plans semi-annually. We have also consistently heard from both PACE organizations and advocacy groups that PACE requirements are overly vague and clarification of CMS's intent is appreciated whenever possible. For these reasons, we are not persuaded to extend the timeframe beyond the proposed 180-days or leave the requirement as it currently is written. Additionally, we clarify that we intend the 180-day timeline to restart every time a new care plan is finalized. We believe this is consistent with other parts of the regulation that contemplate care plans being developed within specific timeframes (for example, §§ 460.104(b) and 460.106(a)) and also the service determination request language which discusses requests made ''prior to completing the development'' of the initial plan of care (see § 460.121(b)(2)). For example, if a participant experiences a change in health status, the participant must be assessed, and a new care plan must be developed and implemented. The participant's next care plan would then be due 180 days from the date the latest care plan was finalized. To ensure there is no ambiguity on when the timeframe begins, we are finalizing the proposed requirement with a modification to the regulation text to state that the 180-day timeline starts from the date when the last care plan was finalized at § 460.106(b)(2).

Comment: Multiple commenters requested that CMS extend the timeframe to conduct unscheduled assessments following a change of status from the 14-day timeline that was proposed to a 30-day timeline to allow PACE organizations more flexibility in complex cases and more time to coordinate with providers outside of the PACE organization's network. A commenter questioned CMS's decision to hold PACE organizations to the same standard as long-term care facilities when it is not clear whether the 14-day timeline used by these facilities improves care. A few commenters requested that CMS add a participant being discharged from a SNF as an exception to the 14-day timeframe, similar to the exception proposed for participants who are hospitalized. These commenters argued that it is beneficial for the participant to be as stable as possible before conducting assessments and developing a care plan. These commenters suggested that if a participant is placed in a SNF for a short-term stay, or another similar environment, the IDT should delay the reassessment timeframe until discharge, similar to the hospital exception. A commenter requested CMS consider providing an exception process to the timeline to allow PACE organizations an exemption when needed, but to limit abuse by requiring 85 percent of care plans to meet the regulatory timeframes to be considered compliant. Another commenter requested that CMS clarify when the timeline would begin for care planning purposes if a PACE organization failed to determine, but should have determined, that there had been a change in the participant's health or psychosocial status.

Response: We thank the commenters for their suggestions to extend the timeline to conduct an unscheduled re-evaluation of the care plan following a change in status. We understand the concerns expressed by commenters about the ability of PACE organizations to obtain necessary information from outside sources, such as hospitals, to complete assessments of the participants after a change in status. We had solicited comment on whether the timeline should be 14, 21, or 30 days and, if commenters believed a different timeline was more appropriate for PACE, why PACE should be held to a

different standard than long term care facilities. While most commenters requested 30 days, we were not persuaded by the commenters' arguments for why this longer timeframe was justified. PACE organizations must have processes in place to ensure their contracted providers are promptly communicating information relating to the participant's condition. Incidents that prompt a change in status reassessment are not minor events, but situations that have a direct impact to a participant's ability to function, and therefore, they need to be considered and addressed as expeditiously as the participant's health requires. As we have stated previously, because PACE and long-term care facilities serve the same vulnerable population, we feel aligning the requirements ensures participants receive the same quality of care they would receive in a nursing home or other SNF. We are also not persuaded to add an exception to the timeframe for conducting a re-evaluation of the care plan to include a participant's discharge from a SNF. SNFs are contracted with the PACE organization, and the PACE organization should already have processes in place to conduct assessments of participants when they are at those facilities as needed. Additionally, while commenters requested exceptions for ''short term'' stays in a SNF, ''short term'' is an undefined period of time which will change for every participant in every situation. While some participants may experience a short term stay of a week, other participants may be admitted for a ''short term'' stay and end up residing in the SNF for a month or even longer. Delaying those participants' re-evaluations until after discharge would be inappropriate as the participant may end up residing for long periods in another care setting without a care plan that is appropriately tailored to their needs. We would note, nothing in our modification prohibits a PACE organization from conducting change in condition assessments and care plans on a more frequent basis. If the PACE organization determines that the participant should be re-assessed following the discharge from the SNF, it is encouraged to do so.

As for the language that the timeframe begins within 14 calendar days after the PACE organization determines, or should have determined, that there has been a change in the participant's health or psychosocial status; this language is meant to convey that the trigger for the timeframe is when the change in status event occurs, even if that event happens prior to the PACE organization becoming aware of it. For example, if the participant has a stroke with hemiplegia on a Monday, and the PACE organization becomes aware of the stroke 2 days later, the 14-calendar day timeframe begins the date of the stroke, not the date the PACE organization becomes aware of the stroke. However, if the participant is hospitalized because of the stroke, the 14-calendar day timeframe would begin upon discharge from the hospital. We are finalizing the 14-calendar day timeframe as proposed.

Comment: Several commenters requested that CMS modify the proposal on the required content of plans of care to focus on what is most important and relevant to participants' needs as identified by the IDT in collaboration with the participant and/or designated representative. A few commenters also requested that CMS clarify that the proposed changes to the content of the care plan will not interfere with the participant's views and wishes, including the participant's desire to decline certain plan goals. A few commenters expressed concern that the minimum requirements for the content of care plans would include such a high level of detail that it would impact the IDT's time and resources and create administrative burden. A commenter stated that long-term care facilities and PACE organizations are different and should not be held to the same standards, and asked for clarification of how CMS would determine the validity of an assessment for a participant who has no needs in a specified area. A commenter requested that CMS clarify what the word ''need'' means in the context of the care plan, and whether that refers to an assessed medical need or a need the participant believes they have. Another commenter stated that it was impractical and duplicative for IDT members to incorporate their individual notes and diagnoses from the medical record into a care plan for all participants.

Response: We thank commenters for sharing their concerns on the proposed required content to the plan of care. Our intent in proposing required content for the plan of care wasn't to override participant's wishes and desires for what is included in their individual plans of care, but instead to ensure that all participants are equally assessed for services that meet their needs, and to ensure the care plan is a comprehensive document that reflects an accurate picture of the care a participant receives. In the event a participant is assessed for a service that they do not wish to include in their plan of care, we would expect the PACE organization to document that the participant was assessed for the service and requested it not to be included in their plan of care. Additionally, if the IDT determined the participant did not have any identified needs in a particular area, they would indicate that in the plan of care. For example, if the participant is assessed as having perfect vision, the care plan content for vision may include an optometry appointment once a year without any further goals or interventions. Or the IDT may note that there are no current needs in a particular area, such as skin integrity. When determining a participant's needs in a particular area the IDT should use all available information including recent assessments to ensure the care plan accurately reflects the participant's condition in a particular area. Per our changes to § 460.121(b)(2), as discussed in section IX.L of this final rule, when a participant believes they have a need, we would expect the IDT to assess the participant for that need to determine if the need is present. Then the IDT would assess what services or interventions are necessary to meet that need, just as the IDT determines whether any request for a specific service is necessary to improve and/or maintain a participant's medical, physical, emotional, or social wellbeing. Then we would expect the IDT to document the request for assistance with the stated need, the IDT's determination, and in the event the need was determined not to be present, the IDT's reasoning for that determination. We would review the available documentation in the medical record to determine if the participant's needs were appropriately assessed and addressed.

We understand that long-term care facilities and PACE organizations are not the same, but they share some important similarities. They are both direct care providers serving nursing home eligible participants. Therefore, we do not believe it is inappropriate to adopt long-term care standards in order to ensure equitable access to care among the vulnerable populations served.

We are not persuaded that requiring the IDT to record its diagnoses into the care plan as well as the medical record is duplicative. PACE was created to care for the individual as a whole, with the IDT and care planning being important components of the program's success. If the care plan does not include all current diagnoses from the different IDT disciplines, then the participant may not receive all the care for which they have been approved. As we stated in the proposed rule, we have seen as part of our oversight and monitoring activities that PACE organizations rely heavily on

discipline specific progress notes causing participant care plans to be sparse and not fully detailing the care received by the participant (87 FR 79655). If the IDT is not fully aware of all of a participant's comorbidities as well as any developments in the participant's medical, physical, emotional, and social status, the participant's planned treatment and services may not be adequate to meet the participant's needs. We are finalizing the required content of the care plan as proposed.

Comment: Multiple commenters agreed with CMS's decision not to include acute diseases or medications in the care plan requirements. A commenter supported CMS's inclusion of vision in the content requirements of the care plan and requested that CMS require PACE organizations to report the number of participants referred to a doctor of optometry for a comprehensive eye exam.

Response: We thank the commenters for their support of the proposed required content of the plan of care. We agree with commenters that the inclusion of acute diseases is not always appropriate in the plan of care and are finalizing the proposed required content without inclusion of acute diseases or medications; however, as we stated in the proposed rule, nothing prevents a PACE organization from including acute diseases or medications in the care plan if they so choose (87 FR 79659). Additionally, while we appreciate the support for including vision as required care plan content, the collection of data including optometry appointments is outside the scope of this rule.

Comment: A few commenters requested CMS refer to the National Consensus Project for Quality Palliative Care to include interventions such as palliative care, non-pain symptoms, caregiver burden, participant's cognitive status and decision-making ability, financial vulnerability, and spiritual concerns.

Response: While we agree with the commenters that interventions for other areas in a participant's life are an important consideration for treating a participant's medical, physical, emotional, and social needs, we are not persuaded to require additional content regarding non-pain symptoms, caregiver burden, participant's cognitive status and decision-making, financial vulnerability, or spiritual concerns. While we agree that these specific areas may be relevant to some participants, we believe it is such a personal matter that we are not adding them to the minimum criteria. However, we encourage PACE organizations to consider whether other interventions would be appropriate when developing the care plan based on the participant's needs and other regulatory requirements, including requirements related to participant rights. We may consider proposing additional minimum content for the plan of care in the future. We would note that nothing in our proposal would prevent PACE organizations from including additional content in the care plan if they so desired. We also extensively discussed the proposed palliative care requirements in section IX.G, Specific Rights to Which a Participant is Entitled, where we proposed to require PACE organizations to define comfort care, palliative care, and end-of-life care, and obtain consent from participants and/or their designated representatives prior to implementing comfort, palliative or end-of-life care. We believe our proposal in that section to require PACE organizations to explain the different treatment options, provide written information of those treatment options, and obtain written consent prior to initiating palliative, comfort or end-of-life care services is the appropriate avenue for addressing palliative care interventions. To the extent that a participant's services change as a result of their designation of palliative care, comfort care or end-of-life care, the IDT should consider how those changes impact the care plan and whether modifications to the care plan are necessary. Therefore, we are finalizing the required content of the plan of care as proposed.

Comment: Multiple commenters requested CMS to modify the proposed participant and/or caregiver participation requirement to allow PACE organizations to document attempts to engage the participant and/or their caregiver. These commenters stated that often participants and/or caregivers are averse to participating in the care planning process. Alternatively, a few commenters suggested CMS grant the IDT a grace period of 15 days to accommodate the participant's and/or caregiver's availability and willingness to review the care plan prior to finalization or to allow PACE organizations to finalize care plans prior to obtaining participant and/or caregiver approval. With respect to the latter alternative, a commenter stated that if the caregiver and/or participant do not approve of the care plan after it has been finalized by the PACE organization, the care plan can be reviewed and revised at that point. Another commenter requested CMS modify the proposed requirement to clarify how PACE organizations can prove compliance when participants and/or their caregivers do not participate in the care planning process.

Response: We thank commenters for sharing their concerns regarding the proposed requirement to include participants and/or caregivers in the plan of care development and implementation process. We recognize that some participants and/or caregivers may be averse to participating in the care planning process. However, we would point out that there are different methods the IDT may use to involve the participant. Some participants may want to participate in the IDT meeting where the care plan is discussed and developed. Other participants may want to participate less in the care planning process. In those cases, we would expect, at a minimum, documentation to demonstrate that the care plan was fully reviewed with the participant, and that any concerns were addressed, prior to the care plan being finalized. It is important that participants and/or caregivers are active in discussions regarding the participant's needs. A collaborative approach to care planning allows participants and/or caregivers to be actively engaged in the care participants receive. As we stated in the proposed rule, often we see through our oversight and monitoring process that participants and/or caregivers are only informed of the new care plan after it has been completed by the IDT (87 FR 79660). We also believe this requirement addresses commenters' concerns, discussed in an earlier comment summary, regarding ensuring the participant's views and wishes are taken into consideration during the development of the plan of care. The best way to ensure that the care plan satisfies the participant's goals for care is to include the participant in the care plan discussion. Therefore, we are finalizing the participant and/or caregiver participation requirements as proposed.

We are also not persuaded by the argument to extend the timeframe beyond 180 days to allow a grace period for finalizing the care plan to accommodate participants' and/or their caregivers' availability and willingness to review the care plan. However, nothing prevents a PACE organization from factoring in their own grace period when calculating the 180-day timeframe to ensure the PACE organization has enough time to meet with the participant before the deadline. For example, if the participant is historically difficult to reach, the IDT may decide to start the care planning discussions a few weeks prior to the

180-day deadline in order to allow ample time to finalize the plan of care.

Our intent in proposing the participant and/or caregiver participation requirement was to reduce the instances of participants and/or caregivers being presented with a finalized care plan after the IDT has completed its assessments and recommendations. As we stated in the proposed rule, we ''want to ensure the participant and/or caregiver has an opportunity to voice concerns and ensure that any concerns are addressed in the proposed plan of care'' (87 FR 79660). While we understand that participants and/or caregivers may not wish to participate in the care planning process, they should at least be given the opportunity prior to the care plan being finalized. We would expect a PACE organization to document attempts to engage the participant and/or caregiver in the care planning process and would consider those attempts in our review of a PACE organization's compliance with this requirement.

After considering the comments, we are finalizing the proposed changes to § 460.106 in part, with a modification to the language at § 460.106(b)(2) to clarify that the required timeline for the care plan reevaluation is 180 days from the date when the previous care plan was finalized.

G. Specific Rights to Which a Participant Is Entitled (§ 460.112)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify in part that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including a patient bill of rights. Previously, we established in § 460.112 certain rights to which a participant is entitled. This includes the participant's right to considerate, respectful care and the right not to be discriminated against (§ 460.112(a)); the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions (§ 460.112(b)); the right to access emergency services without prior authorization (§ 460.112(d)); and the right to participate fully in decisions related to his or her treatment (§ 460.112(e)).

In the proposed rule, CMS proposed to amend § 460.112 to incorporate the following participant rights: the right to appropriate and timely treatment for health conditions including the right to receive all care and services needed to improve or maintain the participant's health condition and to attain the highest practicable physical, emotional and social well-being; the right to have the PACE organization explain all treatment options; the right to be fully informed, in writing, before the PACE organization implements palliative care, comfort care, or end-of-life care services; the right to fully understand the PACE organization's palliative care, comfort care, and end-of-life care services; and the right to request services from the PACE organization, its employees, or contractors through the process described in § 460.121.

Sections 1894(b)(1)(B) and 1934(b)(1)(B) of the Act establish that PACE organizations shall provide participants access to necessary covered items and services 24 hours per day, every day of the year. We codified these required services at § 460.92, which provides that the PACE benefit package for all participants, regardless of the source of payment, must include all Medicare covered services, all Medicaid covered services as specified in the State's approved Medicaid plan, and other services determined necessary by the IDT to improve and maintain the participant's overall health status. At § 460.98(a), we established the requirement for PACE organizations to provide care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year. However, as we discussed in the proposed rule, we have identified some PACE organizations that do not provide care meant to improve or maintain the participant's condition, and instead provide a palliative-like benefit, where the services provided to participants are geared more toward ensuring the participant's comfort even when that is not in line with the participant's wishes or needs (87 FR 79661). We also stated in the proposed rule that we have seen organizations use terms such as palliative care and comfort care without clearly defining those terms for the participants and/or their designated representatives, leaving participants and families confused as to what level of care they are receiving (*Id.*). As we stated in the January 2021 final rule (86 FR 6041), enrollment in the PACE program continues until the participant's death, regardless of changes in health status, unless the participant voluntarily disenrolls or is involuntarily disenrolled. We argued in the proposed rule that it is reasonable that a PACE participant may transition from receiving treatment meant to cure or maintain health conditions at the time of enrollment, to receiving end-of-life care by the time they approach their death (*Id.*). We further stated that it is essential that PACE participants understand their right to receive all treatments in the PACE benefit package that are necessary and appropriate, and that they clearly understand their rights as their health transitions throughout their time in the PACE program (*Id.*).

For the foregoing reasons, we proposed certain modifications to § 460.112. First, we proposed to redesignate current paragraphs (a) through (c) as paragraphs (b) through (d) to allow for the addition of proposed new paragraph (a). Proposed new paragraph (a)(1) would state that participants have a right to appropriate and timely treatment for their health conditions, which includes the right to receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being. As we discussed in the proposed rule, we considered the language in § 460.92 related to services meant to improve or maintain the participant's health condition as well as nursing home regulations at § 483.21(b)(1)(i), which require care plans to describe ''the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being'' (87 FR79661).

In addition, we proposed to add to § 460.112 a new paragraph (a)(2), which would state that participants have the right to appropriate and timely treatment for their health conditions, including the right to access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team. As we discussed in the proposed rule, although the right to access emergency care services currently appears at § 460.112(d), we believe that it relates to the right to treatment, and therefore, we proposed to move the text of current § 460.112(d) to new § 460.112(a)(2) (87 FR 79662).

In the 1999 PACE interim final rule, we codified at § 460.112(a) (which we proposed to redesignate as § 460.112(b)) that all participants have the right to considerate respectful care, and each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment (64 FR 66253). We also codified at § 460.112(e) the right of participants to participate fully in all treatment decisions. As we discussed in the proposed rule, § 460.112(e)(1) has two specific parts; the right to have all treatment options explained in a culturally competent manner, and the right to make health care decisions (87 FR 79662). We stated in the proposed

rule that we believe the first right, the right to have all treatment options explained in a culturally competent manner, relates more to the rights under redesignated § 460.112(b) (''Respect and nondiscrimination'') (*Id.*). Therefore, we proposed to add a new paragraph at § 460.112(b)(8) which states that participants have the right to have all information regarding PACE services and treatment options explained in a culturally competent manner. As we stated in the proposed rule, culturally competent care respects diversity in the patient population and cultural factors that can affect health and health care, and can contribute to the elimination of racial and ethnic health disparities (*Id.*).

In the 1999 PACE interim final rule (64 FR 66254), we codified the participant's rights to receive accurate and easily understood information at current § 460.112(b) (which we proposed to redesignate as § 460.112(c)). In the 2006 PACE final rule, we further stated that this information was necessary for participants to ''comprehensively assess differences in their health care options'' (71 FR 71295). We also codified at § 460.112(e) that ''a participant who is unable to participate fully in treatment decisions has the right to designate a representative'' (64 FR 66290). We argued in the proposed rule that a participant's designated representative should receive the same accurate, easily understood information the participant receives in order to make informed decisions on behalf of the participant (87 FR 79662). We proposed to add language to the newly designated § 460.112(c) that would provide that a participant has the right to have all information in this section shared with their designated representative.

The proposed rule at 87 FR 79662 discussed how we have seen as part of our audit and oversight activities that PACE organizations used the terms palliative care, comfort care, and end-of-life care, without providing participants with clear information on how the PACE organization is defining those terms or offering clear explanations of whether participants who opt to receive those forms of treatment will also continue to receive curative treatments. Although we did not propose to define these terms, we believe it is important for PACE organizations to define the terms within their respective programs, and provide clear information to participants and their designated representatives on what the terms mean. Therefore, we proposed to add language to newly designated § 460.112(c)(5) that would provide that participants have the right to be fully informed, in writing, of several factors before the PACE organization implements palliative care, comfort care, or end-of-life care. We proposed that the written notification to participants must explain four different aspects of the treatment options, which we outlined in proposed § 460.112(c)(5)(i) through (iv).

First, we proposed at § 460.112(c)(5)(i) that the written notification must include a description of the palliative care, comfort care, and end-of-life care services (as applicable) and how they differ from the care the participant is currently receiving to meet their individual needs. As we discussed in the proposed rule, a participant should have the right to fully understand the care they are agreeing to receive prior to that care being initiated (87 FR 79662).

As proposed, § 460.112(c)(5)(ii) would require PACE organizations to explain, in writing, to participants or their designated representative whether palliative care, comfort care, or end-of-life care services (as applicable) will be provided in addition to or in lieu of the care the participant is currently receiving. As we discussed in the proposed rule, we have seen through audit that some PACE participants receive palliative care and/or comfort care in addition to curative treatment; however, we have also seen participants receive palliative care and/or comfort care instead of treatment meant to improve or maintain the participant's health condition when the participant was unaware that in choosing palliative care, they were also choosing to forego curative treatments (*Id.*). We stated that providing palliative care only services may be appropriate in some instances, but we believe it is important that participants fully understand what they are agreeing to when they enter into palliative or comfort care status (*Id.*).

As proposed, § 460.112(c)(5)(iii) would require PACE organizations to identify all services that would be impacted if the participant and/or their designated representative elects to initiate palliative care, comfort care, or end-of-life care. As discussed in the proposed rule, PACE organizations would be required to provide a detailed explanation of how specific services would be impacted by the addition of or transition to palliative care, comfort care, or end-of-life care (87 FR 79663). We further explained that PACE organizations that provide palliative care services in conjunction with curative treatment may not have to provide a detailed analysis and could instead include language in their explanation that palliative or comfort care will not impact existing services (*Id.*).

As proposed, § 460.112(c)(5)(iv) would state that the participant has the right to revoke or withdraw their consent to receive palliative, comfort, or end-of-life care at any time and for any reason either verbally or in writing. We also proposed to require PACE organizations to explain this right to participants both orally and in writing. A participant has the right to fully participate in treatment decisions, as established at current § 460.112(e). That includes the right to participate in the decision-making process of what care to receive, and a participant must not only understand what the proposed care or treatment decisions mean, but also that they can change their mind with regards to treatment decisions previously made. As we discussed in the proposed rule, we have seen situations where participants or their designated representatives want to stop palliative care or comfort care when they realize this means they will no longer receive other services, and they do not know they have the right to revisit prior treatment decisions (87 FR 79663). As we discussed in the proposed rule, participants should be clearly informed, in writing, that they have the ability to change their mind on these important treatment decisions (*Id.*).

In the 1999 PACE interim final rule (64 FR 66255), we established at § 460.112(e) the right for each participant to fully participate in all decisions related to his or her care. Paragraph (e)(1) specifies that this includes the right ''[t]o have all treatment options explained in a culturally competent manner and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions.'' In the proposed rule, we proposed to amend § 460.112(e)(1) by removing the language regarding the participant's right to have all treatment options explained in a culturally competent manner. As we explained in the discussion around our proposed amendments to § 460.112(b), the right to have treatment options explained in a culturally competent manner is better suited for inclusion in that paragraph, which, as amended, sets forth participant rights related to respect and non-discrimination. We also proposed to restructure and modify § 460.112(e)(1) by separating the requirements into three subparts at § 460.112(e)(1)(i), (ii) and (iii). We proposed at § 460.112(e)(1)(i) to establish that a participant's right to make health care decisions includes the right to have all treatment options fully explained to them. As we discussed in

the proposed rule, a participant cannot make an informed health care decision without fully understanding the options available (87 FR 79663).

As proposed, § 460.112(e)(1)(ii) would provide that participants have the right to refuse any and all care and services. As we explained in the 2006 PACE final rule (71 FR 71298), the right to refuse treatment is a type of health care decision, and participants have the right to make those decisions. We proposed at § 460.112(e)(1)(iii) to specify that participants have the right to be informed of the consequences their decisions may have on their health and/or psychosocial status. The language at current § 460.112(e)(1) refers to the participant's right to ''be informed of the consequences of the decisions,'' but we proposed to add additional specificity around that right and the obligation it creates for PACE organizations by modifying the regulatory language to refer to the participant's right to ''be informed of the consequences their decisions may have on their health and/or psychosocial status.'' As we discussed in the proposed rule, we believe this proposed revision would emphasize that the participant should be made aware of how their decision to refuse care may impact their health and/or psychosocial status (87 FR 79663).

We proposed to further amend § 460.112(e) by redesignating current paragraphs (e)(2) through (e)(6) as (e)(3) through (e)(7), and by adding a new paragraph (e)(2), which would state that participants have a right to fully understand the PACE organization's palliative care, comfort care, and end-of-life care services. Proposed paragraph (e)(2) would further require that PACE organizations take several steps, outlined at proposed § 460.112(e)(2)(i) through (iii), in order to ensure that participants understand this right.

At § 460.112(e)(2)(i), we proposed to establish that the PACE organization must fully explain the applicable treatment options to the participant prior to initiating palliative care, comfort care, or end-of-life care services. We proposed at § 460.112(e)(2)(ii) to require that the PACE organization provide the participant with written information about their treatment options in accordance with § 460.112(c)(5). As we discussed in the proposed rule for § 460.112(c)(5), we believe providing written information on these terms is important for the participant, and that the information must include details regarding the treatment and how the participant's current services may be impacted (87 FR 79662). We proposed to add paragraphs (e)(2)(i) and (e)(2)(ii) as separate provisions because the organization should be responsible both for providing the written notification outlined in § 460.112(c)(5), and explaining the treatment options in a way that is understandable to the participant so that the participant has a full understanding of their options. Finally, we proposed at § 460.112(e)(2)(iii) that the PACE organization obtain written consent from the participant or their designated representative to change a treatment plan to include palliative care, comfort care, or end-of-life care. As we discussed in the proposed rule, we have seen that some organizations stop treatments to improve or maintain a participant's condition when a participant enters palliative care or comfort care, and therefore, we believe it is especially important that participants or their designated representatives are in agreement with these treatment options, and consent to receiving this care (87 FR 79664). We proposed to redesignate current paragraphs (e)(2) through (e)(6) of § 460.112 as (e)(3) through (e)(7) to allow for the addition of a new paragraph (e)(2) as discussed in this section. As we emphasized in the proposed rule, this proposed requirement would not take the place of any advanced directives a participant may have and would not eliminate the requirement in current § 460.112(e)(2) (which would be redesignated as (e)(3) under our proposal) that requires a PACE organization to explain advance directives and to establish them, if the participant so desires (*Id.*). That directive is distinct from the notification proposed at new § 460.112(e)(2), which would explain the services under the PACE benefit that may be provided or not provided to the participant as a part of their care decisions.

In the 1999 PACE interim final rule (64 FR 66256, 66290), we codified at § 460.112(g) the participant's right to ''a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review.'' In the January 2021 final rule (86 FR 5864), we added § 460.121 to clearly define service determination requests and specify the requirements for how those requests would be processed. As we explained in that rule, the service determination request process serves as an important participant protection, as it allows a participant to advocate for services (86 FR 6008). We also explained that the service determination request process is the first step of the appeals process (*Id.*). At § 460.112(g)(1), the participant is provided the right to be encouraged and assisted to voice complaints to PACE staff and outside representatives; and § 460.112(g)(2) provides participants the right to appeal any treatment decision of the PACE organization, its employees, or contractors through the process described in § 460.122. As we discussed in the proposed rule, we believe that § 460.112(g) should also reference the right to request a service determination request, which is the first step in the appeals process. Therefore, we proposed to add a new § 460.112(g)(2) to provide that a participant has the right to request services from the PACE organization, its employees, or contractors through the process described in § 460.121. We proposed to redesignate current paragraph (g)(2) as (g)(3) to allow for the addition of a new paragraph (g)(2) as discussed in this section. We believe the burden associated with this provision is related to developing written templates regarding the PACE organization's palliative, comfort, and end-of-life care services and tailoring those templates to the participants. We discuss this burden in the collection of information section of this final rule.

We solicited comments on these proposals and a summary of the comments received and our responses follow.

Comment: A majority of commenters requested that CMS proactively define the terms palliative care and end-of-life care in the final rule, rather than leaving the definition up to each PACE organization. Several commenters referenced CMS's current definition of palliative care in the hospice regulations at § 418.3. A commenter requested that palliative care be defined as care that focuses on improving the quality of life and easing suffering. Most commenters requested CMS to stop using the term ''comfort care'' as they stated that it is not a medically defined term and is more a term of art. Additionally, a majority of commenters requested that CMS stop using the terms interchangeably to avoid furthering the misconceptions around the different terms. A few commenters requested that CMS clarify that end-of-life care is a comprehensive set of services to provide for the physical, psychosocial, spiritual, and emotional needs of terminally ill patients and their family members.

Response: We thank commenters for their feedback. Commenters are correct that the hospice regulations define palliative care at § 418.3 as ''patient and family-centered care that optimizes the quality of life by anticipating, preventing, and treating suffering.'' We

agree that the palliative care definition in the hospice regulations is a national standard and we encourage PACE organizations to consider this definition for use in their own program. We do not intend to define these terms for purposes of the PACE regulations as a part of this rule; however, we will consider defining these terms in future rulemaking. Our intent with this proposal is to ensure that PACE participants have notice of how the terms are defined by the PACE organization and how the definition impacts the care they receive. As we stated in the proposed rule, we have seen through our oversight and monitoring process that PACE organizations are using these terms interchangeably without providing participants with clear definitions or an explanation of how the different terms impact the treatment options available to participants (87 FR 79661). While we do not want to add to the misconceptions around the terms, we routinely see these three terms in PACE organization medical records, without clear definitions applied to them. This provision is intended to provide clarity for participants when PACE organizations use any of these terms in their explanation of benefits. Therefore, we will be finalizing the requirement that PACE organizations provide participants with clear, written definitions to increase transparency and understanding of what services participants can expect to receive in lieu of or in addition to the services they were receiving prior to opting for palliative, comfort, or end-of-life care without modification.

Comment: Several commenters objected to the proposed requirement that the PACE organization obtain written consent from the participant and/or their caregiver prior to implementing palliative care on the grounds that it would be administratively burdensome and unnecessary, as it was their understanding that palliative care is intended to be provided concurrently with curative care. A commenter requested that the proposed regulation language be altered to require consent only when the PACE organization implements a plan of care no longer considered curative or life-prolonging, and instead is focused on only palliative care or end-of-life care.

Response: We thank the commenters for sharing their concerns regarding the proposed requirement for written consent prior to implementation of palliative care. While we understand that palliative care may be provided in addition to all other services at some organizations, that is not always the case. As we stated in the proposed rule, we have seen as part of our oversight and monitoring efforts that some PACE organizations are not continuing to provide curative treatment once a participant has elected to receive palliative care (87 FR 79661). In these situations, some participants are not aware that by consenting to receive palliative care, they are consenting to stop curative treatment in favor of palliative only care. In some cases, the participant may believe they are consenting to receive palliative care in conjunction with continuing to receive curative treatment. We disagree that requiring consent from participants prior to implementing palliative care would be overly burdensome. If a PACE organization offers palliative care in addition to or in conjunction with curative treatment, then the notice required in this provision is minimal. The PACE organization would need to provide a description of the term or benefit and would need to indicate that this is done in addition to all other services received by the participant. This notification could be provided to the participant early on in their enrollment through either enrollment materials or the care plan. However, if palliative or end-of-life care is offered in lieu of curative treatment, participants need to be informed that choosing palliative or end-of-life care will result in a cessation of curative treatment and participants need to consent to the change in treatment. It is only when a participant's services will change as a result of moving to palliative care, comfort care, or end-of-life care that the notification must become more tailored and include a detailed description of how the services being received by a participant will be impacted. We are finalizing the consent requirement as proposed because we believe it will protect participants from agreeing to forego curative treatment when that is not their intent.

Comment: A few commenters expressed support for our proposal to require PACE organizations to fully inform participants about applicable treatment options, including any policies that would limit participants' ability to receive curative treatment. These commenters also supported our proposed requirement that PACE organizations obtain consent from participants before making changes to the treatment plan, as well as our proposal that participants have the right to revoke consent at any time. A commenter expressed concern that in some cases participants have decided to reinstate disease-directed care, but the care was not effectuated until the first of the month following the participant's request. The commenter requested that we clarify that if participants revoke or withdraw their consent to palliative care-only services, that decision to reinstate curative care should be effectuated immediately.

Response: We thank the commenters for their support for our proposal. We share the commenter's concerns about the need to effectuate a return to curative treatment immediately if the participant revokes their agreement for palliative only care. When a participant decides to return to curative treatment and/or forego palliative only care, the PACE organization must act on that information immediately. We would consider this a change in participant status, and per the changes to the plan of care that we are finalizing in section IX.F of this rule, the PACE organization would be required to reassess the participant and re-evaluate the participant's plan of care.

Comment: Several commenters expressed a desire that PACE organizations have the ability to continue to provide and/or coordinate hospice care through a Medicare Advantage or other hospice program to allow participants to remain enrolled in PACE. A couple of commenters requested that the proposed regulation language be altered to require PACE organizations to inform participants of their rights regarding hospice care both within and outside of the PACE program. Specifically, these commenters requested that PACE staff be required to explain to participants about the Medicare hospice benefit and the participants' right to enroll, including an explanation that participants must disenroll from PACE to enroll in the Medicare hospice benefit. A commenter also requested that CMS require PACE staff to disclose any contractual relationship the PACE organization has with hospices in the community. Finally, a few commenters requested that CMS should strengthen requirements regarding the IDT's capabilities to ensure they have sufficient expertise in pain and symptom management for participants with serious illness or who require end-of-life care.

Response: We thank commenters for their concerns. Although we have proposed to require PACE organizations to inform participants of all treatment options, including palliative and end-of-life care, and how those options may impact curative treatment, nothing we have proposed would remove the ability of PACE organizations to continue

providing hospice-like services or contracting with community hospice programs to provide hospice services to participants. The enrollment agreement that PACE participants enter into with the PACE organization is required to provide information regarding disenrollment, including the requirement to disenroll from PACE in order to receive and enroll in the Medicare hospice benefit per § 460.154(i). The PACE organization is also already required to disclose contractual relationships to participants upon enrollment and throughout the time the participant is enrolled in the PACE program. Therefore, we are not persuaded that an additional requirement is needed in regulation regarding hospice care.

As for ensuring that the IDT includes the expertise to provide meaningful end-of-life care to participants, in the April 12, 2023 final rule, we modified the proposed regulation for contracted services to include palliative medicine. Effective January 1, 2024, PACE organizations are required to staff and/or contract with palliative medicine specialists. At this time, we do not believe it is necessary to include a palliative care specialist on the IDT as a routine role. The disciplines that participate in the IDT are the minimum required, but the IDT may always include additional personnel or specialists as it sees fit. To the extent an IDT wants to bring in a palliative care specialist to assist with developing an end-of-life plan of care, it is allowed and encouraged to do so.

Comment: A commenter requested that the language in the regulation be altered to require written notification only when a participant is moving to palliative only care or end-of-life care as it will not be beneficial to the participant and may be overly burdensome to PACE organizations.

Response: As we have stated previously, through our oversight and monitoring efforts, we have seen instances of participants transitioned to palliative-only care or end-of-life care without the PACE organization explaining to the participant that this transition means the participant will no longer receive curative treatment. We believe that requiring written notification to the participant regarding the implementation of palliative, comfort, or end-of-life care will reduce confusion among participants of what care they expect to receive. As we stated in response to a previous comment, if a PACE organization provides palliative care in addition to curative treatment, then inclusion of that additional benefit in the enrollment materials provided to the participant at the time of enrollment or the inclusion of information regarding the palliative care benefit in the participant's care plan would likely be sufficient to meet this requirement.

Comment: A commenter supported the proposed requirement that participants have a right to request services via a service determination request in addition to their right to file a grievance or appeal.

Response: We thank the commenter for their support and are finalizing this provision as proposed.

After considering the comments, and for the reasons set forth in the proposed rule and in the previous responses, we are finalizing the changes to § 460.112 as proposed.

H. Grievance Process (§ 460.120)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. We have codified requirements around the processing of grievances at § 460.120. The grievance process serves as an important participant protection as it allows for participants and their family members to express complaints related to the quality of care a participant receives, or the delivery of services. We have discovered through audits that the current grievance process, which allows PACE organizations latitude to define their own grievance resolution timeframes and develop their own procedures for processing grievances, has created confusion and inconsistency in how grievances are handled from organization to organization. In the December 2022 proposed rule (87 FR 79452), we proposed certain modifications to the grievance requirements at § 460.120 to strengthen participant protections and provide more detailed processing requirements for grievances from PACE participants and their family members. We also proposed certain adjustments that would align the requirements with the service determination process in § 460.121 for consistency.

First, we proposed to amend § 460.120(a) by removing the current paragraph header, which reads ''Process to resolve grievances.'' and added in its place a new paragraph header ''Written procedures.'' Specifically, we proposed to modify the requirement to state that each PACE organization must have formal written procedures to promptly identify, document, investigate, and resolve all medical and nonmedical grievances in accordance with the requirements in this part. In addition, we proposed to further amend § 460.120(a) by removing the list of individuals who can file a grievance, as we proposed to create a new paragraph that outlines who may submit a grievance at § 460.120(d). We proposed to add to § 460.120 a new paragraph (b), which would define a grievance in PACE as a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested; and further that a grievance may be between a participant and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant. We have heard from PACE organizations over the years that they would prefer that the term grievance be better defined in the regulations, and we have received requests from PACE organizations for the grievance definition to be narrowed to exclude complaints that may not rise to the level of a grievance. Based on this feedback, we considered how we might refine the definition of grievance for the purposes of PACE. Specifically, in the December 2022 proposed rule, we discussed how the grievance definitions in other managed care programs and care settings, specifically in MA and in nursing homes, could inform and enhance the grievance definition for PACE.

When considering these other approaches to defining what constitutes a grievance, we concluded that the definition used in PACE is already tailored more narrowly than the MA or nursing home requirements. That being the case, we do not believe it would be appropriate to narrow the definition even more, and potentially limit a PACE participant's ability to complain about their care and have their complaints resolved through a formal process. We noted that the MA regulations specify that a grievance is any complaint that meets the definition at § 422.561 regardless of whether remedial action is requested. We have seen on audit where PACE organizations will not recognize or process complaints that fit within the definition of a grievance, because remedial action was not requested. However, we want to stress that a grievance must be identified and processed if it satisfies the definition, regardless of whether remedial action is requested. This is an important participant safeguard because grievances are required under the current § 460.120(f) to be maintained, aggregated, and analyzed as part of the PACE organization's quality

improvement program. Regardless of whether remedial action is requested, it is important for organizations to analyze all complaints received in order to ensure they are making necessary improvements in their quality program. For these reasons, we proposed to include in our definition of a grievance that a request for remedial action is not required.

We also proposed that the definition of a grievance would provide that a grievance may be between a participant and the PACE organization, but it may also be between any other entity or individual through which the PACE organization provides services to the participant. This proposed change to the PACE grievance definition is based on the MA grievance definition, which provides at the current § 422.564(a) that each MA organization must provide meaningful procedures for timely hearing and resolving grievances between enrollees and the organization or any other entity or individual through which the organization provides health care services under any MA plan it offers. PACE provides a wide array of services through different home care agencies, medical specialists, and facilities such as nursing homes. It is important that a participant or their family have the ability to voice complaints related to any care they receive, even if that care is provided through a contracted entity or individual.

We solicited comment on whether we should modify the PACE grievance definition to more closely resemble the definition of grievances in MA at § 422.561. Specifically, we solicited comment on whether we should consider adopting the following definition of grievance for purposes of the PACE regulations: A grievance means any complaint or dispute expressing dissatisfaction with any aspect of the PACE organization's or its contractors' operations, activities, or behavior, regardless of whether remedial action is requested.

We proposed to redesignate current § 460.120(b) as § 460.120(c), change the title, and amend the regulation text. Specifically, we proposed to change the title from ''Notification to participants.'' to ''Grievance process notification to participants.'', to differentiate from notifications related to grievance resolutions, and to add the requirement that the grievance process notification be written in understandable language. We proposed to add new paragraphs (c)(1), (c)(2), and (c)(3) to § 460.120, which would set forth requirements for the grievance process notification. We solicited comment on whether the other individuals should receive the grievance process notification, in addition to the participant, upon the participant's enrollment and annually thereafter. Specifically, we solicited comment on whether the other individuals specified in § 460.120(d) should receive the grievance process notification, or at a minimum, whether the participant's designated representative should receive the notification in addition to the participant.

First, we proposed at § 460.120(c)(1) that the grievance process notification must include information on the right of the participant or other individual specified in § 460.120(d) to voice grievances without discrimination or reprisal, and without fear of discrimination or reprisal. When we have conducted interviews of PACE participants and their family members as part of our audit process, we have heard that some participants are afraid to voice grievances for fear that the PACE organization will take some punitive action against them. For example, some participants have expressed fears that the PACE organization will eliminate their center attendance, or discontinue other necessary services, if the participant complains about the care they receive. We believe it is important for the grievance process notification to participants to emphasize that a participant or other individual specified in § 460.120(d) has the right to voice grievances without the fear of reprisal or discrimination.

We proposed at § 460.120(c)(2) that the grievance process notification must inform participants that a Medicare participant as defined in § 460.6 or other individual specified in § 460.120(d) acting on behalf of a Medicare participant has the right to file a written complaint with the quality improvement organization (QIO) with regard to Medicare covered services, consistent with section 1154(a)(14) of the Act. Since most PACE participants are Medicare beneficiaries, they are also eligible to submit quality of care grievances to a QIO. This right has not been formally provided to PACE participants before, and we are proposing to require it now in order to ensure that Medicare beneficiaries enrolled in PACE understand this additional right. We proposed at § 460.120(c)(3) to require that the grievance process notification include the grievance definition at § 460.120(b) and provide information on all grievance processing requirements in paragraphs (d) through (k) of § 460.120. In order for the grievance process to serve as a fair and efficient avenue for participants to express their dissatisfaction with service delivery or the quality of care furnished, and to resolve their differences with the PACE organization or any other entity or individual through which the PACE organization provides services to the participant, participants must understand how to submit a grievance to the organization, and how that grievance will be processed once submitted.

We proposed to move the language regarding who can submit a grievance from current § 460.120(a) to a new paragraph at § 460.120(d), as we believe the details regarding who is eligible to submit a grievance will be more easily understood if they are placed in a new paragraph and separated from the remainder of § 460.120(a), which, under the amendments we proposed, would require PACE organizations to have a formal written process to promptly identify, document, investigate, and resolve all medical and nonmedical grievances. We proposed to amend the list of individuals who can submit a grievance to include the participant's caregiver. We believe the addition of the participant's caregiver would be in alignment with the service determination process requirements in § 460.121, which allow a participant's caregiver to request services (§ 460.121(c)(3)), and with the plan of care requirements at § 460.106, which allow the caregiver to be involved in the development and reevaluation of the care plan (§ 460.106(e)).

As we stated in the January 2021 final rule (86 FR 6018), given the fact that caregivers may provide some care to the participants, it is important that caregivers are able to advocate for services on the participant's behalf. Similarly, if caregivers are providing some care to the participant, they should be able to make complaints related to any aspect of the care that the participant receives from the PACE organization.

As we explained in the January 2021 final (86 FR 6018), we have not historically considered ''caregivers'' to include employees or contractors of the PACE organization. We know some organizations may use the term ''caregiver'' to describe an aide at a nursing home, but CMS would not generally consider these individuals to fall within this category. We also explained in that rule (86 FR 6018) that employees and contractors of the PACE organizations enter into a contractual relationship with the PACE organization and generally have a predominately financial incentive to provide care; and we have not considered these

individuals to be ''caregivers'' under the regulations. While these paid individuals may have pertinent information related to the participant's care, their feedback is captured under the requirements for the IDT to remain alert to pertinent information under current § 460.102(d)(2)(ii). We do not believe that these paid individuals would generally be entitled to submit a grievance under § 460.120. In the December 2022 proposed rule (87 FR 79667), we solicited comment on our proposal to amend the list of individuals who can submit a grievance to include a participant's caregiver.

We proposed to add these rules around the submission of grievances in new paragraph § 460.120(e). We proposed § 460.120(e)(1) would provide that any individual permitted to file a grievance with a PACE organization under § 460.120(d) may do so either orally or in writing. We proposed § 460.120(e)(2) would establish that the PACE organization may not require a written grievance to be submitted on a specific form. While we understand that some organizations may use forms to help them process and investigate the grievance, we do not believe that a PACE participant should be restricted in how they can submit the complaint. We have seen participants detail their complaints to PACE organizations in letters and email correspondence. Receipt of these written complaints should be considered grievances and accepted in their original form. If a PACE organization decides to create a grievance form on its own and summarize the original grievance, that would continue to be permitted under our proposal, as long as the PACE organization maintains the written communication in its original form as required by § 460.200(d)(2). Proposed § 460.120(e)(3) would provide that a grievance may be made to any employee or contractor of the PACE organization that provides care to a participant in the participant's residence, the PACE center, or while transporting participants. This language is similar to the method for filing a service determination request at § 460.121(d)(2). As we indicated in the January 2021 final rule (86 FR 6019), these are the settings where participants have the most frequent contact with employees or contractors of the PACE organization, and therefore are logical settings for service determination requests to occur. We believe the same logic can be applied to grievances, and as a result, we limited our proposal to employees and contractors working in these settings.

We proposed at new § 460.120(f) to establish the requirement that the PACE organization must conduct a thorough investigation of all distinct issues within the grievance when the cause of the issue is not already known. Investigating why the situation occurred is an important part of ensuring that appropriate action will be taken in response to a grievance. However, we also recognize there may be some situations where the cause for the complaint or a specific issue is already known and therefore an investigation is not needed. For example, if the PACE bus has a flat tire, and as a result is late to pick up a participant for their center attendance, the participant may complain to the PACE organization about the late pick-up. While this would constitute a grievance and would need to be identified and processed, an investigation would not be necessary because the PACE organization was already aware of the cause of the complaint (that is, the flat tire). If there are multiple issues within a grievance that require investigation, proposed § 460.120(f) would require the PACE organization to conduct a thorough investigation into each distinct issue when the cause of an issue is not known. We have seen on audit that some complaints may contain different issues within the one grievance. For example, a participant may call to complain that their home care aide is routinely late and does not clean the kitchen as is care planned for that participant. These are two different issues, and both may need to be investigated in order to appropriately resolve the grievance. The PACE organization may determine through its investigation that while the aide was late due to poor time management skills, the kitchen was not being cleaned because the home care company did not have the most recent care plan for the participant. The results of the investigation would directly impact how the PACE organization would resolve these concerns.

We proposed at § 460.120(g)(1) that the PACE organization must take action to resolve the grievance based on the results of its investigation as expeditiously as the case requires, but no later than 30 calendar days after the date the PACE organization receives the oral or written grievance. In our proposal for the PACE grievance regulation, we proposed to adopt a modified version of the requirement in the MA regulations, which would specify that the 30-day timeframe is the maximum amount of time the PACE organization has to resolve the grievance, as opposed to the maximum amount of time to notify the participant. Proposed § 460.120(g) would maintain the language regarding ensuring that this timeframe is a maximum length of time, and that organizations may need to resolve grievances more quickly if the participant's case requires. We proposed at § 460.120(g)(2) that the PACE organization must notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE organization resolves the grievance in accordance with § 460.120(g)(1).

We proposed § 460.120(h) would establish requirements for the processing of expedited grievances. Specifically, we proposed to require that the PACE organization must resolve and notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 24 hours after the time the PACE organization receives the oral or written grievance if the nature of the grievance could have an imminent and significant impact on the health or safety of the participant. We proposed at new § 460.120(i) to create grievance resolution notification requirements for how the PACE organization must inform the individual who submitted the grievance of the resolution of that grievance. We proposed at § 460.120(i)(1) that the PACE organization may inform the individual either orally or in writing, based on the individual's preference for notification, except for grievances identified in § 460.120(i)(3). We contemplated following the MA rule around notification in § 422.564(e)(3), which allows for oral grievances to be responded to orally or in writing but requires written grievances to be responded to in writing. However, we understand that because PACE organizations are not only an insurer, but also a provider, they often have calls or other remote communications with participants, and likely talk with them more often than an MA organization would talk with one of their enrollees. We also understand that some PACE participants would prefer oral notification, even if their grievance was submitted in writing. Likewise, some PACE participants may call with a grievance, but may want a formal written notice explaining the resolution. Therefore, we believe that PACE organizations should tailor the notification of the grievance resolution to what a PACE participant prefers.

We proposed to establish at § 460.120(i)(2) that oral or written notification of grievance resolutions

must include a minimum of three requirements. First, we proposed at § 460.120(i)(2)(i) that the notification must include a summary statement of the participant's grievance including all distinct issues. Second, we proposed at § 460.120(i)(2)(ii) that for each distinct issue that requires an investigation, the notification must include the steps taken to investigate the issue and a summary of the pertinent findings or conclusions regarding the concerns for each issue. Third, we proposed at § 460.120(i)(2)(iii) that for a grievance that requires corrective action, the grievance resolution notification must include corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur. In the example we used earlier, we noted that during the investigation into the home care aide not cleaning the kitchen, the PACE organization discovered that the home care agency did not have the most current care plan for that participant. The correction that would likely result from that investigation would be to provide the updated care plan to the home care agency and ensure they have received and understand it. This action should be communicated to the participant in order for them to understand how their grievance has been handled and resolved. Proposed § 460.120(i)(3) proposed requirements related to how PACE organizations must provide notification when the complaint relates to a Medicare quality of care issue. Specifically, we proposed that for Medicare participants, any grievance related to quality of care, regardless of how the grievance is filed, must be responded to in writing. This is consistent with the MA requirement in § 422.564(e)(3)(iii). As previously discussed, Medicare beneficiaries, and by extension, Medicare participants enrolled in PACE, have the right to submit quality of care grievances and complaints to a QIO under section 1154(a)(14) of the Act.

We proposed to establish at § 460.120(i)(3) that, when a grievance relates to a Medicare quality of care issue, the PACE organization must provide a written grievance resolution notification that describes the right of a Medicare participant or other individual specified in § 460.120(d) acting on behalf of a Medicare participant to file a written complaint with the QIO with regard to Medicare covered services. The only exception to this requirement to provide a written resolution notice would be when the submitter specifically requests not to receive notification as specified in proposed § 460.120(i)(4), which is discussed in more detail in this section of this final rule. We also proposed to specify that for any complaint submitted to a QIO, the PACE organization must cooperate with the QIO in resolving the complaint. This language is consistent with the language used in the MA program, and therefore we are proposing it be added to the PACE regulation as well. Because the QIO's statutory function related to review of quality of care concerns and responses to beneficiary complaints is only applicable to Medicare services and only available to Medicare beneficiaries, and because PACE organizations may have some participants who are not Medicare beneficiaries and may cover non-Medicare services, we expect PACE organizations to work with participants to help them understand whether their grievance relates to a Medicare quality of care issue.

We proposed to establish at new § 460.120(i)(4) that the PACE organization may withhold notification of the grievance resolution if the individual who submitted the grievance specifically requests not to receive notification of the grievance resolution, and the PACE organization has documented this request in writing. In order to balance the need for an organization to track and process grievances, with respect for the preferences of participants who wish to not receive communications related to the resolution of a grievance after submitting the initial complaint, we proposed to specify in new § 460.120(i)(4) that PACE participants must have an option to request not to receive any further communication or notification of the grievance resolution following their initial complaint submission. In order for a PACE organization to withhold notification of the grievance resolution for participants who request to exercise this option, the PACE organization would be required to document the participant's request in writing.

We proposed to include in a new § 460.120(i)(4) language that provides the PACE organization would still be responsible for all other parts of this section. Section § 460.120(d) specifies the PACE organization must continue to furnish all required services to the participant during the grievance process. We proposed to redesignate current § 460.120(d) as 460.120(j) to account for our other proposals.

We proposed to add a new paragraph § 460.120(k) that would redesignate and modify the requirement that is currently included at § 460.120(c)(4). Specifically, we proposed that the PACE organization must develop and implement procedures to ensure that they maintain the confidentiality of a grievance, including protecting the identity of any individuals involved in the grievance from other employees and contractors when appropriate. As we stated when discussing the proposed notification requirements at § 460.120(i)(4), we understand that some grievances may be sensitive, and some participants or other submitters may wish for their complaint to be kept confidential. For example, if a participant has a complaint related to their physical therapist, that participant may not want the physical therapist to be aware of the complaint. We expect that PACE organizations consider these situations and have a method for participants that may want certain information to be kept confidential. There may be instances where a person submitting the complaint may want their identity to be protected, or where the complaint involves a sensitive matter where the identity of all individuals may need to be protected, and we would expect the PACE organization to have a process for ensuring that there is a way to maintain the confidentiality of the identity of any individual involved in the grievance from other employees or contractors when it is appropriate. However, we reiterate that accepting and processing a confidential grievance would not negate the PACE organization's responsibilities to investigate and resolve the grievance. It also would not negate the responsibilities to document, aggregate and analyze the grievance, as required under current § 460.120(f). Additionally, as we discussed earlier, we have heard from multiple PACE participants that sometimes participants or their family members are afraid to complain to the PACE organization for fear of reprisal. While we require a PACE organization to ensure that confidentiality of a grievance is maintained, we also want to remind PACE organizations that participants have the right to submit grievances without fear of reprisal. We have heard through oversight and monitoring activities that participants are afraid that they will lose necessary services, or not be approved for services, if they complain regarding the care received by an organization. PACE organizations should ensure that all participants understand that they are free to complain without any fear of reprisal, regardless of what their grievance is about.

We proposed to add a new paragraph at § 460.120(l) that aligns with the record keeping requirements for service

determination requests, which are set forth at § 460.121(m). Specifically, proposed § 460.120(l) would require that a PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for grievances received both orally and in writing. We believe that proposed § 460.120(k), similar to the § 460.121(m) service determination request, would ensure that all relevant parts of the grievance process are documented, including details of the investigation, the findings, any corrective action that was taken, and the notification (oral and/or written) that was provided to the participant in the resolution.

Finally, current § 460.120(f) requires PACE organizations to maintain, aggregate, and analyze information on grievance proceedings. We proposed to redesignate this as paragraph (m) to account for our other proposals. We also proposed to remove the word ''maintain'' that appears in the current regulation text, since the requirement to maintain records has been added to the proposed paragraph (l). Redesignated § 460.120(m), as revised under our proposal, would state that the PACE organization must aggregate and analyze the information collected under the proposed paragraph (l) of this section for purposes of its internal quality improvement program. We noted that this requirement applies to all grievances; oral or written, including anonymous grievances.

We estimated a one-time burden for PACE organizations to update their grievance materials to meet these proposed requirements. We do not believe there will be a change in annual burden as a PACE organization is already required to provide notification to participants regarding their grievance resolution and may opt to do so orally or in writing. Therefore, we believe that the ongoing burden will not change with this proposal. We discuss and account for the one-time burden for PACE organizations to update their grievance materials to meet the proposed new requirements in the Collection of Information Requirements section. We solicited comment on this proposal regarding burden.

We summarize the comments received on the proposal at § 460.120 and provide our responses to those comments in this section of this rule.

Comment: Most commenters expressed their general support for CMS's proposal to clarify the grievance process at § 460.120. A commenter preferred that CMS not formalize the grievance process in regulation, because they believed that establishing specific grievance process requirements in regulation would add to PACE organizations' administrative burden and would divert resources from participant care. Another commenter agreed with formalizing certain aspects of the grievance process but did not want to formalize the grievance process for all complaints, particularly for what the commenter referred to as ''lower-level concerns.''

Response: We thank commenters for their support of formalizing the grievance process at § 460.120. Throughout the years, PACE organizations have expressed interest in a more clearly defined grievance definition, among other process clarifications in the regulation. We do not believe formalizing the grievance process in regulation will be overly burdensome for PACE organizations, as PACE organizations already must process grievances, including evaluating, resolving, responding to, and documenting grievances in a timely manner. Additionally, we included flexibilities in the proposed regulation at § 460.120 when certain conditions are met. For example, PACE organizations may provide oral or written resolution of the grievance, depending on the participant's preference, as specified at the redesignated § 460.120(h)(1). Another flexibility at the redesignated § 460.120(h)(4) allows PACE organizations to withhold notification of the grievance resolution if the individual who submitted the grievance specifically requests not to receive the notification, and the PACE organization has documented this request in writing. We disagree with the commenter's suggestion to categorically exclude certain types of complaints from the formal grievance process at § 460.120. As established at § 460.112(g), each participant has the right to a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review. Specifically, it is a participant's right to be encouraged and assisted to voice complaints to PACE staff and outside representatives of their choice, free of any restraint, interference, coercion, discrimination, or reprisal by the PACE staff.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the proposed amendments to § 460.120 without modification.

Comment: Most commenters supported CMS's proposed definition of grievance at § 460.120(b), and specifically mentioned their agreement with the part of the proposed definition that describes complaints as grievances regardless of whether remedial action is requested. Many of these commenters, while agreeing with this aspect of the proposed grievance definition at § 460.120(b), generally rejected CMS's consideration of the MA grievance regulations at §§ 422.561 and § 422.564 in the development of PACE grievance requirements. These commenters emphasized the uniqueness of PACE, as an insurer and provider, and recommended that PACE grievance requirements consider the program's uniqueness, rather than repurposing MA grievance regulations for the PACE regulation.

A few commenters disagreed with including complaints for which no remedial action is requested as part of the proposed grievance definition at § 460.120(b). These commenters generally considered the proposed grievance definition at § 460.120(b) to be broader and more administratively burdensome than the current grievance definition at § 460.120, and either did not want to process these complaints as grievances or recommended a separate administrative process for such complaints. A commenter suggested that including complaints for which no remedial action is requested in the grievance definition would increase the number of complaints that would be considered grievances, which the commenter believed would increase the administrative burden of processing grievances without improving participant care and outcomes. The commenter recommended that CMS amend the proposed grievance definition to give PACE organizations the flexibility to not have to document complaints as grievances when the participant declines remediation. The commenter emphasized the uniqueness of the PACE care model and how it requires frequent communication and interaction between staff and participants, which they believed made documenting all complaints as grievances unreasonable and unnecessary. Another commenter indicated CMS's proposed grievance definition emphasized process compliance over staff judgment to the detriment of quality care, participant outcomes, and organizational culture.

Response: We appreciate the commenters' support for the grievance definition proposed at § 460.120(b), including where we specified that complaints can be grievances regardless of whether remedial action is requested. We acknowledge the commenters' general concerns regarding developing

PACE requirements based on MA requirements and agree that there are significant differences between these programs in terms of design and function. We carefully considered the relevance of the MA grievance regulations at §§ 422.561 and § 422.564 as we developed the PACE grievance definition for the December 2022 proposed rule (87 FR 79665). Based on our review of MA grievance regulations, we proposed a PACE grievance definition that includes complaints as grievances regardless of whether remedial action is requested and provides that grievances may be between participants and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant (87 FR 79665). We have considered commenters' specific feedback on the proposed grievance definition at § 460.120(b) in the responses to comments that follow.

We disagree with the commenters that described the proposed definition of grievance at § 460.120(b) as overly broad, unnecessary, and burdensome with potentially negative consequences for participant care and PACE organizations' workplace culture. As explained in the December 2022 proposed rule, we believe the proposed grievance definition at § 460.120(b) clarifies how we expect PACE organizations to identify grievances. The proposed grievance definition was the result of requests from PACE organizations over the years for CMS to better define grievances in the PACE regulation. We believe the proposed grievance definition clarifies our expectations for grievances and would not necessitate major changes to PACE organizations' existing grievance processes if they are already compliant with the current requirements at § 460.120.

Additionally, we have determined that categorically excluding complaints that do not require remedial action would be counter to compliance with other requirements within the PACE statute and regulation. As established at § 460.112(g), each participant has the right to a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review. Specifically, it is a participant right to be encouraged and assisted to voice complaints to PACE staff and outside representatives of their choice, free of any restraint, interference, coercion, discrimination, or reprisal by PACE staff. Therefore, amending the regulation to clarify that the definition of grievance includes complaints regardless of whether remedial action was requested provides important guidance to PACE organizations on how to achieve program compliance with current program requirements. Also, PACE organizations are required to aggregate and analyze grievances as part of their quality improvement organization (see §§ 460.120(l) and 460.134(a)(5)). A participant may feel that remedial action is not necessary in a particular situation, but that does not mean the PACE organization should not consider, analyze, and aggregate that information as part of its quality improvement efforts as a whole. If multiple participants have the same complaint, and none of them request remedial action, it may still be indicative of a larger, systemic breakdown that needs to be considered by the PACE organization.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing the grievance definition at § 460.120(b) as proposed, which includes complaints regardless of whether remedial action was requested.

Comment: Most commenters disagreed with our proposed inclusion of ''caregiver'' among the list of individuals who can submit a grievance at § 460.120(d). Mostly these commenters expressed concern that the term ''caregiver'' is not defined in the PACE regulation at 42 CFR 460, and recommended that we define, clarify, or provide guidance regarding the term ''caregiver'' so that PACE organizations are not required to include individuals in the grievance process who may not have formal legal authority to act on behalf of the participant. Several of these commenters expressed that allowing a caregiver without formal legal authority to submit grievances on behalf of the participant could influence the participant's care in a way that would not align with the participant's goals, could pose risks to HIPAA Privacy Rule compliance, or may cause confusion when coordinating care for participants with support networks made of many individuals with complex dynamics. Many commenters questioned why it would be necessary for caregivers to have the ability to submit grievances when the participant, participant's family, and participant's designated representatives can already submit grievances per the current requirement at § 460.120(a). One commenter suggested that adding caregivers to the list of individuals who may submit grievances on behalf of participants creates more administrative burden for PACE organizations, because PACE organizations would have to provide and document an increased number of grievance resolution notifications.

Response: We believe that the guidance provided in the December 2022 proposed rule (87 FR 79666) and this response offers adequate clarification of CMS's expectations for PACE organizations regarding how caregivers may participate in the grievance process. As we originally discussed in the January 2021 final rule (86 FR 6018) and reiterated in the December 2022 proposed rule (87 FR 79666), caregivers are typically aware of the participant's situation and are involved in care planning activities, as required at the current § 460.106(e), which states that the IDT must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver or both. Because caregivers are involved in the care planning process and are presumably providing at least some care to the participant, we believe that it is also appropriate for these individuals to be able to advocate for services as necessary on behalf of a participant and voice complaints about participant care, regardless of whether these service determination requests or complaints result in changes to the plan of care. Additionally, since caregivers are often the participant's family member and/or designated representative, we do not believe that allowing caregivers to submit grievances on behalf of participants will meaningfully increase burden for PACE organizations, as PACE organizations already must receive, process, and provide notification for grievances submitted by participant family members and/or designated representatives. Also, we reiterate that, as we explained in the January 2021 final rule (86 FR 6018), we have not historically considered ''caregivers'' to include employees or contractors of the PACE organization, though their feedback is captured under the requirements for the IDT to remain alert to pertinent information under current § 460.102(d)(2)(ii). We do not believe that these paid individuals would generally be entitled to file a grievance under § 460.120. Lastly, we believe that caregiver involvement in the grievance process would benefit, rather than negatively impact, participant care, even when PACE organizations must coordinate within the complexities of participants' support systems. The PACE organization remains responsible for resolving a grievance based on the

facts of the situation and not based on who may have initiated the complaint.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.120(d) to require that PACE organizations accept grievances from participants' caregivers without modification.

Comment: A commenter requested that we clarify whether the proposed maximum timeframe requirement for notification of a grievance resolution at § 460.120(g)(2) could be satisfied with attempts to notify the individual who submitted the grievance of the resolution within the 3-calendar day maximum timeframe, or whether the individual who submitted the grievance must receive the notification within that timeframe.

Response: We clarify that we would consider the individual who submitted the grievance resolution to be notified for the purposes of § 460.120(g)(2) when the PACE organization furnishes them with the resolution notification within the 3-calendar day maximum timeframe, but as expeditiously as the case requires. However, during a review of PACE organizations' grievance notification documentation, CMS may consider mitigating circumstances based on outreach attempts and when they occurred.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal at § 460.120(g)(2) to require that PACE organizations notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE organization resolves the grievance in accordance with § 460.120(g)(1) without modification.

Comment: Some commenters recommended a longer timeframe for processing expedited grievances than 24 hours after the time the PACE organization receives the oral or written grievance, as proposed at § 460.120(h). Most of the commenters recommended increasing the maximum timeframe for processing expedited grievances to 72 hours. A commenter recommended that we modify the maximum timeframe to process expedited grievances to require the PACE organization to initiate an investigation within 24 hours, rather than fully resolving the expedited grievance within that timeframe. Another commenter suggested lengthening the maximum timeframe for processing expedited grievances to 2 business days. These commenters all expressed concerns with the possibility that the proposed timeframe at § 460.120(h) would require staff to be available to process grievances at all times, including evenings and weekends, which may burden staff and exacerbate workforce shortages. A commenter suggested that more time may be needed to investigate the grievances at issue to determine if it is imminent or significant and should be processed as an expedited grievance. Most of the commenters expressed their support for allowing PACE organizations the flexibility to determine which grievances could have an imminent and significant impact on the health or safety of participants and should be processed as expedited grievances as proposed at § 460.120(h).

Response: We thank the commenters for their input regarding the proposed expedited grievance requirements at § 460.120(h). After consideration of the concerns raised by commenters, we are declining to finalize our proposal to establish an expedited grievance process at § 460.120(h), and we are redesignating all of our proposed provisions in § 460.120(i) to instead appear at § 460.120(h). While we are not finalizing the expedited grievance process, we remind PACE organizations that they are still required, as part of their quality improvement program at § 460.136(a)(5), to immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant. Additionally, we emphasize that the IDT is responsible for triaging grievances to determine what needs to be processed more quickly in order to meet the participant's needs. Ultimately, as per § 460.98(a), PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and PACE organizations must continue to meet this requirement as they process grievances.

Comment: A commenter disagreed with the proposal to establish at § 460.120(i)(1) the requirement that the PACE organization must provide notification of the grievance resolution either orally or in writing based on the individual's preference for notification, with the exception of quality of care grievances as proposed at § 460.120(i)(3). The commenter recommended that all grievance resolution notifications be provided in writing, regardless of the nature of the grievance, as a participant safeguard. Another commenter expressed general support for the flexibility to provide oral or written notice of the grievance resolution as proposed at § 460.120(i)(1).

Response: We thank the commenter for expressing their concern regarding the impact of this provision on participant wellbeing. As discussed in the December 2022 proposed rule (87 FR 79668), we believe that PACE organizations should tailor the grievance resolution notification to the preference of the PACE participant or individual submitting the grievance. Based on our monitoring experience, we believe that requiring all grievance resolutions to be communicated in writing would be unnecessarily burdensome to PACE organizations and would not always be desired by the family members or participants filing the grievance. Therefore, we decline to modify the proposal.

After consideration of the comments received and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal to require that PACE organizations must provide notification of the grievance resolution either orally or in writing, based on the individual's preference for notification, without modification, except we are redesignating proposed § 460.120(i)(1) as § 460.120(h)(1).

Comment: A few commenters disagreed with the proposal at § 460.120(i)(2)(ii) to require PACE organizations to provide the steps taken to investigate the grievance in the grievance resolution notification. The commenters expressed concern that providing the steps taken to investigate the grievance in the notification adds burden to PACE organizations with no additional value to the participant, because detailing the investigation steps is not the same as providing a resolution.

Response: As we stated in the December 2022 proposed rule (87 FR 79668), we do not believe that every grievance, or every issue within a grievance, will require an investigation, and some issues may require minimal investigation; however, when an investigation is appropriate, we believe it would be important for the individual who submitted the grievance to understand what the organization found during its investigation. We agree with commenters that the value to the participant is the summary of the findings for each distinct issue, and not the specific steps taken to investigate the grievance.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing this provision by redesignating

§ 460.120(i)(2)(ii) as § 460.120(h)(2)(ii) and modifying § 460.120(h)(2)(ii) to require a summary of the pertinent findings or conclusions regarding the concerns for each distinct issue that requires investigation, and not requiring that the specific steps taken to investigate the grievance be included in the grievance resolution notification.

Comment: A few commenters disagreed with the proposal at § 460.120(i)(2)(iii) to require that grievance resolution notifications include corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur. These commenters noted that PACE organizations do not always know when corrective action will be fully implemented, especially when the corrective action requires a system change to a process within the PACE organization, and they did not believe it would be reasonable for CMS to expect PACE organizations to have all improvements in place and all grievance issues fully resolved in 30 days. Another commenter expressed concern that including corrective actions in the grievance resolution notification could include administrative or human resources actions that are not appropriate to share with participants or their designated representatives and stated that the finalized provision should protect the rights and privacy of participants, clinicians, and staff.

Response: We believe the commenters misunderstood our expectations regarding the proposal at § 460.120(i)(2)(iii). The § 460.120(g) grievance resolution and notification timeframe requirements apply to taking action to resolve the grievance and notifying the individual who submitted the grievance of the grievance resolution. Taking action to resolve the grievance and providing notification does not necessarily require that all corrective actions be completely implemented within the grievance resolution and notification timeframes proposed at § 460.120(g) for all grievances issues.

Additionally, we do not specify the level of detail a PACE organization should provide in the grievance resolution notification to describe the corrective actions taken, or when the participant may expect the corrective action(s) to occur. As explained in the December 2022 proposed rule (87 FR 79668), the purpose of including information on corrective actions that have or will be taken by the PACE organization in response to a grievance is for the participant to understand how their grievance has been resolved or how it will be resolved. PACE organizations may protect provider privacy and business confidentiality in how they disclose the details of their investigation and any corrective action when providing grievance resolution notification. An appropriate level of detail for the corrective action demonstrates that the PACE organization has addressed each specific grievance issue, has taken or will take action to resolve the issue(s), and that the individual submitting the grievance can understand what actions were taken or will be taken to resolve the grievance. For example, if the complaint relates to a participant always being picked up by the PACE driver late, the correction may be that a new driver will be assigned to pick up that participant and the new driver will start in a week.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal to require the grievance notification to include, for grievances that require corrective action, the corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur without modification, except we are redesignating proposed § 460.120(i)(2)(iii) as § 460.120(h)(2)(iii).

Comment: A commenter disagreed with the proposed requirement to include Quality Improvement Organization (QIO) rights in grievance resolution letters as proposed at § 460.120(i)(3), because they believed modifying standardized grievance notification forms would be administratively burdensome for PACE organizations and they expressed that participants already have many other options available when filing complaints with Medicare.

Response: Medicare beneficiaries, and by extension, Medicare participants enrolled in PACE, have the right to submit quality of care grievances and complaints to a QIO under section 1154(a)(14) of the Act. The fact that there are other ways for participants to file complaints with Medicare has no bearing on participants' right to file quality of care grievances with the QIO. Up to this point, the PACE regulations have been silent as to this right, and the proposed requirement at § 460.120(i)(3) meant to ensure that participants understand and can access this platform for complaints related to quality of care. We would expect PACE organizations to communicate this right to participants, as applicable.

After consideration of the comments received and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal to include QIO rights in grievance resolution letters to Medicare participants with quality of care grievances about Medicare covered services without modification, except that we are redesignating § 460.120(i)(3) as § 460.120(h)(3) and paragraphs § 460.120(h)(3)(i) and § 460.120(h)(3)(ii).

Comment: A commenter expressed wanting to better understand CMS's expectations for PACE organizations' cooperation with QIOs regarding quality of care grievances, as well as whether the quality of care grievance requirements we originally proposed at § 460.120(i)(3) (which we redesignate and finalize as § 460.120(h)(3), as noted in the previous response), would apply to Medicaid-only participants.

Response: We appreciate the commenter's interest in learning more about how PACE organizations should participate in the QIO quality of care grievance process, as required by section 1154(a)(14) of the Act and as proposed in the December 2022 proposed rule at § 460.120(i)(3). We will consider future educational opportunities that may help PACE organizations better understand the QIO quality of care grievance process and their role within it.

In the December 2022 proposed rule (87 FR 79668), we explained that Medicare beneficiaries, and by extension, Medicare participants enrolled in PACE, have the right to submit quality of care grievances and complaints to a QIO under section 1154(a)(14) of the Act. We proposed at § 460.120(i)(3) that, when a grievance relates to a Medicare quality of care issue, the PACE organization must provide a written grievance resolution notification that describes the right of a Medicare participant or other individual specified in § 460.120(d) acting on behalf of a Medicare participant to file a written complaint with the QIO with regard to Medicare covered services. We reiterate that the QIO quality of care grievance process applies to Medicare participants' quality of care grievances regarding Medicare covered services. Therefore, participants who are not enrolled in Medicare, including Medicaid-only participants, would not be eligible for the QIO quality of care grievance process.

After consideration of the comments received, and for the reasons outlined in the proposed rule and our response to comments, we are finalizing our proposal to include QIO rights in grievance resolution letters to Medicare participants with quality of care grievances about Medicare covered

services without modification, except we are redesignating § 460.120(i)(3) as § 460.120(h)(3). Additionally, we are redesignating § 460.120(j) through § 460.120(m) as § 460.120(k) through § 460.120(l) and any redesignated provision citations therein, without further modification.

I. PACE Participant Notification Requirement for PACE Organizations With Performance Issues or Compliance Deficiencies (§ 460.198)

Sections 1894(f)(3) and 1934(f)(3) of the Act provide CMS the discretion to apply such requirements of Part C of title XVIII and sections 1903(m) and 1932 of the Act relating to protection of beneficiaries and program integrity as would apply to Medicare Advantage (MA) organizations under Part C and to Medicaid managed care organizations under prepaid capitation agreements under section 1903(m) of the Act. Some examples of where CMS has previously exercised this discretion include the development and implementation of requirements related to PACE compliance and oversight, PACE enforcement actions (CMPs, sanctions, and termination), and PACE participant rights and protections.

Under §§ 422.111(g) and 423.128(f), CMS may require an MA organization or Part D plan sponsor to disclose to its enrollees or potential enrollees, the MA organization or Part D sponsor's performance and contract compliance deficiencies in a manner specified by CMS. The purpose of these beneficiary protections is to provide beneficiaries with the information they need to assess the quality of care they are receiving and to make sponsoring organizations accountable for their performance deficiencies, which should improve compliance with the rules and requirements of the Medicare program. Further, in the final rule titled ''Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (75 FR 19677, hereinafter referred to as the April 2010 final rule), which appeared in the April 15, 2010 issue of the **Federal Register**, we explained that ''our intent is to invoke this disclosure authority when we become aware that a sponsoring organization has serious compliance or performance deficiencies such as those that may lead to an intermediate sanction or require immediate correction and where we believe beneficiaries should be specifically notified.''

In contrast to the Part C and D regulations at 42 CFR parts 422 and 423, respectively, the PACE regulations at Part 460 do not include a requirement for PACE organizations to notify current and potential PACE participants of the organization's performance and contract compliance deficiencies. In addition, we note that although regulations at Part 423 generally apply to PACE organizations, § 423.128 was waived for PACE organizations in 2005 (*see* January Part D 2005 final rule (70 FR 4430, 4432–33)). However, as explained in the proposed rule, we believe the disclosure of this information would serve as an important protection for PACE participants as it would help to ensure current and potential PACE participants and their caregivers have adequate information to make informed decisions about whether to enroll in, or to continue their enrollment, with a PACE organization. We also believe it is important to ensure there is public transparency regarding a PACE organization that has, or has had, performance and contract compliance deficiencies.

Therefore, we proposed to amend the regulations at 42 CFR part 460 by adding § 460.198, which would require PACE organizations to disclose to current PACE participants and potential PACE participants information specific to PACE organization performance and contract compliance deficiencies, in a manner specified by CMS. As in the MA and Part D programs, we anticipate that we would invoke the disclosure requirement when we become aware that a PACE organization has serious compliance or performance deficiencies such as those that may lead to intermediate sanctions or requires immediate correction, and where we believe PACE participants and potential PACE participants should be specifically notified.

Consistent with § 423.128(d), CMS waives any provision of the Part D regulations to the extent that CMS determines that the provision is duplicative of, or conflicts with, a provision otherwise applicable to PACE organizations under sections 1894 or 1934 of the Act, or as necessary to promote coordination between Part D and PACE. Because sections 1894 and 1934 of the Act do not include a requirement for PACE organizations to notify current and potential PACE participants of the organization's performance and contract compliance deficiencies, the regulation at § 423.128(f) does not duplicate, conflict with, or impede coordination between Part D and PACE. In addition, we note that at the time CMS announced the waiver of § 423.128 in the January Part D 2005 final rule (*see* 70 FR 4432–33), the disclosure requirement in paragraph (f) did not appear in § 423.128.[258] Therefore, we believe the 2005 waiver of the rest of § 423.128 does not apply to § 423.128(f), and the disclosure of information regarding performance and contract deficiencies concerning a PACE organization in its capacity as a Part D sponsor will serve as an important protection for PACE participants. This policy does not impact the waiver of the remainder of § 423.128 for PACE organizations, as applicable.

We received the following comments on this proposal, which are summarized later in this section:

Comment: Numerous commenters expressed support for this proposal.

Response: We thank the commenters for their support of our proposal, which would enable CMS to require PACE organizations to disclose to current and potential PACE participants information specific to PACE organization performance and contract compliance deficiencies, in a manner specified by CMS.

Comment: Several commenters suggested that we clarify the scope, mechanism, format, and timing in which we would require PACE organizations to disclose contract and compliance deficiencies to current and potential participants.

Response: We currently anticipate limiting this requirement to situations where we are imposing an intermediate sanction on a PACE organization, and we will follow a disclosure process that is similar to the process in MA and Part D. As in the MA and Part D programs, we would provide PACE organizations with a letter template, and the PACE organization would complete the required information in the template (for example, the bases for the intermediate sanction and participants' rights to a special election period if they have been impacted by the issues identified). We will then review and approve the notification and provide a date for the PACE organization to mail the notice to participants. We will also require the PACE organization to post the notice to its website.

Comment: Several commenters suggested that we clarify the types of contract and performance deficiencies that we might require PACE organizations to disclose to current and potential participants.

Response: As previously discussed, we intend to use these disclosures for instances where we are imposing an intermediate sanction on a PACE organization. We recognize, however, that there may be other instances where

[258] The April 2010 final rule (75 FR 19677) amended § 423.128 to include paragraph (f).

a PACE organization has serious compliance or performance deficiencies such as those that may lead to intermediate sanctions or require immediate correction where we believe PACE participants and potential PACE participants should be specifically notified. We may also require disclosures in these instances.

We received a comment on the following topic which is outside the scope of our proposal and to which we are therefore not responding: A request for CMS to create public reporting of performance for PACE organizations similar to Nursing Home Compare and an updated PACE manual with interpretive guidance prior to instituting a disclosure requirement.

After consideration of the comments received, and for the reasons set forth in the proposed rule and our responses to comments, we are finalizing our proposal to add § 460.198 to require PACE organizations to disclose to current PACE participants and potential PACE participants information specific to PACE organization performance and contract compliance deficiencies, in a manner specified by CMS, without modification.

J. PACE Participant Health Outcomes Data (§ 460.202)

Sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act require PACE organizations to collect, maintain, and report data necessary to monitor the operation, cost, and effectiveness of the PACE program to CMS and the State administering agency (SAA).

Following publication of the 1999 PACE interim final rule, CMS established a set of participant health outcomes data that PACE organizations were required to report to CMS. In subsequent years, we have modified the participant health outcomes data on a routine basis to ensure that we are collecting data that is relevant and useful to our efforts to monitor and oversee the PACE program. According to 5 CFR 1320.15, at least once every 3 years, to comply with the Paperwork Reduction Act of 1995 (Pub L. 104–13) (PRA), CMS is required to publish the proposed data collection and solicit public comment. The data collection requirements related to participant health outcomes data can be found in the information collection request currently approved under OMB control number 0938–1264 (CMS–10525). Section 460.202 currently requires participant health outcomes data reported to CMS and the SAA to be specified in the PACE program agreement; however, CMS does not routinely update program agreements based on changes to the required participant health outcomes data. As a result, the quality data collection specified in the program agreement is often out of date and no longer applicable within a few years.

Since the participant health outcomes data that PACE organizations must report to CMS and the SAA are specified and routinely updated through the PRA process, we proposed to amend paragraph (b) of § 460.202 by striking the final sentence, which states, ''The items collected are specified in the PACE program agreement.'' As explained in the proposed rule, we believe this change would eliminate any confusion regarding where the data collection requirements may be found (87 FR 79673).

The PACE program agreement would still include a statement of the data collected, as required by § 460.32(a)(11), but it would not include the level of specificity regarding the data collection that is included in the CMS PRA information collection request approved under OMB control number 0938–1264. We believe modifying § 460.202 as proposed would not increase the burden on PACE organizations as they are currently required to furnish information to CMS and the SAA through the aforementioned information collection request.

We solicited comment on this proposal and a summary of the comments received and our response follows.

Comment: A few commenters expressed support of the proposal to amend § 460.202(b) by removing the requirement that the PACE program agreement specify the data to be collected.

Response: We thank commenters for their support. We are finalizing our proposal without modification.

K. Corrective Action (§ 460.194)

Sections 1894(e)(4) and 1934(e)(4) of the Act require CMS, in cooperation with the State administering agency (SAA), to conduct comprehensive reviews of PACE organizations' compliance with all significant program requirements. Additionally, sections 18941(e)(6)(A)(i) and 1934(e)(6)(A)(i) of the Act condition the continuation of the PACE program agreement upon timely execution of a corrective action plan if the PACE provider fails to substantially comply with the program requirements as set forth in the Act and regulation. In the 1999 PACE interim final rule, we specified at § 460.194(a) and (c) that PACE organizations must take action to correct deficiencies identified by CMS or the SAA, or PACE organizations may be subject to sanction or termination (84 FR 66296). The 2019 PACE final rule amended § 460.194(a) to expand the ways CMS or the SAA may identify deficiencies that the PACE organization must correct (84 FR 25677). These include ongoing monitoring, reviews, audits, or participant or caregiver complaints, and for any other instance in which CMS or SAA identifies programmatic deficiencies requiring correction (84 FR 25677).

The 1999 PACE interim final rule also specified at § 460.194(b) that CMS or the SAA monitors the effectiveness of PACE organizations' corrective actions. The burden on CMS and SAAs to always monitor the effectiveness of every corrective action taken by the organization after an audit is high, and the number of audits, and thus the number of instances in which monitoring is required, increases each year because the PACE program continues to rapidly grow, and CMS is required to conduct audits in each year of the three-year trial period for new PACE contracts. However, as discussed in the November 2023 proposed rule, our experience overseeing this program has shown that it is not always necessary or worthwhile for CMS to monitor the effectiveness of every corrective action taken by an audited organization. We provided the example that a PACE organization may implement a corrective action that impacts its unscheduled reassessments due to a change in participant status, but historically, these types of assessments are not conducted frequently; thus, it may not be worthwhile for CMS or the states to spend resources monitoring the effectiveness of that correction due to limited data available for CMS or the SAA to monitor. Additionally, as PACE continues to grow, it will be increasingly important that CMS and the SAA have the flexibility to determine how to use their oversight resources most effectively. Therefore, in the November 2023 proposed rule, we proposed an amendment to § 460.194(b) that specified, at their discretion, CMS or the SAA may monitor the effectiveness of corrective actions (88 FR 78587).

As discussed in the November 2023 proposed rule, the flexibility afforded under this proposed amendment to § 460.194(b) would not change our expectation that PACE organizations expeditiously and fully correct any identified deficiencies, and CMS and the SAAs would continue to engage in monitoring efforts that prioritize participant health and safety and program integrity. In addition, as a part

of a PACE organization's oversight compliance program, we require at § 460.63 that PACE organizations adopt and implement effective oversight requirements, which include measures that prevent, detect and correct non-compliance with CMS's program requirements. A PACE organization's oversight compliance program must, at a minimum, include establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised. In addition, compliance oversight programs must ensure ongoing compliance with CMS requirements (88 FR 78587).

Since the effect of the proposed change would be to provide CMS and the SAA more flexibility when monitoring the effectiveness of corrective actions without placing new requirements on CMS, the SAAs, or PACE organizations, we believe this change would create no additional burden for PACE organizations. Additionally, we do not expect this change to have economic impact on the Medicare Trust Fund.

We solicited comment on this proposal. A summary of the comments received, and our response follows.

Comment: Most commenters that addressed the proposed change to § 460.194(b) supported the proposal that, at their discretion, CMS or the SAA may monitor the effectiveness of corrective actions. Some of those commenters, while supportive of the proposal, requested clarification regarding how CMS and the SAA will implement the provision. A few of these commenters offered conditional support for the proposed change at § 460.194(b) based on whether CMS and the SAA's increased discretion when monitoring the effectiveness of corrective actions could lead to increases in burden for PACE organizations, particularly during corrective action plan implementation, monitoring, and release following any issues of non-compliance that CMS or the SAA identify during PACE audits as requiring corrective action. Therefore, these commenters suggested that CMS clarify whether the proposed change at § 460.194(b) could increase burden for PACE organizations. One commenter that supported the proposed change at § 460.194(b) requested clarification regarding any thresholds or criteria that would govern CMS's or the SAA's discretion over corrective action monitoring activities. Another commenter in support of the change at § 460.194(b) recommended that CMS and the SAA ''liberally'' apply their discretion authorities under § 460.194(b) to reduce burden concerns for PACE organizations related to what the commenter considered unnecessary and prolonged monitoring. In reference to the proposed change at § 460.194(b), one commenter stated that they do not support any proposals that reduce the oversight of corrective actions.

Response: We thank commenters for their general support of the proposed change to § 460.194(b), which specifies that, at their discretion, CMS or the SAA may monitor the effectiveness of corrective actions. In response to the one commenter that expressed they do not support any proposals that reduce the oversight of corrective actions, as initially discussed in the November 2023 proposed rule, we reiterate that the proposed change at § 460.194(b) and subsequent discretion afforded to CMS and the SAA regarding the monitoring of the effectiveness of corrective actions would not reduce meaningful oversight of corrective actions (88 FR 78587). Based on our experience overseeing PACE, it is not always necessary or worthwhile for CMS to monitor the effectiveness of every corrective action taken by an audited PACE organization. The example we provided in the November 2023 proposed rule pertained to unscheduled reassessments due to a change in participant status. Historically, these types of assessments are not conducted frequently; therefore, it may not be worthwhile for CMS or the SAA to expend significant resources monitoring the effectiveness of that correction due to limited data available for CMS or the SAA to monitor (88 FR 78587). CMS and the SAA will implement the flexibility provided by the change at § 460.194(b) such that we safeguard PACE participant wellbeing and safety and program integrity, and effectively adapt to the growing monitoring demands of the program's rapid expansion. Additionally, regardless of the change to § 460.194(b), PACE organizations must continue to comply with all applicable PACE requirements, and CMS and the SAA will continue to oversee PACE organization compliance through a variety of monitoring and oversight activities that ensure accountability.

In response to commenters that support the change to § 460.194(b), we offer the following clarifications. First, we clarify that we do not expect the implementation of the change at § 460.194(b) to alter the PACE audit corrective action monitoring process in a way that increases PACE organizations' burden. Second, we clarify that, given the complexity and scope of potential corrective actions, we decline to establish specific criteria or thresholds as determinants of whether CMS or the SAA will monitor the effectiveness of a particular corrective action for the purposes of this final rule. Moreover, it is important for any corrective action monitoring threshold we create as a result of the discretion afforded under § 460.194(b) to be internal to CMS and the SAA in order to ensure we have the flexibility to reassess any thresholds, as needed, based on new information and changing data. However, such discretion, when applied, will safeguard PACE participant wellbeing and safety and program integrity while considering the monitoring resources available to CMS and the SAA, and will be consistently applied across organizations. Whether monitoring a specific corrective action is necessary or worthwhile will depend on CMS and SAA consideration of these objectives.

In response to the commenter that supported the change at § 460.194(b) and recommended that CMS and the SAA use their corrective action monitoring discretion ''liberally'' to reduce burden for PACE organizations, we emphasize that, although the change to § 460.194(b) might reduce burden for audited PACE organizations, we do not anticipate a significant burden reduction for PACE organizations as a result of this provision. Regardless of formal monitoring of corrective actions by CMS or the SAA, as previously mentioned, PACE organizations must correct any issues of noncompliance identified by CMS and the SAA and adopt their own oversight compliance program in accordance with § 460.63 compliance oversight requirements. Additionally, we expect PACE organizations to demonstrate that they have appropriately corrected all noncompliance identified during their previous audit during subsequent audits by CMS and the SAA.

After consideration of the comments we received, we are finalizing the proposed amendments to § 460.194(b) without modification.

L. Service Determination Requests Pending Initial Plan of Care (§ 460.121)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. Along with the regulations at § 460.120 related to grievances, and § 460.122 related to appeals, CMS created a process for service determination requests, the first stage of an appeal, at § 460.121.

The PACE regulations define a service determination request as a request to

initiate a service; modify an existing service, including to increase, reduce, eliminate, or otherwise change a service; or to continue coverage of a service that the PACE organization is recommending be discontinued or reduced (see § 460.121(b)(1)(i)-(iii)). In the January 2021 final rule (86 FR 6024), CMS finalized an exception to the definition of service determination request at § 460.121(b)(2), which, as amended, provides that requests to initiate, modify, or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care. When CMS proposed this exception in the February 2020 proposed rule, we noted that the exception would apply any time before the initial plan was finalized and discussions among the interdisciplinary team (IDT) ceased (85 FR 9125). We explained that we believed this change would benefit both participants and PACE organizations because it would allow the IDT and the participant and/or caregiver ''to continue to discuss the comprehensive plan of care taking into account all aspects of the participant's condition as well as the participant's wishes'' (*Id.*). We also stated that ''if a service was not incorporated into the plan of care in a way that satisfies the participant, the participant would always have the right to make a service determination request at that time'' (85 FR 9126).

Our intention for this provision was that the IDT would discuss specific requests made by a participant and/or caregiver as part of the care planning process and determine whether these requests needed to be addressed in the plan of care. We stated in the February 2020 proposed rule that if a participant asked for a specific number of home care hours, that the request would not need to be processed as a service determination request because the IDT was actively considering how many home care hours the participant should receive as part of the development of the initial plan of care (85 FR 9125). This rationale is also consistent with our statement in the proposed rule titled ''Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE),'' which appeared in the August 16, 2016 **Federal Register**, that ''CMS expects the plan of care to reflect that the participant was assessed for all services even where a determination is made that certain services were unnecessary at that time'' (81 FR 54684).

However, as part of our oversight and monitoring of PACE organizations, we have found that often requests made by participants and/or caregivers prior to the finalizing of the care plan are not discussed during the care planning process and are therefore not considered by the IDT. These requests are some of the first communications from participants related to the care they will be receiving from the PACE organization and would otherwise be considered service determination requests at any other stage of their enrollment. While we continue to believe that it is not prudent for the PACE organization to process these requests as service determination requests, it is important that the IDT consider these requests and determine whether they are necessary for the participant.

Therefore, we proposed to modify the regulation text at § 460.121(b)(2) to specify that service requests made prior to developing the participant's initial plan of care must either be approved and incorporated into the participant's initial plan of care, or the rationale for why it was not approved and incorporated must be documented. Specifically, we proposed to add the following sentence at the end of current § 460.121(b)(2): ''For all requests identified in this section, the interdisciplinary team must (i) document the request, and (ii) discuss the request during the care plan meeting, and either: A) approve the requested service and incorporate it into the participant's initial plan of care, or B) document their rationale for not approving the service in the initial plan of care.'' As we stated in the November 2023 proposed rule at 88 FR 78588, we believe this change is consistent with existing plan of care requirements at § 460.104(b) and aligns with our plan of care proposals in the December 2022 proposed rule (87 FR 79452), which we discuss in section IX.F of this final rule.

As the development of the plan of care is a typical responsibility for the IDT, any burden associated with this would be incurred by persons in their normal course of business. Therefore, the burden associated with documenting the determination of any assessment of a participant and/or caregiver service request during the initial care planning process is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

We solicited comment on this proposal. A summary of the comments received and our responses follow.

Comment: Most commenters supported our proposal to modify the requirements regarding documenting and responding to requests received prior to the finalization of the initial plan of care.

Response: We thank commenters for their support.

Comment: A couple of commenters requested that the regulation language be modified to clarify that the requirement does not pertain to requests for services made by participants prior to the first day of the participant's enrollment. A commenter opposed the proposed requirement because some States require initial plans of care to be completed prior to enrollment, and the commenter stated it would be inappropriate to process these requests as service determination requests.

Response: We are not persuaded to modify our proposal to clarify that the requirement to document requests for services is only from the time the participant enrolls until the finalization of the initial plan of care. The initial plan of care developed by the IDT is intended to be a comprehensive document that details all necessary services the participant should receive from the PACE organization. As part of that plan of care, the IDT is required to consider the assessments conducted by members of the IDT, but it should also consider the participant's wishes, and any specific requests for services that the participant makes prior to that initial plan of care being developed. The intention of our proposal was to ensure PACE organizations were appropriately addressing participant service requests during the process of creating the initial plan of care regardless of when the requests are received. We would reiterate that we are not asking that the requests for services received prior to the finalization of the initial plan of care be processed as service determination requests as defined in § 460.121(b)(1). As we stated in the November 2023 proposed rule, we do not believe it is appropriate to process these early requests for services as service determination requests (88 FR 78588). However, we further stated in the November 2023 proposed rule that we have seen through our oversight and monitoring activities instances of participants and/or caregivers making requests during the process of creating the initial care plan, which the IDT did not consider (*Id.*).

While we understand that certain service areas may require PACE organizations to finalize the initial plan of care prior to enrollment, we would expect that any request for service received during the initial care planning process would be documented and that the IDT would discuss the request as part of the normal course of creating the initial plan of care regardless of whether the care planning process occurs prior to or after enrollment. We have seen through our oversight and monitoring activities that these requests for services

are typically made by participants during the initial assessment. Therefore, if a PACE organization chooses (or is required by a State) to conduct initial assessments prior to the date of enrollment, we would expect requests made during that time to be documented and considered by the IDT.

Comment: A commenter expressed concern that the documentation requirement was overly burdensome and does not offer any additional value to the participant as PACE organizations are already required to review the care plan with the participant prior to finalization. The same commenter stated that it was more appropriate to begin documenting requests for services after the participant has an initial plan of care to allow the participant time to become familiar with the PACE organization's services.

Response: We are not persuaded by the argument that the requirement to document requests for services received prior to the finalization of the initial plan of care is overly burdensome or that this proposed requirement holds no inherent value to the participant. While we agree that PACE organizations are already required to develop the care plan in collaboration with the participant and/or caregiver prior to finalization, as we stated in the December 2022 proposed rule in our discussion regarding our proposed changes to the plan of care requirements, we have seen instances ''where participants and/or caregivers are unaware of the contents of their plan of care or what services they should be receiving'' (87 FR 79660). We have also seen through oversight and monitoring that each PACE organization develops its own approach concerning the participant's involvement in the care planning process. Although § 460.102(d)(2)(ii) requires the IDT to remain alert to pertinent information about participants, including input that comes from the participants themselves, for many PACE organizations, there is no detailed discussion with the participant. Instead, following the IDT meeting, the PACE organization mails the participant the care plan or other information regarding what services have been included in the care plan. This method of informing the participant of the finalized care plan after the fact does not often allow the participant to make a meaningful contribution to the services being incorporated by the IDT into the initial plan of care. When participants are not able to actively participate in the care planning process, participants may not understand why requested services were not included or considered in the initial plan of care. By documenting the requests for services received during the initial care planning process, the IDT can track the requests to ensure they have addressed all concerns the participant expressed during the initial care planning process and demonstrate to the participant that their concerns were reviewed and considered.

We are also not persuaded by the argument that it is more appropriate to wait until the participant has an initial plan of care to document their requests for services to allow the participant to become more familiar with the services provided by the PACE organization. Per § 460.98(a), PACE organizations are required to provide care that meets participant needs across all care settings, 24 hours a day, every day of the year regardless of whether the participant is familiar with what services are available to them. Additionally, in the early part of a participant's enrollment into PACE, prior to an initial plan of care being finalized, participants are actively engaged in communicating the services they hope to receive from the PACE organization. Those requests that indicate the participant's wishes for treatment should be considered and addressed as part of the development of the initial plan of care. It is the IDT's responsibility to document, assess, and determine whether a requested service is necessary to meet the needs of the participant based on the requirements in § 460.92(b). Due to the PACE benefit including any service that is determined necessary by the IDT, the participant's understanding of the benefit should not hinder their ability to advocate for services they believe are necessary for their medical, physical, social, or emotional needs.

Comment: A commenter supported the proposed changes but requested that we require PACE organizations to inform participants of the formal grievance process for any declined requests. The same commenter requested that we add a requirement for data collection and reporting related to declined requests to identify inequities and systemic issues to hold PACE organizations accountable.

Response: We are not persuaded by the suggestion to modify our proposal to require PACE organizations to discuss the grievance process for any declined requests received prior to the finalization of the initial plan of care. If the IDT reviews a request for a service and decides not to include the request in the initial plan of care, nothing in our proposal would prevent the IDT from explaining the grievance process and providing the participant the right to submit a grievance. However, to the extent that a participant still wants a service that was not included in the initial plan of care, we would expect the PACE organization to process that request as a service determination request and, if the service determination request were denied, to provide appeal rights as detailed in § 460.121(j)(2) and § 460.122. The grievance process would not be the appropriate process if a participant still wanted to advocate for the inclusion of a particular service. The suggestion to require data collection and reporting of declined service requests is beyond the scope of our proposal.

After reviewing and considering the public comments received, we are finalizing the regulation as proposed.

X. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information,'' as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In our December 27, 2022 (CMS–4201–P; RIN 0938–AU96; 87 FR 79452) and November 15, 2023 (CMS–4205–P; RIN 0938–AV24; 88 FR 78476) proposed rules we solicited public comment on each of the aforementioned issues for the following information collection requirements. The following ICRs received PRA-related comment: #2 (Standards for Electronic Prescribing), #7 (Mid-Year Notice of Unused Supplemental Benefits), #9 (Agent Broker Compensation), and #14 (Part D Medication Therapy Management Program Eligibility Criteria). A summary of the comments and our response can be found below under the applicable ICR section.

A. Wage Data

1. Private Sector

To derive mean costs, we are using data from the most current U.S. Bureau of Labor Statistics' (BLS's) National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/2022/may/oes_nat.htm*), which, at the time of publication of this final rule, provides May 2022 wages. In this regard, Table J1 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

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TABLE J1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Business operations specialists (all others)	13-1199	39.75	39.75	79.50
Compliance officers	13-1041	37.01	37.01	74.02
Computer programmer	15-1251	49.42	49.42	98.84
Healthcare Social workers	21-1022	30.17	30.17	60.34
Marketing Managers	11-2021	76.10	76.10	152.20
Pharmacist	29-1051	62.22	62.22	124.44
Pharmacy Technician	29-2052	19.35	19.35	38.70
Physician all others	29-1229	114.76	114.76	229.52
Registered Nurse*	29-1141	42.80	42.80	85.60
Software and Web Developers, Programmers, Testers	15-1250	60.07	60.07	120.14
Software Developers	15-1252	63.91	63.91	127.82

*The November 2023 NPRM had inadvertently set out "24-1141" as the occupation code for Registered Nurses. The correct code is "29-1141."

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As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. In this regard, we believe that doubling the hourly wage to estimate costs is a reasonably accurate estimation method.

The December 2022 NPRM's (CMS–4201–P) wages were based on BLS' 2021 wage data. This final rule updates those wages to reflect BLS' 2022 wage data. Table J2 compares BLS' May 2021 and May 2022 mean hourly wages for the applicable occupation codes.

The November 2023 NPRM (CMS–4205–P) set out BLS' May 2022 wages. In that regard they are unchanged in this final rule.

TABLE J2: COMPARISON OF 2021 and 2022 MEAN HOURLY WAGES*

Occupation Title	Occupational Code	2021 Mean Hourly Wage ($/hr)	2022 Mean Hourly Wage ($/hr)	Percent Change from 2021 to 2022
Business operations specialists (all others)	13-1199	38.10	39.75	4.33%
Compliance officers	13-1041	36.45	37.01	1.54%
Computer programmer	15-1251	46.46	49.42	6.37%
Healthcare Social workers	21-1022	29.96	30.17	0.7%
Pharmacist	29-1051	60.43	62.22	2.96%
Registered Nurse	29-1141	39.78	42.80	7.59%

2. Beneficiaries

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $20.71/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $998, divided by 40 hours to calculate

an hourly pre-tax wage rate of $24.95/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of $20.71/hr. Unlike our private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment. There is logic to valuing time spent outside of work, but there is also logic for using a fully loaded wage. In the past, we have used occupational code 00–0000, the average of all occupational codes, which currently is $29.76/hr. Thus we propose a range for enrollees of $20.71/hr–$29.76/hr. Nevertheless, the upper limit is based on an average over all occupations while the lower limit reflects a detailed analysis by ASPE targeted at enrollees many of whom are over 65 and unemployed; consequently, in our primary estimates we will exclusively use the lower limit as we consider it more accurate. However, the effect of using the alternate upper limit will be included in a footnote referenced in Table J7 and the summary table.

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble of this final rule.

1. ICRs Regarding Network Adequacy in Behavioral Health (§ 422.116(b)(2) and (d)(2) and (5))

The following changes will be submitted to OMB for approval under control number 0938–1346 (CMS–10636).

To ensure that MA enrollees have access to provider networks sufficient to provide covered services, including behavioral health service providers, we are proposing to add one new facility-specialty type that will be subject to network adequacy evaluation under § 422.116. As discussed in the ''Expanding Network Adequacy Requirements for Behavioral Health'' section of the preamble, we are finalizing our proposal to amend the network adequacy requirements and add one combined facility-specialty category called ''Outpatient Behavioral Health'' under § 422.116(b)(2) and to add ''Outpatient Behavioral Health'' to the time and distance requirements at § 422.116(d)(2). For network adequacy evaluation purposes, provider types under this category can include, Marriage and Family Therapists (MFTs), Mental Health Counselors (MHCs), Opioid Treatment Program (OTP) providers Community Mental Health Centers or other behavioral health and addiction medicine specialists and facilities. Based on the current regulation at § 422.116(e)(2) for all facility-specialty types other than acute inpatient hospitals, the minimum provider number requirement for this proposed new provider type is one. Finally, we also proposed to add the new ''Outpatient Behavioral Health'' facility-specialty type to the list at § 422.116(d)(5) of the specialty types that will receive a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards for certain providers when the plan includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, in its contracted network. To determine the potential burden regarding this proposal, we considered cost estimates for MA organizations to update policies and procedures. However, the burden for updating the HPMS system is a burden to CMS and its contractors and hence is not subject to the requirements of the PRA.

Although there is no cost for MA organizations to report new specialty types to CMS for their network adequacy reviews as this proposal requires, we have determined that there is a minimal one-time cost for MA organizations to update their policies and procedures associated with this proposal.

First, regarding reporting the new specialty types to CMS, MA organizations are already conducting ongoing work related to network adequacy reviews that happen during the initial or service area application, or every 3 years for the triennial review. This provision requires that the specialty type be added to the Health Services Delivery (HSD) tables during any network adequacy evaluation requested by CMS. The time to conduct tasks related to adding additional specialty types on the HSD tables is negligible.

We understand that MA organizations will need to update their policies and procedures related to submission of HSD tables to ensure that the new required behavioral health specialty type is included. We estimate that it would take 5 minutes (0.0833 hr) at $79.50/hr for a business operations specialist to update policies and procedures related to this task. In aggregate we estimate a one-time burden of 62 hours (742 MA contracts * 0.0833 hr) at a cost of $4,929 (62 hr * $79.50/hr).

We received no comments specific to our analysis of paperwork burden and are therefore finalizing our estimates as is.

3. ICRs Regarding Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products (§§ 423.4, 423.100, 423.104, 423.120, 423.128, and 423.578)

The following changes will be posted for public review under control number 0938–0964 (CMS–10141) using the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. The 60-day notice will publish soon after the publication of this final rule.

In the provision, ''Changes to an Approved Formulary'' (see section III.Q. of the December 2022 proposed rule [87 FR 79452]) we proposed to codify guidance in place since early in the Part D program and in section VII.B.10. of the December 2022 proposed rule (87 FR 79680), we outlined ICRs regarding the proposed provision. In the provision ''Additional Changes to an Approved Formulary—Biosimilar Biological Product Maintenance Changes and Timing of Substitutions'' (see section III.F. of the November 2023 proposed rule [88 FR 78476]), we proposed to update the regulatory text proposed in the December 2022 proposed rule to permit Part D sponsors to treat substitutions of biosimilar biological products other than interchangeable biological products as ''maintenance changes'' under § 423.100 as proposed in the December 2022 rule. We also proposed to revise paragraphs (1) and (2) of the § 423.100 definition of ''maintenance changes'' to clarify that certain substitutions need not take place ''at the same time'' but that Part D sponsors can remove or make negative changes to a brand name drug or reference product within a certain time period after adding a corresponding drug or a biosimilar biological product other than an interchangeable biological product to the formulary. Lastly, we proposed a few technical changes, including in support of the above specified proposals. In this final rule, we are finalizing the proposed changes with some technical clarifications that do not impact our estimates.

The burden estimates in the December 2022 proposed rule were based on actual formulary changes submitted to CMS for contract year (CY) 2021 since the ''Changes to an Approved Formulary'' proposals primarily set out to codify existing guidance that Part D sponsors had already been following. We did not make adjustments to the methodology for this collection request

based on the proposal in the November 2023 proposed rule to permit formulary substitutions of a biosimilar biological product other than an interchangeable biological product for the reference product as a maintenance change. New drugs and biological products are approved or licensed by the FDA and become available on the market at irregular intervals. Therefore, with respect to this provision, we cannot predict when new biosimilar biological products will enter the market or to what extent Part D sponsors will make formulary substitutions as a result. Several biosimilar biological products entered the market in 2023,[259] but CMS did not receive any non-maintenance negative change requests from Part D sponsors requesting to apply a negative change to a reference product when adding a corresponding biosimilar biological product to the formulary. It is unclear whether Part D sponsors are not requesting midyear formulary changes due to concerns about patient and provider hesitancy towards biosimilar biological products, or if the current policy that treats such formulary changes as non-maintenance changes disincentivizes Part D sponsors from making midyear formulary changes that will not apply to all enrollees currently taking the reference product. For this final rule, we are revising our burden estimates using the same methodology as the collection request in the December 2022 proposed rule but updated based on actual formulary changes submitted to CMS for CY 2023.

The burden associated with the negative change request process and notice of negative formulary changes to CMS, affected enrollees, current and prospective enrollees, and other specified entities (as listed in *§ 423.120(b)(5)(i)*) was not accurately captured under the aforementioned OMB control number, which simply included a lump sum of 40 hours annually per Part D contract for a business operations specialist to complete notice requirements to CMS and other specified entities, but this estimate did not include notice to affected enrollees. As discussed later in this section, multiple contracts share the same formulary; therefore, there are efficiencies in managing formularies such that each contract does not assume burden independently. See Table J3 for the burden estimates currently in CMS–10141 that will be removed from the package along with our revised burden estimates. Similarly, the aforementioned control number does not include burden associated with updating the Part D formulary on the Part D sponsor website as required per *§ 423.128(d)(2)(ii) and(iii).* We are now quantifying burden associated with negative formulary changes in a more granular fashion, which includes notice to affected enrollees and online notice by updating the formulary posted on the Part D sponsor website, which we believe to reflect the operational processes which Part D sponsors have been following. We believe Part D sponsors have been following published guidance since CMS has operational oversight of negative change requests and corresponding formulary updates and we are not aware of significant complaints that beneficiaries are being subjected to negative formulary changes without proper notice.

Immediate formulary changes require advance general notice that such changes may occur at any time. Advance general notice to CMS of immediate substitutions is currently incorporated into annual bid submission workflow as a simple checkbox, which we do not believe has added substantial burden to the overall bid submission process. Language constituting advance general notice of immediate formulary changes (that is, immediate substitutions, positive formulary changes, and market withdrawals) for other specified entities and current and prospective enrollees, is already incorporated into model formulary and evidence of coverage documents and we do not believe our changes would add a substantial burden to preparing the documents outside of the routine annual updates. The burden attributed to the dissemination of Part D plan information is approved under the aforementioned control number at 80 hours annually for each Part D contract's business operations specialist to prepare required plan materials consistent with *§ 423.128(a),* which includes annual updates to the formulary and evidence of coverage documents, among other information. Since language has already been incorporated into the model documents used by Part D sponsors to update their materials and since CMS–10141 has been posted for comment multiple times since the requirements related to advance general notice were codified at *§ 423.120(b)(5)(iv)(C)* (which we are moving to § 423.120(f)(2)), we continue to assume the accuracy of this estimate.

Part D sponsors notify CMS of their intent to make a negative formulary change by submitting a negative change request (NCR) via the Health Plan Management System (HPMS) NCR module. Part D sponsors provide CMS notice of changes which do not require NCRs by submitting updated formulary files during monthly windows, which is a standard formulary management operation. Part D sponsors submit formularies which can be used across multiple contracts and plans. In 2023, CMS approved 542 formularies which were used across 1,556 contracts and 7,048 plans offered by 197 parent organizations. Since there are some efficiencies with respect to formulary management and NCR submissions (for example, NCRs submitted for one formulary can be applied to others in a streamlined manner), we estimate burden at the parent organization level. However, not all Part D sponsors submit NCRs. In 2023, 89 parent organizations submitted 2,642 NCRs for 219 formularies. We believe that generally a pharmacist is responsible for managing NCR submissions and that each NCR takes approximately 5 minutes (0.0833 hr) to submit through the HPMS module, based on CMS internal user testing. In total, for 89 parent organizations, the burden to submit NCRs is estimated to be 220 hours (2,642 NCRs × 0.0833 hr per NCR) at a cost of $ 27,377 ($124.44/hr × 220 hr).

Part D sponsors include immediate formulary changes, approved negative changes, and any enhancements (for example, addition of newly approved drugs, moving a drug to a lower cost-sharing tier, removing or making less restrictive utilization management requirements) to their formularies consistent with formulary requirements. Generally, every formulary is updated during these monthly formulary update windows and CMS reviews all changes to ensure they are consistent with regulatory requirements. Since every parent organization generally updates their formulary regardless of whether any negative changes are made, we estimate burden for all 197 parent organizations representing 542 formularies in 2023. There are 11 formulary update windows per year (monthly from January to November). We believe a pharmacist is generally responsible for managing formulary submissions. In this case, 5,962 formulary submissions (542 formularies × 11 submission windows). We estimate that each formulary file update requires 2 hours to prepare, for a total of 11,924 hours (5,962 submissions × 2 hr per submission) at a cost of $1,483,823 (11,924 hr × $124.44/hr).

In addition to notifying CMS in the manner described, Part D sponsors are required to notify other specified entities of formulary changes. As

[259] Billingsly A. Is There a Biosimilar for Humira? Yes, Here Are 9 Humira Biosimilars Launching in 2023. GoodRxHealth. July 12, 2023. Available from: *https://www.goodrx.com/humira/biosimilars.*

defined in *§ 423.100,* ''other specified entities'' are 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. Online postings that are otherwise consistent with requirements for notice to other specified entities may constitute sufficient notice of negative formulary changes, although sponsors may use mechanisms other than the online postings to notify other specified entities of midyear formulary changes as well. Requirements for Part D sponsors' internet website include the current formulary for the Part D plan, updated at least monthly consistent with *§ 423.128(d)(2)(ii),* and advance notice of negative formulary changes for current and prospective enrollees, consistent with *§ 423.128(d)(2)(iii).* To estimate burden associated with providing notice of formulary changes to other specified entities, we calculate the time and cost associated with updating the formulary and providing notice of drugs affected by negative formulary changes (such as a summary table which lists such changes) on the Part D sponsor's website. For 542 formularies in 2023, monthly updates would be posted at least 12 times annually for a total of 6,504 postings (542 formularies × 12 updates/year) by all 197 parent organizations. We estimate that it would take 1 hour to update the website consistent with the requirements at *§ 423.128(d)(2)(ii) and (iii)* and that a computer programmer would be responsible for such postings for a total annual burden of 6,504 hours (6,504 updates × 1 hr/update) at a cost of $642,855 ($98.84/hr × 6,504 hr).

Enrollees affected by negative formulary changes are currently required to receive direct written notice as described at *§ 423.120(b)(5)(i)(A) and (b)(5)(ii).* We are finalizing our proposal to move this requirement to § 423.120(f)(1) and (f)(4), respectively. CMS provides a model ''Notice of Formulary Change'' which sponsors may use to meet regulatory requirements. Affected enrollees include those who are subject to immediate substitutions and maintenance formulary changes. The notice requirement is the same, with the exception that enrollees subject to immediate substitutions receive notice retrospectively while enrollees subject to maintenance formulary changes receive notice in advance of the change. There are no affected enrollees subject to non-maintenance changes since these types of changes are permitted only when enrollees taking the drug subject to the non-maintenance change are exempt from the change (that is, ''grandfathered'') for the remainder of the contract year. CMS does not collect data on the number of enrollees affected by negative formulary changes. In order to estimate the number of affected enrollees, we used 2022 data on the total number of Part D enrollees (across the entire program) taking each drug subject to the negative formulary change during the contract year. We then calculated the estimated number of affected enrollees by prorating the number of enrollees taking the drug across the entire program based on the relative proportion of the Part D plan's enrollment in 2023 to the total Medicare Part D enrollment in 2023.

The following example illustrates this process. As of December 2023, there were 52,376,078 Part D enrollees. As stated previously, multiple contracts and plans may share the same formulary. A negative formulary change submitted for Drug A on a particular formulary impacted a total of 108 individual plans utilizing this formulary. The total number of Part D enrollees taking Drug A in 2022 was 364,930. The total number of enrollees in the 108 plans implementing the negative formulary change was 1,776,856, representing 3.392 percent of the total Part D enrollment (1,776,856/52,376,078). We then assume that of the 364,930 Part D enrollees taking Drug A during 2022, that 3.392 percent or 12,380 enrollees (364,930 × 0.03392) were affected by the negative formulary change assuming they were still taking the drug in 2023. This logic was applied across all immediate substitutions and maintenance formulary changes submitted for contract year 2023. We do not estimate enrollees affected by market withdrawals since these occur infrequently and unpredictably (historically occurring every few years) and the number of enrollees affected could vary substantially depending on the drug implicated.

In total, there were 143 parent organizations that implemented immediate substitutions or maintenance formulary changes for 348 formularies used for 528 contracts and 2,298 plans affecting a total of 54,114 enrollees. We do not attribute substantial burden associated with incorporating the model notice into Part D sponsors' internal systems for mailing, since this would have been a one-time initial upload with minor updates annually. We therefore calculate non-labor costs associated with sending notice of formulary change to affected enrollees. Enrollees may opt in to receiving communication materials electronically rather than via hard-copy mailings; however, consistent with informal communication from stakeholders for other required documents, we assume all affected enrollees prefer hard-copy mailings. Costs for hard-copy mailings include paper, toner, envelopes, and postage.

- *Cost of paper:* We assume $3.50 for a ream of 500 sheets. The cost for one page is $0.007 ($3.50/500 sheets).
- *Cost of toner:* We assume a cost of $70 for 10,000 pages. The toner cost per page is $0.007 ($70/10,000 pages).
- *Cost of envelopes:* We assume a cost of $440 for 10,000 envelopes. The cost per envelope is $0.044.
- *Cost of postage:* The current cost of first-class metered mail is $0.64 per letter up to 1 ounce. We are using metered mail because these notifications contain confidential beneficiary information and therefore a bulk mailing cannot be used.

++ A sheet of paper weights 0.16 ounces (5 pounds/500 sheets × 16 ounces/pound). We estimate each mailing to consist of 2 pages or 0.32 ounces, so no additional postage for mailings in excess of 1 ounce is anticipated.

Thus, the cost per mailing is $0.712 ([$0.007 for paper × 2 pages] + [$0.007 for toner × 2 pages] + $0.64 for postage + $0.044 per envelope). We estimate the total annual mailing cost at $38,529 ($0.7120 per notice × 54,114 affected enrollees).

The summary of burden, labor and non-labor costs, associated with this provision follows in Table J3.

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We received no comments specific to our analysis of paperwork burden based on our proposed changes to an approved formulary in the December 2022

TABLE J3: CHANGES TO AN APPROVED FORMULARY—INCLUDING SUBSTITUTIONS OF BIOSIMILAR BIOLOGICAL PRODUCTS

Regulatory Citation	Response Summary	Total Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Wage ($/hr)	Total Annual Cost ($)
Current Burden to be Removed from Package CMS-10141							
§423.120(b)(5)(i)	Provide Notice of Formulary Change to CMS and Other Specified Entities	(990)	(990)	40	(39,600)	79.50	(3,148,200)
Revised Burden to be Added to Package CMS-10141							
Current Location: §423.120(b)(6)(ii)(A)(*1*) Revised Location: §423.120(e)(1)	Submit Negative Change Request	89	2,642	0.0833	220	124.44	27,377
Current Location: §423.120(b) Revised Location: §423.120(f)	Update Formulary in HPMS	197	5,962	2	11,924	124.44	1,483,823
Current: §423.128(d)(2)(ii)-(iii) Revised Location: No change.	Updating Formulary and Providing Online Notice of Changes on Website	197	6,504	1	6,504	98.84	642,855
Current Location: §423.120(b)(5)(i)(A) and (b)(5)(ii) Revised Location: §423.120(f)(1) and (f)(4)	Direct Written Notice to Affected Enrollees	143	54,114	n/a	n/a	n/a	38,529*
TOTAL		n/a	68,232	Varies	(20,952)	Varies	(955,616)

*Non-labor cost.

proposed rule and the November 2023 proposed rule and are therefore finalizing our estimates based on the proposed methodology but updated with more current data as discussed. In aggregate, our revised estimates result in a reduction of $955,616 and 20,952 hours from the previous annual burden estimates.

4. ICRs Regarding to Improvements to Drug Management Programs (§§ 423.100 and 423.153)

The following changes will be submitted to OMB for approval under control number 0938–TBD (CMS–10874). At this time, the OMB control number has not been determined, but it will be assigned by OMB upon its clearance of our collection of information request. We intend to identify the new control number in the subsequent final rule. The control number's expiration date will be issued by OMB upon its approval of our final rule's collection of information request. When ready, the expiration date can be found on *reginfo.gov.*

Ordinarily, the changes would be submitted to OMB for approval under control number 0938–0964 (CMS–10141), where the current OMB-approved Part D drug management program (DMP) information collection and burden is located. However, based on internal review, we are removing the DMP information collection and related burden from CMS–10141 and submitting it under a new collection of information request (OMB 0938–TBD, CMS–10874). This change will streamline clearance processes and minimize duplicative administrative burden for CMS and other stakeholders. Although we are removing DMP burden from CMS–10141, that collection will continue to include burden associated with many other aspects of the Part D program.

As described in section III.L. Improvements to Drug Management Programs, Definition of Exempted Beneficiary of this final rule, we are amending regulations regarding Part D DMPs for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs). Specifically, we are amending the definition of ''exempted beneficiary'' at § 423.100 by replacing the reference to ''active cancer-related pain'' with ''cancer-related pain.'' This change will reduce the overall burden associated with sponsors providing DMP case management and notices to potentially at-risk beneficiaries (PARBs) and at-risk beneficiaries (ARBs) because some beneficiaries identified as PARBs under the current definition would be excluded under the amended definition.

Under § 423.153(a), all Part D plan sponsors must have a DMP to address overutilization of FADs for enrollees in their prescription drug benefit plans. Based on 2023 data, there are 319 Part D parent organizations. The provisions codified at § 423.153(f)(2) require that Part D sponsors conduct case management of beneficiaries identified by the minimum overutilization monitoring system (OMS) criteria through contact with their prescribers to determine if a beneficiary is at-risk for abuse or misuse of opioids and/or benzodiazepines. Case management must include informing the beneficiary's prescriber(s) of the beneficiary's potential risk for misuse or abuse of FADs and requesting information from the prescribers relevant to evaluating the beneficiary's risk, including whether they meet the regulatory definition of exempted beneficiary. Under current CMS regulations at § 423.100, if a beneficiary meets the definition of an exempted beneficiary, the beneficiary does not meet the definition of a PARB. For this reason, exempted beneficiaries cannot be placed in a Part D sponsor's DMP.

In 2022, the OMS identified 43,915 PARBs meeting the minimum criteria prior to applying exclusions and 30,411 after excluding exempted beneficiaries. Thus, 13,504 beneficiaries (43,915 − 30,411) met the definition of exempted beneficiary. Amending the definition of ''exempted beneficiary'' at § 423.100 by replacing the reference to ''active cancer-related pain'' with ''cancer-related pain'' results in 46 additional enrollees meeting the definition of exempted beneficiary, or 13,550 exempted beneficiaries total (13,504 + 46). This yields 30,365 (43,915 − 13,550) instead of 30,411 beneficiaries requiring case management under the amended definition.

We estimate it takes an average of 5 hours for a sponsor to conduct case management for a PARB. We assume certain components of case management can be completed by staff of differing specialization and credentialing. Of the 5 hours, we assume that 2 hours at $124.44/hr would be conducted by a pharmacist (such as initial review of medication profiles, utilization, etc.), 2 hours at $38.70/hr would be conducted by a pharmacy technician, and 1 hour at $229.52/hr would be conducted by a physician to work directly with prescribers on discussing available options and determining the best course of action. The case management team would require 5 hours at a cost of $555.80 per PARB case managed ([2 hr × $124.44/hr] + [2 hr * $38.70/hr] + [1 hr * $229.52/hr]). Therefore, the case management team's average hourly wage is $111.16/hr ($555.80/5 hr). In aggregate, we estimate annual burden with the changes for case management is 151,825 hours (30,365 enrollees subject to case management * 5 hr/response) at a cost of $16,876,867 (151,825 hr * $111.16/hr); see case management row in Table J5. CMS 10141 included an estimate for the current case management burden of 178,855 hours and, with the hourly wage updated, a cost of $19,881,522; see case management row in Table J4. Thus, we calculate a savings of 27,030 hours (178,855 hr − 151,825 hr) and $3,004,655 ($19,955,671 − $16,876,867) with this updated burden; see case management row in Table J6 and note that in Table J6 we list savings as a negative number.

As a result of case management, a portion of PARBs may receive notice from a plan sponsor informing the beneficiary of the sponsor's intention to limit their access to coverage of opioids and/or benzodiazepines. Approximately 5 percent of PARBs identified by OMS criteria receive an initial and either a second notice or an alternate second notice. Amending the definition of ''exempted beneficiary'' would reduce the number of notices sent. Therefore, it follows that 2 fewer PARBs would receive notices (46 additional individuals * 0.05) and there would be 4 fewer notices total (2 enrollees * 2 notices/enrollee). Approximately 1,518 (30,365 * 0.05) PARBs overall would receive an initial and second notice (or alternate second notice) annually. We estimate it takes a pharmacy technician at $38.70/hr approximately 5 minutes (0.0833 hr) to send each notice and a total of 10 minutes (0.1667 hr) per enrollee to send both notices. In aggregate, we estimate an annual burden with the changes for sending notices of 253 hours (1,518 enrollees * 0.1667 hr) at a cost of $9,791 (253 hr * $38.70/hr) to send both notices; see the row for notification for enrollees in Table J5. CMS 10141, presenting the current burden, includes an estimated notice burden of 1,319 hours and, with the hourly wage updated, a cost of $51,045; see the row for notification for enrollees in Table J4 Thus, we calculate a savings of 1,066 hours (1,319 hr − 253 hr) and $41,254 ($51,045 − $9,791) with this updated burden; see the row for notification for enrollees in Table J6 and note that in Table J6 we list savings as a negative number.

Amending the definition of ''exempted beneficiary'' also reduces the burden of disclosure of DMP data to CMS based on the outcome of case management of PARBs. Using 30,365

beneficiaries requiring DMP data disclosure, we estimate that it would take (on average) 1 minute (0.0167 hr) at $38.70/hr for a sponsor's pharmacy technician to document the outcome of case management and any applicable coverage limitations in OMS and/or MARx. In aggregate, we estimate an annual burden with the changes for notification to CMS of 507 hours (30,365 PARBs * 0.0167 hr) at a cost of $19,621 (507 hr * $38.70/hr); see the row for notification to CMS in Table J5. CMS–10141, presenting the current burden, includes an estimated data disclosure burden of 597 hours and, with updated hourly wages, a cost of $23,104; see the row for notification to CMS of TableJ4. Thus, we calculate a savings of 90 hours (597 hr − 507 hr) and $3,483 ($23,104 − $19,621) with this updated burden; see the row for notification to CMS in Table J6 and note that in Table J6 we list savings as a negative number.

TABLE J4: CURRENTLY APPROVED BURDEN ESTIMATES WITH UPDATED WAGES

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
423.153(f)(2)	Conduct Case Management (Annualized)	306	35,771	5	178,855	111.16	19,881,522
423.153(f)(5-8)	Send Notices (Annualized)	306	7,911	0.1667	1,319	38.70	51,045
423.153(f)(15)	Report to CMS (Annualized)	306	35,771	0.0167	597	38.70	23,104
Total		306	79,453	Varies	180,771	Varies	19,955,671

Table J5 presents the estimated burden in this final rule which will be submitted with the new package, CMS–10874, which uses the currently approved burden from CMS–10141 as a baseline.

TABLE J5: ESTIMATED BURDEN FROM THIS FINAL RULE

Regulatory Citation	Subject	Number of Respondents	Number of Responses (PARBs after exclusions)	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
423.153(f)(2)	Conduct Case Management (Annualized)	319	30,365	5	15,1825	111.16	16,876,867
423.153(f)(5-8)	Send Notices (Annualized)	319	1,518	0.1667	253	38.70	9,791
423.153(f)(15)	Report to CMS (Annualized)	319	30,365	0.0167	507	38.70	19,621
Total		319	62,248	Varies	152,585	Varies	16,906,279

In aggregate, these changes will result in an annual reduction of cost of $3,049,392 and reduction of 28,186 hours. The aggregate burden change (reduction) is presented in Table J6, and will be submitted with the new package, CMS–10874.

TABLE J6: BURDEN CHANGES *

Regulatory Citation	Subject	Number of responses (PARBs after exclusion)	Time per response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
423.153(f)(2)	Conduct Case Management (Annualized)	(5,406)	5	(27,030)	111.16	(3,004,655)
423.153(f)(5-8)	Send Notices (annualized)	(6,393)	0.1667	(1,066)	38.70	(41,254)
423.153(f)(15)	Report to CMS (annualized)	(5,406)	0.0167	(90)	38.70	(3,483)
Total		Varies	Varies	(28,186)	Varies	(3,049,392)

* Table J6 is obtained by subtracting from Table J5 (burden of final regulation), Table J4 (current burden). For example, for Case Management, -27,030 hr =151,825 hr - 171,855 hr. Additionally, Table J6 is consistent with the line items in the COI Summary Table.

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

5. ICRs Regarding Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310)

In section III.Q. of this final rule, we discuss two provisions to improve access to MA encounter data for certain purposes. We noted that our current regulatory language limits CMS's ability to use and disclose MA encounter data to States for activities in support of administration or evaluation of the Medicaid program, including care coordination. Further, the regulation delays when CMS may share MA encounter data to State Medicaid agencies for care coordination and quality review and improvement activities for the Medicaid program, particularly with regard to dually eligible individuals. This final rule improves access to MA encounter data by:

- Adding ''and Medicaid programs'' to the current MA risk adjustment data use purposes codified at § 422.310(f)(1)(vi) and (vii); and
- Adding § 422.310(f)(3)(v) to allow for risk adjustment data to be released prior to reconciliation if the data will be released to States for the purpose of coordinating care for dually eligible individuals.

Together, these provisions clarify and broaden the allowable data uses for CMS and external entities (for data disclosed in accordance with § 422.310(f)(2) and (3)). We discuss the regulatory impact on CMS review and fulfillment of new MA encounter data requests in section XI. of this rule, explaining that we did not anticipate any significant impact to CMS.

As discussed in sections III.Q. and XI. of this rule, these provisions will allow States to voluntarily request MA encounter data from CMS for certain allowable purposes to support the Medicaid program. Currently, States can request MA encounter data to support the administration of the Medicare program or Medicare-Medicaid demonstrations, and to conduct evaluations and other analyses to support the Medicare program (including demonstrations). In addition, we interpret the regulation as permitting use and disclosure of MA encounter data for quality review and improvement activities for Medicaid as well as Medicare.

When determining the potential burden on States, we considered our existing data sharing program for States to request Medicare data for initiatives related to their dually eligible population. We expected the process to request MA encounter data would be similar to the process that States currently undertake to request new Medicare FFS claims and events data files or to update allowable data uses. All States, including the District of Columbia, maintain agreements with CMS that cover operational data exchanges related to the Medicare and Medicaid program administration as well as optional data requests for Medicare claims and events data. Therefore, States interested in requesting MA encounter data will not need to complete and submit a new data agreement for MA encounter data; instead, they will submit a use justification for the new data request and update their existing data agreement form. We note that requesting Medicare data is voluntary and that not all States currently request Medicare FFS claims or prescription drug events data for coordinating care of dually eligible beneficiaries, and of those States that request Medicare data, not all States request the same Medicare data files. As with Medicare FFS claims and events data, States will maintain the ability to choose if and when they want to request MA encounter data for existing or newly expanded uses. We further note that the process for States to submit a request for data and for CMS to review these requests are part of standard operations for CMS and many States. Additionally, we have technical assistance support to help States navigate the data request process and maintain their data agreements.

In the August 2014 final rule, when we established several of the current provisions around CMS disclosure of MA encounter data, we explained that we had determined that ''the proposed regulatory amendments would not impose a burden on the entity requesting data files.'' (79 FR 50445). Similarly, for the proposed refinements to the approved data uses and the data disclosure in the November 2023 proposed rule, we did not anticipate a significant change in burden for States.

In the November 2023 proposed rule, we solicited comments specific to our analysis of no impact on paperwork burden. We received no comments on this analysis. We are finalizing the ICR narrative as is.

6. ICRs Regarding Standards for Determining Whether a Special Supplemental Benefit for the Chronically Ill Has a Reasonable Expectation of Improving the Health or Overall Function of an Enrollee (§ 422.102(f)(3)(iii) and (iv) and (f)(4))

The following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

As explained in section IV.B. of this rule, due to increased offering of SSCBI, we are finalizing our proposal with modification to: (1) require the MA organization to establish, by the date on which it submits its bid, a bibliography of ''relevant acceptable evidence'' related to the item or service the MA

organization would offer as an SSBCI during the applicable coverage year; (2) require that an MA plan follow its written policies (that must be based on objective criteria) for determining eligibility for an SSBCI when making such determinations, and prohibit plans from modifying policies like utilization management requirements, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations; (3) require the MA plan to document SSBCI eligibility determinations, including approvals and denials; and (4) codify CMS's authority to decline to accept a bid due to the SSBCI the MA organization includes in its bid and to review SSBCI offerings annually for compliance, taking into account the evidence available at the time. We now estimate burden.

Item (4) is a burden specific to CMS and is therefore not subject to collection of information requirements. We choose to combine the burdens of: (1) and (2) as the evidence gathered under (1) will likely directly inform the criteria established under (2).

In estimating the impact, we note the following: (i) Not all contracts offer SSBCI (only about 40 percent); (ii) not all plan benefit packages (PBP) offer them (only about 20 percent); (iii) the distribution of the number of SSBCI per PBP is highly skewed (for example, for 2023 the average is about 8 while the median is 2); and (iv) both the median and 3rd quartile of the number of SSBCI per PBP reflect only a handful of SSBCI offered.

Based on internal CMS data we are using 10,000 SSBCI per year for the three-year estimates required by the Collection of Information requirements. To comply with the requirements of the provision that would require bibliography, a staff member knowledgeable in health should be deployed. We are using a registered nurse. Establishing a bibliography requires research, including reading papers and assessing their quality. Because the bibliography would contain only citations and copies of the necessary information, and not any narrative, we assume these activities would take a day of work (8 hours), which can refer to the aggregate activity of 1 nurse working 8 hours or 2 nurses working 4 hours each. A plan would need to review and update its bibliography annually. We assume that updating an existing bibliography would take less time than establishing an initial bibliography. We estimate that it would take 8 hours each year to update existing bibliographies.

To create a single line-item, we estimate that it would take 8 hours at $85.60/hr for a registered nurse to create the bibliography for one plan. Thus, the median burden per plan is 16 hours (8/hr per SSBCI * a median of 2 SSBCI) at a cost of $1,397 ($85.60/hr *16 hr). The aggregate cost across all plans would be 80,000 hours (8 hours per SSBCI * 10,000 aggregate SSBCI) at a cost of $6,848,000 (80,000 * $85.60/hr).

Regarding the requirement for plans to document approvals and denials of SSCBI eligibility, it is reasonable that plans already have this information stored in their systems. Thus, we assume that plans will need to compile data already collected into a report or other transmittable format. We estimate that it would take 2 hours at $98.84/hr for a programmer to complete the initial software update. In aggregate, we estimate a one-time burden of 1,548 hours (774 plans × 2 hr) at a cost of $153,004 (1,548 hr × $98.84/hr).

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

7. ICRs Regarding Mid-Year Notice of Unused Supplemental Benefits (§§ 422.111 and 422.2267)

When ready, the following changes will be posted for public review under control number 0938–TBD (CMS–10893) using the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. The 60-day notice will publish after the publication of this final rule and when the model notice has been completed. In the meantime, we are scoring the burden to identify the expected PRA-related costs. At this time, the OMB control number has not been determined, but it will be assigned by OMB upon its approval of our new collection of information request.

We note that in the proposed rule, we stated that the changes would be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). However, because (as discussed in the preamble) we intend to create a model notice which will require additional burden analysis and scoring, CMS believes providing the additional 60-day and 30-day public notices through a standalone PRA package will allow both the agency and stakeholders to give the model notice more comprehensive and thoughtful consideration.

Per CMS regulations at § 422.101, MA organizations are permitted to offer mandatory supplemental benefits, optional supplemental benefits, and special supplemental benefits for the chronically ill (SSBCI). The number of supplemental benefit offerings has risen significantly in recent years, as observed through trends identified in CMS's annual PBP reviews. At the same time, CMS has received reports that MA organizations have observed low utilization for many of these benefits by their enrollees and it is unclear whether plans are actively encouraging utilization of these benefits by their enrollees. The finalization of this new requirement will establish a minimum requirement for MA organizations to conduct outreach to enrollees to encourage utilization of supplemental benefits.

We have several concerns about this low utilization of some supplemental benefits. First, we are concerned that beneficiaries may be making enrollment decisions based on the allure of supplemental benefits that are extensively marketed by a given MA plan during the annual election period (AEP), but once enrolled in the plan the beneficiaries do not fully utilize, or utilize at all, those supplemental benefits during the plan year. Such under-utilization of supplemental benefits may hinder or nullify any potential health benefit value offered by these extra benefits. Additionally, section 1854(b)(1)(C) of the Act requires MA plans to provide the value of the MA rebates to enrollees; per CMS regulations at § 422.266, MA rebates must be provided to enrollees in the form of payment for supplemental benefits (including reductions in cost sharing for Part A and B benefits compared to Original Medicare), or payment of Part B or D premiums. Therefore, CMS has an interest in ensuring that the MA rebate is provided to enrollees in a way that they can benefit from the value of these rebate dollars.

Hence, we are finalizing the proposal to require plans engage in targeted outreach to inform enrollees of their unused supplemental benefits they have not yet accessed. This targeted outreach aims to increase utilization of these benefits, as it would increase enrollees' awareness of the supplemental benefits available to them.

This new requirement will ensure that a minimum outreach effort is conducted by MA organizations to inform enrollees of supplemental benefits available under their plans they have not yet accessed. Beginning January 1, 2026, MA organizations must mail a mid-year notice annually, but not sooner than June 30 and not later than July 31 of the

plan year, to each enrollee with information pertaining to each supplemental benefit available through the plan year that the enrollee has not accessed, by June 30 of the plan year. For each covered mandatory supplemental benefit and optional supplemental benefit (if elected) the enrollee is eligible for but has not accessed, the MA organization must list in the notice the information about each such benefit that appears in the Evidence of Coverage (EOC). For SSBCI, the notice must also include the proposed new SSBCI disclaimer. Finally, all notices must include the scope of the supplemental benefit(s), applicable cost-sharing, instructions on how to access the benefit(s), applicable information on use of any network providers application information for each available benefit consistent with the format of the EOC, and a toll-free customer service number and, as required, corresponding TTY number to call if additional help is needed.

When estimating the burden of this provision, we first noted that plans already keep track of utilization patterns of benefits by enrollees. The primary burden is therefore dissemination of notices. In this regard, there are three burdens: (1) a one-time update to software systems to produce reports; (2) a one-time update of policies and procedures; and (3) the printing and sending of notices to beneficiaries.

- We estimate that a software developer working at $127.82/hr would take about 4 hours to update systems. In aggregate we estimate a one-time burden of 3,096 hours (774 prepaid contracts * 4 hr/contract) at a cost of $395,731 (3,096 hr * $127.82/hr).
- We estimate that a business operations specialist working at $79.50/hr would take 1 hour to update of policies and procedures. In aggregate we estimate a one-time burden of 774 hours (774 prepaid contracts * 1 hour/contract) at a cost of $61,533 (774 hr * $79.50/hr).
- The major cost would be printing and dissemination. There have been several recent CMS rules in which such printing and dissemination has been estimated.

A recent estimate was presented in proposed rule, ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications,'' CMS–4201–P, (87 FR 79452) published on December 27, 2022. We have checked the prices listed there for paper and toner and found them consistent with current pricing.

- *Cost of paper:* We assume $3.50 for a ream of 500 sheets. The cost for one page is $0.007 ($3.50/500 sheets).
- *Cost of toner:* We assume a cost of $70 for 10,000 pages. The toner cost per page is $0.007 ($70/10,000 pages).
- *Cost of postage:* As a result of comments discussed in detail at the end of this ICR we are revising our estimate of cost of postage to $0.64, the cost of 1st class metered postage for the first ounce per enrollee. The mailings have personally identifiable information necessitating first class mailings.
- *Cost of envelopes:* Because we are not using bulk mailings, we require envelopes. Accordingly, 10,000 envelopes cost approximately $440, resulting in a cost per envelope of $0.044.

To make a final calculation we need to estimate the number of enrollees affected and the average number of pages involved.

We believe it reasonable that every MA enrollee has at least one supplemental benefit that they have not used. Since PDPs do not provide supplemental benefits, we would require 32 million mailings for the 32 million enrollees in prepaid contracts. We do not have a definite basis for estimating the average number of pages needed per enrollee. Some enrollees may only require 1 page listing 1 to 3 benefits with all information required by CMS. Some enrollees may require more. We are estimating 3 pages on average per enrollee. Consistent with a 3-page average we are not estimating extra postage (extra postage would first be required for mailings of seven or more pages and we have no way of estimating how many plans if any would require an excess of 6 pages).

Therefore, costs per mailing are $0.726 per mailing ([3 * $0.007 for paper] + [3 * $0.007 for toner] + $0.64 for postage + $0.044 for an envelope). The aggregate non-labor cost for 32 million mailings of one page would be $23,232,000 (32,000,000 * $0.726).

We received the following comment:

Comment: For various reasons, some commenters believed CMS underestimated the costs associated with printing and mailing documents that consist of personalized information; for example, a commenter stated their printing costs were always higher for personalized materials; some commenters estimated average document lengths would be much higher than the CMS estimate, from 18 to over 20 pages.

Response: With regard to the cost of mailing, we thank the commenters for pointing out the increased cost for mailing personalized materials and agree. Therefore, we revised mailing costs to reflect first order postage and the cost of envelopes versus bulk mailing consistent with HIPAA requirements.

With regard to length, the Mid-Year Notice of Unused Supplemental Benefits is intended to be a concise and user-friendly document, and CMS is committed to the formulation of a model design that is both informative and succinct. The length of the document will ultimately vary from enrollee to enrollee, depending on individual utilization and the number of supplemental benefits offered under the plan.

8. ICRs Regarding New Requirements for the Utilization Management Committee (§ 422.137)

The following changes will be submitted to OMB for approval under control number 0938–0964 (CMS–10141).

As discussed in section IV.F. of this rule, we are adding new requirements related to the Utilization Management (UM) Committee established at § 422.137.

We are finalizing at § 422.137(c)(5) to require a member of the UM committee have expertise in health equity. Reviewing UM policies and procedures is an important beneficiary protection, and adding a committee member with expertise in health equity will ensure that policies and procedures are reviewed from a health equity perspective. We estimate that a compliance officer working at $74.02/hr would take 30 minutes for a one-time update of the policies and procedures. In aggregate, we estimate a one-time burden of 483 hours (966 plans * 0.5 hr) at a cost of $35,752 (483 hr * $74.02/hr).

We are finalizing at § 422.137(d)(6) to require the UM committee to conduct an annual health equity analysis of the use of prior authorization and publicly post the results of the analysis to the plan's website. The analysis will examine the impact of prior authorization, at the plan level, on enrollees with one or more of the following social risk factors: (i) receipt of the low-income subsidy for Medicare Part D, or being dually eligible for Medicare and Medicaid, or (ii) having a disability, as reflected in CMS's records regarding the basis for Medicare Part A entitlement. To gain a deeper understanding of the impact of prior authorization practices on

enrollees with the specified SRFs, the proposed analysis must compare metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. The metrics that must be stratified and aggregated for all items and services for this analysis are as follows:

- The percentage of standard prior authorization requests that were approved.
- The percentage of standard prior authorization requests that were denied.
- The percentage of standard prior authorization requests that were approved after appeal.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved.
- The percentage of expedited prior authorization requests that were approved.
- The percentage of expedited prior authorization requests that were denied.
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations.
- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations.

We estimate that a software and web developer working at an hourly wage of $120.14/hr would take 8 hours at a cost of $961 (8 hr * $120.14/hr) for developing the software necessary to collect and aggregate the health equity analysis data required to produce the report. In aggregate, we estimate a one-time burden of 7,728 hr (966 plans * 8 hr/plan) at a cost of $928,442 (7,728 hr * $120.14/hr).

Annually, the report must be produced and posted to the plan's website. The health equity analysis and public reporting must be easily accessible, without barriers, including but not limited to ensuring the information is available: free of charge; without having to establish a user account or password; without having to submit personal identifying information (PII); to automated searches and direct file downloads through a link posted in the footer on the plan's publicly available website, and includes a txt file in the root directory that includes a direct link to the machine-readable file of public reporting and health equity analysis to establish and maintain automated access. We believe that making this information more easily accessible to automated searches and data pulls and capturing this information in a meaningful way across MA organizations will help third parties develop tools and researchers conduct studies that further aid the public in understanding the information. We assume the plans' programmers will make this an automated process accessing data already in the plans' systems; hence, we estimate minimal time to produce and inspect the report prior to posting. We estimate a Business Operations Specialist working at $79.50/hr would take 0.1667 hr (10 minutes) to produce, inspect, and post the report at a cost of $13 ($79.50/hr * 0.1667 hr). In the aggregate, we estimate an annual burden of 161 hours (966 plans * 0.1667 hr/plan) at a cost of $12,800 (161 hr * $79.50/hr).

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

9. ICRs Regarding Agent Broker Compensation (§ 422.2274)

Since we are scoring this provision as having no burden, we are not submitting any changes to OMB. The active requirements and burden estimates are approved by OMB under control number 0938–0753 (CMS–R–267).

Currently, agents and brokers are compensated by MA plans at national fair market value (FMV) base rate a base rate with a maximum of $611 per enrollee, plus administrative payments. As explained in section X.X of this finalized rule, separate administrative payments are being eliminated but the base rate per enrollee is increasing by $100 per enrollee for new enrollments in MA plans, beginning with contract year 2025. We are also eliminating administrative payments for PDPs and increasing their base rate by $100. For each renewal, agents and brokers receive compensation equal up to 50 percent of the compensation rate so that for MA and PDP enrollees' agents and brokers would receive up to $50 more per enrollee renewal, as permitted under § 422.2274(d)(3).

These increases of $100 per enrollee for MA plan enrollment, and up to $50 for renewals of MA and PDP plans are not costs but rather transfers. The money that formerly was being paid for administrative is sufficient to cover these increases. While we do not have detailed quantitative information on payments, many commenters, from both those who pay as well as those who receive, submitted overall quantitative payment recommendations for administrative payments. The numbers range from $50 to about $500. In other words, currently, several hundred dollars is already being paid per enrollee for administrative payments; this finalized regulation, requiring a payment of $100 per new enrollment would not, according to most commentators, increase net payments but transfer a portion of them to increased compensation.

The differences between this finalized version and the proposed version are explained below in our response to comments.

Comment: Many commenters provided feedback on our estimates for administrative costs in the proposed rule. These comments were both purely qualitative (for example, too low), semi-qualitative (for example, the variance and volatility of the estimates preclude using one number), and quantitative with a wide range of $50 to $500 per enrollee. Comments were submitted by individuals and organizations that that both receive these payments as well as those that make payments.

The comments also included a variety of line items besides the training and transcription items discussed in the NPRM, which commenters believed should be included in estimating the minimum necessary cost of administrative activities.

Response: We thank the commenters for their detailed observations. After careful consideration of these comments several changes were made from the NPRM. We adopted a total cost approach in the Final Rule versus the line-item-approach used in the NPRM. Generally, line-item approaches are appropriate when variability is small and detailed quantitative information is available. This is not the case for agent-brokers and therefore we adopted a total cost approach. We used the wide range of total costs supplied by the commenters. The reasons for adopting the $100 total cost are detailed in section X.X of the preamble. Our basic goals were to provide sufficient funds so that payments for legitimate MA and PDP enrollment could be made while excessive funding being used for other purposes was not encouraged. Because the current administrative payments rates are estimated to be significantly higher than the flat $100 increase to encompass these administrative payments, we have classified this $100 payment as a transfer rather than as a new cost.

As a result of comments, we are finalizing our impact analysis as a transfer with no additional cost.

10. ICRs Regarding Rationales for an Exception From the Network Adequacy Requirements (§ 422.116(b) Through (e))

The following changes will be submitted to OMB for approval under

control number 0938–1346 (CMS–10636).

Historically, the industry has stated that CMS's current network adequacy criteria under § 422.116 create challenges for facility-based Institutional Special Needs Plans (I–SNP) because facility-based I–SNP enrollees access services and seek care in a different way than enrollees of other plan types. Thus, we are finalizing provisions to broaden our acceptable rationales for facility-based I–SNPs when submitting a network exception under § 422.116(f). The first new basis for an exception request is that a facility-based I–SNP is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in facility-based I–SNPs receive care. Facility-based I–SNPs may also request an exception from the network adequacy requirements in § 422.116(b) through (e) if: The I–SNP covers Additional Telehealth Benefits (ATBs) consistent with § 422.135 and uses ATB telehealth providers of the specialties listed in paragraph (d)(5) to furnish services to enrollees; when substituting ATB telehealth providers of the specialties listed in paragraph (d)(5) for in-person providers, the facility-based I–SNP would fulfill the network adequacy requirements in § 422.116(b) through (e); the I–SNP complies with § 422.135(c)(1) and (2) by covering in-person services from an out-of-network provider at in-network cost sharing for the enrollee who requests in-person services instead of ATBs; and the I–SNP provides substantial and credible evidence that the enrollees of the facility-based I–SNP receive sufficient and adequate access to all covered benefits.

To determine the potential burden, we considered the one-time burden for MA organizations to update policies. The other burden associated with this provision involve updates to the HPMS system, which is done by CMS and its contractors and hence is not subject to the requirements of the PRA.

MA organizations that offer facility-based I–SNPs are already required to conduct work related to network adequacy reviews that happen during the initial or service area expansion application process, or every 3 years for the triennial review. Further, MA organizations that offer facility-based I–SNPs should already have measures in place to submit data to meet CMS network adequacy review requirements to CMS, so there is no additional burden.

We understand that MA organizations will need to update their policies and procedures related to broadening our acceptable rationales for facility-based I–SNPs when submitting a network exception. We estimate that a business operations specialist working at $79.50/hr would take 5 minutes (0.0833 hr) to update policies and procedures related to this task. In aggregate, we estimate a one-time burden of 0.8 hour (10 facility-based I–SNP contracts * 0.0833 hr) at a cost of $64 (0.8 hr * $79.50/hr).

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

11. ICRs Regarding Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization (§§ 422.503, 422.504, 422.514, 422.530, and 423.38)

a. MA Plan Requirements and Burden

In section VIII.F. of this final rule, we are amending §§ 422.514(h), 422.503(b), 422.504(a), and 422.530(c). Section 422.514(h) will require an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, where that MA organization offers a D–SNP (and that parent organization also contracts with the State as a Medicaid managed care organization (MCO) in the same service area), to only offer one D–SNP for full-benefit dually eligible individuals. We are finalizing the regulation at § 422.514(h) with a minor technical modification at § 422.514(h)(1) to correct the terminology to use the term ''full-benefit dual eligible individual(s)'' where necessary. We are finalizing § 422.514(h)(2) with a modification to clarify that any D–SNP(s) subject to enrollment limitations in § 422.514(h)(1) may only enroll (or continue coverage of people already enrolled) individuals also enrolled in (or in the process of enrolling in) the Medicaid MCO beginning in 2030. We are finalizing with modifications our proposal at § 422.514(h)(3)(i) to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, to offer more than one D–SNP for full-benefit dually eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO only when a SMAC requires it in order to differentiate enrollment into D–SNPs by age group or to align enrollment in each D–SNP with the eligibility criteria or benefit design used in the State's Medicaid managed care program(s). We are also finalizing with technical modifications our proposed amendment at § 422.514(h)(3)(ii) to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization that offers both HMO D–SNP(s) and PPO D–SNP(s) to continue to offer both the HMO and PPO D–SNPs only if the D–SNP(s) not subject to the enrollment limitations at § 422.514(h)(1) no longer accepts new full-benefit dual eligible enrollment in the same service area as the D–SNP affected by the new regulations at §§ 422.504(a)(20) and 422.514(h). This finalized provision will also require the affected D–SNP to limit new enrollment to individuals enrolling in, or in the process of enrolling in, the affiliated Medicaid MCO effective 2027, and further require the D–SNP to limit all enrollment to individuals enrolled in, or in the process of enrolling in the affiliated MCO effective 2030. A new contract provision that we are finalizing at § 422.503(b)(8) will prohibit parent organizations from offering a new D–SNP when that D–SNP would result in noncompliance with the regulation finalized at § 422.514(h). Additionally, the finalized regulation at § 422.504(a)(20) will require compliance with § 422.514(h). To support parent organizations seeking to consolidate D–SNPs, we are also finalizing § 422.530(c)(4)(iii) that will provide a new crosswalk exception to allow D–SNP parent organizations to crosswalk enrollees (within the same parent organization and among consistent plan types) where they are impacted by the requirements at § 422.514(h).

The provisions we are finalizing at §§ 422.514(h) and 422.530(c)(4)(iii) will create burden for MA organizations where they offer multiple D–SNPs in a service area with a Medicaid MCO. Impacted MA organizations will need to non-renew or (more likely) combine plans and update systems as well as notify enrollees of plan changes. We expect that MA organizations will need two software engineers with each working 4 hours at $127.82/hr to update software in the first year with no additional burden in future years and one business operations specialist working 4 hours at $79.50/hr to update plan policies and procedures in the first year with no additional burden in future years. In aggregate, we estimate a one-time burden (for plan year 2027) of 600 hours (50 plans * 12 hr/plan) at a cost of $67,028 (50 plans × [(8 hr * $127.82/hr) + (4 hr * $79.50/hr)]). The aforementioned changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

We are finalizing a proposal to redesignate § 423.38(c)(35) as § 423.38(c)(36) and finalizing with modification a new integrated care special enrollment period (SEP) at § 423.38(c)(35). This final policy narrows the scope from the proposed policy that would have allowed enrollment in any month into FIDE SNPs, HIDE SNPs, and AIPs for those dually eligible individuals who meet the qualifications for such plans. Instead, the integrated care SEP that we are finalizing at § 423.38(c)(35) will only be available to facilitate aligned enrollment as defined at § 422.2 and are clarifying in § 423.38(c)(35)(i) that the SEP is available only for full-benefit dual eligible individuals as defined in § 423.772. The integrated care SEP at § 423.38(c)(35) will require plans to update guidance and train staff. That new burden would be limited to FIDE SNPs, HIDE SNPs, and AIPs. We expect that plans will need one software engineer working 4 hours at $127.82/hr to update software and one business operations specialist working 4 hours at $79.50/hr to update plan policies and procedures and train staff in the first year with no additional burden in future years. In aggregate, we estimate a one-time burden (for plan year 2025) of 904 hours (113 plans * 8 hr/plan) at a cost of $93,709 (113 plans × [(4 hr * $127.82/hr) + (4 hr * $79.50/hr)]). We do not anticipate any new burden to plans after the initial year. The aforementioned changes will be submitted to OMB for approval under control number 0938–0964 (CMS–10141).

b. Medicare Enrollee Requirements and Burden

At § 423.38(c)(4) we are replacing the current quarterly special enrollment period (SEP) with a one-time-per month SEP for dually eligible individuals and others enrolled in the Part D low-income subsidy program to elect a standalone PDP. At § 423.38(c)(35), we proposed a new integrated care SEP to allow dually eligible individuals to elect an integrated D–SNP on a monthly basis and are finalizing this proposal with a modification that will narrow the scope of the SEP.

The amendments we are finalizing at § 423.38(c)(4) and (35) will affect the circumstances in which individuals can change plans. Individuals can complete an enrollment form to effectuate such changes, and we have previously estimated that the forms take 0.3333 hours (20 min) to complete as cited under OMB control number 0938–1378 (CMS–10718). However, Medicare beneficiaries make enrollment choices currently, and we do not expect the overall volume of enrollment selections to materially change with our finalized provisions. Therefore, we do not believe the provisions at § 423.38(c)(4) and (35) will impact the burden estimates that are currently approved under 0938–1378 (CMS–10718). Similarly, we are not finalizing any changes to that collection's currently approved forms.

In section XI. of this rule, we describe the impacts related to the expected enrollment shift from non-integrated MA–PDs into FIDE SNPs, HIDE SNPs, and AIPs over time as more D–SNPs align with Medicaid MCOs.

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

The following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267) consistent with burden on MA plans identified as D–SNP look-alikes under § 422.514(d) through (e). While mentioned below, we are not making any changes under control number 0938–0935 (CMS–10237) and control number 0938–1051 (CMS–10260).

As described in section VIII.J. of this final rule, we are reducing the D–SNP look-alike threshold from 80 percent to 60 percent over a two-year period. We are finalizing a limitation on non-SNP MA plans with 70 or greater percent dually eligible individuals for CY 2025. For CY 2026, we are reducing the threshold from 70 percent to 60 percent or greater dually eligible enrollment as a share of total enrollment. This incremental approach will minimize disruptions to dually eligible individuals and allow plans and CMS to operationalize these transitions over a two-year period.

We will maintain processes to minimize disruption for the enrollees in plans affected by this change. We are applying the existing transition processes and procedures at § 422.514(e) to non-SNP MA plans that meet the D–SNP look-alike contracting limitation of 70 percent or greater dually eligible individuals effective plan year 2025 and 60 percent or greater dually eligible individuals effective plan year 2026. Consistent with the initial years of implementation of the D–SNP look-alike contract limitations with the 80-percent threshold, maintaining these transition processes and procedures will help to minimize disruption for current enrollees as a result of the prohibition on contract renewal for existing D–SNP look-alikes. For plan year 2027 and subsequent years, we are limiting the § 422.514(e) transition processes and procedures to D–SNP look-alikes transitioning dually eligible enrollees into D–SNPs. Based on our experience with D–SNP look-alike transitions through plan year 2024, the vast majority of enrollees transitioned to other MA–PDs under the same parent organization as the D–SNP look-alike.

MA organizations can utilize other CMS processes to transition D–SNP look-alike enrollees to other MA plans. For example, an MA organization can utilize the CMS crosswalk process if it is transitioning the full D–SNP look-alike enrollment to one non-SNP plan benefit package (PBP) of the same type offered by the same MA organization under the same contract and the requirements at § 422.530 for a crosswalk are met. An MA organization moving the entire enrollment of the D–SNP look-alike PBP to another PBP of the same type under the same contract may structure this action as a consolidation of PBPs and use the crosswalk for consolidated renewal process, under § 422.530(b)(1)(ii). An MA organization may utilize the crosswalk exception process, subject to CMS approval, at § 422.530(c)(2) to transition the entire enrollment of the MA contract (including the D–SNP look-alike) to another MA contract (of the same type) offered by another MA organization with the same parent organization as part of a contract consolidation of separate MA contracts. While multiple options exist for MA organizations to transition D–SNP look-alike enrollees to other non-SNP MA plans, these pathways are not available for moving enrollees to D–SNPs.

Using data from the 2023 contract year, we estimate that there are 30 non-SNP MA plans that have enrollment of dually eligible individuals of 70 percent through 79.9 percent of total enrollment and 40 non-SNP MA plans that have enrollment of dually eligible individuals of 60 percent through 69.9 percent of total enrollment. As of January 2023, the 30 non-SNP MA plans had total enrollment of 53,334 enrollees and the 40 non-SNP MA plans had 92,100 enrollees collectively. Of the 30 non-SNP MA plans with 70–79.9 percent dually eligible enrollment, 28 are in States where for contract year 2023 there are D–SNPs or comparable managed care plans and would be subject to § 422.514(d). Of the 40 non-SNP MA plans with 60–69.9 percent dually eligible enrollment, all are in States where for contract year 2023 there are D–SNPs or comparable managed care plans and would be subject to § 422.514(d). As of January 2023, these 68 plans had total enrollment of 145,434 for contract year 2023. If these plans all have the same

enrollment pattern in 2024, MA organizations will need to non-renew for plan year 2025 those 28 plans that exceed the criteria we are finalizing in this rulemaking to lower the threshold to 70 percent for plan year 2025. Similarly, MA organizations with plans that exceed the criteria we are finalizing in this rulemaking to lower the threshold to 60 percent for plan year 2026 would need to non-renew 40 plans for plan year 2026. Each MA organization will have the opportunity to make an informed decision to transition enrollees into another MA–PD plan (offered by it or by its parent organization) by: (1) identifying, or applying, or contracting for, a qualified MA–PD plan, including a D–SNP, in the same service area; or (2) creating a new D–SNP through the annual bid submission process. Consistent with our experience with D–SNP look-alikes non-renewing for plan years 2021 through 2024, we expect the vast majority of D–SNP look-alike enrollees to be transitioned into a plan offered by the same parent organization as the D–SNP look-alike, and we expect in rare instances that the non-renewing plan may choose to not transition enrollees. In plan year 2023, 9 of the 47 D–SNP look-alikes transitioned approximately 3,300 enrollees to Traditional Medicare, which accounted for less than 2 percent of total enrollees transitioned from D–SNP look-alikes. In plan year 2024, 3 of the 12 D–SNP look-alikes transitioned approximately 1,414 enrollees to Traditional Medicare, which accounted for 7 percent of total enrollees transitioned from D–SNP look-alikes. The changes required of MA organizations based on this rule will impact D–SNP look-alikes and their enrollees (see section VIII.J. of this final rule). While we cannot predict the actions of each affected MA organization with 100 percent certainty, we base our burden estimates on the current landscape of D–SNP look-alikes and our experience with transitions of D–SNP look-alikes through plan year 2024.

a. MA Plan Requirements and Burden

As indicated, the following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

At § 422.514(e), we established a process for an MA organization with a D–SNP look-alike to transition individuals who are enrolled in its D–SNP look-alike to another MA–PD plan offered by the MA organization, or by the same parent organization as the MA organization, to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. This process allows, but does not require, the MA organization to transition dually eligible enrollees from D–SNP look-alikes into D–SNPs and other qualifying MA–PD plans for which the enrollees are eligible without the transitioned enrollees having to complete an election form. This transition process is conceptually similar to the ''crosswalk exception'' procedures at § 422.530(a) and (b); however, § 422.514(e) allows the transition process to apply across contracts or legal entities and from non-SNP to SNPs provided that the receiving plan is otherwise of the same plan type (for example, HMO or PPO) as the D–SNP look-alike.

Based on the experience of D–SNP look-alike transitions through plan year 2024, we believe 94 percent of D–SNP look-alikes for plan years 2025 and 2026 will be able to move enrollees into another MA–PD plan using the transition process established at § 422.514(e) or existing crosswalk functionality at § 422.530 and will choose to transition enrollment for plan years 2025 and 2026. All are in States where for contract year 2023 there are D–SNPs or comparable managed care plans that would be subject to § 422.514(d). Therefore, we are assuming the burden of 26 of the 28 non-SNP MA plans with 70–79.9 percent dually eligible enrollment and offered in a State with a D–SNP would transition enrollees for plan year 2025 (for a January 2025 effective date) and 38 of the 40 non-SNP MA plans with 60–69.9 percent dually eligible enrollment would transition enrollees for plan year 2026 (for a January 2026 effective date). In 2027 and subsequent years, we estimate that 12 plans per year would be identified as D–SNP look-alikes under § 422.514(d). Consistent with our assumptions for plan years 2025 and 2026, we assume 94 percent of D–SNP look-alikes for plan year 2027, which is 11 D–SNP look-alikes, will be able to move enrollees into another MA–PD plan. Consistent with our estimates from the June 2020 final rule, we estimate each plan will take a one-time amount of 2 hours at $79.50/hr for a business operations specialist to submit all enrollment changes to CMS necessary to complete the transition process. D–SNP look-alikes that transition enrollees into another non-SNP plan will take less time than D–SNP look-alikes that transition eligible beneficiaries into a D–SNP because they would not need to verify enrollees' Medicaid eligibility. The 2-hour time estimate accounts for any additional work to confirm enrollees' Medicaid eligibility for D–SNP lookalikes transitioning eligible enrollees to a D–SNP. Based on the previous discussion, the estimates for the burden for MA organizations to transition enrollees to other MA–PD plans during the 2025–2027 plan years is summarized in Table J7.

TABLE J7: BURDEN FOR TRANSITIONING D-SNP LOOK-ALIKE ENROLLEES INTO ANOTHER MA-PD (FOR YEARS 2025–2027)

Year	Number of Plans	Time per Response (hr)	Total Time (hr)	Total Cost (using $79.50/hr for a business operations specialist) ($)
2025	26	2	52	4,134
2026	38	2	76	6,042
2027	11	2	22	1,749
Total	75	6	150	11,925
Average	25 (75/3)	2 (6/3)	50 (150/3)	3,975 (11925/3)

Based on our experience through plan year 2024, we expect the vast majority of MA organizations with non-SNP MA plans with dually eligible enrollment between 60 and 80 percent of total enrollment also have an MA–PD plan with a premium of $0 or a D–SNP in the same service area as the D–SNP look-alike. Based on 2023 plan year data, of the 30 non-SNP MA plans with 70 to 79.9 percent dually eligible enrollment, 19 of these plans (63 percent) have a D–SNP within the same service area or nearly the same service area. Also based on 2023 plan year data, of the 40 non-SNP MA plans with 60 to 69.9 percent dually eligible enrollment, 24 of these plans (60 percent) have a D–SNP within the same service area or nearly the same service area. An MA organization with one of these non-SNP MA plans could expand its service area for an existing MA–PD plan or D–SNP. The MA organizations with the non-SNP MA plans between 60 and 79.9 percent dually eligible enrollment already have the opportunity to establish a D–SNP and expand their service areas. Any burden associated with these MA organizations establishing new D–SNPs and/or expanding their service areas is already captured under currently approved burden under control number 0938–0935 (CMS–10237) for creating a new MA–PD plan to receive non-SNP MA plan enrollees. In this regard, we are not making any changes under that control number.

Per § 422.514(e)(2)(ii), in the Annual Notice of Change (ANOC) that the MA organization must send consistent with § 422.111(a), (d), and (e), the MA organization will be required to describe changes to the MA–PD plan benefits and provide information about the MA–PD plan into which the individual is enrolled.

Consistent with § 422.111(d)(2), enrollees will receive this ANOC describing the change in plan enrollment and any differences in plan enrollment at least 15 days prior to the first date of the annual election period (AEP). As each MA plan must send out the ANOC to all enrollees annually, we do not estimate that MA organizations will incur additional burden for transitioned enrollees. The current burden for the ANOC is approved by OMB under control number 0938–1051 (CMS–10260). In this regard, we are not making any changes under that control number.

We expect one plan for plan year 2025 and two plans for plan year 2026 will be required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2) and described at § 422.514(e)(4), as we anticipate—based on our experience with transitions through plan year 2024—not all D–SNP look-alikes will be able to transition their enrollees into another MA–PD plan (or plans).

b. Enrollee Requirements and Burden

In 2027 and subsequent years, we estimate that 12 plans per year would be identified as D–SNP look-alikes under § 422.514(d). We base our estimate on the fact that there are 12 D–SNP look-alikes for plan year 2024, which is the first year following the phase in of the 80-percent threshold. We expect the policy we are finalizing in this rule to lower the threshold for identifying D–SNP look-alikes from 80 percent to 60 percent will increase the number of plans identified as D–SNP look-alikes. However, we expect this increase to be offset by a reduction in D–SNP look-alikes due to our changes to the § 422.514(e) transition process, which will limit use of the § 422.514(e) transition process to D–SNP look-alikes transitioning dually eligible enrollees into D–SNPs. Under our provision, D–SNP look-alikes transitioning effective for plan year 2025 and plan year 2026—including the newly identified D–SNP look-alikes based on the threshold lowered to 70 percent and then 60 percent—can continue to use the existing transition process under § 422.514(e). Once the newly identified D–SNP look-alikes at the lower thresholds complete their transitions for plan year 2025 and plan year 2026, the § 422.514(e) transition process can only be used for D–SNP look-alike transitioning enrollees into D–SNPs. We believe this limit will give MA organizations a stronger incentive to avoid creating D–SNP look-alikes, due to the more limited opportunity for these plans to transition enrollees to non-D–SNPs. The limit on the § 422.514(e) transitions will be effective for plan year 2027 and subsequent years. We believe that these 12 D–SNP look-alikes will non-renew and transition their enrollment into a D–SNP or other MA–PD plan. The annual burden is summarized in Table J7.

As indicated, the following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

An individual transitioned from a D–SNP look-alike to another MA–PD plan may stay in the MA–PD plan receiving the enrollment or, using the AEP or another enrollment period (such as the MA OEP), make a different election. The enrollees may choose new forms of coverage for the following plan year, including a new MA–PD plan or receiving services through Traditional Medicare and enrollment in a stand-alone PDP. Because the enrollment transition process is effective on January 1 and notices would be provided during the AEP, affected individuals have opportunities to make different plan selections through the AEP (prior to January 1) or the MA open enrollment period (OEP) (after January 1). Affected individuals may also qualify for a special enrollment period (SEP), such as the SEP for plan non-renewals at § 422.62(b)(1) or the SEP for dually eligible/LIS beneficiaries at § 423.38(c)(4), which we are revising as discussed in section VIII.F. of this final rule. Based on our experience with D–SNP look-alike transitions through plan year 2024, we estimate that 98 percent of the 53,334 D–SNP look-alike enrollees (52,267 enrollees = 53,334 enrollees × 0.98) in the 30 non-SNP MA plans with dually eligible enrollment of 70 to 79.9 percent and 98 percent of the 92,100 D–SNP look-alike enrollees (90,258 enrollees = 92,100 enrollees × 0.98) in the 40 non-SNP MA plans with dually eligible enrollment of 60 to 69.9 percent would transition into another plan under the same parent organization as the D–SNP look-alike. Of these 142,525 transitioning enrollees (52,267 enrollees + 90,258 enrollees), our experience with D–SNP look-alike transitions through plan year 2023 suggests that 14 percent will select a new plan or the Traditional Medicare and PDP option rather than accepting the transition into a different MA–PD plan or D–SNP under the same MA organization as the D–SNP in which they are currently enrolled. For plan year 2025, we estimate that 7,317 enrollees (52,2677 transitioning D–SNP look-alike enrollees * 0.14), will opt out of the new plan into which the D–SNP look-alike transitioned them. For plan year 2026, we estimate that 12,636 enrollees (90,258 transitioning D–SNP look-alike enrollees * 0.14), will opt out of the new plan into which the D–SNP look-alike transitioned them. Consistent with the per response time estimate that is currently approved by OMB under control number 0938–0753 (CMS–R–267), we continue to estimate that the enrollment process requires 20 minutes (0.3333 hr).

Based on the aforementioned discussion, Table J8, summarizes the hour and dollar burden for added enrollments for years 2025 to 2027.

TABLE J8: BURDEN ON ENROLLEES FOR YEARS 2025-2027

Year	Number of Affected Enrollees	Time /Enrollee (hr)	Total Time (hr)	Total Cost (@ $20.71/hr) ($)*
2025	7,317	0.3333	2,439	50,512
2026	12,636	0.3333	4,212	87,231
2027	3,421	0.3333	1,140	23,690
Total	23,374	0.9999	7,791	161,433
Average	7,791 (23,374/3)	0.3333 (0.9999/3)	2,597 (7,791/3)	53,811 (161,433/3)

*Had we used $29.76/hour the mean wage for occupational code 00-0000 representing all occupations, the burden would change from $53,811 to $77,326 an increase of $23,515.

As stated previously, we believe that in 2027 and subsequent years, 12 plans will be identified as D–SNP look-alikes and therefore this rule would have a much smaller impact on MA enrollees after the initial period of implementation. Since the current 70 non-SNP MA plans with dually eligible enrollment of 60.0 to 79.9 percent have 145,434 enrollees in 70 plans, we estimate 24,932 enrollees (145,434 enrollees * 12/70 plans) in 12 plans. For plan year 2027, we estimate that 98 percent of the 24,433 D–SNP look-alike enrollees (24,433 enrollees = 24,932 enrollees × 0.98) in the 12 non-SNP MA plans would transition into another plan under the same parent organization as the D–SNP look-alike. We further estimate that we estimate that 3,421 enrollees (24,433 transitioning D–SNP look-alike enrollees * 0.14) will opt out of the new plan into which the D–SNP look-alike transitioned them. The burden on D–SNP look-alike enrollees is summarized in Table J7. The average annual enrollee burden over 3 years is presented in Table J8.

We received no comments specific to our analysis of paperwork burden and, except for modifications made to reflect 2024 plan year experience with D–SNP look-alike transitions, we are therefore finalizing our estimates as is.

13. ICRs Regarding Update to the Multi-Language Insert Regulation (§§ 422.2267 and 423.2267)

The following changes will be submitted to OMB for approval under control number 0938–1421 (CMS–10802).

The multi-language insert (MLI) required at §§ 422.2267(e)(31) and 423.2267(e)(33) is a standardized communications material that informs enrollees and prospective enrollees that interpreter services are available in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese. These were the 15 most common non-English languages in the United States when we reinstituted the MLI in the May 2022 final rule. Additionally, §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i) require plans to provide the MLI in any non-English language that is the primary language of at least 5 percent of the individuals in a PBP service area but is not already included on the MLI. These regulations also provide that a plan may opt to include the MLI in any additional languages that do not meet the 5 percent threshold, where it determines that including the language would be appropriate.

As discussed in section III.P. of this final rule, we are finalizing an update to §§ 422.2267(e)(31) and 423.2267(e)(33) to require that notice of availability of language assistance services and auxiliary aids and services be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency in a State and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication. We are finalizing this provision with one amendment: We are adding ''or States associated with the plan's service area'' between the language ''relevant State'' and ''and must be provided . . .'' to reduce the burden on organizations with plan benefit packages that operate in more than one State and conform with the OCR proposed rule, and to clarify that the requirement is based on the plan benefit package service area. Thus, under the final provision, MA organizations and Part D sponsors would send the Notice of Availability in English and at least the 15 most common non-English languages in a State or States associated with the plan's service area instead of the current MLI in the 15 most common non-English languages nationally. This policy is consistent with a proposed rule that OCR published in August 2022 (87 FR 47824). We also expect that this policy will better align with the Medicaid translation requirements at § 438.10(d)(2).[260] We are modifying the language to note that this is a model communication material rather than a standardized communication material because we are no longer specifying the exact text that must be used. Even though the MA organizations and Part D sponsors could change the Notice of Availability, we are not accounting for such changes because we do not expect any MA organizations or Part D sponsors to make such changes. It is possible that some States may require the use of a specific tagline to meet this requirement, however if this is the case, we again do not anticipate an additional burden to plans since the State would provide the specific language and translations to be used.

We did not expect this policy to create any new collection of information burden for MA organizations or Part D sponsors since the August 2022 proposed rule indicates that OCR would provide translations of the Notice of Availability. Also, the MA organizations and Part D sponsors are already distributing the MLI and, under this final provision, would instead distribute the Notice of Availability, so we do not anticipate any new burden associated with printing or mailing. In addition, the Notice of Availability will be a one-page document that would never be sent

[260] We expect the 15 most common languages for a given State to include any language required by the Medicaid program at § 438.10(d)(2). Therefore, our NPRM would not impose additional burden on fully integrated dual eligible special needs plans and highly integrated dual eligible special needs plans, as defined at § 422.2, and applicable integrated plans, as defined at § 422.561, to comply with regulations at §§ 422.2267(a)(4) and 423.2267(a)(4).

alone and therefore does not create additional postage costs.

We expected some new burden for MA organizations and Part D sponsors operating plans across multiple States. Rather than sending the same MLI with the same 15 non-English language translations to plans in any State, under the final rule the plans under these MA organizations or Part D sponsors would need to send the Notice of Availability with translations in at least the 15 most common non-English languages in each State or States in which the plan operates. Based on plan year 2023 data, we estimated there are approximately 20 MA parent organizations offering MA plans in multiple States with approximately 3,900 PBPs and approximately 20 Part D sponsors offering Part D plans in multiple States with approximately 1,400 Part D plans. Since many of these parent organizations have MA organizations at the State level, we estimated that these 20 parent organizations have approximately 220 MA organizations covering PBPs by State. Similarly, we estimated that the 20 Part D sponsors had approximately 50 parent organizations covering PBPs by State. We believe the parent organizations will update systems software and plan policies and procedures as well as train staff at the MA organization and Part D sponsor level to cover all PBPs and Part D plans, respectively, offered in a State. We expected that MA organizations and Part D sponsors would need one software engineer working one hour to update systems software in the first year with no additional burden in future years and 1 hour at $127.82/hr to update systems software in the first year with no additional burden in future years and one business operations specialist working 1 hour at $79.50/hr to update plan policies and procedures and train staff in the first year with no additional burden in future years.

For MA organizations, we estimated the burden for plan year 2025 at 440 hours (220 MA organizations * 2 hr/plan) at a cost of $56,241 (440 hr * $127.82/hr) for a software engineer to update systems to ensure the Notice of Availability with the correct State or States-specific languages is distributed with other communications and marketing materials. We estimated the burden for MA organizations for plan year 2025 to be 440 hours (220 MA organizations * 2 hr/plan) at a cost of $34,980 (440 hr * $79.50/hr) for a business operations specialist to update plan policies and procedures and train staff.

For Part D sponsors, we estimate the burden for plan year 2025 at 100 hours (50 Part D sponsors * 2 hr/plan) at a cost of $12,782 (100 hr * $127.82/hr) for a software engineer to update systems to ensure the Notice of Availability with the correct State or States-specific languages is distributed with other communications and marketing materials. We estimated the burden for Part D sponsors for plan year 2025 to be 100 hours (50 Part D sponsors * 2 hr/plan) at a cost of $7,950 (100 hr * $79.50/hr) for a business operations specialist to update plan policies and procedures and train staff. We do not anticipate any new burden to plans after the initial year.

We also note that, as part of the current MLI required at §§ 422.2267(e)(31) and 423.2267(e)(33), MA organizations and Part D sponsors must already include additional languages that meet the 5 percent service area threshold as required under §§ 422.2267(a)(2) and 423.2267(a)(3). Thus, MA organizations and Part D sponsors must currently review the most frequently used languages in a service area beyond the top 15 national languages. As a result, we did not believe the burden will be greater than our estimate noted previously.

We do not believe that the modified policy poses any additional impact on burden. We received no comments specific to our analysis of paperwork burden and are therefore finalizing our estimates as is.

14. ICRs Regarding Part D Medication Therapy Management (MTM) Program Eligibility Criteria (§ 423.153(d))

The following changes will be submitted to OMB for approval under control number 0938–1154 (CMS–10396). Based on comments summarized in section III.E., we are finalizing our proposed changes to the MTM eligibility criteria with modification, as follows:

- Requiring plan sponsors to target all core chronic diseases and continuing to allow them to Add other chronic diseases.
- Codifying the current nine core chronic diseases in regulation and adding HIV/AIDS, for a total of 10 core chronic diseases.
- Maintaining the maximum number of covered Part D drugs a sponsor may require at eight drugs, requiring sponsors to include all Part D maintenance drugs in their targeting criteria, and continuing to allow them to include all covered Part D drugs in their targeting criteria.
- Revising the annual cost threshold ($5,330 in 2024) methodology to be based on the average annual cost of eight generic drugs ($1,623 for 2025 based on 2023 data).

We are also revising our estimates to reflect our final policies and updated data, including more accurate postage rates. Taken together, we estimate that the changes to the MTM eligibility criteria will increase the number (and percentage) of Part D enrollees eligible for MTM services by 3,466,029 beneficiaries, from 3,599,356 (7 percent of all Part D enrollees) to 7,065,385 (13 percent of all Part D enrollees). While we considered multiple alternative proposals, we ultimately finalized this combination of changes as a way to close significant gaps in MTM eligibility while being responsive to concerns about program size and burden on Part D sponsors.

Under § 423.153(d)(1)(vii), all MTM enrollees must be offered a CMR at least annually and TMRs no less than quarterly. A CMR is an interactive consultation, performed by a pharmacist or other qualified provider, that is either in person or performed via synchronous telehealth, that includes a review of the individual's medications and may result in the creation of a recommended medication action plan as required in § 423.153(d)(1)(vii)(B)(*1*) as amended in this final rule. An individualized, written summary in CMS's Standardized Format must be provided following each CMR. For ongoing monitoring, sponsors are required to perform TMRs for all beneficiaries enrolled in the MTM program with follow-up interventions when necessary. The TMRs must occur at least quarterly beginning immediately upon enrollment in the MTM program and may address specific or potential medication-related problems. TMRs may be performed to assess medication use, to monitor whether any unresolved issues need attention, to determine if new drug therapy problems have arisen, or assess if the beneficiary has experienced a transition in care. Under § 423.153(d)(1)(vii)(E), plans are also required to provide all enrollees targeted for MTM services with information about safe disposal of prescription medications that are controlled substances. Plans may mail this information as part of the CMR summary, a TMR, or other MTM correspondence or service. In this section, we are estimating the additional burden on plan sponsors to conduct CMRs (labor cost) and mail the written CMR summaries (non-labor cost) to the additional beneficiaries that will be targeted for MTM enrollment based on our revisions. We also estimate the cost of sending safe disposal information to the beneficiaries who will be newly

targeted under these revised criteria, but do not receive a CMR.

To obtain aggregate burden we separately estimate: (1) the burden for pharmacists to complete the CMR; (2) the mailing costs of the CMRs; and (3) the cost of mailing of safe disposal instructions to those targeted beneficiaries who do not Accept the offer of a CMR.

- *The burden for pharmacists to complete the additional CMRs:* Based on internal data, we found 66.2 percent of MTM program enrollees accepted the offer of a CMR in 2022. To estimate the cost of conducting the additional CMRs, we multiply the expected number of additional MTM program enrollees (3,466,029) by 0.662 to obtain the number of additional CMRs we estimate will actually be conducted (2,294,511). We estimate a pharmacist would take 40 minutes (0.6667 hr) at $124.44/hr to complete a CMR. Thus, the total burden is 1,529,750 hours (0.6667 hr/CMR * 2,294,511 enrollees who accept the CMR offer) at a cost of $190,362,090 (1,529,750 hr * $124.44/hr).
- *Mailing Costs of CMRs:* To estimate the cost of sending the CMR summaries, we assume that the average length of a CMR is 7 pages double-sided (including 1 page for information regarding safe disposal). The cost of mailing one CMR summary is the cost of postage plus the cost of printing one CMR summary. First-class postage costs $0.64 per metered mailing. Paper costs are $0.007 per sheet ($3.50 per ream/500 sheets per ream;), and toner costs $70.00 per cartridge and lasts for 10,000 sheets (at $0.007 per sheet = $70.00/10,000 sheets). Bulk envelope costs are $440 for 10,000 envelopes or $0.044 per envelope. Therefore, the cost of printing the average CMR summary is $1.0220 ($0.64 postage for the first ounce + 0.24 for the second ounce + 7 sheets * $0.007 for paper + 7 sheets*$0.007 for toner + 0.044 for envelopes). And taken as a whole, the annual cost of mailing CMRs to the additional 2,294,511 beneficiaries expected to accept the CMR offer is $2,344,990 (2,294,511 enrollees × $1.0220/mailing).
- *Mailing costs for safe disposal information:* Out of the 3,466,029 additional beneficiaries expected to be targeted for MTM based on the revised criteria, we expect that 33.8 percent or 1,171,518 (3,466,029 * 0.338) beneficiaries will decline a CMR. These beneficiaries will still need to receive information regarding the safe disposal of prescription drugs that are controlled substances. For purposes of calculating the burden, we are assuming that any safe disposal information that is not included in a CMR is either (1) being mailed in a TMR, which may be as short as one page and may contain private health information; or (2) is mailed as a standalone document which does not contain any private health information. For purposes of impact, (1) if one additional page is included in the TMR, then there is no additional postage; and (2) if the safe disposal information is mailed separately, there would be no private health information, and the burden would be the cost of one page plus bulk postage. Due to a lack of data with regard to what percentage of safe disposal information will be mailed as part of a TMR or other MTM correspondence or service, we are assuming that all safe disposal information not sent with a CMR will be one page that is mailed separately using bulk postage in order to project the maximum cost of such mailing. If the letter does not contain private health information and thus bulk mailing costs (which include the envelope, typically a fold over paper) is used, the cost to mail one page of safe disposal information is $0.01495 per enrollee [(1 page $0.007/sheet) + (1 page * $0.007 toner) + ($0.19/200 items for bulk postage).] Therefore, we estimate that the cost of mailing safe disposal information to those beneficiaries targeted for MTM who do not receive it in a CMR summary is $17,514 ($0.01495 * 1,171,518).

Therefore, the total burden associated with the finalized revisions to the MTM targeting criteria is 1,529,750 hours and $192,724,594 ($190,362,090 for a pharmacist to perform the CMRs for beneficiaries newly targeted for MTM under the revised criteria + $2,344,990 to mail the CMR written summary in the CMS Standardized Format with safe disposal information + $17,514 for mailing information regarding safe disposal to beneficiaries newly targeted for MTM who do not receive a CMR).

We received the following comments on the estimates included in this section of the proposed rule, and our responses follow:

Comment: A commenter pointed out that the increase in program size and burden would not be evenly distributed, and that some plans would be disproportionately affected due to member population and plan type. Another commenter suggested simplifying the program by focusing only on CMRs to improve participation and decrease the cost.

Response: We acknowledge that eligibility rates for MTM are not evenly distributed among Part D contracts. Similar to current MTM programs, some contracts may have actual MTM enrollment rates above or below the average rate for the program as a whole. CMS took the cost burden into consideration when developing its policies for this final rule and modified the eligibility criteria to lessen the burden on plans but still provide access to MTM to more beneficiaries. As a key component of the MTM program, the CMR is also the costliest component as evidenced by our calculations. Therefore, it is unlikely that focusing solely on the CMR would significantly decrease the cost burden.

Comment: One commenter suggested that the time for a pharmacist or other qualified provider to complete the CMR was underestimated and should be 60 minutes. While the average CMR consultation with the enrollee may take 20–40 minutes, the pharmacist or other qualified provider spends additional time reviewing the case before the consultation with the enrollee and preparing the CMR summary.

Response: CMS disagrees. The time spent conducting a CMR for the purposes of our burden calculations is an average; as supported by the range of 20 to 60 minutes provided in this comment, 40 minutes is an accurate estimate. CMS considers the preparatory time for the CMR summary to be negligible since most sponsors and MTM providers use an automated system to complete the Standardized Format.

15. ICRs Regarding Required Notices for Involuntary Disenrollment for Loss of Special Needs Status (§ 422.74)

The following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

MA organizations that offer special needs plans are currently effectuating involuntary disenrollments for loss of special needs status as part of existing disenrollment processes, including the member notifications; therefore, no additional burden is anticipated from this change. However, because a burden estimate for these member notifications has not previously been submitted to OMB, due to inadvertent oversight, we are seeking OMB approval under the aforementioned OMB control number.

We are codifying current policy on MA plan notices prior to a member disenrollment for loss of special needs status. MA organizations will be required to provide the member a minimum of 30 days advance notice of disenrollment regardless of the date of the loss of special needs status. Additionally, the organization will be required to provide the member a final notice of involuntary disenrollment, sent within 3 business days following

the disenrollment effective date, and before the disenrollment transaction is submitted to CMS.

Where an individual is involuntarily disenrolled from an MA plan for any reason other than death, loss of entitlement to Part A or Part B, the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual, pursuant to § 422.74(c). The notice requirement in § 422.74(c) is currently approved by OMB under the aforementioned control number.

To estimate the number of notices required due to involuntary disenrollments for loss of special needs status, we determined the average number of annual disenrollments due to loss of special needs status. Between 2017 and 2021, there were an average of 55,127 involuntary disenrollments per year due to loss of special needs status.

We estimate that it would take each MA organization 1 minute (0.017 hr) to assemble and disseminate the advance notice, 5 minutes (0.083 hr) to submit the required transaction to CMS for each disenrollment, and 0.017 hr to assemble and disseminate the final notice for each disenrollment. Therefore, the total annual time for each MA organization is 0.117 hours (0.017 hr + 0.083 hr + 0.017 hr).

We estimate the aggregate annual burden for all MA organizations to process these disenrollments to be 6,450 hours (55,127 disenrollments * 0.117 hr) at a cost of $512,775 (6,450 hr * $79.50/hr)

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

16. ICRs Regarding Involuntary Disenrollment for Individuals Enrolled in an MA Medical Savings Account (MSA) Plan (§ 422.74(b)(2))

The requirement at § 422.74(b)(2)(vii) to establish a process for involuntary disenrollment for an individual who loses eligibility mid-year to be enrolled in an MA MSA plan, and more specifically, the requirement for the MA organization to give the individual a written notice of the disenrollment at § 422.74(c) with an explanation of why the MA organization is planning to disenroll the individual, will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267).

The annual burden associated with this requirement consists of the time and cost to notify the individual and CMS. Based on the active burden in CMS–R–267, we estimate that each disenrollment will require 1 minute (0.017 hr) for the MA MSA plan to notify CMS and 5 minutes (0.083 hr) for the MA MSA plan to notify the individual. Thus, the total burden per disenrollment is estimated at 6 minutes (0.1 hr) (1 minute to assemble and disseminate the notice to CMS and 5 minutes to assemble and disseminate the notice to the individual) at a cost of $7.95 (0.1 hr × $79.50/hr for a business operations specialist to perform the work).

To obtain aggregate burden we used data from 2019 and 2021 in which there were an average of 4 MSA contracts. We used an average since the data had no visible trend but hovered around a central value. There was an average of 8,624 enrollees during 2019–2021 and the average disenrollment was 124. Thus, we estimate an aggregate burden of 12 hours (124 disenrollments * 0.1 hr per disenrollment) at a cost of $954 (12 hr * $79.50/hr).

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

17. ICRs Regarding Required Notice for Reinstatements Based on Beneficiary Cancellation of New Enrollment (§§ 422.60 and 423.32)

The following changes will be submitted to OMB for approval under control number 0938–1378 (CMS–10718).

CMS's subregulatory guidance currently provides that MA and PDP plans send notification of enrollment reinstatement based on the cancellation of enrollment in a new plan. Our change will not add to existing reinstatement processes; therefore, no additional burden is anticipated. However, because a burden estimate for these enrollment reinstatement notifications has not previously been submitted to OMB, we are correcting that oversight by requesting OMB's review and approval under the aforementioned control number.

We are codifying CMS's current policy that plans notify an individual when the individual's enrollment is reinstated due to the individual's cancellation of enrollment in a different plan. The MA or PDP plan from which the individual was disenrolled will be required to send the notification of the enrollment reinstatement within 10 days of receipt of Daily Transaction Reply Report (DTRR) confirmation of the individual's reinstatement. The reinstatement notice will include confirmation of the individual's enrollment in the previous plan with no break in coverage, plan-specific information as needed, and plan contact information.

To estimate the number of reinstatement notices required due to an individual's cancellation of enrollment in a new plan, we determined the number of annual reinstatements based on the cancellations of enrollment in a new plan. In 2021, there were 5,686,989 disenrollments from MA and MA–PD plans due to enrollments in another plan and 4,292,426 disenrollments from PDP plans due to enrollments in another plan. Further, between 2017 and 2021, there was an average of 193,183 cancelled enrollments per year in a new MA plan (including MA–PD plans). Between 2017 and 2021, there was an average of 32,723 cancelled enrollments per year in a new PDP plan. Each cancelled enrollment in a new plan results in a reinstatement notice sent to the beneficiary. Thus, we estimate 225,906 (193,183 + 32,723) reinstatements annually.

We estimate that it will take 1 minute (0.017 hr) at $79.50/hr for a MA or PDP plan's business operations specialist to assemble and disseminate the notice for each reinstatement. In aggregate, we estimate an annual burden of 3,840 hours (225,906 reinstatements * 0.017 hr) at a cost of $305,280 (3,840 hr * $79.50/hr).

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

18. ICRs Regarding Medicare Final Settlement Process and Final Settlement Appeals Process for Organizations and Sponsors That Are Consolidating, Non-Renewing, or Otherwise Terminating a Contract (§§ 422.500, 422.528, 422.529, 423.501, 423.521, and 423.522).

In this rule, §§ 422.528, 422.529, 423.521, and 423.522 will permit that MA organizations and Part D sponsors who disagree with the CMS calculated final settlement amount appeal the final settlement amount, if any, for each contract that consolidates, non-renews, or terminates. In the December 2022 proposed rule, we had erroneously estimated the burden of the proposed provision. We are correcting that oversight in this final rule by removing such burden since the preparation and submission of appeals are in response to an administrative action, investigation or audit pertaining to specific individuals or entities (5 CFR 1320.4(a)(2) and (c)). In this regard, the preparation and submission of appeals

are not subject to the requirements of the PRA.

19. ICRs Regarding Personnel Requirements Under PACE (§§ 460.64 and 460.71)

The following changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244).

Section 460.64 currently includes the requirements relating to the qualifications of PACE personnel who have direct contact with PACE participants. This includes the requirement that PACE organizations medically clear personnel of communicable diseases. As discussed in section IX.C. of this final rule, we are finalizing our proposal to allow PACE organizations the option to create and implement a risk assessment tool to assist with this medical clearance process. Therefore, we estimate there will be a one-time burden for PACE organizations associated with these new requirements to update policies and procedures related to medical clearance, and when applicable, to develop a risk assessment tool. We believe the compliance officer and primary care physician (PCP) would be responsible for ensuring the necessary materials are updated, for determining medical clearance, and developing the risk assessment tool. For revising policies and procedures related to medical clearance, we estimate it would take 1 hour at $74.02/hr for a compliance officer at each PACE organization to update these materials. In aggregate, we estimate a one-time burden of 156 hours (156 PACE organizations * 1 hr) at a cost of $11,547 (156 hr * $74.02/hr) for the update of policies and procedures.

For the development of the risk assessment tool, we estimate it would take each PACE organization 5 hours consisting of: 4 hours of work by the compliance officer at $74.02/hr and 1 hour of work by the PCP at $229.52/hr. The weighted hourly wage for the compliance officer and PCP to create a risk assessment tool is $105.12/hr ([(4 hr * $74.02/hr) + (1 hr * $229.52/hr)]/5 hr of aggregate burden). In aggregate, we estimate a one-time burden of 780 hours (156 PACE organizations * 5 hr) at a cost of $81,994 (780 hr * $105.12/hr) for both the compliance officer and PCP roles in developing the risk assessment tool.

Based on internal CMS data, there were 156 active PACE organizations as of February 2024. This number of active PACE organization represents an increase of 7 PACE organizations from the 149 active PACE organizations counted in the December 2022 proposed rule and based on September 2022 data.

We received no comments specific to our analysis of paperwork burden and are therefore finalizing our estimates as is, except that we have made updates related to the increased number of PACE organizations and changes to mean hourly wages.

20. ICRs Regarding Service Delivery Under PACE (§ 460.98)

The following changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244).

Section 460.98 currently includes requirements related to delivery of services to PACE participants. This includes the minimum requirements for the provision of services PACE organizations must provide and how the services must be furnished. The current requirement that PACE organizations must provide all necessary services to meet the needs of participants as expeditiously as the participant's health conditions require would not change with this final rule, but as discussed in section IX.D. of this final rule, we are finalizing our proposal to add required maximum timeframes for arranging and scheduling services for PACE participants. We believe there will be a one-time burden for PACE organizations to update their policies and procedures to reflect the finalized timeframes. We believe the compliance officer will be responsible for updating the policies and procedures. We estimate that it would take the compliance officer 1 hour at $74.02/hr to update the necessary materials. Therefore, we estimate a one-time burden of 156 hours (156 PACE organizations * 1 hr) at a cost of $11,547 (156 hr * $74.02/hr).

We received no comments specific to our analysis of paperwork burden and are therefore finalizing our estimates as is, except that we have made updates related to the increased number of PACE organizations and changes to mean hourly wages.

21. ICRs Regarding PACE Participant Rights (§ 460.112)

The following changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244).

Section 460.112 currently includes the specific rights to which PACE participants are entitled. As discussed in section IX.G. of this final rule, we are finalizing our proposal to add new participant rights and modify existing participant rights to enhance participant protections. Specifically, we are finalizing our proposal to add and/or modify the rights to appropriate and timely treatment; to be fully informed, in writing, of different treatment options including palliative, comfort, and end-of-life care; to fully understand the PACE organization's palliative, comfort, and end-of-life care services; and to request services from the PACE organization through the process described in § 460.121. PACE organizations are currently required to provide a copy of the participant rights listed in § 460.112 to participants at the time of enrollment, and to post a copy of the rights in the PACE center. Under our finalized changes to § 460.112, PACE organizations must revise the materials they provide to participants at the time of enrollment and the posting in the PACE center to account for the new and modified requirements. Therefore, we estimate a one-time burden for PACE organizations to update the participant rights included in the enrollment information and post the new participant rights in PACE centers. We believe it would take a compliance officer 2 hours at $74.02/hr to update these materials.

Additionally, PACE organizations must develop written templates explaining palliative care, comfort care, and end-of-life care services. We believe the development of these materials is a one-time burden and would take a compliance officer 2 hours to complete at $74.02/hr.

In aggregate, we estimate a one-time burden of 624 hours (156 PACE organizations * (2 hr + 2 hr)) at a cost of $46,188 (624 hr * $74.02/hr).

We also estimate this provision would result in increased ongoing costs to PACE organizations. As discussed in section IX.G. of this final rule, we are finalizing the requirement that PACE organizations provide participants with written documentation explaining the different treatment options including palliative, comfort, and end-of-life care services. Specifically, we are finalizing the requirement that PACE organizations must describe their palliative care, comfort care, and end-of-life care services and how they differ from the care the participant is currently receiving; whether these treatment options will be provided in addition to or in lieu of the care the participant is currently receiving; a detailed description of all services that will be impacted and how they will be impacted if the participant and/or designated representative elects to initiate a different treatment option; and that the participant has the right to revoke or withdraw their consent to receive these treatment options at any time and for any reason.

We estimate that a registered nurse (RN) will need to tailor written

templates for each participant based on the treatment option they choose and the impact that treatment option will have on their current services. We estimate it would take the RN 1 hour to tailor the written template to each participant at $85.60/hr. We also estimate the Master's-level Social Worker (MSW) would either provide the materials in person to the participant and/or their designated representative or they would mail the materials to the participant. We estimate it would take the MSW 10 minutes (0.1667 hr) to mail or present the materials to each participant at $60.34/hr.

For tailoring information within the written templates and providing written materials to participants as specified at finalized § 460.112(c)(5), we estimate ongoing burden using the weighted hourly wage for the RN and MSW. The weighted average can be obtained as follows. The total cost per participant is $95.66/hr [(1 hr * $85.60/hr (RN)) + (0.1667 hr * $60.34/hr (MSW))]. The total time is 1.1667 hours (1 hr for the RN plus 0.1667 hr the MSW). Thus, the average hourly wage is $81.99/hr (total cost of $95.66/1.1667 hr).

Using these assumptions, we estimate the ongoing burden for the finalized requirements at § 460.112(c)(5) would affect 12,169 participants (60,847 enrollees times 20 percent of participants who are expected to need end-of-life explanations). Therefore, to tailor and mail materials there is an annual burden of 14,198 hours (12,169 affected participants * 1.1667 hr) at a cost of $1,164,094 (14,198 hr * $81.99/hr).

We are also finalizing our proposal requiring that PACE organizations explain the treatment options to participants and/or their designated representatives before palliative care, comfort care, or end-of-life care services can be initiated. This includes fully explaining the treatment options, providing the participant and/or designated representative with the written materials discussed previously, and obtaining written consent from the participant and/or designated representative. We estimate it would take the MSW 1 hour at $60.34/hr to explain the services and answer any questions the participant and/or designated representative might have.

To estimate the increased burden, we use the following assumptions about the number of participants who may pursue palliative care, comfort care, and/or end-of-life care services, based on our experience monitoring and auditing PACE organizations. We estimate that 2 out of every 10 participants in a given year (20 percent) will require written materials for palliative care, comfort care, or end-of-life care services. Based on CMS internal data, the total national enrollment in PACE as of February 2024 was 60,847. This enrollment data represents an 11 percent increase from the national PACE enrollment data utilized in the December 2022 proposed rule, 54,637 enrollees, which was based on September 2022 enrollment data.

We estimate an ongoing burden for PACE organizations' MSW to explain treatment options to participants as specified at § 460.112(e)(2) to be 12,169 hours (60,847 participants * 0.20 * 1 hr) at a cost of $734,277 (12,169 hr to discuss treatment options * $60.34/hr).

We estimate a total one-time burden of 624 hours at a cost of $46,188 and a total annual ongoing burden of 26,367 hours (14,198 hr + 12,169 hr) at a cost of $1,898,371 ($1,164,094 + $734,277).

We received no comments specific to our analysis of paperwork burden and are therefore finalizing our estimates as is, except that we have made updates related to the increased number of PACE organizations, national PACE enrollment data, and changes to mean hourly wages.

22. ICRs Regarding PACE Grievance Process (§ 460.120)

The following changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244).

Section 460.120 currently includes the grievance process PACE organizations are required to follow. As discussed in section IX.H. of this final rule, PACE organizations are already required to develop procedures on processing grievances and to provide notification of the grievance process to participants upon enrollment and at least annually. We are finalizing our proposed changes to further require that PACE organizations update those procedures. Specifically, we are finalizing our proposal that written or oral notification of the grievance resolution must include a summary of the grievance issues, a summary of the findings for each distinct issue that requires an investigation, the corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur (if applicable). Our finalized changes, which add requirements on what must be included in grievance resolution notifications, require PACE organizations to revise and update their notification templates. Therefore, we estimate a one-time burden for PACE organizations to update their materials to meet these new requirements. We do not believe the finalized changes to § 460.120 will impact the annual hours of burden for PACE organizations, because they are already required to provide notification of grievance resolutions to participants and may opt to do so orally or in writing. Therefore, we believe that the ongoing burden will not change with this requirement.

For the one-time burden for updating policies and procedures, we estimate that it would take the compliance officer 2 hours to update these materials at $74.02/hr. For the revised notification of the grievance process, that is provided both upon enrollment and at least annually, we estimate it would take the compliance officer 1 hour to revise these notifications at $74.02/hr. For the written grievance resolution notification, we estimate it will take the compliance officer 1 hour to revise the written resolution notification at $74.02/hr.

In aggregate, we estimate it would take PACE organizations 624 hours [156 PACE organizations * (2 hr + 1 hr + 1 hr)] at a cost of $46,188 (624 hr * $74.02/hr).

We received no comments specific to our analysis of paperwork burden and are therefore finalizing our estimates as is, except that we have made updates related to the increased number of PACE organizations and changes to mean hourly wages.

23. ICRs Regarding PACE Participant Notification Requirement for PACE Organizations With Past Performance Issues or Compliance Deficiencies (§ 460.198)

The following changes will be submitted to OMB for approval under control number 0938–0790 (CMS–R–244).

To enable CMS to better protect PACE participants by ensuring that PACE participants and their caregivers have adequate information to make informed decisions regarding the PACE organization, this rule adds a new provision, § 460.198, which gives CMS the authority to, at its discretion, require a PACE organization to disclose to its PACE participants or potential PACE participants, the PACE organization's performance and contract compliance deficiencies in a manner specified by CMS.

The overall PACE organization burden of this requirement is expected to be minimal. In the past, CMS has only required organizations to send these notices to enrollees when CMS sanctioned the organization, which is an extremely rare occurrence. Regarding PACE organizations, between CY 2019 and 2021, CMS sanctioned a total of 3

PACE organizations for an average of 1 per year. As a result, CMS projects that between one and two PACE organizations per year would be required to notify participants and potential participants of their performance and contract compliance deficiencies. In addition, CMS will provide the PACE organization with a template of what to include in the notice, and organizations have the capability to send notices to participants. Therefore, we estimate a burden for PACE Organizations to complete and send the template to participants and potential participants.

For the annual burden for completing the template and sending it to participants and potential participants, we estimate that it would take the compliance officer at the PACE organization 1 hour at $74.02/hr to complete and send out the template (which would be automated). In aggregate, we estimate it would take 2 hours (2 PACE organizations * 1 hr) at a cost of $148 (2 hr * $74.02/hr).

We did not receive any comments related to the aforementioned collection of information requirements and burden estimates and are finalizing them in this rule as proposed.

24. ICRs Regarding Distribution of Personal Beneficiary Data by Third Party Marketing Organizations (TPMOs) (§§ 422.2274(g) and 423.2274(g))

The following changes will be submitted to OMB for approval under control number (0938–0753) (CMS–R–267).

As explained in section VI.A. of this rule, personal beneficiary data collected by a TPMO for marketing or enrolling them into an MA plan may only be shared with another when prior express written consent is given by the beneficiary. Additionally, we codified that prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained through a clear and conspicuous disclosure that lists each TPMO receiving the data and allows the beneficiary to consent or reject to the sharing of their information with each entity. We expect that each TPMO that collects personal beneficiary data and intends to share it with TPMOs must update their disclosure process to obtain individual consent for each TPMO with whom it will share the information. We expect that this collection of a consent to have information shared with other TPMOs will impact both TPMOs and Medicare beneficiaries.

a. Beneficiaries

To estimate the information collection burden for beneficiaries, we have estimated the number of beneficiaries enrolling through agents and brokers that received their contact information from a TPMO and the time it takes for the beneficiary to complete the consent to sharing their information with specific entities. First, we estimate that it will take a beneficiary approximately five minutes to read the disclosure and provide consent to have their information shared with the entities of their choosing. We estimate that there are approximately 2 million new MA enrollees every year [261] and approximately 50 percent of those enrollees utilized a TPMO and/or agent/broker to assist with their enrollment into an MA plan.[262] Thus, in total, we expect that 1,000,000 (2,000,000 new MA enrollees * 50 percent assisted by an agent broker) beneficiaries to spend five minutes (0.083 hr) consenting or rejecting to the disclosure resulting in an aggregate burden of 83,000 hours (1 million new enrollees * 0.083 hr) and $1,718,930 (83,000 hr * $20.71/hr).

b. TPMOs

To estimate the information collection burden on TPMOs, we have estimated the number of TPMOs that collect personal beneficiary data for purposes of marketing or enrolling them into an MA or Part D plan. The most current industry profile for Market Research and Analysis and Marketing Specialists provided by the U.S. Bureau of Labor Statistics [263] states that there are 66,900 people employed in management capacity in this area. We estimate that there are approximately 10 managers per company,[264] resulting in 6,690 marketing organizations (66,900 people in management capacity divided by 10 managers per organization). Further, we estimate that 10 percent of these companies are operating in the healthcare industry,[265] which results in about 669 TPMOs or other entities (6,690 organizations * 0.10) that potentially would need to comply with this rule. We estimate it will take approximately 20 hours for a single TPMO manager and a single web and software developer to update the proper disclosure and form to obtain consent and a software engineer to program it into the company's workflow and process for collection. We therefore use the average wage of $136.17/hr (the average of $152.20/hr for a marketing manager and $120.14/hr for a software and web developer) In aggregate we estimate a burden of 13,380 (669 entities * 20 hr) at a cost of $1,821,955 (13,380 hr * $136.17/hr).

25. ICRs Regarding Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.162, 422.164, 422.166, 422.260, 423.182, 423.184, and 423.186)

As described in section VII. of this final rule, we are finalizing adding, removing, and updating certain measures. Most of the new measures will be calculated from administrative data and, as such, there will be no increase in plan burden. The other measure-level changes entail moving existing measures from the display page to Star Ratings, which also will have no impact on plan burden. We are also finalizing a series of technical clarifications related to QBP appeals processes, consolidations, and weighting of measures with a substantive specification change. The finalized provisions will not change any respondent requirements or burden pertaining to any of CMS's 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), OMB control number 0938–0992 for Part D Reporting Requirements (CMS–10185),

[261] Published CMS data (*https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenroldata*) shows MA non employer enrollment increasing steadily by 2 million a year since 2020. It shows PDP enrollment decreasing steadily by ½ million a year. This number is an overestimate since it includes deaths, ignores migrations from MA to FFS, ignores the downward trend in PDPs, and ignores migrations between plans.

[262] This was stated in the NPRM. Additionally the following source supports this: *https://deftresearch.com/wp-content/uploads/2023/11/Deft-Research-Gut-Check-Study-Snapshot.pdf.*

[263] *https://www.bls.gov/oes/current/oes131161.htm* Another BLS page for the profile specific to ''Marketing Managers'', *https://www.bls.gov/oes/current/oes112021.htm,* lists 44710 managers. In our estimates we used the higher estimate for the number of managers (66,900) and higher estimate for the mean hourly wage ($76.10, for Marketing Managers, Occupational code 11–2021) We then adjusted this for overtime and fringe and benefits.

[264] Typically, managers include top-level, middle-level, first-line, and team-leads. Top level itself might include the president, vice-president, CEO, and CFO. Thus, we believe the number 10 reasonable and possibly an underestimate.

[265] The BLS does not further break down the area specialty, ''Market Research Analysts and Marketing Specialists'' Occupational code 13–1161, by sub-areas. However, the area includes marketing for real-estate, life and property insurance, scientific and technical companies, and software companies. Thus, we believe 10 percent a reasonable estimate for health-insurance marketing specialists.

and OMB control number 0938–1129 for Appeals of Quality Bonus Payment Determinations (CMS–10346). Since the provisions will not impose any new or revised information collection requirements or burden, we are not making changes under any of the aforementioned control numbers.

C. Summary of Information Collection Requirements and Associated Burden Estimates

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TABLE J9: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN*

Section(s) under Title 42 of the CFR	Item	OMB Control No. (CMS ID No.)	Respondents	Number of Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost of Reporting ($/hr)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
§ 422.116(b)(2) and (d)(2) and (5)	Network Adequacy for Behavioral Health	0938-1346 (CMS-10636)	742 Plan Sponsors	742	0.0833	62	79.50	4,929	-
§§ 423.4, 423.100, 423.104, 423.120, and 423.128	Changes to an Approved Formulary Submission	0938-0964 (CMS-10141)	197 Plan sponsors	68,232	Varies	(20,952)	Varies	(955,616)	(955,616)
§§ 423.100 and 423.153	DMP:Case Management	0938-TBD (CMS-10874)	319 Plan Sponsors	30,365	5	(27030)	111.16	(3,004,655)	(3,004,655)
§§ 423.100 and 423.153	DMP:Enrollee notification	0938-TBD (CMS-10874)	319 Plan Sponsors	1,518	0.1667	(1066)	38.70	(41,254)	(41,254)
§§ 423.100 and 423.153	DMP: CMS Notification	0938-TBD (CMS-10874)	319 Plan Sponsors	30,365	0.0167	(90)	38.70	(3,483)	(3,483)
§ 422.102(f)(3)(iii) and (iv) and (f)(4)	SSBCI: Reasonable expectation of improving health	0938-0753 (CMS-R-267)	774 Plans and Plan Sponsors	774	2	1548	98.84	153,004	-
§ 422.102(f)(3)(iii) and (iv) and (f)(4)	SSBCI: Reasonable expectation of improving health	0938-0753 (CMS-R-267)	310 MA Plans Offering SSBCI	10,000	8	80000	85.60	6,848,000	6,848,000
§§ 422.111 and 422.2267	Mid-Year Notification of unused Supplemental Benefits	0938-0753 (CMS-R-267)	774 Plans and Plan Sponsors	774	4	3096	127.82	395,731	-
§§ 422.111 and 422.2267	Mid-Year Notification of unused Supplemental Benefits	0938-0753 (CMS-R-267)	774 Plans and Plan Sponsors	774	1	774	79.50	61,533	-
§§ 422.111 and 422.2267	Mid-Year Notification of unused Supplemental Benefits	0938-0753 (CMS-R-267)	774 Plans and Plan Sponsors	32,000,000	Non Labor	Non Labor	Non Labor	23,232,000	23,232,000
§ 422.137	UM committee: Expertise in Health Equity	0938-0964 (CMS-10141)	966 Plans	966	0.5	483	74.02	35,752	-
§ 422.137	UM committee: Expertise in Health Equity	0938-0964 (CMS-10141)	966 Plans	966	8	7728	120.14	928,442	-
§ 422.137	UM committee: Expertise in Health Equity	0938-0964 (CMS-10141)	966 Plans	966	0.1667	161	79.50	12,800	12,800
§ 422.116(b) through (e)	Exceptions for Network Adequacy	0938-1346 (CMS-10636)	10 MA Plans	10	0.0833	0.8	79.50	64	-
§§ 422.503, 422.504, 422.514, 422.530, and 423.38	Increasing D-SNP Enrollment: Notification, Software updates	0938-0753 (CMS-R-267)	50 Plans	50	8	400	127.82	51,128	-
§§ 422.503, 422.504, 422.514, 422.530, and 423.38	Increasing D-SNP Enrollment:Integrated SEP, Software	0938-0964 (CMS-10141)	113 SNPS	113	4	452	127.82	57,775	-
§§ 422.503, 422.504, 422.514, 422.530, and 423.38	Increasing D-SNP Enrollment: Notification, Update Policies	0938-0753 (CMS-R-267)	50 Plans	50	4	200	79.50	15,900	-
§§ 422.503, 422.504, 422.514, 422.530, and 423.38	Increasing D-SNP Enrollment:Integrated SEP, Update Policies	0938-0964 (CMS-10141)	113 SNPS	113	4	452	79.50	35,934	-
§ 422.514(d) and (e)	D-SNP Look alikes	0938-0753 (CMS-R-267)	25 MA Plans	25	2	50	79.50	3,975	3,975

Section(s) under Title 42 of the CFR	Item	OMB Control No. (CMS ID No.)	Respondents	Number of Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost of Reporting ($/hr)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
§ 422.514(d) and (e)	D-SNP Look alikes	0938-0753 (CMS-R-267)	7791 Enrollees	7,791	0.3333	2597	20.71	53,811	53,811
§§ 422.2267 and 423.2267	Multi Language Insert: Software, Part C	0938-1421 (CMS-10802)	220 Plans	220	2	440	127.82	56,241	-
§§ 422.2267 and 423.2267	Multi Language Insert: Updates, Part C	0938-1421 (CMS-10802)	220 Plans	220	2	440	79.50	34,980	-
§§ 422.2267 and 423.2267	Multi Language Insert: Software, Part D	0938-1421 (CMS-10802)	50 States	50	2	100	127.82	12,782	-
§§ 422.2267 and 423.2267	Multi Language Insert: Update Policies, Part D	0938-1421 (CMS-10802)	50 States	50	2	100	79.50	7,950	-
(§ 423.153(d))	MTM: CMRs	0938-1154 (CMS-10396)	3,466,029 Enrollees	2,294,511	0.6667	1529750	124.44	190,362,090	190,362,090
(§ 423.153(d))	MTM: Mail CMRs	0938-1154 (CMS-10396)	3,466,029 Enrollees	2,294,511	NA	NA	NA	2,344,990	2,344,990
(§ 423.153(d))	MTM: Mail Safe Disposal	0938-1154 (CMS-10396)	3,466,029 Enrollees	1,171,518	NA	NA	NA	17,514	17,514
§ 422.74	Notice for Involuntary Disenrollment from SNPS	0938-0753 (CMS-R-267)	620 Special Needs Plans	55,127	0.117	6450	79.50	512,775	512,775
§ 422.74(b)(2)	Involuntary Disenrollment from MSAs	0938-0753 (CMS-R-267)	4 MSA Plans	124	0.1	12	79.50	954	954
§§ 422.60 and 423.32	Reinstatements from Cancellation of New Enrollments	0938-1378 (CMS-10718)	803 (740 MA Organizations and 63 Part D Sponsors)	225,906	0.017	3840	79.50	305,280	305,280
§§ 460.64 and 460.71	PACE Personnel Requirements: Update Policies and Procedures	0938-0790 (CMS-R-244)	156 PO	156	1	156	74.02	11,547	-
§§ 460.64 and 460.71	PACE Personnel Requirements: Risk Assessment Tool	0938-0790 (CMS-R-244)	156 PO	156	5	780	105.12	81,994	-
§ 460.98	PACE Service Delivery	0938-0790 (CMS-R-244)	156 PO	156	1	156	74.02	11,547	-
§ 460.112	PACE Participant Rights: Update materials & create templates	0938-0790 (CMS-R-244)	156 PO	156	4	624	74.02	46,188	-
§ 460.112	PACE Participant Rights: Taylor Templates for individual enrollees	0938-0790 (CMS-R-244)	156 PO	12,169	1.1667	14198	81.99	1,164,094	1,164,094
§ 460.112	PACE Participant Rights: Explain options and answer questions	0938-0790 (CMS-R-244)	156 PO	12,169	1	12169	60.34	734,277	734,277
(§ 460.120	PACE Grievance Process: Update policies, annual notifications, and resolution notifications	0938-0790 (CMS-R-244)	156 PO	156	4	624	74.02	46,188	-
§ 460.198	PACE participant notification of past performance issues	0938-0790 (CMS-R-244)	2 PO	2	1	2	74.02	148	148
§§ 422.2274(g) and 423.2274(g)	TMPO Sharing of Information	0938-0753 (CMS-R-267)	-	1,000,000	0.083	83000	20.71	1,718,930	1,718,930

Section(s) under Title 42 of the CFR	Item	OMB Control No. (CMS ID No.)	Respondents	Number of Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost of Reporting ($/hr)	Total Cost First Year ($)	Total Cost Subsequent Years ($)
§§ 422.2274(g) and 423.2274(g)	TMPO Sharing of Information	0938-0753 (CMS-R-267)	669 MA Plans	669	20	13380	136.17	1,821,955	1,821,955
Totals			3474836	39,222,620	*Varies*	1,715,087	*Varies*	227,178,194	225,128,585

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XI. Regulatory Impact Analysis

A. Statement of Need

The primary purpose of this final rule is to amend the regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicare cost plan program, and Program of All-Inclusive Care for the Elderly (PACE). This final rule includes several new policies that would improve these programs beginning with contract year 2025 as well as codify existing Part C and Part D sub-regulatory guidance. This final rule also includes revisions to existing regulations in the Risk Adjustment Data Validation (RADV) audit appeals process and the appeal process for quality bonus payment determination that would take effect 60 days after publication. Revisions to existing regulations for the use and release of risk adjustment data would also take effect 60 days after publication of a final rule. Additionally, this final rule would implement certain sections of the following Federal laws related to the Parts C and D programs:

- The Bipartisan Budget Act (BBA) of 2018.
- Consolidated Appropriations Act (CAA) of 2023

B. Overall Impact

We have examined the impacts 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), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), 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) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094, entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.), amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely affecting in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order.

A regulatory impact analysis (RIA) must be prepared for regulatory actions that are significant under 3(f)(1). The total economic impact for this final rule exceeds $200 million in several years. Therefore, based on our estimates, OMB's Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f)(1). Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has also determined that this rule meets the criteria set forth in 5 U.S.C. 804(2). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

Section 202 of UMRA 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 2023, the most recent year for which we have complete data, that threshold is approximately $183 million. This final rule is not anticipated to have an unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector of $183 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, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

C. Cost of Reviewing the Rule

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that—

- The hourly cost per reviewer for reviewing this final rule is $123.06 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Had a general business operations specialist been used (say for an entity without medical and health service managers) the cost per hour would be less than that for a medical and health services manager. Therefore, we are at most over-estimating the cost per hour and will use $123.06/hr.
- We estimate that there will be less than 2,000 reviewers of this final rule: There are currently less than 1,000 contracts (which includes MA, MA–PD, and PDP contracts), 55 State Medicaid agencies, and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, PBMs). We expect that each organization will designate one person to review the rule. Therefore, a reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.
- The rule is about 150,000 words. Average reading speeds vary from 180 to 240 words per minute. Since the rule is technical and presumably notes are being taken, we use the lower estimate. Furthermore, since in addition to notetaking, summaries would be submitted to leadership we are lowering the 180 words/minutes to 150. Accordingly, we assume it would take staff 17 hours to review this final rule (150,000 words/150 words per minute/60 minutes hour). This may be an overestimate since each entity will likely only read the provisions affecting them and not the entire rule.
- Therefore, the estimated cost per reviewing entity for reading this entire rule is $2,100 (17 hr × $123.06/hr), and the total cost over all entities for reviewing this entire final rule is $ 4.2 million ($2,100 × 2,000 reviewers). However, we expect that many reviewers, for example pharmaceutical companies and PBMs, will not review the entire rule but just the sections that are relevant to them. Thus, it is very likely that on average only half or a

quarter of the rule will be read resulting in a range of $2 million to $5 million.

Please note that this analysis assumes one reader per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we believe it is likely that review will be performed by contract. The argument for this is that a parent organization might have local reviewers assessing potential local, or region-specific effects from this final rule.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by OMB.

D. Impact on Small Businesses—Regulatory Flexibility Analysis (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

A wide range of policies are being finalized in this rule. These policies codify, modify, and update current guidance governing MA organization and Part D Plan Sponsor bid requirements.

This rule has several affected stakeholders. They include: (1) MA organizations such as HMOs, local and regional PPOs, MSAs, PFFS and Part D sponsors; (2) providers, including institutional providers, outpatient providers, clinical laboratories, and pharmacies; (3) agents and brokers, and (4) enrollees. Some descriptive data on these stakeholders are provided in Table K–1.

TABLE K-1: STAKEHOLDERS AFFECTED BY THIS RULE, THEIR NAICS CODE, AND THRESHOLD FOR SMALL BUSINESS STATUS

Stakeholder	NAICS Code (2022)	Threshold for Small Business (2021) (in millions of dollars)
Pharmacy and Drug stores	456110	37.5
Direct Health and Medical Insurance Carriers	524114	47
Ambulatory Health Services	621	
Dialysis Centers	621492	47
Insurance Brokerages & Agencies	524210	15
Physician offices	621111	16
Hospitals	622	47
Skilled Nursing Facilities	623110	34

We are certifying that this final rule does not have a significant economic impact on a substantial number of small entities. To explain our position, we explain certain operational aspects of the Medicare program.

Each year, MA plans submit a bid for furnishing Part A and B benefits and the entire bid amount is paid by the government to the plan if the plan's bid is below an administratively set benchmark. If the plan's bid exceeds that benchmark, the beneficiary pays the difference in the form of a basic premium (note that a small percentage of plans bid above the benchmark, whereby enrollees pay basic premium, thus this percentage of plans is not ''significant'' as defined by the RFA and as justified in this section of this final rule).

MA plans can also offer extra benefits, that is, benefits not covered under Traditional Medicare Parts A and B, called supplemental benefits. These benefits are paid for through enrollee premiums, rebate dollars or a combination. Under the statutory payment formula, if the bid submitted by a Medicare Advantage plan for furnishing Parts A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a rebate. The rebate must be used to provide supplemental benefits (that is benefits not covered under Traditional Medicare, including lower cost sharing) and or/lower beneficiary Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, and hearing, fitness and worldwide coverage of emergency and urgently needed services.

Part D plans, including MA–PD plans, submit bids and those amounts are paid to plans through a combination Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries, Part D plans receive special government payments to cover most of the premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by MA and Part D plans is funded by a variety of government fundingsources and in some cases by enrollee premiums. As a result, MA and Part D plans are not expected to incur burden or losses since the private companies' costs are being supported by the government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

Small entities that must comply with MA and Part D regulations, such as those in this final rule, are expected to include the costs of compliance in their bids, thus avoiding additional burden, since the cost of complying with any final rule is funded by payments from the government and, if applicable, enrollee premiums.

For Direct Health and Medical Insurance Carriers, NAICS 524114, plans estimate their costs for the upcoming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either (1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from Traditional Medicare data; or (2)

the benchmark, if the bid amount is greater than the benchmark.

Theoretically, there is additional burden if plans bid above the benchmark. However, consistent with the RFA, the number of these plans is not substantial. Historically, only two percent of plans bid above the benchmark, and they contain roughly one percent of all plan enrollees. Since the CMS criteria for a substantial number of small entities is 3 to 5 percent, the number of plans bidding above the benchmark is not substantial.

The preceding analysis shows that meeting the direct cost of this final rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA.

Therefore, we next examine in detail each of the other stakeholders and explain how they can bear cost. Each of the following are providers (inpatient, outpatient, or pharmacy) that furnish plan-covered services to plan enrollees for:

- Pharmacies and Drug Stores, NAICS 446110;
- Ambulatory Health Care Services, NAICS 621, including about two dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, and Dialysis Centers, NAICD 621492;
- Insurance Brokerages & Agencies, NAICS 524210;
- Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and
- SNFs, NAICS 623110.

Except for insurance brokers and agencies, each of these are providers that furnish plan-covered services to plan enrollees. Whether these providers are contracted or, in the case of PPOs and PFFS MA plans, not contracted with the MA plan, their aggregate payment for services is the sum of the enrollee cost Sharing and plan payments.

- For non-contracted providers, § 422.214 and sections 1852(k)(1) and 1866(a)(1)(O) of the Act require that a non-contracted provider that furnishes covered services to an MA enrollee accept payment that is at least what the provider would have been paid had the services been furnished to A Medicare FFS beneficiary.
- For contracted providers, § 422.520 requires that the payment is governed by a mutually agreed upon contract between the provider and the plan. CMS is prohibited from requiring MA plans to contract with a particular health care provider or to use a particular price structure for payment by section 1854(a)(6)(B)(iii) of the Act.

Consequently, for providers, there is no additional cost burden above the already existing burden in Traditional Medicare.

Our finalized provision requires TPMOs that collect personal beneficiary data for purposes of marketing or enrolling them into an MA or Part D plan to obtain prior express written consent through a disclosure to share that data with another TPMO. In response to our proposal to ban the distribution of beneficiary data, one commenter said that CMS failed to provide a cost-benefit analysis showing the impact of a data distribution ban on TPMOs and independent agents. However, since we are not completely prohibiting the sharing of beneficiary data in this final rule, we expect that TPMOs can make adjustments to their disclosures to conform to these new requirements without a major disruption to their business model or having a negative impact on independent agents and brokers. Further, we believe beneficiaries that are interested in obtaining more information about their plan options will complete the required consent processes. We expect some minor reduction in collection of data and a corresponding reduction in the sharing of that data, to which beneficiaries did not previously consent, as this data sharing may not have been wanted by beneficiaries who unknowingly consented to the sharing, and which resulted in complaints received by CMS. This consent requirement and a reduction in unwanted contacts is, in fact, the goal of the provision. We, however, have no way of estimating how much data-sharing occurred nor do we know the extent to which requiring beneficiaries to consent to their data being shared will reduce the amount of data shared in the future.

Based on the previous discussion, the Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

There are certain indirect consequences of these provisions which also create impact. We have already explained that at least 98 percent of the plans bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal Government, given that as previously noted, under the statutory payment formula, if a bid submitted by a Medicare Advantage plan for furnishing Part A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in the form of a beneficiary rebate, which must be used to provide supplemental and/or lower beneficiary Part B or Part D premiums. If the plan's bid exceeds the administratively set benchmark, the beneficiary pays the difference in the form of a basic premium. However, as also noted previously, the number of MA plans bidding above the benchmark to whom this burden applies does not meet the RFA criteria of a significant number of plans.

If the provisions of this final rule were to cause bids to increase and if the benchmark remains unchanged or increases by less than the bid does, the result could be a reduced rebate. Plans have different ways to address this in the short-term, such as reducing administrative costs, modifying benefit structures, and/or adjusting profit margins. These decisions may be driven by market forces. Part of the challenge in pinpointing the indirect effects is that there are many other factors combining with the effects of proposed and final rules, making it effectively impossible to determine whether a particular policy had a long-term effect on bids, administrative costs, margins, or supplemental benefits.

Comment: As indicated above, one commenter commented that CMS did not provide a cost-benefit analysis of the impact of its provisions on TPMOs. Additionally, this commenter pointed out that completely banning sharing personal beneficiary data, as originally proposed in the NPRM, would have an adverse effect on small businesses.

Response: We agree that a prohibition on sharing personal beneficiary data without any exception would adversely affect TPMOs and small businesses alike. We are therefore modifying our original proposal by allowing the sharing of personal beneficiary data when it's specifically consented to by the beneficiary. The paperwork burden for this has been properly estimated in the Collection of Information section. Since we are not completely prohibiting the sharing of beneficiary data in this final rule, we expect that TPMOs can make adjustments to their disclosures to conform to these new requirements without a major disruption to their business model or having a negative impact or TPMOs. Further, we believe enrollees that are interested in obtaining more information about their plan options will complete the required consent process or forms. We expect some minor changes in collection corresponding to a reduction in the sharing of data, to which there previously was not a requirement for consent, and this data sharing and subsequent contact was previously not

wanted or desired or knowingly agreed to and resulted in complaints to CMS and others. The goal of the provision is to require the consent of beneficiaries to the sharing of their personal data. However, we have not provided a more detailed quantification of the effect of this consent requirement, since CMS lacks internal and external data for estimating how much unauthorized data sharing was occurring previously nor do we know the extent to which requiring a beneficiary to consent to their data being shared will reduce the amount of data sharing in the future.

Comment: Several commentators provided comments on the agent-broker compensation provision. They noted: (1) the lack of any cost analysis; (2) the possible adverse impact this would have on independent agent-brokers or small agencies; (3) the high volatility and variance of several line-items contributing administrative costs and expenses to agent broker compensation may be inconsistent with a uniform flat compensation rate, and iv) that not all line-item costs are mentioned in the NPRM. These comments came from both those who receive agent broker compensation as well as those (such as plans) who pay for them. The comments were both qualitative and quantitative. In particular, several commentators said that administrative costs were significantly higher than what we said in the NPRM; these quantitative estimates ranged from $50 to $500 per enrollee with many commentors targeting the higher amounts.

Response: Our finalized provisions simultaneously eliminate administrative payments but provide for higher compensation per enrollee. The increased compensation above the base line compensation rate is $100 for each new MA or PDP enrollee. As discussed in section X.X of the preamble and section X.C.10 of the collection of information section, our goals were to: (1) provide sufficient funding which would compensate agents, brokers, and related entities for their work; (2) not to give excesses; and (3) to select increases consistent with current payments (that is not exceeding current administrative payments). In other words, the finalized provision transfers funds currently being allocated to administrative to compensation in a transparent and uniform manner. We have consequently scored this impact as having no cost, and therefore do not believe this will have an adverse effect, either on TMPOs, FMOs, or independent brokers.

E. Anticipated Effects

Many provisions of this final rule have negligible impact either because they are technical provisions, clarifications, or are provisions that codify existing guidance. Other provisions have an impact that cannot be quantified. Throughout the preamble, we have noted when we estimated that provisions have no impact either because they are codifying already existing practices, or, for example, because contractors for CMS have asserted that changes work within their current contract without the need for additional compensation. Additionally, this Regulatory Impact Statement discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions' effects are estimated in section XXX of this final rule and in this RIA. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this Regulatory Impact Statement cross-references impacts from section XXX of this final rule in order to arrive at total impact.

1. Effects of Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310)

We discussed in section III.Q. of this final rule two provisions to improve access to MA encounter data for certain purposes. We noted that our current regulatory language limits CMS's ability to use and disclose MA encounter data for activities in support of administration or evaluation of the Medicaid program, including care coordination. Further, the regulation delays when CMS may share MA encounter data to State Medicaid agencies for care coordination and quality review and improvement activities for the Medicaid program, particularly with regard to dually eligible individuals. This final rule improves access to MA data by—

- Adding ''and Medicaid programs'' to the current MA risk adjustment data use purposes codified at § 422.310(f)(1)(vi) and (vii); and
- Adding a new § 422.310(f)(3)(v) to allow for risk adjustment data to be released prior to reconciliation if the data will be released to State Medicaid agencies for the purpose of coordinating care for dually eligible individuals.

Together, these provisions clarify and broaden the allowable data uses for CMS and external entities (for data disclosed in accordance with § 422.310(f)(2) and (3)). These proposals do not change the external entities allowed to request MA encounter data from CMS.

As discussed in sections X and III.Q. of this final rule, these provisions will allow external entities to voluntarily request MA encounter data for allowable data uses to support the Medicare program, Medicaid program, and Medicare and Medicaid combined purposes. In the November 2023 proposed rule, we noted that there was one area where this provision could have impacted the burden to CMS: CMS reviewing and fulfilling new MA encounter data requests. However, in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program final rule, when we initially established CMS disclosure of MA encounter data, we explained that we had determined that ''there are not any economically significant effects of the proposed provisions'' (79 FR 50445). The same applies for the proposed refinements to the approved data uses and the data disclosure in this rule. We received no comments specific to our analysis of burden. We are finalizing our estimate as-is.

2. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization (§§ 422.503, 422.504, 422.514, 422.530, and 423.38)

We discussed collection of information burden associated with this provision in section X of this final rule. In this section, we describe the impacts of our changes to the dual/LIS SEP, new integrated care SEP, and contract limitations for non-integrated MA–PD plans.

These final provisions will impact dually eligible and other LIS eligible individuals that currently use the quarterly dual/LIS SEP to change their enrollment in MA–PD plans. We are finalizing a change the quarterly dual/LIS SEP to a one-time-per month SEP for dually eligible individuals and other LIS eligible individuals to elect a standalone PDP. The finalized provision will allow individuals to switch PDPs or leave their MA–PD plans for Traditional Medicare (with a standalone PDP) in any month. The finalized dual/LIS SEP will no longer permit enrollment into MA–PD plans or changes between MA–PD plans (although such options would remain available through other enrollment periods and SEPs). In

addition, we are finalizing with modification a new integrated care SEP that will allow enrollment in any month into a FIDE SNP, HIDE SNP, or AIP to facilitate aligned enrollment as defined at § 422.2 for full-benefit dual eligible individuals who meet the qualifications of such plans.

We are finalizing §§ 422.504(a)(20) and 422.514(h) largely as proposed with modifications to § 422.514(h). These provisions will establish a new requirement for an MA organization, that, beginning in plan year 2027, when an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, also contracts with a State as a Medicaid MCO that enrolls full-benefit dual eligible individuals in the same service area, that the MA organization's D–SNP(s) must limit new enrollment to individuals enrolled in (or in the process of enrolling in) the D–SNP's aligned Medicaid MCO. We are finalizing the proposed regulation at § 422.514(h) with a minor technical modification at § 422.514(h)(1) to correct the terminology to use the term ''full-benefit dual eligible individual(s)'' where necessary. We are finalizing § 422.514(h)(2) with a modification to clarify that any D–SNP(s) subject to enrollment limitations in § 422.514(h)(1) may only enroll (or continue coverage of people already enrolled) individuals also enrolled in (or in the process of enrolling in) the Medicaid MCO beginning in 2030. We are finalizing with modifications our proposal at § 422.514(h)(3)(i) to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, to offer more than one D–SNP for full-benefit dual eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO only when a SMAC requires it in order to differentiate enrollment into D–SNPs by age group or to align enrollment in each D–SNP with the eligibility criteria or benefit design used in the State's Medicaid managed care program(s). We are also finalizing with minor technical modifications at § 422.514(h)(3)(ii) to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization that offers both HMO D–SNP(s) and PPO D–SNP(s) to continue to offer both the HMO and PPO D–SNPs only if the D–SNP(s) not subject to the enrollment limitations at § 422.514(h)(1) no longer accept new full-benefit dual eligible enrollment in the same service area as the D–SNP affected by the new regulations at §§ 422.504(a)(20) and 422.514(h). Additionally, an MA organization (or its parent organization or another MA organization with the same parent organization) in this situation would only be able to offer one D–SNP for full-benefit dual eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO (with limited exceptions as described in section VIII.F. of this final rule). Further, beginning in plan year 2030, such D–SNPs must only enroll (or continue to cover) individuals enrolled in (or in the process of enrolling in) the affiliated Medicaid MCO.

Full-benefit dual eligible individuals enrolled in a D–SNP that consolidates due to our proposals at §§ 422.504(a)(20) and 422.514(h) will be moved into a new plan. The impacted enrollees will receive materials about the plan consolidation and materials associated with the new plan. We believe the plan benefit packages of the plans required to consolidate to be similar if not the same and do not expect impact to enrollees.

We expect there to be an enrollment shift from MA–PDs into FIDE SNPs, HIDE SNPs, or AIPs over time as more D–SNPs align with Medicaid MCOs. Starting in plan year 2027, we expect new D–SNP enrollment to be limited and then we expect integrated D–SNP enrollment to accelerate in 2030 when D–SNPs under a parent organization with an affiliated Medicaid MCO would need to disenroll individuals who are not enrolled in both the D–SNP and affiliated MCO.

We examined contract year 2023 bid data for D–SNPs that enroll beneficiaries in States that also use Medicaid managed care to cover some or all benefits for dually eligible individuals. In general, the data shows that the more integrated D–SNPs have higher per capita MA rebates than those in less integrated plans. MA rebates are used to reduce beneficiary cost sharing, lower beneficiary premiums, and provide additional supplemental benefits. MA rebates are calculated by multiplying the difference in the risk-adjusted benchmarks and the risk-adjusted bids by a percentage called the rebate percentage. The Federal Government retains the complement of the rebate percentage (or 1 − rebate percentage) multiplied by the difference in the risk-adjusted benchmarks and bids. The (risk-adjusted) bid-to-benchmark ratios, in general, are smaller for the more integrated plans versus the less integrated plans. This suggests that the more integrated D–SNPs can provide Traditional Medicare benefits (represented by the risk adjusted bid) at a lower or more efficient level than the less integrated D–SNPs. We have assumed that this provision's requirement for greater alignment between the D–SNP and the affiliated Medicaid MCO will lead to greater health benefit efficiencies and incur Federal Government savings since the Federal Government retains the complement of the difference between the submitted risk adjusted bids and benchmarks.

In calculating our estimates, we assumed savings would begin in 2027 when new D–SNPs enrollment would be limited. We expect integrated D–SNP enrollment and related savings to accelerate in 2030 when D–SNPs under a parent organization participating in Medicaid managed care would need to disenroll individuals who are not enrolled in both the D–SNP and affiliated Medicaid MCO under the same parent organization. We estimated that the other elements of this proposal (including the proposed changes to the SEP) would have a negligible impact.

To develop the savings projections, we calculated the bid-to-benchmark ratios for the integrated D–SNPs based on the calendar year 2023 plan data and applied them to the coordination-only D–SNPs that we assume would convert to aligned D–SNPs by 2030. We assumed that a large percentage of the coordination-only D–SNP enrollment would convert to integrated D–SNPs by 2030. For trending purposes, we used 2023 bid data and 2023 enrollment data as the starting point and trended those data points by values found in the 2023 Medicare Trustees Report. We calculated gross costs (savings are represented by negative dollar amounts) by multiplying the per member per month expenditure differences by the enrollment that is projected to switch to aligned plans. Then, we calculated the net cost by multiplying the gross costs by the net of Part B premium amount which averages between 85.1 percent and 84.6 percent from 2025–2034. This yields an overall annual estimate of net Part C costs ranging from − $6 million in contract year 2027 to − $207 million in contract year 2034.

TABLE K-2: ESTIMATED PART C COSTS (SAVINGS) PER YEAR ($ MILLIONS) TO THE MEDICARE TRUST FUND FOR PROPOSALS TO INCREASE THE PERCENTAGE OF DUALLY ELIGIBLE MANAGED CARE ENROLLEES WHO RECEIVE MEDICARE AND MEDICAID SERVICES FROM THE SAME ORGANIZATION

Contract Year	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
BID + REBATE PMPM Difference	-	-	(13.10)	(13.16)	(13.02)	(12.89)	(12.93)	(13.04)	(13.92)	(14.51)	
PROJECTED CO D-SNP Enrollment Switchers to Aligned Medicare and Medicaid MCOs	-	-	41,578	81,567	119,630	1,303,863	1,334,476	1,361,197	1,385,109	1,405,696	
Gross Cost ($ millions):	-	-	(7)	(13)	(19)	(202)	(207)	(213)	(231)	(245)	(1,136)
Net of Part B Premium:	85.1%	85.0%	84.9%	84.8%	84.8%	84.7%	84.7%	84.6%	84.6%	84.6%	
Net Cost ($ millions):	-	-	(6)	(11)	(16)	(171)	(175)	(180)	(196)	(207)	(961)

We performed a similar comparison of contract year 2023 bids for Part D on the same MA plans and their associated population. The data also suggests that the more integrated D–SNPs had lower combined bid and reinsurance amounts for contract year 2023. As a result, we also projected that there would be efficiencies when D–SNPs aligned more with the Medicaid MCOs. The observed 2023 difference (efficiency) in the combined bid and reinsurance amounts is projected with the corresponding D–SNP trend assumed in the 2023 Medicare Trustees' Report (not shown in that report). The Part D gross savings are the product of the efficiency and the associated switchers from Table K–3. Since the premiums for the Medicaid beneficiaries are subsidized, there would be no premium offset. As a result, the net savings would be the same as the gross savings. We estimated the net costs would range from −$7 million in contract year 2027 to −$286 million in contract year 2034.

We also have reviewed the impact to the Medicaid program and have concluded that the Medicaid impacts would be negligible. The majority of States have a ''lesser-of'' policy, under which the State caps its payment of Medicare cost sharing so that the sum of Medicare payment and cost-sharing does not exceed the Medicaid rate for a particular service. Under this policy, the Medicare payment and the cost sharing are not expected to increase resulting in non-significant impacts to Medicaid payments. For Part D, given that the Medicaid liability is limited to the beneficiary cost sharing and that the vast majority of dually eligible individuals qualify for low-income cost sharing, we anticipate no significant impacts to Medicaid costs.

TABLE K-3: ESTIMATED PART D COSTS (SAVINGS) PER YEAR ($ MILLIONS) TO THE MEDICARE TRUST FUND FOR PROPOSALS TO INCREASE THE PERCENTAGE OF DUALLY ELIGIBLE MANAGED CARE ENROLLEES WHO RECEIVE MEDICARE AND MEDICAID SERVICES FROM THE SAME ORGANIZATION

Contract Year	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
BID + REINSURANCE PMPM Difference	-	-	(14.09)	(14.25)	(14.67)	(15.00)	(15.30)	(15.87)	(16.47)	(16.97)	
Gross Cost ($ millions):	-	-	(7)	(14)	(21)	(235)	(245)	(259)	(274)	(286)	(1,341)
Net Part D Premium:	0	0	0	0	0	0	0	0	0	0	0
Net Cost ($ millions):	-	-	(7)	(14)	(21)	(235)	(245)	(259)	(274)	(286)	(1,341)

In addition to the estimated savings from limiting enrollment into certain D–SNPs starting in plan year 2027, these provisions require updates to a variety of CMS manual systems.

The finalized change to § 423.38(c)(4) and the finalized provision at § 423.38(c)(35) will create burden for CMS to update MA–PD plan manual chapters, the plan communication user guide (PCUG), and model enrollment notices. Additionally, the MARx system will require coding changes for the finalized amended dual/LIS SEP at § 423.38(c)(4) and finalized integrated care SEP at § 423.38(c)(35). The CMS call center 1–800–MEDICARE will need training on the finalized SEPs to be able to identify beneficiaries eligible for the SEPs. The updates and changes will require two GS–13 staff 20 hours to complete the necessary updates. We estimate the burden for plan year 2025, would be at 40 hours (2 GS–13 * 20 hrs) at a cost of $2,433 (40 hrs * $60.83) for two GS–13 staff to update manual chapters, the PCUG, enrollment notices, and complete coding for MARx. This is a one-time cost that will not create new burden in subsequent years.

The finalized provision at § 422.514(h)(3)(ii) with modification will allow plans to continue operating a PPO and HMO in the same service area but not allow new enrollments of full-benefit dually eligible individuals into the plan (or plans) that are not aligned with the affiliated MCO as described § 422.514(h)(1). This provision will not create new administrative cost for CMS since CMS would use its existing process to suppress these plans from Medicare Plan Finder.

The finalized provision at § 422.530(c)(4)(iii) allowing a crosswalk exception for plans consolidating their D–SNPs will create burden for CMS. The coding to create the crosswalk exception would require one GS–13 10 hours to complete the necessary updates. The burden for plan year 2025, is estimated at 10 hours (1 GS–13 * 10 hrs) at a cost of $608.30 (10 hrs * $60.83) for a GS–13 to complete coding for crosswalk exceptions. This is a one-time cost that will not create new burden in subsequent years. The burden associated with crosswalks and plan consolidation could create additional burden such as breaking plans into

different PBPs or having fewer PBPs to manage in the future. We cannot estimate these actions and associated burden but generally believe they cancel each other out.

3. Effects of Changes to an Approved Formulary—Including Substitutions of Biosimilar Biological Products (§§ 423.4, 423.100, 423.104, 423.120, 423.128, and 423.578)

We do not estimate any impact on the Medicare Trust Fund as a result of the provisions to permit immediate substitutions of new interchangeable biological products for their reference products or to treat substitutions of biosimilar biological products other than interchangeable biological products for their reference products as maintenance changes. New biosimilar biological products are approved or licensed by the FDA and become available on the market at irregular intervals. Therefore, with respect to this provision, we cannot predict when new biosimilar biological products will enter the market or to what extent Part D sponsors will make formulary substitutions as a result. The introduction of biosimilar biological products to the market is relatively recent compared to generic small molecule drugs. We believe there is a potential for savings to the Medicare Trust Fund in the long term as acceptance of biosimilar biological products grows and increased competition drives down costs; however, a number cannot be estimated right now. We received no comments on our estimate and are therefore finalizing without change.

4. Mid-Year Notice of Unused Supplemental Benefits

This proposal would require plans to notify enrollees about any supplemental benefit they have not used during the first half-year of the contract year. We lack data to quantify the effects of this provision. Therefore, we present a qualitative analysis below. The provision has 3 impacts on plans and the MA program.

One impact is the burden to plans to notify enrollees. This burden has been quantified in the Collection of Information in section X. of this finalized rule. The burden consists of: (1) a system update to identify supplemental benefits not utilized by enrollees; and (2) the burden to notify enrollees.

The second impact relates to the intent of the provision, which is to increase utilization of benefits when appropriate. In some cases, this could initially involve a cost to both enrollees for their share of cost sharing, and to the plans for providing the benefit. In assessing the impact, there are several dimensions of impact for which we lack complete data: (1) which supplemental benefits are not being utilized at all by some enrollees; (2) for each plan offering supplemental benefits, how many enrollees do and do not utilize these benefits; (3) how many more enrollees would utilize these benefits as a result of the notification; and (4) what is the range and distribution of the cost to provide these supplemental benefits.

The third impact relates to savings expected from increased utilization. Normally, such savings are considered consequences of a provision and not typically analyzed in an RIA. We use dental and gym benefits to show several complications and possibilities in this analysis.

Enrollees who use their preventive supplemental dental benefits may uncover problems early, thus preventing unnecessary complications. For example, the filling of cavities may prevent a costlier root canal later. Also note that the filling may happen in one plan while the costlier root canal that was prevented refers to a possible event several years later possibly in another plan (or out of pocket for the enrollee).

An interesting subtlety of this example is that enrollees who have preventive dental checkups may do so annually or semi-annually. The effect of the notification might be to increase annual checkups to semi-annual checkups. It is harder to quantify the savings from such a change in frequency.

From discussions with plans, we know that enrollees may incur the cost of a gym membership benefit without utilizing it. The intent of the provision would be to increase gym utilization. In the case of gym benefits the savings from increased prevention is challenging to analyze since different frequencies of gym attendance have different effects on health. An enrollee, for example, who decides to visit the gym only once because of the notification might not have any significant health benefits generating savings; even enrollees who switch to monthly visits may not experience savings. The savings on enrollees who decide to continue gym visits on a regular basis might arise from varied consequences since increased exercise has the potential to ''reduce risk of chronic conditions like obesity, type 2 diabetes, heart disease, many types of cancer, depression and anxiety, and dementia.'' [266]

In summary, this is the type of provision that has a savings impact that can be analyzed only after several years of experience with the provision.

5. Agent Broker Compensation (§ 422.2274)

In the NPRM we proposed to: (1) generally prohibit contract terms between MA organizations and agents, brokers, or other TMPOs that may interfere with the agent's or broker's ability to objectively assess and recommend the plan which best fits a beneficiary's health care needs; (2) set a single agent and broker compensation rate for all plans, while revising the scope of what is considered ''compensation;'' and (3) eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services. We also proposed to make conforming edits to the agent broker compensation rules at § 423.2274.

We are finalizing the above provisions as proposed, but with the following modifications.

We are finalizing our proposal to generally prohibit contract terms between MA organizations and agents, brokers, or other TMPOs that may interfere with the agent's or broker's ability to objectively assess and recommend the plan which best fits a beneficiary's health care needs. We are finalizing the policies to set a single agent and broker compensation rate for all plans, while revising the scope of what is considered ''compensation,'' and clarify the applicability date of October 1, 2024. And we are finalizing our policy to eliminate the use of administrative payments, with an applicability date of October 1, 2024. In addition, we are finalizing a one-time $100 increase to the FMV compensation rate for agents and brokers to reimburse them for necessary administrative activities.

As explained in the Section X.C.9 of this final rule, as a result of comments we replaced the line-item approach to estimating costs with a holistic cost estimate. This holistic cost estimate was based on the wide range of estimates of current administrative costs provided by stakeholders in response to our solicitation of comments. Additionally, since the finalized $100 flat rate to be paid by plans directly to agent brokers is less than the current administrative payments by plans—which are being eliminated, we regard the costs

[266] *https://www.cdc.gov/chronicdisease/resources/infographic/physical-activity.htm#.*

associated with this provision as a transfer; that is, a portion of the money currently being spent on administrative expenses is going towards the $100 flat rate but is not an additional cost.

The true cost of most administrative expenses can vary greatly from one agent or broker to another and is based in data and contracts that CMS does not have access to, so it would be extremely difficult for us to accurately capture, making a line-item calculation not practicable. This was further reflected in the wide variation among alternate rates posed by commenters, with a few commenters suggesting an alternate rate increase of $50, another $75, while the majority recommended higher rates beginning at $100 and some going as high as $500. Some commenters suggested that we should calculate the compensation increase as a percentage of the base rate, such as 30% or 33% of the current $611 compensation figure.

Considering the complexities involved in balancing the incentives not only between MA organizations and agents, brokers, and other TPMOs, but also balancing incentives between MA and other parts of Medicare, such as Traditional Medicare with PDP or supplemental Medigap plans, we believe that choosing a flat rate for calculating the increase is an appropriate path forward. By taking a flat-rate approach, we are able to create parity among agents, regardless of which plan, plan type, or type of Medicare enrollment they effectuate on behalf of the beneficiary. Given the fact that the administrative payments are intended to cover administrative costs that do not substantially differ based on which plan a beneficiary ultimately enrolls in, the flat rate approach is the best way to achieve our goals.

Several commenters suggested that an increase of $100 would be an appropriate starting point, and reflects the minimum monthly costs of necessary licensing and technology costs. We understand that other commenters recommended an increase of more than $100, including some suggesting an increase of $200 or more. However, we believe, based on the totality of comments, that recommendations for an increase above $100 may have been inflated to include the full price of all technology and systems that are also utilized to effectuate sales in other markets. In addition, it appears that such recommendations may reflect the lost ''bonuses'' and other ''administrative payments'' agents and brokers may previously have received, some of which were beyond the scope and FMV of the services involved in enrolling beneficiaries into MA plans and, therefore, should not have been included under compensation or administrative payments.

6. Enhancing Enrollees' Right To Appeal an MA Plan's Decision To Terminate Coverage for Non-Hospital Provider Services (§ 422.626)

In § 422.626, we proposed to (1) require the QIO instead of the MA plan, to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF; and (2) fully eliminate the provision requiring the forfeiture of an enrollee's right to appeal a termination of services decision when they leave the facility or end home health, CORF, or home-based hospice services before the proposed terminate date.

Currently, there is no data collected on the volume of fast-track appeals conducted by MA plans for untimely requests. The QIO conducts appeals for FFS fast-track appeals for untimely requests but does not formally collect data on appeals based on untimely requests from MA enrollees. Thus, the following estimates were speculative given the lack of precise data on the number of the fast-track appeals for untimely FFS requests.

Anecdotal data from the QIOs conducting these fast-track appeals indicates that approximately 2.5 percent of all fee-for-service (FFS) fast-track appeal requests are untimely. In CY 2021 (most recent year available), there were 190,031 MA fast-track appeals to the QIO. Thus, we estimate that approximately 4,751 fast track appeals will be shifted from MA plans to the QIO ($0.025 \times 190{,}031$).

The shift of these untimely appeals from the MA plans to the QIOs will result in an increased burden to QIOs and a reduced burden to MA plans. There is an estimated per case cost for QIOs to conduct these appeals (per the Financial Information and Vouchering System (FIVS) from 5/1/2019–7/31/2023), while MA plans are not specifically reimbursed for this activity. The average QIO appeal of this type takes 1.69 hours at $85.18/hr.

In aggregate we estimate an annual burden of 8,029 hours (4,751 responses * 1.69 hr/response) at a cost of $683,910 ($8{,}029 \text{ hr} \times \$85.18/\text{hr}$). This is being classified as a transfer from MA plans to QIOs.

We were unable to estimate how many new QIO reviews will be conducted under the proposed provision at § 422.626(a)(3) to eliminate the provision requiring the forfeiture of an enrollee's right to appeal a termination of services decision when they leave the skilled nursing facility or end home health, CORF, or home-based hospice services before the proposed termination date. No entity tracks how many appeals are not conducted because the enrollee stopped the services at issue before the last day of coverage. Further, because this provision has never existed for FFS, we have no basis from which to derive an estimate.

We received no comments on our estimate and are therefore finalizing without change.

7. Part D Medication Therapy Management (MTM) Program Targeting Requirements (§ 423.153)

We proposed to revise § 423.153(d)(2) to: (1) codify the current nine core chronic diseases in regulation, and add HIV/AIDS to the list of core chronic diseases for a total of 10 core chronic diseases and require Part D sponsors to include all core chronic diseases in their MTM targeting criteria; (2) lower the maximum number of Part D drugs a Part D sponsor may require from eight to five drugs and require sponsors to include all Part D maintenance drugs in their targeting criteria; and (3) change the annual cost threshold methodology to be commensurate with the average annual cost of five generic drugs ($1,004 in 2020). We estimated that these proposals would increase the number of Part D beneficiaries eligible for MTM services.

These proposed changes would allow us to address specific problems identified in the Part D MTM program by improving access to MTM services for enrollees with multiple chronic conditions who are taking multiple Part D drugs, reducing marked variability in MTM eligibility across plans, better aligning with Congressional intent to improve medication use and reduce the risk of adverse events by focusing more on case complexity and drug regimen, and establishing a more reasonable cost threshold that would keep the MTM program size manageable. Almost all of the chronic diseases that CMS proposed to codify as core chronic diseases are more prevalent among underserved populations, including minority and lower income populations. As a result, we anticipated that our proposed changes would increase eligibility rates among those populations.

We did not receive any comments on this section of the proposed rule. After consideration of the comments we did receive, we are finalizing our proposal with modifications. We are finalizing the requirement that sponsors include all core chronic conditions in their targeting criteria (the current nine core

chronic diseases, as well as HIV/AIDS), for a total of 10 core chronic conditions. Plan sponsors would also be required to include all Part D maintenance drugs in their targeting criteria. We are not finalizing the change to the maximum number of Part D drugs sponsors may require in their targeting criteria (remains at eight), and for alignment, modifying the calculation of the MTM cost threshold to be commensurate with the average annual cost of eight generic Part D drugs. This would result in a program size of 7,065,385 (or 13 percent of the Part D enrollees using 2022 data) compared to the current 3,599,356 (7 percent of Part D enrollees using actual 2022 MTM enrollment). The changes would allow us to address specific gaps identified in MTM program eligibility by reducing marked variability across plans and ensuring more equitable access to MTM services; better align with Congressional intent while focusing on more beneficiaries with complex drug regimens; and keep the program size increase manageable. The changes also take into consideration the burden a change in the MTM program size would have on sponsors, MTM vendors, and the health care workforce as a whole. A moderate expansion also offers opportunities to focus on quality through the development of new, outcomes-based MTM measures, promoting consistent, equitable, and expanded access to MTM services.

We cannot definitively score this proposal because there may be other administrative costs attributable to MTM, and MTM program costs are not a specific line item that can be easily extracted from the bid. Additionally, published studies have found that MTM services may generate overall medical savings, for example, through reduced adverse outcomes including reduced hospitalizations and readmissions, outpatient encounters, or nursing home admissions. CMS is unable to generate reliable savings estimates from the published studies due to limitations in potential study design, including the lack of a control group and numerous intervening variables. The burden associated with these changes is addressed in the Collection of Information section (section X.) of this final rule in the ICR section for MTM targeting criteria.

F. Alternatives Considered

In this section, CMS includes discussions of alternatives considered. Several provisions of this final rule reflect a codification of existing policy where we have evidence, as discussed in the appropriate preamble sections, that the codification of this existing policy would not affect compliance. In such cases, the preamble typically discusses the effectiveness metrics of these provisions for public health. Also, in these cases, traditional categories of alternative analysis such as different compliance dates, different enforcement methods, different levels of stringency, as outlined in section C of OMB's Circular A–4, are not fully relevant since the provision is already being complied with adequately. Consequently, alternative analysis is not provided for these provisions.

1. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes (§ 422.514)

We are finalizing a reduction to the threshold for D–SNP look-alikes from 80 percent to 60 percent over a 2-year period. We considered an alternative proposal to lower the D–SNP look-alike threshold to 60 percent in 1 year, allowing an earlier phase-out of these non-SNP MA plans. But we are finalizing the more incremental approach to minimize disruptions to dually eligible individuals and allow plans and CMS more time to operationalize these transitions.

We considered and solicited comment on an alternative to our proposal that would eliminate the proposed 70 percent threshold for plan year 2025 but would involve additional conditions and changes related to the transition authority. Specifically, this alternative would:

- Apply the 60 percent threshold beginning in plan year 2026;
- Permit use of the transition authority into non-SNP MA plans (as currently permitted under § 422.514(e) for plan year 2025; and
- Limit use of transition authority under § 422.514(e) to transition D–SNP look-alike enrollees into D–SNPs for plan year 2026 and subsequent plan years.

Relative to our final provision, this alternative would have given plans with dually eligible individual enrollment between 70 and 80 percent of total enrollment based on January 2024 enrollment data one additional year to apply for a new D–SNP or service area expansion to an existing D–SNP, such that these plans could transition enrollees into a D–SNP for plan year 2026. The alternative would have balanced the additional year using the existing 80 percent enrollment threshold to identify prohibited D–SNP look-alikes with an earlier limitation on the § 422.514(e) transition authority to enrollees transitioning into non-SNPs. We solicited comment on whether this alternative is a better balance of the goals of our policy to prohibit circumvention of the requirements for D–SNPs and to encourage and incentivize enrollment in integrated care plans.

Among the factors we considered related to the alternative is the extent to which plans with 70 percent or more dually eligible enrollment in plan year 2024 expect to be able to establish a D–SNP in the same service area as the D–SNP look-alike if given an additional year (that is, 2026) to transition enrollees. Based on 2023 plan year data, approximately two-thirds of the MA organizations with non-SNP MA plans with between 70 and 80 percent dually eligible individuals already have a D–SNP under the same MA organization with the vast majority of those D–SNPs having a service area that covers the service area as the non-SNP MA plan. The other approximately one-third of the MA organizations with non-SNP MA plans with between 70 and 80 percent dually eligible individuals do not have a D–SNP in the same service area in plan year 2023. If given an additional year, these MA organizations would have had more time in which to establish D–SNPs in the same service areas as non-SNP MA plans and transition the enrollees into a D–SNP.

We are not finalizing any of these alternative policies, and instead are finalizing this provision as proposed, as discussed in section VIII.J. of this final rule.

2. Part D Medication Therapy Management (MTM) Program Targeting Criteria (§ 423.153)

We considered two alternatives to our original proposal. The first alternative we considered would maintain our proposed changes related to chronic diseases and Part D drug utilization, but would establish a cost threshold commensurate with the average annual cost of 2 Part D maintenance drugs. Under this alternative, CMS would calculate the dollar amount based on the average daily cost of both brand and generic drugs identified as maintenance drugs in Medi-Span. Based on 2020 PDE data, the cost threshold under this alternative would be $1,657, with an estimated program size of about 9,363,087 beneficiaries (19.53 percent of the total Part D population) and an estimated increased burden of $251,600,394.

The second alternative we considered would include our proposed changes related to chronic diseases, retain the current maximum number of Part D drugs a sponsor may require for MTM program enrollment at 8 drugs, require sponsors to include all Part D

maintenance drugs in their targeting criteria, and establish a cost threshold commensurate with the average annual cost of 5 generic maintenance drugs. Under this alternative, CMS would calculate the dollar amount of the cost threshold as proposed but would only include generic maintenance drugs. Based on 2020 PDE data, the cost threshold under this alternative would be $840, with an estimated program size of 7,924,203 beneficiaries (16.53 percent of the total Part D population) and an estimated increased burden of $177,022,820.

We did not receive any comments in response to the specific alternatives considered in the proposed rule; therefore, we did not pursue finalizing either of these alternatives. We are instead finalizing the proposed changes with modifications to the Part D MTM program eligibility requirements as discussed in section III.E. of this final rule which includes our proposed changes related to chronic diseases, retains the current maximum number of Part D drugs a sponsor may require for MTM program enrollment at 8 drugs, requires sponsors to include all Part D maintenance drugs in their targeting criteria, and establishes a cost threshold commensurate with the average annual cost of 8 generic maintenance drugs. The changes we are finalizing allows us to be responsive to commenters' concerns regarding the potential impact of reducing the maximum number of Part D drugs from eight to five to maintain, about program size, and the ability to administer effective MTM services, while still addressing the barriers to eligibility posed by the increasingly restrictive plan criteria (for example, by targeting select core chronic diseases or drugs) and the high cost threshold, which were identified in our analysis as the main drivers of reduced eligibility rates for MTM.

G. Accounting Statement and Table

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*) in Table K4, we have prepared an accounting statement showing the costs and transfers associated with the provisions of this final rule for calendar years 2025 through 2034. Table K4 is based on Tables K–5a Table K5b which list savings and costs by provision and year. Tables K4, K5a and K5b list annual costs as positive numbers and savings as positive numbers. As can be seen, expenditures of the Medicare Trust Fund are reduced by about $200 million annually, the savings arising from increased efficiencies in operating Dual Eligibles Special Needs Plans. This is offset by the approximately $224 million annual cost of this rule. The major contributors to this annualized cost are a variety of mailings and notifications. Minor seeming discrepancies in totals in Tables K4, K5a, and K5b reflect use of underlying spreadsheets, rather than intermediate rounded amounts.

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TABLE K4: ACCOUNTING TABLE ($ MILLIONS)*

Item	Annualized at 3%	Annualized at 7%	Period	Who is affected
Net Annualized Monetized Costs	224.1	224.1	CYs 2025–2034	MA Organizations, Part D Sponsors, Contractors for the Federal Government, MA Enrollees, Agents and Brokers,
Annualized Monetized Savings	$4.0	$4.0	CYs 2025–2034	MA Organizations, Part D Sponsors, Contractors for the Federal Government, MA Enrollees, Agents and Brokers,
Annualized Monetized Costs	$228.1	$228.1	CYs 2025–2034	MA Organizations, Part D Sponsors, Contractors for the Federal Government, MA Enrollees, Agents and Brokers,
Transfers	214.1	192.8	CYs 2025–2034	Reduced dollar spending of the Medicare Trust Fund to Medicare Advantage Plans and Plan sponsors who are spending less to buy the same benefits

* The savings and cost are expressed with positive numbers. For example, at 3%, this final rule annually costs $228.1 million but saves $4.0 million resulting in a net cost of $224.1 million (errors are due to rounding). The transfers, listed as positive numbers, reflect savings, dollar reductions to the Medicare Trust Fund.

The following Tables K5a and K5b summarize costs, and savings by provision and year, and form a basis for the accounting Table K4. In Tables K5a and K5b, annual costs and savings are expressed as positive numbers and, except for the last two rows, are true costs and savings reflecting increases or decreases in consumption of services and goods. However, the provisions presenting impacts of increasing enrollment for D–SNPs on Part C and Part D which affect the Medicare Trust Fund are transfers reflecting buying the same goods and services with greater efficiency. These transfers are expressed as positive numbers and reflect reduced dollar spending to the Trust Fund, that is savings. The provision enhancing enrollee appeal rights is a transfer from MA administrative costs to QIO costs. The 10-year aggregate impacts in the right-most column use positive numbers to reflect costs and negative numbers to reflect savings, Tables K5a and K5b combine related provisions. For example, all provisions in the COI summary table related to PACE are combined into one line item in the RIA.

TABLE K5a: SAVINGS AND COSTS ($ Millions) BY PROVISION AND YEAR *

Item	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers	2029 Savings	2029 Cost	2029 Transfers
Total Savings	4.0			4.0			4.0			4.0			4.0		
Total Costs		229.4			227.9			227.9			227.9			227.9	
Aggregate Total	225.4			223.9			223.9			223.9			223.9		
Savings of the Medicare Trust Fund			0.7			0.7			13.3			25.6			37.6
DMP	3.0			3.0			3.0			3.0			3.0		
Multi Language Inserts		0.1			0.0			0.0			0.0			0.0	
Formulary Provisions	1.0			1.0			1.0			1.0			1.0		
Mid-Year Notification of unused Supplemental Benefits		23.7			23.7			23.7			23.7			23.7	
Utilization Committee		1.0			0.0			0.0			0.0			0.0	
SSBCI Provision		7.0			7.0			7.0			7.0			7.0	
D-SNP Look Alike Provision		0.1			0.1			0.1			0.1			0.1	
PACE Provisions		2.1			1.9			1.9			1.9			1.9	
Increasing D-SNP Enrollment, Paperwork burden		0.2			0.0			0.0			0.0			0.0	
Involuntary Disenrollment from D-SNPS		0.5			0.5			0.5			0.5			0.5	
TMPO Sharing of Information		1.7			1.7			1.7			1.7			1.7	
MTM		192.7			192.7			192.7			192.7			192.7	
Reinstatements from Cancellation of New Enrollments		0.3			0.3			0.3			0.3			0.3	
Increasing D-SNP Enrollment, Part C									5.5			10.9			15.9
Increased Enrollment in D-SNPS, Part D									7.0			13.9			21.1
Increasing Enrollee appeal rights			0.7			0.7			0.7			0.7			0.7

*Table K5a is continued in Table K5b

TABLE K5b: SAVINGS AND COSTS ($ Millions) BY PROVISION AND YEAR (Continued from Table K5a)*

Item	2030 Savings	2030 Costs	2030 Transfers	2031 Savings	2031 Cost	2031 Transfers	2032 Savings	2032 Cost	2032 Transfers	2033 Savings	2033 Cost	2033 Transfers	2034 Savings	2034 Cost	2034 Transfers	Raw 10 Year Totals
Total Savings	4.0			4.0			4.0			4.0			4.0			40.1
Total Costs		227.9			227.9			227.9			227.9			227.9		2280.6
Aggregate Total	223.9			223.9			223.9			223.9			223.9			2240.6
Savings of the Medicare Trust Fund			406.3			421.1			440.1			470.0			493.9	2,307.8
DMP	3.0			3.0			3.0			3.0			3.0			-30.5
Multi Language Inserts		0.0			0.0			0.0			0.0			0.0		0.1
Formulary Provisions	1.0			1.0			1.0			1.0			1.0			-9.6
Mid-Year Notification of unused Supplemental Benefits		23.7			23.7			23.7			23.7			23.7		236.9
Utilization Committee		0.0			0.0			0.0			0.0			0.0		1.1
SSBCI Provision		7.0			7.0			7.0			7.0			7.0		70.0
D-SNP Look Alike Provision		0.1			0.1			0.1			0.1			0.1		0.6
PACE Provisions		1.9			1.9			1.9			1.9			1.9		19.2
Increasing D-SNP Enrollment, Paperwork burden		0.0			0.0			0.0			0.0			0.0		0.2
Involuntary Disenrollment from D-SNPS		0.5			0.5			0.5			0.5			0.5		5.1
TMPO Sharing of Information		1.7			1.7			1.7			1.7			1.7		17.2
MTM		192.7			192.7			192.7			192.7			192.7		1927.2
Reinstatements from Cancellation of New Enrollments		0.3			0.3			0.3			0.3			0.3		3.1
Increasing D-SNP Enrollment, Part C			170.8			175.3			180.3			195.7			206.9	961.4
Increased Enrollment in D-SNPS, Part D			234.8			245.0			259.2			273.7			286.3	1340.9
Increasing Enrollee appeal rights			0.7			0.7			0.7			0.7			0.7	6.8

NOTES:

- Positive numbers in the annual cost columns reflect costs while positive numbers in the annual savings columns reflect savings. The aggregate row subtracts the savings from the cost and therefore lists the aggregate total as a cost expressed as a positive number. The raw total column (over 10 years) expresses costs as positive numbers and savings as negative numbers.
- Two-line items effect the Trust Fund: Increased Enrollment in D-SNPs, Part C, and Increased Enrollment in D-SNPs, Part D. Over 10 years they save, $961, and $1,341 million respectively.
- When the aggregate of line items for a provision is below $50,000, for example the paperwork burden of $4929 associated with the provision for network adequacy of behavioral health, or the cost to CMS staff to perform certain tasks listed in this section, they were not included in the table (since they do not have an effect on numbers). However, when the aggregate of several provisions rounded to at least $0.1 million it was included.
- Line items belonging to one class of provisions in the COI Summary table are included under one line item in this RIA summary table. For example, the three line items contributing to the paper burden of Medication Therapy Management (MTM) are added together in one line in this RIA Summary table.

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H. Conclusion

In aggregate this final rule combines both savings and costs. Three provisions reduce spending by the Medicare Trust Fund: (1) the effect on Part C plans from the provisions designed to increase the

percentage of dually eligible managed care enrollees who are enrolled in integrated D–SNPs; (2) the effect on Part D plans from these D–SNP provisions and (3) enhancing enrollee appeal rights. Over a 10-year period they reduce spending of the Medicare Trust Fund of $961, $1,341, and $6.8 million respectively for a combined savings of $2.3 billion. These savings are offset by various paperwork burden and some minor savings which in aggregate over 10 years cost $2.2 billion. The major drivers of cost are the mailings to enrollees regarding unused supplemental benefits and medication therapy management (MTM). The provisions for the Drug Management Program reduce paperwork burden by $3 million annually saving $30.5 million over 10 years.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on March 29, 2024.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health Insurance, Health maintenance organizations (HMO), Loan programs—health Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

■ 2. Section 417.460 is amended by revising paragraphs (c)(3), (e)(2), (e)(4), and adding (e)(7) to read as follows:

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

* * * * *

(c) * * *

(3) *Good cause and reinstatement.* When an individual is disenrolled for failure to pay premiums or other charges imposed by the HMO or CMP for deductible and coinsurance amounts for which the enrollee is liable, CMS (or a third party to which CMS has assigned this responsibility, such as an HMO or CMP) may reinstate enrollment in the plan, without interruption of coverage, if the individual does all of the following:

(i) Submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date.

(ii) Has not previously requested reinstatement for good cause during the same 60-day period following the involuntary disenrollment.

(iii) Shows good cause for failure to pay.

(iv) Pays all overdue premiums or other charges within 3 calendar months after the disenrollment date.

(v) Establishes by a credible statement that failure to pay premiums or other charges was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(e) * * *

(2) *Effort to resolve the problem.* (i) The HMO or CMP must make a serious effort to resolve the problem presented by the enrollee, including the use (or attempted use) of internal grievance procedures, and including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities.

(ii) The HMO or CMP must inform the individual of the right to use the organization's grievance procedures, through the notices described in paragraph (e)(7) of this section.

* * * * *

(4) *Documentation.* The HMO or CMP must document the problems, efforts, and medical conditions as described in paragraphs (e)(1) through (3) of this section. Dated copies of the notices required in paragraph (d)(2)(iv) of this section must also be submitted to CMS.

* * * * *

(7) *Other required notices.* The HMO or CMP must provide the individual two notices before submitting the request for disenrollment to CMS.

(i) The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action.

(A) If the disruptive behavior ceases after the enrollee receives the advance notice and then later resumes, the HMO or CMP must begin the process again.

(B) The HMO or CMP must wait at least 30 days after sending the advance notice before sending the second notice, during which 30-days period the individual has to provide an opportunity for the individual to cease their behavior.

(ii) The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the enrollee that the HMO or CMP requests CMS permission to involuntarily disenroll the enrollee. This notice must be provided before submission of the request to CMS.

* * * * *

■ 3. Section 417.472 is amended by adding paragraph (l) to read as follows:

§ 417.472 Basic contract requirements.

* * * * *

(l) *Resolution of complaints in the complaints tracking module.* The HMO or CMP must comply with requirements of §§ 422.125 and 422.504(a)(15) of this chapter to, through the CMS complaints tracking module as defined in § 422.125(a) of this chapter, address and resolve complaints received by CMS against the HMO or CMP within the required timeframes. References to the MA organization or MA plan in those regulations shall be read as references to the HMO or CMP.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 4. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

■ 5. Section 422.2 is amended by—

■ a. Revising the definition of ''Basic benefits'';
■ b. Adding the definition of ''Chronic condition special needs plan (C–SNPs)'', ''Facility-based institutional special needs plan (FI–SNP)'', ''Hybrid institutional special needs plan (HI–SNP)'', ''Institutional-equivalent special needs plan (IE–SNP)'', ''Institutional special needs plan (I–SNP)'', and ''Network-based plan'' in alphabetical order; and
■ c. Revising the definition of ''Severe or disabling chronic condition''.

The revisions and additions read as follows:

§ 422.2 Definitions.

* * * * *

Basic benefits means Part A and Part B benefits except—

(1) Hospice services; and

(2) Beginning in 2021, organ acquisitions for kidney transplants, including costs covered under section 1881(d) of the Act.

* * * * *

Chronic condition special needs plan (C–SNPs) means an SNP that restricts enrollment to MA eligible individuals who have one or more severe or disabling chronic conditions, as defined under this section, including restricting enrollment based on the multiple commonly co-morbid and clinically linked condition groupings specified in § 422.4(a)(1)(iv).

* * * * *

Facility-based Institutional special needs plan (FI–SNP) means a type of I–SNP that—

(1) Restricts enrollment to MA eligible individuals who meet the definition of institutionalized;

(2) Must own or contract with at least one institution, specified in the definition of institutionalized in this section, for each county in the plan's service area; and

(3) Must own or have a contractual arrangement with each institutionalized facility serving enrollees in the plan.

* * * * *

Hybrid Institutional special needs plan (HI–SNP) means a type of I–SNP that—

(1) Restricts enrollment to both MA eligible individuals who meet the definition of institutionalized and MA eligible individuals who meet the definition of institutionalized-equivalent in this section; and

(2) Meet the standards specified in the definitions of FI–SNP and IE–SNP.

* * * * *

Institutional-equivalent special needs plan (IE–SNP) means a type of I–SNP that restricts enrollment to MA eligible individuals who meet the definition of institutionalized-equivalent in this section.

* * * * *

Institutional special needs plan (I–SNP) means a SNP that restricts enrollment to MA eligible individuals who meet the definition of institutionalized and institutionalized-equivalent in this section. I–SNPs include the following subtypes:

(1) IE–SNP.

(2) HI–SNP.

(3) FI–SNP.

* * * * *

Network-based plan—

(1) Means—

(i) A coordinated care plan as specified in § 422.4(a)(1)(iii);

(ii) A network-based MSA plan; or

(iii) A section 1876 reasonable cost plan; and

(2) Excludes an MA regional plan that meets access requirements substantially through the authority of § 422.112(a)(1)(ii) instead of written contracts.

* * * * *

Severe or disabling chronic condition means, for the purpose of defining a special needs individual, the following co-morbid and medically complex chronic conditions that are life-threatening or significantly limit overall health or function, has a high risk of hospitalization or other significant adverse health outcomes, and requires intensive care coordination, and that which is designated by the Secretary under sections 1859(b)(6)(B)(iii)(II) and 1859(f)(9)(A) of the Act:

(1) Chronic alcohol use disorder and other substance use disorders (SUDs).

(2) Autoimmune disorders:

(i) Polyarteritis nodosa.

(ii) Polymyalgia rheumatica.

(iii) Polymyositis.

(iv) Dermatomyositis.

(v) Rheumatoid arthritis.

(vi) Systemic lupus erythematosus.

(vii) Psoriatic arthritis.

(viii) Scleroderma.

(3) Cancer.

(4) Cardiovascular disorders:

(i) Cardiac arrhythmias.

(ii) Coronary artery disease.

(iii) Peripheral vascular disease.

(iv) Valvular heart disease.

(5) Chronic heart failure.

(6) Dementia.

(7) Diabetes mellitus.

(8) Overweight, obesity, and metabolic syndrome.

(9) Chronic gastrointestinal disease:

(i) Chronic liver disease.

(ii) Non-alcoholic fatty liver disease (NAFLD).

(iii) Hepatitis B.

(iv) Hepatitis C.

(v) Pancreatitis.

(vi) Irritable bowel syndrome.

(vii) Inflammatory bowel disease.

(10) Chronic kidney disease (CKD):

(i) CKD requiring dialysis/End-stage renal disease (ESRD).

(ii) CKD not requiring dialysis.

(11) Severe hematologic disorders:

(i) Aplastic anemia.

(ii) Hemophilia.

(iii) Immune thrombocytopenic purpura.

(iv) Myelodysplastic syndrome.

(v) Sickle-cell disease (excluding sickle-cell trait).

(vi) Chronic venous thromboembolic disorder.

(12) HIV/AIDS.

(13) Chronic lung disorders:

(i) Asthma, Chronic bronchitis.

(ii) Cystic Fibrosis.

(iii) Emphysema.

(iv) Pulmonary fibrosis.

(v) Pulmonary hypertension.

(vi) Chronic Obstructive Pulmonary Disease (COPD).

(14) Chronic and disabling mental health conditions:

(i) Bipolar disorders.

(ii) Major depressive disorders.

(iii) Paranoid disorder.

(iv) Schizophrenia.

(v) Schizoaffective disorder.

(vi) Post-traumatic stress disorder (PTSD).

(vii) Eating Disorders.

(viii) Anxiety disorders.

(15) Neurologic disorders:

(i) Amyotrophic lateral sclerosis (ALS).

(ii) Epilepsy.

(iii) Extensive paralysis (that is, hemiplegia, quadriplegia, paraplegia, monoplegia).

(iv) Huntington's disease.

(v) Multiple sclerosis.

(vi) Parkinson's disease.

(vii) Polyneuropathy.

(viii) Fibromyalgia.

(ix) Chronic fatigue syndrome.

(x) Spinal cord injuries.

(xi) Spinal stenosis.

(xii) Stroke-related neurologic deficit.

(16) Stroke.

(17) Post-organ transplantation care.

(18) Immunodeficiency and Immunosuppressive disorders.

(19) Conditions associated with cognitive impairment:

(i) Alzheimer's disease.

(ii) Intellectual disabilities and developmental disabilities.

(iii) Traumatic brain injuries.

(iv) Disabling mental illness associated with cognitive impairment.

(v) Mild cognitive impairment.

(20) Conditions with functional challenges and require similar services including the following:

(i) Spinal cord injuries.
(ii) Paralysis.
(iii) Limb loss.
(iv) Stroke.
(v) Arthritis.
(21) Chronic conditions that impair vision, hearing (deafness), taste, touch, and smell.
(22) Conditions that require continued therapy services in order for individuals to maintain or retain functioning.
* * * * *

■ 6. Section 422.4 is amended by adding paragraphs (a)(1)(iv)(A) and (B) to read as follows:

§ 422.4 Types of MA plans.

(a) * * *
(1) * * *
(iv) * * *
(A) A C–SNP may focus on one severe or disabling chronic condition, as defined in § 422.2, or on a grouping of severe or disabling chronic conditions.
(B) Upon CMS approval, an MA organization may offer a C–SNP that focuses on multiple commonly co-morbid and clinically linked conditions from the following list of groupings:
(*1*) Diabetes mellitus and chronic heart failure.
(*2*) Chronic heart failure and cardiovascular disorders.
(*3*) Diabetes mellitus and cardiovascular disorders.
(*4*) Diabetes mellitus, chronic heart failure, and cardiovascular disorders.
(*5*) Stroke and cardiovascular disorders.
(*6*) Anxiety associated with COPD.
(*7*) Chronic kidney disease (CKD) and post-(renal) organ transplantation.
(*8*) Substance use disorders (SUD) and chronic mental health disorders.
* * * * *

■ 7. Section 422.52 is amended by—
■ a. Revising paragraph (b)(2);
■ b. Revising paragraph (f); and
■ c. Adding paragraph (g).
The revision and additions read as follows:

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

* * * * *
(b) * * *
(2) Meet the eligibility requirements for that specific SNP, including any additional eligibility requirements established in the State Medicaid agency contract (as described at § 422.107(a)) for dual eligible special needs plans; and
* * * * *
(f) Establishing eligibility for enrollment. (1) For enrollments into an SNP that exclusively enrolls individuals that have severe or disabling chronic conditions (C–SNP), the organization must contact the applicant's current health care provider, who is a physician as defined in section 1861(r)(1) of the Act, physician assistant as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.74(c) of this chapter, or a nurse practitioner as defined in section 1861(aa)(5)(A) of the Act and who meets the qualifications specified in § 410.75(b)(1)(i) and (ii) of this chapter to confirm that the applicant has the qualifying condition(s). The organization must obtain this information in one of the following two ways described in paragraph (f)(1)(i) or (ii) of this section:
(i) Contact the current health care provider or current health care provider's office and obtain verification of the applicant's condition(s) prior to enrollment in a form and manner authorized by CMS.
(ii) Through an assessment with the enrollee using a pre-enrollment qualification assessment tool (PQAT) where the assessment and the information gathered are verified (as described in paragraph (f)(1)(iii) of this section) before the end of the first month of enrollment in the C–SNP. Use of a PQAT requires the following:
(A) The PQAT must do all of the following:
(*1*) Include clinically appropriate questions relevant to the chronic condition(s) on which the C–SNP focuses.
(*2*) Gather sufficient reliable evidence of having the applicable condition using the applicant's past medical history, current signs or symptoms, and current medications.
(*3*) Include the date and time of the assessment completion if done face-to-face with the applicant, or the receipt date if the C–SNP receives the completed PQAT by mail or by electronic means (if available).
(*4*) Include a signature line for and, once completed, be signed by the current health care provider specified in paragraph (f)(1) of this section to confirm the individual's eligibility for C–SNP enrollment.
(B) The C–SNP conducts a post-enrollment confirmation of each enrollee's information and eligibility by having the completed PQAT reviewed and signed by the enrollee's current health care provider as specified in paragraph (f)(1) of this section.
(C) The C–SNP must include the information gathered in the PQAT and used in this verification process in its records related to or about the enrollee that are subject to the confidentiality requirements in § 422.118.
(D)(*1*) The C–SNP tracks the total number of enrollees and the number and percent by condition whose post-enrollment verification matches the pre-enrollment assessment.
(*2*) Data and supporting documentation are made available upon request by CMS.
(E) If the organization does not obtain verification of the enrollees' required chronic condition(s) by the end of the first month of enrollment in the C–SNP, the organization must—
(*1*) Disenroll the enrollee as of the end of the second month of enrollment; and
(*2*) Send the enrollee notice of the disenrollment within the first 7 calendar days of the second month of enrollment.
(F) The organization must maintain the enrollment of the individual if verification of the required condition(s) is obtained at any point before the end of the second month of enrollment.
(iii) Prior to enrollment, the PQAT must be completed by the enrollee, completed by the enrollee's current health care provider, or administered with the enrollee by a provider employed or contracted by the plan. The PQAT must be signed by the enrollee's current health care provider as verification and confirmation that the enrollee has the severe or disabling chronic condition required to be eligible for the C–SNP, which may be done post-enrollment.
(2) [Reserved]
(g) *Special eligibility rule for certain C–SNPs.* For C–SNPs that use a group of multiple severe or disabling chronic conditions as described in § 422.4(a)(1)(iv) of this chapter, special needs individuals need only have one of the qualifying severe or disabling chronic conditions in order to be eligible to enroll.

■ 8. Section 422.60 is amended by—
■ a. Revising paragraph (a)(1); and
■ b. Adding paragraphs (a)(3), (h) and (i).
The revision and additions read as follows:

§ 422.60 Election process.

(a) * * *
(1) Except for the limitations on enrollment in an MA MSA plan provided by § 422.62(d)(1) and except as specified in paragraphs (a)(2) and (3) of this section, each MA organization must accept without restriction (except for an MA RFB plan as provided by § 422.57) individuals who are eligible to elect an MA plan that the MA organization offers and who elect an MA plan during initial coverage election periods under § 422.62(a)(1), annual election periods under § 422.62(a)(2), and under the

circumstances described in § 422.62(b)(1) through (b)(4).

* * * * *

(3) Dual eligible special needs plans must limit enrollments to those individuals who meet the eligibility requirements established in the state Medicaid agency contract, as specified at § 422.52(b)(2).

* * * * *

(h) *Notification of reinstatement based on beneficiary cancellation of new enrollment.* When an individual is disenrolled from an MA plan due to the election of a new plan, the MA organization must reinstate the individual's enrollment in that plan if the individual cancels the election in the new plan within timeframes established by CMS. The MA organization offering the plan from which the individual was disenrolled must send the member notification of the reinstatement within 10 calendar days of receiving confirmation of the individual's reinstatement.

* * * * *

(i) *Authorized representatives.* As used in this subpart, an authorized representative is an individual who is the legal representative or otherwise legally able to act on behalf of an enrollee, as the law of the State in which the beneficiary resides may allow, in order to execute an enrollment or disenrollment request.

(1) The authorized representative would constitute the ''beneficiary'' or the ''enrollee'' for the purpose of making an election.

(2) Authorized representatives may include court-appointed legal guardians, persons having durable power of attorney for health care decisions, or individuals authorized to make health care decisions under state surrogate consent laws, provided they have the authority to act for the beneficiary in this capacity.

■ 9. Section 422.62 is amended by—

■ a. Revising paragraphs (a)(1)(i), (a)(4), (b)(2), and (b)(18) introductory text;

■ b. Redesignating paragraphs (b)(18)(i) through (b)(18)(iii) as paragraphs (b)(18)(ii) through (b)(18)(iv), respectively; and

■ c. Adding new paragraph (b)(18)(i).

The revisions and addition read as follows:

§ 422.62 Election of coverage under an MA plan.

(a) * * *

(1) * * *

(i) The last day of the second month after the month in which they are first entitled to Part A and enrolled in Part B; or

* * * * *

(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.

(i) 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.

(ii) The open enrollment period for institutionalized individuals ends on the last day of the second month after the month the individual ceases to reside in one of the long-term care facility settings described in the definition of ''institutionalized'' in § 422.2.

* * * * *

(b) * * *

(2) The individual is not eligible to remain enrolled in the plan because of a change in his or her place of residence to a location out of the service area or continuation area or other change in circumstances as determined by CMS but not including terminations resulting from a failure to make timely payment of an MA monthly or supplemental beneficiary premium, or from disruptive behavior. Also eligible for this SEP are individuals who, as a result of a change in permanent residence, have new MA plan options available to them.

* * * * *

(18) Individuals affected by an emergency or major disaster declared by a Federal, State or local government entity are eligible for an SEP to make an MA enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier. The SEP ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, the date the incident automatically ends under applicable state or local law, or, if the incident end date is not otherwise identified, the incident end date specified in paragraph (b)(18)(i) of this section.

(i) If the incident end date of an emergency or major disaster is not otherwise identified, the incident end date is 1 year after the SEP start date; or, if applicable, the date of a renewal or extension of the emergency or disaster declaration, whichever is later. The maximum length of this SEP, if the incident end date is not otherwise identified, is 14 full calendar months after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration.

* * * * *

■ 10. Section 422.66 is amended by adding paragraphs (b)(3)(v) and (b)(6) to read as follows:

§ 422.66 Coordination of enrollment and disenrollment through MA organizations.

* * * * *

(b) * * *

(3) * * *

(v) In the case of an incomplete disenrollment request—

(A) Document its efforts to obtain information to complete the disenrollment request;

(B) Notify the individual (in writing or verbally) within 10 calendar days of receipt of the disenrollment request.

(C) The organization must deny the request if any additional information needed to make the disenrollment request ''complete'' is not received within the following timeframes:

(*1*) For disenrollment requests received during the AEP, by December 7, or within 21 calendar days of the request for additional information, whichever is later.

(*2*) For disenrollment requests received during all other election periods, by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information, whichever is later.

* * * * *

(6) *When a disenrollment request is considered incomplete.* A disenrollment request is considered to be incomplete if the required but missing information is not received by the MA organization within the timeframe specified in paragraph (b)(3)(v)(C) of this section.

* * * * *

■ 11. Section 422.68 is amended by adding paragraph (g) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(g) *Beneficiary choice of effective date.* If a beneficiary is eligible for more than one election period, resulting in more than one possible effective date, the MA organization must allow the beneficiary to choose the election period that results in the individual's desired effective date.

(1) To determine the beneficiary's choice of election period and effective

date, the MA organization must attempt to contact the beneficiary and must document its attempts.

(2) If the MA organization is unable to obtain the beneficiary's desired enrollment effective date, the MA organization must assign an election period using the following ranking of election periods:

(i) ICEP/Part D IEP.

(ii) MA–OEP.

(iii) SEP.

(iv) AEP.

(v) OEPI.

(3) If the MA organization is unable to obtain the beneficiary's desired disenrollment effective date, the MA organization must assign an election period that results in the earliest disenrollment.

■ 12. Section 422.74 is amended by—

■ a. Adding paragraph (b)(2)(vi);

■ b. Revising paragraphs (c) and (d)(1)(i)(B)(*1*);

■ c. Revising paragraph (d)(1)(v)

■ e. Revising paragraphs (d)(2)(iii) and (d)(2)(iv);

■ f. Adding paragraph (d)(2)(vii);

■ g. Revising paragraphs (d)(4)(i) and (d)(4)(iv);

■ i. Adding paragraphs (d)(4)(ii)(A), adding and reserving (d)(4)(ii)(B) and adding (d)(4)(iii)(F);

■ j. Redesignating paragraph (d)(8) as (d)(9);

■ k. Adding new paragraph (d)(8);

■ l. Adding paragraph (d)(10); and

■ m. Revising paragraph (e)(1).

The addition and revisions read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(b) * * *

(2) * * *

(vi) The individual no longer meets the MA MSA's eligibility criteria specified under § 422.56 due to a mid-year change in eligibility.

* * * * *

(c) *Notice requirement.* If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i), (b)(2)(vi), or (b)(3) of this section (that is, other than death or loss of entitlement to Part A or Part B) the MA organization must give the individual a written notice of the disenrollment with an explanation of why the MA organization is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2)(i) and (b)(2)(vi) of this section must—

(1) Be provided to the individual before submission of the disenrollment to CMS; and

(2) Include an explanation of the individual's right to submit a grievance under the MA organization's grievance procedures.

(d) * * *

(1) * * *

(i) * * *

(B) * * *

(*1*) Be at least 2 whole calendar months; and

* * * * *

(v) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS (or a third party to which CMS has assigned this responsibility, such as an MA organization) may reinstate enrollment in the MA plan, without interruption of coverage, if the individual does all of the following:

(A) Submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date;

(B) Has not previously requested reinstatement for good cause during the same 60-day period following the involuntary disenrollment;

(C) Shows good cause for failure to pay within the initial grace period;

(D) Pays all overdue premiums within 3 calendar months after the disenrollment date; and

(E) Establishes by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(2) * * *

(iii) *Effort to resolve the problem.* (A) The MA organization must—

(*1*) Make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities.

(*2*) Inform the individual of the right to use the organization's grievance procedures, through the notices described in paragraph (d)(2)(vii) of this section.

(B) The beneficiary has a right to submit any information or explanation that he or she may wish to the MA organization.

(iv) *Documentation.* The MA organization—

(A) Must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances.

(B) May request from CMS the ability to decline future enrollment by the individual.

(C) Must submit to CMS—

(*1*) The information specified in paragraph (d)(2)(iv)(A) of this section;

(*2*) Any documentation received by the beneficiary;

(*3*) Dated copies of the notices required in paragraph (d)(2)(vii) of this section.

* * * * *

(vii) *Required notices.* The MA organization must provide the individual two notices prior to submitting the request for disenrollment to CMS.

(A) The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action.

(*1*) If the disruptive behavior ceases after the member receives the advance notice and then later resumes, the organization must begin the process again.

(*2*) The organization must wait at least 30 days after sending the advance notice before sending the second notice, during which 30-day period the individual has the opportunity to cease their behavior.

(B) The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the member that the MA organization requests CMS permission to involuntarily disenroll the member.

(*1*) This notice must be provided prior to submission of the request to CMS.

(*2*) These notices are in addition to the disenrollment submission notice required under § 422.74(c).

* * * * *

(4) * * *

(i) *Basis for disenrollment.* Unless continuation of enrollment is elected under § 422.54, the MA organization must disenroll an individual, and must document the basis for such action, if the MA organization establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved—

* * * * *

(ii) * * *

(A) The individual is considered to be temporarily absent from the plan service area when one or more of the required materials and content referenced in § 422.2267(e), if provided by mail, is returned to the MA organization by the U.S. Postal Service as undeliverable and a forwarding address is not provided.

(B) [Reserved]

* * * * *

(iii) * * *

(F) The individual is considered to be temporarily absent from the plan service

area when one or more of the required materials and content referenced in § 422.2267(e), if provided by mail, is returned to the MA organization by the U.S. Postal Service as undeliverable and a forwarding address is not provided.

* * * * *

(iv) *Notice of disenrollment.* The MA organization must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section within 10 calendar days of the plan's confirmation of the individual's residence outside of the plan service area or within the first 10 calendar days of the sixth month of an individual's temporary absence from the plan service area or, for individuals using a visitor/traveler benefit, within the first 10 calendar days of the last month of the allowable absence. If the plan learns of an individual's temporary absence from the plan service area after the expiration of the allowable period, the plan must send this notice within 10 calendar days of the plan learning of the absence.

* * * * *

(8) *Loss of special needs status.* If an enrollee loses special needs status and must be disenrolled under paragraph (b)(2)(iv) of this section, the SNP must provide the enrollee with a minimum of 30 days' advance notice of disenrollment, regardless of the date of loss of special needs status.

(i) The advance notice must be provided to the enrollee within 10 calendar days of the plan learning of the loss of special needs status and must afford the enrollee an opportunity to prove that they are still eligible to remain in the plan.

(ii) The advance notice must include all of the following:

(A) The disenrollment effective date.

(B) A description of eligibility for the SEP described in § 422.62(b)(11).

(C) If applicable all of the following:

(*1*) Information regarding the period of deemed continued eligibility authorized by § 422.52(d).

(*2*) The duration of the period of deemed continued eligibility.

(*3*) The consequences of not regaining special needs status within the period of deemed continued eligibility.

(iii) A final notice of involuntary disenrollment must be sent as follows:

(A) Within 3 business days following the disenrollment effective date, which is either—

(*1*) The last day of the period of deemed continued eligibility, if applicable; or

(*2*) A minimum of 30 days after providing the advance notice of disenrollment.

(B) Before submission of the disenrollment to CMS.

(iv) The final notice of involuntary disenrollment must include an explanation of the enrollee's right to file a grievance under the MA organization's grievance procedures that are required by § 422.564.

* * * * *

(10) *Mid-year change in MSA eligibility.* If an individual is no longer eligible for an MA MSA plan due to a mid-year change in eligibility, disenrollment is effective the first day of the calendar month following the MA organization's notice to the individual that they are ineligible in accordance with § 422.74(b)(2)(vi) of this section.

(e) * * *

(1) *Disenrollment for non-payment of premiums, disruptive behavior, fraud or abuse, loss of Part A or Part B or mid-year loss of MSA eligibility.* An individual who is disenrolled under paragraph (b)(1)(i) through (iii), (b)(2)(ii) or (b)(2)(vi) of this section is deemed to have elected original Medicare.

* * * * *

■ 13. Section 422.100 is amended by adding paragraph (o) to read as follows:

§ 422.100 General requirements.

* * * * *

(o) *Cost sharing standards for D–SNP PPOs.* Beginning on or after January 1, 2026, an MA organization offering a local PPO plan or regional PPO plan that is a dual eligible special needs plan must establish cost sharing for out-of-network services that—

(1) Complies with the limits described in paragraph (f)(6) of this section with the exception that references to the MOOP amounts refer to the total catastrophic limits under § 422.101(d)(3) for local PPOs and MA regional plans; and

(2) Complies with the limits described in paragraph (j)(1) of this section with the exception that references to the MOOP amounts refer to the total catastrophic limits under § 422.101(d)(3) for local PPOs and MA regional plans and, for regional PPO dual eligible special needs plans, excluding paragraph (j)(1)(i)(C)(*2*) and the last sentence of paragraph (j)(1)(i)(E) of this section.

■ 14. Section 422.101 is amended by—

■ a. Adding paragraph (f)(2)(vi);

■ b. Revising paragraph (f)(3)(iii); and

■ c. Adding (f)(3)(iv).

The additions and revisions read as follows:

§ 422.101 Requirements relating to basic benefits.

* * * * *

(f) * * *

(2) * * *

(vi) For I–SNPs, ensure that contracts with long-term care institutions (listed in the definition of the term institutionalized in § 422.2) contain requirements allowing I–SNP clinical and care coordination staff access to enrollees of the I–SNP who are institutionalized.

(3) * * *

(iii) Each element of the model of care of a plan must meet a minimum benchmark score of 50 percent and each MOC must meet an aggregate minimum benchmark of 70 percent, and a plan's model of care is only approved if each element of the model of care meets the minimum benchmark and the model of care meets the aggregate minimum benchmark.

(A) An MOC for a C–SNP that receives a passing score is approved for 1 year.

(B)(*1*) An MOC for an I–SNP or D–SNP that receives an aggregate minimum benchmark score of 85 percent or greater is approved for 3 years.

(*2*) An MOC for an I–SNP or D–SNP that receives a score of 75 percent to 84 percent is approved for 2 years.

(*3*) An MOC for an I–SNP or DSNP that receives a score of 70 percent to 74 percent is approved for 1 year.

(C) For an MOC that fails to meet a minimum element benchmark score of 50 percent or an MOC that fails to meet the aggregate minimum benchmark of 70 percent, the MA organization is permitted a one-time opportunity to resubmit the corrected MOC for reevaluation; and an MOC that is corrected and resubmitted using this cure period is approved for only 1 year.

(iv) An MA organization sponsoring a SNP that seeks to revise the MOC before the end of the MOC approval period may submit changes to the MOC as off-cycle MOC submissions for review by NCQA as follows:

(A) C–SNPs, D–SNPs and I–SNPs must submit updates and corrections to their NCQA-approved MOC when CMS requires an off-cycle submission to ensure compliance with applicable law.

(B) D–SNPs and I–SNPs must submit updates and corrections to their NCQA approved MOC between June 1st and November 30th of each calendar year if the I–SNP or D–SNP wishes to make any of the following revisions:

(*1*) Substantial changes in policies or procedures pertinent to any of the following:

(*i*) The health risk assessment (HRA) process.

(*ii*) Revising processes to develop and update the Individualized Care Plan (ICP).

(*iii*) The integrated care team process.
(*iv*) Risk stratification methodology.
(*v*) Care transition protocols.
(*2*) Target population changes that warrant modifications to care management approaches.
(*3*) Changes in a SNP's plan benefit package between consecutive contract years that can considerably impact critical functions necessary to maintain member well-being and are related SNP operations.
(*4*) Changes in level of authority or oversight for personnel conducting care coordination activities (for example, medical provider to non-medical provider, clinical vs. non-clinical personnel).
(*5*) Changes to quality metrics used to measure performance.
(C) NCQA only reviews off-cycle submissions after the start of the effective date of the current MOC unless CMS deems it necessary to ensure compliance with the applicable regulations.
(D) SNPs may not implement any changes to a MOC until NCQA has reviewed and approved the off-cycle MOC changes. NCQA does not rescore the MOC during the off-cycle review of changes to the MOC, but changes are reviewed and determined by NCQA to be either ''Acceptable'' or ''Non-acceptable.'' ''Acceptable'' means that the changes have been approved by NCQA and the MOC has been updated; ''Non-acceptable'' means the changes have been rejected by NCQA and the MOC has not been changed. If NCQA determines that off-cycle changes are unacceptable, the SNP must continue to implement the MOC as originally approved.
(E) Successful revision of the MOC under paragraph (f)(3)(iv)(B) of this section does not change the MOC's original period of approval.
(F) C–SNPs are only permitted to submit an off-cycle MOC submission when CMS requires an off-cycle submission to ensure compliance with applicable law.
(G) When a deficiency is identified in the off-cycle MOC revision(s) submitted by a SNP, the SNP has one opportunity to submit a corrected off-cycle revision between June 1st and November 30th of each calendar year.

■ 15. Section 422.102 is amended by revising paragraphs (f)(1)(i)(A)(*2*), (f)(3), (f)(4) and adding paragraph (f)(5) to read as follows:

§ 422.102 Supplemental benefits.

* * * * *
(f) * * *
(1) * * *
(i) * * *
(A) * * *
(*2*) Has a high risk of hospitalization or other adverse health outcomes; and
* * * * *

(3) *MA organization responsibilities.* An MA organization that includes an item or service as SSBCI in its bid must be able to demonstrate through relevant acceptable evidence that the item or service has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. By the date on which an MA organization submits its bid, the MA organization must establish a written bibliography of relevant acceptable evidence concerning the impact that the item or service has on the health or overall function of its recipient. For each citation in the written bibliography, the MA organization must include a working hyperlink to or a document containing the entire source cited.
(i) Relevant acceptable evidence includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to investigate whether the item or service impacts the health or overall function of a population, or large systematic reviews or meta-analyses summarizing the literature of the same.
(ii) An MA organization must include in its bibliography a comprehensive list of relevant acceptable evidence published within the 10 years prior to the June immediately preceding the coverage year during which the SSBCI will be offered, including any available negative evidence and literature.
(iii) If no evidence of the type described in paragraphs (f)(3)(i) and (ii) of this section exists for a given item or service, then MA organization may cite case studies, federal policies or reports, internal analyses, or any other investigation of the impact that the item or service has on the health or overall function of its recipient as relevant acceptable evidence in the MA organization's bibliography.
(iv) The MA organization must make its bibliography of relevant acceptable evidence available to CMS upon request.

(4) *Plan responsibilities.* An MA plan offering SSBCI must do all of the following:
(i) Have written policies for determining enrollee eligibility and must document its determination that an enrollee is a chronically ill enrollee based on the definition in *paragraph (f)(1)(i)* of this section.
(ii) Make information and documentation related to determining enrollee eligibility available to CMS upon request.
(iii)(A) Have and apply written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI; and
(B) Document the written policies specified in paragraph (f)(4)(iii)(A) of this paragraph and the objective criteria on which the written policies are based.
(iv) Document each eligibility determination for an enrollee, whether eligible or ineligible, to receive a specific SSBCI and make this information available to CMS upon request.
(v) Maintain without modification, as it relates to an SSBCI, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations for the full coverage year.

(5) *CMS review of SSBCI offerings in bids.* (i) CMS may decline to approve an MA organization's bid if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting.
(ii) CMS may annually review the items or services that an MA organization includes as SSBCI in its bid for compliance with all applicable requirements, taking into account updates to the relevant acceptable evidence applicable to each item or service.
(iii) This provision does not limit CMS's authority to review and negotiate bids or to reject bids under section 1854(a) of the Act and 42 CFR part 422 subpart F nor does it limit CMS's authority to review plan benefits and bids for compliance with all applicable requirements.

■ 16. Section 422.111 is amended by—
■ a. Revising paragraph (h)(1)(iv)(B); and
■ b. Adding paragraph (l).

The revision and addition read as follows:

§ 422.111 Disclosure requirements.

* * * * *
(h) * * *
(1) * * *
(iv) * * *
(B) Establishes contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.
* * * * *

(l) *Mid-year notice of unused supplemental benefits.* Beginning January 1, 2026, MA organizations must send notification annually, no sooner than June 30 and no later than July 31, to each enrollee with unused supplemental benefits consistent with the requirements of § 422.2267(e)(42).

■ 17. Section 422.114 is amended by revising paragraph (a)(3)(ii) to read as follows:

§ 422.114 Access to services under an MA private fee-for-service plan.

* * * * *

(a) * * *

(3) * * *

(ii) Network-based plan as defined in § 422.2.

* * * * *

■ 18. Section 422.116 is amended by—

■ a. Adding paragraph (b)(2)(xiv);

■ b. In paragraph (d)(2), amend Table 1 by revising the column headings and adding an entry for ''Outpatient Behavioral Health'' in alphabetical order;

■ c. Adding paragraph (d)(5)(xv);

■ d. In paragraph (f)(1) introductory text, removing the phrase ''both of the following occur'' and adding in its place the phrase ''either of the following occur'';

■ e. Revising paragraph (f)(1); and

■ f. Adding paragraph (f)(2)(iv) and (f)(3).

The additions and revisions read as follows:

§ 422.116 Network adequacy.

(b) * * *

(2) * * *

(xiv) Outpatient behavioral health, which can include marriage and family therapists (as defined in section 1861(lll) of the Act), mental health counselors (as defined in section 1861(lll) of the act), opioid treatment programs (as defined in section 1861(jjj) of the act), community mental health centers (as defined in section 1861(ff)(3)(b) of the act), or those of the following who regularly furnish or will regularly furnish behavioral health counseling or therapy services including psychotherapy or prescription of medication for substance use disorders; physician assistants, nurse practitioners and clinical nurse specialists (as defined in section 1861(aa)(5) of the Act); addiction medicine physicians; or outpatient mental health and substance use treatment facilities.

(A) To be considered as regularly furnishing behavioral health services for the purposes of this regulation, a physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS) must have furnished specific psychotherapy or medication prescription services (including, buprenorphine and methadone, for substance use disorders) to at least 20 patients within a 12-month period. CMS will identify, by detailed descriptions or Healthcare Common Procedure Coding System (HCPCS) code(s), the specific services in the HSD Reference File described in paragraph (a)(4)(i) of this section.

(B) To determine that a PA, NP, or CNS meets the standard in paragraph (b)(2)(xiv)(A) of this section, an MA organization must do all of the following:

(*1*) On an annual basis, independently verify that the provider has furnished such services within a recent 12-month period, using reliable information about services furnished by the provider such as the MA organization's claims data, prescription drug claims data, electronic health records, or similar data.

(*2*) If there is insufficient evidence of past practice by the provider, have a reasonable and supportable basis for concluding that the provider will meet the standard in paragraph (b)(2)(xiv)(A) of this section in the next 12 months.

(*3*) Submit evidence and documentation to CMS, upon request and in the form and manner specified by CMS, of the MA organization's determination that the provider meets the standard in paragraph (b)(2)(xiv)(A) of this section.

* * * * *

(d) * * *

(2) * * *

TABLE 1 TO PARAGRAPH (d)(2)

Provider/facility type	Large metro		Metro		Micro		Rural		CEAC	
	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance
* * *										
Outpatient Behavioral Health	20	10	40	25	55	40	60	50	110	100
* * *										

* * * * *

(5) * * *

(xv) Outpatient Behavioral Health, described in paragraph (b)(2)(xiv) of this section.

* * * * *

(f) *Exception requests.* (1) An MA plan may request an exception to network adequacy criteria in paragraphs (b) through (e) of this section when either paragraph (f)(1)(i) or (f)(1)(ii) of this section is met:

(i)(A) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type; and

(B) The MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

(ii)(A) A facility-based Institutional-Special Needs Plan (I–SNP) is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in facility-based I–SNPs receive care; or

(B) A facility-based I–SNP provides sufficient and adequate access to basic benefits through additional telehealth benefits (in compliance with § 422.135) when using telehealth providers of the specialties listed in paragraph (d)(5) of this section in place of in-person providers to fulfill network adequacy standards in paragraphs (b) through (e) of this section.

(2) * * *

(iv) As applicable, the facility-based I–SNP submits:

(A) Evidence of the inability to contract with certain specialty types required under this section due to the way enrollees in facility-based I–SNPs receive care; or

(B) Substantial and credible evidence that sufficient and adequate access to basic benefits is provided to enrollees using additional telehealth benefits (in compliance with § 422.135) furnished by providers of the specialties listed in paragraph (d)(5) of this section and the

facility-based I–SNP covers out-of-network services furnished by a provider in person when requested by the enrollee as provided in § 422.135(c)(1) and (2), with in-network cost sharing for the enrollee.

(3) Any MA organization that receives the exception provided for facility-based I–SNPs must agree to offer only facility-based I–SNPs under the MA contract that receives the exception.

■ 19. Section 422.125 is added to read as follows:

§ 422.125 Resolution of complaints in a Complaints Tracking Module.

(a) *Definitions.* For the purposes of this section, the terms have the following meanings:

Assignment date is the date CMS assigns a complaint to a particular MA organization in the Complaints Tracking Module.

Complaints Tracking Module means an electronic system maintained by CMS to record and track complaints submitted to CMS about Medicare health and drug plans from beneficiaries and others.

Immediate need complaint means a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 2 or fewer days.

Urgent complaint means a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they do not have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 3 to 14 days.

(b) *Timelines for complaint resolution*—(1) *Immediate need complaints.* The MA organization must resolve immediate need complaints within 2 calendar days of the assignment date.

(2) *Urgent complaints.* The MA organization must resolve urgent complaints within 7 calendar days of the assignment date.

(3) *All other complaints.* The MA organization must resolve all other complaints within 30 calendar days of the assignment date.

(4) *Extensions.* Except for immediate need complaints, urgent complaints, and any complaint that requires expedited treatment under §§ 422.564(f) or 422.630(d), if a complaint is also a grievance within the scope of §§ 422.564 or 422.630 and the requirements for an extension of the time to provide a response in §§ 422.564(e)(2) or 422.630(e)(2) are met, the MA organization may extend the timeline to provide a response.

(5) *Coordination with timeframes for grievances, PACE service determination requests, and PACE appeals.* When a complaint under this section is also a grievance within the scope of §§ 422.564, 422.630, or 460.120, a PACE service determination request within the scope of § 460.121, or a PACE appeal within the definition of § 460.122, the MA organization must comply with the shortest applicable timeframe for resolution of the complaint.

(c) *Timeline for contacting individual filing a complaint.:* Regardless of the type of complaint received, the MA organization must attempt to contact the individual who filed a complaint within 7 calendar days of the assignment date.

■ 20. Section 422.137 is amended by adding paragraphs (c)(5), (d)(6), and (7) to read as follows:

§ 422.137 Medicare Advantage Utilization Management Committee

* * * * *

(c) * * *

(5) Beginning January 1, 2025, include at least one member with expertise in health equity. Expertise in health equity includes educational degrees or credentials with an emphasis on health equity; experience conducting studies identifying disparities amongst different population groups; experience leading organization-wide policies, programs, or services to achieve health equity; or experience leading advocacy efforts to achieve health equity.

(d) * * *

(6) Beginning in 2025, annually conduct a health equity analysis of the use of prior authorization.

(i) The final report of the analysis must be approved by the member of the committee with expertise in health equity before it is publicly posted.

(ii) The analysis must examine the impact of prior authorization on enrollees with one or more of the following social risk factors:

(A) Receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid.

(B) Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

(iii) The analysis must use the following metrics, calculated for enrollees with the specified social risk factors and enrollees without the specified social risk factors, to conduct the analysis at the plan level using data from the prior contract year regarding coverage of items and services excluding data on drugs as defined in § 422.119(b)(1)(v):

(A) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.

(B) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.

(C) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.

(D) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.

(E) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.

(F) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.

(G) The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, aggregated for all items and services.

(H) The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services.

(7) By July 1, 2025, and annually thereafter, publicly post the results of the health equity analysis of the utilization management policies and procedures on the plan's website meeting the following requirements:

(i) In a prominent manner and clearly identified in the footer of the website.

(ii) Easily accessible to the general public, without barriers, including but not limited to ensuring the information is accessible:

(A) Free of charge.

(B) Without having to establish a user account or password.

(C) Without having to submit personal identifying information.

(iii) In a machine-readable format with the data contained within that file being digitally searchable and downloadable.

(iv) Include a txt file in the root directory of the website domain that includes a direct link to the machine-readable file to establish and maintain automated access.

■ 21. Section 422.164 is amended by—

■ a. Revising paragraph (d)(1)(v);

■ b. Revising and republishing (g)(1)(iii)

■ d. Adding paragraph (h)(3).

The revisions and addition read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(d) * * *

(1) * * *

(v) Add alternative data sources or expand modes of data collection.

* * * * *

(g) * * *

(1) * * *

(iii) For the appeals measures, CMS uses statistical criteria to estimate the percentage of missing data for each contract using data from MA organizations, the independent review entity (IRE), or CMS administrative sources to determine whether the data at the IRE are complete. CMS uses scaled reductions for the Star Ratings for the applicable appeals measures to account for the degree to which the IRE data are missing.

(A)(*1*) The data reported by the MA organization on appeals, including the number of reconsiderations requested, denied, upheld, dismissed, or otherwise disposed of by the MA organization, and data from the IRE or CMS administrative sources, that align with the Star Ratings year measurement period are used to determine the scaled reduction.

(*2*) If there is a contract consolidation as described at § 422.162(b)(3), the data described in paragraph (g)(1)(iii)(A)(*1*) of this section are combined for the consumed and surviving contracts before the methodology provided in paragraphs (g)(1)(iii)(B) through (O) of this section is applied.

(B) [Reserved]

(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) [Reserved]

(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 1 minus the quotient of the total number of cases received by the IRE that were supposed to be sent and the total number of cases that should have been forwarded to the IRE. The total number of cases that should have been forwarded to the IRE is determined by the sum of the partially favorable (adverse) reconsiderations and unfavorable (adverse) reconsiderations for the applicable measurement year.

(I) [Reserved]

(J) [Reserved]

(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 number of cases not forwarded to the IRE is at least 10 for the measurement year.

(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.

(O) CMS reduces the measure rating to 1 star for the applicable appeals measure(s) if CMS does not have accurate, complete, and unbiased data to validate the completeness of the Part C appeals measures.

(2) * * *

(h) * * *

(3) Beginning with the 2025 measurement year (2027 Star Ratings), an MA organization may request that CMS review its contract's administrative data for Patient Safety measures provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

* * * * *

■ 22. Section 422.166 is amended by—

■ a. Revising paragraph (e)(2);

■ b. Revising paragraph (f)(2)(i)(B); and

■ c. Adding paragraphs (f)(3)(viii)(A) and (B).

The revisions and addition read as follows:

§ 422.166 Calculation of Star Ratings.

* * * * *

(e) * * *

(2) *Rules for new and substantively updated measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. Substantively updated measures will receive a weight of 1 in their first year returning to the Star Ratings after being on the display page. In subsequent years, a new or substantively updated measure will be assigned the weight associated with its category.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(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.

(*1*) For the first 2 years following a consolidation, for the surviving contract of a contract consolidation involving two or more contracts for health or drug services of the same plan type under the same parent organization, the enrollment data for the month of December for the measurement period of the Star Ratings year are combined across the surviving and consumed contracts in the consolidation.

(*2*) 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.

(*3*) 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.

(*4*) 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.

* * * * *

(3) * * *

(viii) * * *

(A) 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 calculates the HEI reward for the surviving contract accounting for both the surviving and consumed contract(s). For the first year following a consolidation, the HEI reward for the surviving contract is calculated as the enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using total contract enrollment from July of the most recent measurement year used in calculating the HEI reward. A reward value of zero is used in calculating the enrollment-weighted mean for contracts that do not meet the minimum percentage of enrollees with the SRF thresholds or the minimum performance threshold specified at paragraph (f)(3)(vii) of this section.

(B) For the second year following a consolidation when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score will be combined from the consumed and surviving contracts and used in calculating the HEI score.

* * * * *

■ 23. Section 422.254 is amended by adding paragraph (a)(5) to read as follows.

§ 422.254 Submission of bids.

(a) * * *

(5) After an MA organization is permitted to begin marketing prospective plan year offerings for the following contract year (consistent with § 422.2263(a)), the MA organization must not change and must provide the benefits described in its CMS-approved plan benefit package (PBP) (as defined in § 422.162) for the following contract year without modification, except where a modification in benefits is required by law. This prohibition on changes applies to cost sharing and premiums as well as benefits.

* * * * *

■ 24. Section 422.260 is amended by—
■ a. Revising paragraphs (c)(1)(i), (c)(2)(v), and (c)(2)(vii);
■ b. Adding paragraph (c)(3)(iii); and
■ c. Revising paragraph (d).

The revisions and addition read as follows:

§ 422.260 Appeals of quality bonus payment determinations.

* * * * *

(c) * * *

(1) * * *

(i) The MA organization requesting reconsideration of its QBP status must do so by providing written notice to CMS within 10 business days of the release of its QBP status. The request must specify the given measure(s) in question and the basis for reconsideration such as a calculation error or incorrect data was used to determine the QBP status. Requests are limited to those circumstances where the error could impact an individual measure's value or the overall Star Rating. Based on any corrections, any applicable measure-level Star Ratings could go up, stay the same, or go down. The overall Star Rating also may go up, stay the same, or go down based on any corrections.

* * * * *

(2) * * *

(v) The MA organization must prove by a preponderance of evidence that CMS' calculations of the measure(s) and value(s) in question were incorrect. The burden of proof is on the MA organization to prove an error was made in the calculation of the QBP status.

* * * * *

(vii) After the hearing officer's decision is issued to the MA organization and the CMS Administrator, the hearing officer's decision is subject to review and modification by the CMS Administrator within 10 business days of issuance. If the Administrator does not review and issue a decision within 10 business days, the hearing officer's decision is final and binding.

* * * * *

(3) * * *

(iii) The MA organization may not request a review based on data inaccuracy for the following data sources:

(A) HEDIS.

(B) CAHPS.

(C) HOS.

(D) Part C and D Reporting Requirements.

(E) PDE.

(F) Medicare Plan Finder pricing files.

(G) Data from the Medicare Beneficiary Database Suite of Systems.

(H) Medicare Advantage Prescription Drug (MARx) system.

(I) Other Federal data sources.

* * * * *

(d) *Reopening of QBP determinations.* CMS may, on its own initiative, revise an MA organization's QBP status at any time after the initial release of the QBP determinations through April 1 of each year. CMS may take this action on the basis of any credible information, including the information provided during the administrative review process by a different MA organization, that demonstrates that the initial QBP determination was incorrect. If a contract's QBP determination is reopened as a result of a systemic calculation issue that impacts more than the MA organization that submitted an appeal, the QBP rating for MA organizations that did not appeal will only be updated if it results in a higher QBP rating.

* * * * *

■ 25. Section 422.310 is amended by—
■ a. Revising paragraphs (f)(1)(vi) and (f)(1)(vii); and
■ b. Adding new paragraph (f)(3)(v).

The revisions and addition read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(f) * * *

(1) * * *

(vi) To conduct evaluations and other analysis to support the Medicare and Medicaid programs (including demonstrations) and to support public health initiatives and other health care-related research;

(vii) For activities to support the administration of the Medicare and Medicaid programs;

* * * * *

(3) * * *

(v) CMS determines that releasing data to State Medicaid agencies before reconciliation for the purpose of coordinating care for dually eligible individuals is necessary and appropriate to support activities or authorized uses under paragraph (f)(1)(vii) of this section.

* * * * *

■ 26. Section 422.311 is amended by—
■ a. Revising paragraph (a);
■ b. Revising paragraph (c)(5)(ii)(B);
■ c. Removing paragraph (c)(5)(ii)(C);
■ d. Revising paragraph (c)(5)(iii);
■ e. Adding paragraph (c)(5)(iv);
■ f. Revising paragraphs (c)(6)(i)(A) and (c)(6)(iv)(B);
■ g. Adding paragraph (c)(6)(v);
■ h. Revising paragraph (c)(7)(ix);
■ i. Revising paragraphs (c)(8)(iii), (c)(8)(iv), (c)(8)(v), and (c)(8)(vi); and
■ j. Adding paragraphs (c)(8)(vii) and (c)(9).

The revisions and additions read as follows:

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk adjustment data validation (RADV) audits.* In accordance with §§ 422.2 and 422.310(e), the Secretary conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.

(1) Recovery of improper payments from MA organizations is conducted in accordance with the Secretary's payment error extrapolation and recovery methodologies.

(2) CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years.

* * * * *

(c) * * *

(5) * * *

(ii) * * *

(B) Whether the MA organization requests a payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements. MA organizations will forgo their medical record review determination appeal if they choose to file only a payment error calculation appeal because medical record review determinations need to be final prior to adjudicating a payment error calculation appeal.

(iii) For MA organizations that intend to appeal both the medical record

review determination and the RADV payment error calculation, an MA organization's request for appeal of its RADV payment error calculation may not be filed and will not be adjudicated until—

(A) The administrative appeal process for the RADV medical record review determinations filed by the MA organization has been exhausted; or

(B) The MA organization does not timely request a RADV medical record review determination appeal at the hearing stage and/or the CMS Administrator review stage, as applicable.

(iv) An MA organization whose medical record review determination appeal has been completed as described in paragraph (c)(5)(iii) of this section has 60 days from the date of issuance of a revised RADV audit report, based on the final medical record review determination, to file a written request with CMS for a RADV payment error calculation appeal. This request for RADV payment error calculation appeal must clearly specify where the Secretary's RADV payment error calculation was erroneous, what the MA organization disagrees with, and the reasons for the disagreements.

(6) * * *

(i) * * *

(A) Any and all HCC(s) that the Secretary identified as being in error that the MA organization wishes to appeal.

* * * * *

(iv) * * *

(B) The reconsideration official's decision is final unless it is reversed or modified by a final decision of the hearing officer as defined at § 422.311(c)(7)(x).

* * * * *

(v) *Computations based on reconsideration official's decision.* (A) Once the reconsideration official's medical record review determination decision is considered final in accordance with paragraph (c)(6)(iv)(B) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(B) For MA organizations appealing the RADV payment error calculation only, once the reconsideration official's payment error calculation decision is considered final in accordance with paragraph (c)(6)(iv)(B) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

* * * * *

(7) * * *

(ix) *Computations based on Hearing Officer's decision.* (A) Once the hearing officer's medical record review determination decision is considered final in accordance with paragraph (c)(7)(x) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(B) For MA organizations appealing the RADV payment error calculation only, once the hearing officer's payment error calculation decision is considered final in accordance with paragraph (c)(7)(x) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

* * * * *

(8) * * *

(iii) After reviewing a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision. If the CMS Administrator does not decline to review or does not elect to review within 90 days of receipt of either the MA organization or CMS's timely request for review (whichever is later), the hearing officer's decision becomes final.

* * * * *

(iv) If the CMS Administrator elects to review the hearing decision—

(A) The CMS Administrator acknowledges the decision to review the hearing decision in writing and notifies CMS and the MA organization of their right to submit comments within 15 days of the date of the issuance of the notification that the Administrator has elected to review the hearing decision; and

* * * * *

(v) The CMS Administrator renders his or her final decision in writing within 60 days of the date of the issuance of the notice acknowledging his or her decision to elect to review the hearing officer's decision.

* * * * *

(vi) The decision of the hearing officer is final if the CMS Administrator—

(A) Declines to review the hearing officer's decision; or

(B) Does not decline to review or elect to review within 90 days of the date of the receipt of either the MA organization or CMS's request for review (whichever is later); or

(C) Does not make a decision within 60 days of the date of the issuance of the notice acknowledging his or her decision to elect to review the hearing officer's decision.

* * * * *

(vii) *Computations based on CMS Administrator decision.* (A) Once the CMS Administrator's medical record review determination decision is considered final in accordance with paragraph (c)(8)(vi) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(B) For MA organizations appealing the RADV payment error calculation only, once the CMS Administrator's payment error calculation decision is considered final in accordance with paragraph (c)(8)(vi) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised and final RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

* * * * *

(9) *Final agency action.* In cases when an MA organization files a payment error calculation appeal subsequent to a medical record review determination appeal that has completed the administrative appeals process, the medical record review determination appeal final decision and the payment error calculation appeal final decision will not be considered a final agency action until the payment error calculation appeal has completed the administrative appeals process and a final revised audit report superseding all prior RADV audit reports has been issued to the appellant MA organization.

* * * * *

■ 27. Section 422.500(b) is amended by adding the definitions of ''Final settlement adjustment period'', ''Final settlement amount'', and ''Final settlement process'' in alphabetical order to read as follows:

§ 422.500 Scope and definitions.

* * * * *

(b) * * *

Final settlement adjustment period means the period of time between when the contract terminates and the date the MA organization is issued a notice of the final settlement amount.

Final settlement amount is the final payment amount that CMS owes and

ultimately pays to an MA organization, or that an MA organization owes and ultimately pays to CMS, with respect to an MA contract that has consolidated, nonrenewed, or terminated. The final settlement amount is calculated by summing final retroactive payment adjustments for a specific contract that accumulated after that contract ceases operation but before the calculation of the final settlement amount and the following applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating these reconciliation amounts:

(1) Risk adjustment reconciliation (described in § 422.310);

(2) Part D annual reconciliation (described in § 423.343);

(3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320) and;

(4) MLR remittances (described in §§ 422.2470 and 423.2470).

Final settlement process means for a contract that has been consolidated, nonrenewed, or terminated, the process by which CMS calculates the final settlement amount, issues the final settlement amount along with supporting documentation in the notice of final settlement to the MA organization, receives responses from the MA organization requesting an appeal of the final settlement amount, and takes final actions to adjudicate an appeal (if requested) and make payments to or receive payments from the MA organization. The final settlement amount is calculated after all applicable reconciliations have occurred after a contract has been consolidated, nonrenewed, or terminated.

* * * * *

■ 28. Section § 422.502 is amended by—

■ a. Adding paragraph headings for paragraphs (a)(1) and (a)(2) and adding paragraph (a)(3);

■ b. Revising paragraphs (b)(1)(i)(A), (B), and (C);

■ c. Removing paragraphs (b)(1)(i)(E)(*2*)(*A*) and (*B*).

The additions and revisions read as follows.

§ 422.502 Evaluation and determination procedures.

* * * * *

(a) * * *

(1) *Information used to evaluate applications.* * * *

(2) *Issuing application determination.* * * *

(3) *Substantially incomplete applications.* (i) CMS does not evaluate or issue a notice of determination described in § 422.502(c) when an organization submits a substantially incomplete application.

(ii) An application is substantially incomplete when the submission as of the deadline for applications established by CMS is missing content or responsive materials for one or more sections of the application form required by CMS.

(iii) A determination that an application is substantially incomplete is not a contract determination as defined in § 422.641 and a determination that an organization submitted a substantially incomplete application is not subject to the appeals provisions of subpart N of this part.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(A) Was under intermediate sanction under subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees in accordance with § 422.2410(c), with the exception of a sanction imposed under § 422.752(d).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(a)(14).

(C) Filed for or is currently in federal or state bankruptcy proceedings.

* * * * *

■ 29. Section 422.503 is amended by adding paragraph (b)(8) to read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(8) Not newly offer a dual eligible special needs plan that would result in noncompliance with § 422.514(h).

* * * * *

■ 30. Section 422.504 is amended by revising paragraph (a)(15) and adding paragraphs (a)(20) and (a)(21) to read as follows.

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(15) As described in § 422.125 of this part, address and resolve complaints received by CMS against the MA organization in the Complaints Tracking Module.

* * * * *

(20) To comply with the requirements established in § 422.514(h).

* * * * *

(21) Not to establish additional MA plans that are not facility based I–SNPs to contracts described in § 422.116(f)(3).

* * * * *

■ 31. Section 422.510 is amended by adding paragraph (e) to read as follows:

§ 422.510 Termination of contract by CMS.

* * * * *

(e) If CMS makes a determination to terminate a MA organization's contract under § 422.510(a), CMS also imposes the intermediate sanctions at § 422.750(a)(1) and (3) in accordance with the following procedures:

(1) The sanction goes into effect 15 days after the termination notice is sent.

(2) The MA organization has a right to appeal the intermediate sanction in the same proceeding as the termination appeal specified in paragraph (d) of this section.

(3) A request for a hearing does not delay the date specified by CMS when the sanction becomes effective.

(4) The sanction remains in effect—

(i) Until the effective date of the termination; or

(ii) If the termination decision is overturned on appeal, when a final decision is made by the hearing officer or Administrator.

■ 32. Section 422.514 is amended by—

■ a. Revising paragraphs (d)(1) introductory text, (d)(1)(ii), (d)(2) introductory text, and (d)(2)(ii);.

■ b. In paragraph (e)(1)(i), removing the phrase ''Specialized MA Plan for Special Needs Individuals'' and adding in its place the phrase ''specialized MA plan for special needs individuals'';

■ c. In paragraph (e)(1)(iii), removing the phrase ''chapter; and'' and adding in its place ''chapter;'';

■ d. In paragraph (e)(1)(iv), removing the phrase ''of this section.'' and adding in its place ''of this section; and''; and

■ e. Adding paragraphs (e)(1)(v) and (h).

The revisions and additions read as follows:

§ 422.514 Enrollment requirements.

* * * * *

(d) * * *

(1) Enter into or renew a contract under this subpart for a MA plan that—

* * * * *

(ii) Projects enrollment in its bid submitted under § 422.254 in which enrollees entitled to medical assistance under a State plan under title XIX constitute a percentage of the plan's total enrollment that meets or exceeds one of the following:—

(A) For plan year 2024, 80 percent.

(B) For plan year 2025, 70 percent.

(C) For plan year 2026 and subsequent years, 60 percent.

(2) Renew a contract under this subpart for an MA plan that—

* * * * *

(ii) Unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination, has

actual enrollment, as determined by CMS using the January enrollment of the current year in which enrollees who are entitled to medical assistance under a state plan under title XIX, constitute a percentage of the plan's total enrollment that meets or exceeds one of the following:

(A) For renewals for plan year 2024, 80 percent.

(B) For renewals for plan year 2025, 70 percent.

(C) For renewals for plan year 2026 and subsequent years, 60 percent.

(e) * * *

(1) * * *

(v) For transitions for plan year 2027 and subsequent years, is a dual eligible special needs plan as defined in § 422.2.

* * * * *

(h) *Rule on dual eligible special needs plans in relation to Medicaid managed care.*

(1) Beginning in 2027, where an MA organization offers a dual eligible special needs plan and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid managed care organization (MCO) (as defined in § 438.2) that enrolls full-benefit dual eligible individuals as defined in § 423.772, during the effective dates and in the same service area (even if there is only partial overlap of the service areas) of that Medicaid MCO contract, the MA organization—

(i) May only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D–SNP for full-benefit dual eligible individuals, except as permitted in paragraph (h)(3) of this section; and

(ii) Must limit new enrollment in the D–SNP to individuals enrolled in, or in the process of enrolling in, the Medicaid MCO.

(2) Beginning in 2030, such D–SNPs may only enroll (or continue to cover individuals enrolled in (or in the process of enrolling in) the Medicaid MCO, except that such D–SNPs may continue to implement deemed continued eligibility requirements as described in § 422.52(d).

(3)(i) If a State Medicaid agency's contract(s) with the MA organization differentiates enrollment into D–SNPs by age group or to align enrollment in each D–SNP with the eligibility or benefit design used in the State's Medicaid managed care program(s) (as defined in § 438.2), the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization may offer one or more additional D–SNPs for full-benefit dual eligible individuals in the same service area in accordance with the group (or groups) eligible for D–SNPs based on provisions of the contract with the State Medicaid agency under § 422.107.

(ii) If the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D–SNP(s) and PPO D–SNP(s), and one or more of the—

(A) HMO D–SNPs is subject to paragraph (h)(1) of this section, the PPO D–SNP(s) not subject to paragraph (h)(1) of this section may continue if they no longer accept new enrollment of full-benefit dual eligible individuals in the same service area as the plan (or plans) subject to paragraph (h)(1) of this section.

(B) PPO D–SNPs is subject to paragraph (h)(1) of this section, the HMO D–SNP(s) not subject to paragraph (h)(1) of this section may continue if they no longer accept new enrollment of full-benefit dual eligible individuals in the same service area as the plan (or plans) subject to paragraph (h)(1) of this section.

■ 33. Section 422.516 is amended by revising paragraphs (a) introductory text and (a)(2) to read as follows:

§ 422.516 Validation of Part C reporting requirements.

(a) *Required information.* Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the provider-patient relationship, information with respect to the following:

* * * * *

(2) The procedures related to and utilization of its services and items.

* * * * *

■ 34. Section 422.528 is added to read as follows:

§ 422.528 Final settlement process and payment.

(a) *Notice of final settlement.* After the calculation of the final settlement amount, CMS sends the MA organization a notice of final settlement. The notice of final settlement contains at least all of the following information:

(1) A final settlement amount, which may be either an amount due to the MA organization, or an amount due from the MA organization, or $0 if nothing is due to or from the MA organization, for the contract that has been consolidated, nonrenewed, or terminated.

(2) Relevant banking and financial mailing instructions for MA organizations that owe CMS a final settlement amount.

(3) Relevant CMS contact information.

(4) A description of the steps for requesting an appeal of the final settlement amount calculation, in accordance with the requirements specified in § 422.529.

(b) *Request for an appeal.* An MA organization that disagrees with the final settlement amount has 15 calendar days from issuance of the notice of final settlement, as described in paragraph (a) of this section, to request an appeal of the final settlement amount under the process described in § 422.529.

(1) If an MA organization agrees with the final settlement amount, no response is required.

(2) If an MA organization disagrees with the final settlement amount but does not request an appeal within 15 calendar days from the date of the issuance of the notice of final settlement, CMS does not consider subsequent requests for appeal.

(c) *Actions if an MA organization does not request an appeal.* (1) For MA organizations that are owed money by CMS, CMS remits payment to the MA organization within 60 calendar days from the date of the issuance of the notice of final settlement.

(2) For MA organizations that owe CMS money, the MA organization is required to remit payment to CMS within 120 calendar days from issuance of the notice of final settlement. If the MA organization fails to remit payment within that 120-calendar-day period, CMS refers the debt owed to CMS to the Department of the Treasury for collection.

(d) *Actions following submission of a request for appeal.* If an MA organization responds to the notice of final settlement disagreeing with the final settlement amount and requesting appeal, CMS conducts a review under the process described at§ 422.529.

(e) *No additional payment adjustments.* After the final settlement amount is calculated and the notice of final settlement, as described under § 422.528(a), is issued to the MA organization, CMS no longer apply retroactive payment adjustments to the terminated, consolidated or nonrenewed contract and there are no adjustments applied to amounts used in the calculation of the final settlement amount.

■ 35. Section 422.529 is added to read as follows:

§ 422.529 Requesting an appeal of the final settlement amount.

(a) *Appeals process.* If an MA organization does not agree with the final settlement amount described in § 422.528(a), it may appeal under the following three-level appeal process:

(1) *Reconsideration.* An MA organization may request reconsideration of the final settlement amount described in § 422.528(a) according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 15 calendar days from the date that CMS issued the notice of final settlement to the MA organization.

(ii) *Content of request.* The written request for reconsideration must do all of the following:

(A) Specify the calculation with which the MA organization disagrees and the reasons for its disagreement.

(B) Include evidence supporting the assertion that CMS' calculation of the final settlement amount is incorrect.

(C) Not include new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS does not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the calculations that were used to determine the final settlement amount and any additional evidence timely submitted by the MA organization.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the MA organization of its decision on the reconsideration in writing.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (a)(2) of this section.

(2) *Informal hearing.* An MA organization dissatisfied with CMS' reconsideration decision made under paragraph (a)(1) of this section is entitled to an informal hearing as provided for under paragraphs (a)(2)(i) through (a)(2)(iv) of this section.

(i) *Manner and timing of request.* A request for an informal hearing must be made in writing and filed with CMS within 15 calendar days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the MA organization disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing is conducted in accordance with the following:

(A) The CMS Hearing Officer provides written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

(B) The CMS reconsideration official provides a copy of the record that was before CMS when CMS made its decision to the hearing officer.

(C) The hearing officer review is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made its decision.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the MA organization explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with paragraph (a)(3) of this section.

(3) *Review by the Administrator.* The Administrator's review is conducted in the following manner:

(i) *Manner and timing of request.* An MA organization that has received a hearing officer's decision may request review by the Administrator within 15 calendar days of the date of issuance of the hearing officer's decision under paragraph (a)(2)(iv) of this section. An MA organization may submit written arguments to the Administrator for review.

(ii) *Discretionary review.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (a)(3)(iii) of this section or to decline to review the hearing officer's decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iii) *Administrator's review.* If the Administrator elects to review the hearing officer's decision, the Administrator reviews the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(iv) *Effect of Administrator's decision.* The Administrator's decision is final and binding.

(b) *Matters subject to appeal and burden of proof.* (1) The MA organization's appeal is limited to CMS' calculation of the final settlement amount. CMS does not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(2) The MA organization bears the burden of proof by providing evidence demonstrating that CMS' calculation of the final settlement amount is incorrect.

(c) *Stay of financial transaction until appeals are exhausted.* If an MA organization requests review of the final settlement amount, the financial transaction associated with the issuance or payment of the final settlement amount is stayed until all appeals are exhausted. Once all levels of appeal are exhausted or the MA organization fails to request further review within the applicable 15-calendar-day timeframe, CMS communicates with the MA organization to complete the financial transaction associated with the issuance or payment of the final settlement amount, as appropriate.

(d) *Continued compliance with other law required.* Nothing in this section limits an MA organization's responsibility to comply with any other applicable statute or regulation.

■ 35a. Section 422.530 is amended by adding paragraph (c)(4)(iii) to read as follows:

§ 422.530 Plan crosswalks.

(c) * * *

(4) * * *

(iii) For contract year 2027 and subsequent years, where one or more MA organizations that share a parent organization seek to consolidate D–SNPs in the same service area down to a single D–SNP under one MA–PD contract to comply with requirements at §§ 422.514(h) and 422.504(a)(20), CMS permits enrollees to be moved between different contracts.

* * * * *

■ 36. Section 422.550 is amended by revising paragraph (d) to read as follows:

§ 422.550 General provisions.

* * * * *

(d) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (b)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The current MA organization, with respect to the affected contract, has substantially failed to comply with the regulatory requirements as described in § 422.510(a)(4)(ix) and the contract may

be subject to intermediate enrollment and marketing sanctions as outlined in § 422.750(a)(1) and (a)(3). Intermediate sanctions imposed as part of this section remain in place until CMS approves the change of ownership (including execution of an approved novation agreement), or the contract is terminated.

(i)(A) If the new owner does not participate in the Medicare program in the same service area as the affected contract, it must apply for, and enter into, a contract in accordance with subpart K of this part and part 423 if applicable; and

(B) If the application is conditionally approved, must submit, within 30 days of the conditional approval, the documentation required under § 422.550(c) for review and approval by CMS; or

(ii) If the new owner currently participates in the Medicare program and operates in the same service area as the affected contract, it must, within 30 days of imposition of intermediate sanctions as outlined in paragraph (d)(1) of this section, submit the documentation required under § 422.550(c) for review and approval by CMS.

(2) If the new owner fails to begin the processes required under paragraph (d)(1)(i) or (d)(1)(ii) of this section within 30 days of imposition of intermediate sanctions as outlined in paragraph (d)(1) of this section, the existing contract is subject to termination in accordance with § 422.510(a)(4)(ix).

* * * * *

■ 37. Section 422.582 is amended by revising paragraph (b) to read as follows:

§ 422.582 Request for a standard reconsideration.

* * * * *

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for reconsideration must be filed within 60 calendar days after receipt of the written organization determination notice.

(1) The date of receipt of the organization determination is presumed to be 5 calendar days after the date of the written organization determination, unless there is evidence to the contrary.

(2) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the plan or delegated entity specified in the MA organization's written organization determination.

* * * * *

■ 38. Section 422.584 is amended by revising paragraph (b) introductory text and adding paragraphs (b)(3) and (4) to read as follows:

§ 422.584 Expediting certain reconsiderations.

* * * * *

(b) *Procedure and timeframe for filing a request.* A request for reconsideration must be filed within 60 calendar days after receipt of the written organization determination notice.

* * * * *

(3) The date of receipt of the organization determination is presumed to be 5 calendar days after the date of the written organization determination, unless there is evidence to the contrary.

(4) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the plan or delegated entity specified in the MA organization's written organization determination.

* * * * *

■ 39. Section 422.626 is amended by revising paragraph (a)(2) and removing paragraph (a)(3) to read as follows:

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

(a) * * *

(2) If an enrollee makes an untimely request to an IRE, the IRE accepts the request and makes a determination as soon as possible, but the timeframe under paragraph (d)(5) of this section and the financial liability protection under paragraph (b) of this section do not apply.

* * * * *

■ 40. Section 422.633 is amended by revising paragraph (d)(1) to read as follows:

§ 422.633 Integrated reconsiderations.

* * * * *

(d) * * *

(1) *Timeframe for filing*—An enrollee has 60 calendar days after receipt of the adverse organization determination notice to file a request for an integrated reconsideration with the applicable integrated plan.

(i) The date of receipt of the adverse organization determination is presumed to be 5 calendar days after the date of the integrated organization determination notice, unless there is evidence to the contrary.

(ii) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the applicable integrated plan.

* * * * *

■ 41. Section 422.760 is amended by revising paragraph (b)(3) to read as follows:

§ 422.760 Determinations regarding the amount of civil money penalties and assessment imposed by CMS.

* * * * *

(b) * * *

(3)(i) *Definitions for calculating penalty amounts*—(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination penalty amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(ii) CMS sets minimum penalty amounts in accordance with paragraphs (b)(1) and (2) of this section.

(iii) CMS announces the standard minimum penalty amounts and aggravating factor amounts for per determination and per enrollee penalties on an annual basis.

(iv) CMS has the discretion to issue penalties up to the maximum amount under paragraphs (b)(1) and (2) of this section when CMS determines that an organization's non-compliance warrants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

* * * * *

■ 42. Section 422.2267 is amended by—

■ a. Revising paragraphs (e)(31) and (34);

■ b. Adding paragraph (e)(42).

The revisions and additions read as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(31) *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability).*

(i) Prior to contract year 2026 marketing on September 30, 2025, the notice is referred to as the *Multi-language insert (MLI).* This is a standardized communications material which states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian,

Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(A) Additional languages that meet the 5 percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5 percent service area threshold, where it determines that this inclusion would be appropriate.

(B) Except where otherwise provided in paragraph (e)(31)(i)(G) of this section, the MLI must be provided with all required materials under paragraph (e) of this section.

(C) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(D) When used as a standalone material, the MLI may include organization name and logo.

(E) When mailing multiple required materials together, only one MLI is required.

(F) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

(G) At plan option for CY 2025 marketing and communications beginning September 30, 2024, the plan may use the model notice described in § 422.2267(e)(31)(ii) to satisfy the MLI requirements set forth in paragraph (e)(31)(i) of this section.

(ii) For CY 2026 marketing and communications beginning September 30, 2025, the required notice is referred to as the Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability). This is a model communications material through which MA organizations must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge.

(A) This notice of availability of language assistance services and auxiliary aids and services must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States associated with the plan's service area and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(B) If there are additional languages in a particular service area that meet the 5 percent service area threshold, described in paragraph (a)(2) of this section, beyond the languages described in paragraph (e)(31)(i) of this section, the notice of availability of language assistance services and auxiliary aids and services must also be translated into those languages. MA organizations may also opt to translate the notice in any additional languages that do not meet the 5 percent service area threshold, where the MA organization determines that this inclusion would be appropriate.

(C) The notice must be provided with all required materials under paragraph (e) of this section.

(D) The notice may be included as a part of the required material or as a standalone material in conjunction with the required material.

(E) When used as a standalone material, the notice may include organization name and logo.

(F) When mailing multiple required materials together, only one notice is required.

(G) The notice may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

(34) *SSBCI disclaimer.* This is model content and must be used by MA organizations that offer CMS-approved SSBCI as specified in § 422.102(f). In the SSBCI disclaimer, MA organizations must include the information required in paragraphs (i) through (iii) of this section. MA organizations must—

(i) * * *

(ii) List the chronic condition(s) the enrollee must have to be eligible for the SSBCI offered by the applicable MA plan(s), in accordance with the following requirements.

(A) The following applies when only one type of SSBCI is mentioned:

(*1*) If the number of condition(s) is five or fewer, then list all condition(s).

(*2*) If the number of conditions is more than five, then list the top five conditions, as determined by the MA organization, and convey that there are other eligible conditions not listed.

(B) The following applies when multiple types of SSBCI are mentioned:

(*1*) If the number of condition(s) is five or fewer, then list all condition(s), and if relevant, state that these conditions may not apply to all types of SSBCI mentioned.

(*2*) If the number of conditions is more than five, then list the top five conditions, as determined by the MA organization, for which one or more listed SSBCI is available, and convey that there are other eligible conditions not listed.

(iii) Convey that even if the enrollee has a listed chronic condition, the enrollee will not necessarily receive the benefit because coverage of the item or service depends on the enrollee being a ''chronically ill enrollee'' as defined in § 422.102(f)(1)(i)(A) and on the applicable MA plan's coverage criteria for a specific SSBCI required by § 422.102(f)(4).

(iv) Meet the following requirements for the SSBCI disclaimer in ads:

(A) For television, online, social media, radio, or other voice-based ads, either read the disclaimer at the same pace as, or display the disclaimer in the same font size as, the advertised phone number or other contact information.

(B) For outdoor advertising (as defined in § 422.2260), display the disclaimer in the same font size as the advertised phone number or other contact information.

(v) Include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI.

* * * * *

(42) *Mid-year supplemental benefits notice.* This is a model communications material through which plans must inform each enrollee of the availability of any item or service covered as a supplemental benefit that the enrollee has not begun to use by June 30 of the plan year.

(i) The notice must be sent on an annual basis, no earlier than June 30 of the plan year, and no later than July 31 of the plan year.

(ii) The notice must include the following content:

(A) *Mandatory supplemental benefits.* For each mandatory supplemental benefit an enrollee has not used, the MA organization must include the same information about the benefit that is provided in the Evidence of Coverage.

(B) *Optional supplemental benefits.* For each optional supplemental benefit an enrollee has not used, the MA organization must include the same information about the benefit that is provided in the Evidence of Coverage.

(C) *SSBCI.* For plans that include SSBCI—

(*1*) The MA organization must include an explanation of SSBCI available under the plan (including eligibility criteria and limitations and scope of the covered items and services) and must include point-of-contact information for eligibility assessments, including providing point-of-contact information (which can be the customer service line or a separate dedicated line), with trained staff that enrollees can contact to inquire about or begin the SSBCI eligibility determination process and to

address any other questions the enrollee may have about the availability of SSBCI under their plan;

(*2*) When an enrollee has been determined eligible for SSBCI but has not used SSBCI, the MA organization must include a description of the unused SSBCI for which the enrollee is eligible, and must include a description of any limitations on the benefit; and

(*3*) The disclaimer specified at paragraph (e)(34) of this section.

(D) The information about all supplemental benefits listed in the notice must include all of the following:

(*1*) Scope of benefit.

(*2*) Applicable cost-sharing.

(*3*) Instructions on how to access the benefit.

(*4*) Any applicable network information.

(E) Supplemental benefits listed consistent with the format of the EOC.

(F) A customer service number, and required TTY number, to call for additional help.

■ 43. Section 422.2274 is amended by—

■ a. In paragraph (a), revising the definitions for ''Compensation'' and ''Fair market value'';

■ b. Revising paragraphs (c)(5) and (c)(13), (d)(1)(ii), (d)(2) introductory text, (d)(3) introductory text, (e)(1) and (e)(2); and

■ c. Adding paragraph (g)(4).

The revisions and addition read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(a) * * *

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale, renewal, or services related to a plan or product offered by an MA organization including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or awards.

(E) Beginning with contract year 2025, payment of fees to comply with state appointment laws, training, certification, and testing costs.

(F) Beginning with contract year 2025, reimbursement for mileage to, and from, appointments with beneficiaries.

(G) Beginning with contract year 2025, reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

(H) Beginning with contract year 2025, any other payments made to an agent or broker that are tied to enrollment, related to an enrollment in an MA plan or product, or for services conducted as a part of the relationship associated with the enrollment into an MA plan or product.

* * * * *

Fair market value (FMV) means, for purposes of evaluating agent or broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into an MA plan. Beginning January 1, 2021, the national FMV is $539, the FMV for Connecticut, Pennsylvania, and the District of Columbia is $607, the FMV for California and New Jersey is $672, and the FMV for Puerto Rico and the U.S. Virgin Islands is $370. For contract year 2025, there will be a one-time increase of $100 to the FMV to account for administrative payments included under the compensation rate. For subsequent years, FMV is calculated by adding the current year FMV and the product of the current year FMV and MA growth percentage for aged and disabled beneficiaries, which is published for each year in the rate announcement issued under § 422.312.

* * * * *

(c) * * *

(5) On an annual basis for plan years through 2024, by the last Friday in July, report to CMS whether the MA organization intends to use employed, captive, or independent agents or brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents and brokers. Following the reporting deadline, MA organizations may not change their decisions related to agent or broker type, or their compensation rates and ranges, until the next plan year.

* * * * *

(13) Beginning with contract year 2025, ensure that no provision of a contract with an agent, broker, or other TPMO has a direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best fits the health care needs of a beneficiary.

* * * * *

(d) * * *

(1) * * *

(ii) For contract years through contract year 2024, MA organizations may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section. Beginning with contract year 2025, MA organizations are limited to the compensation amounts outlined in this section.

(2) Initial enrollment year compensation. For each enrollment in an initial enrollment year for contract years through contract year 2024, MA organizations may pay compensation at or below FMV.

* * * * *

(3) *Renewal compensation.* For each enrollment in a renewal year for contract years through contract year 2024, MA plans may pay compensation at a rate of up to 50 percent of FMV. For contract years beginning with contract year 2025, for each enrollment in a renewal year, MA organizations may pay compensation at 50 percent of FMV.

* * * * *

(e) * * *

(1) For contract years through contract year 2024, payments made for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Beginning with contract year 2025, administrative payments are included in the calculation of enrollment-based compensation.

(g) * * *

(4) Beginning October 1, 2024, personal beneficiary data collected by a TPMO for marketing or enrolling them into an MA plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Prior express written consent from the beneficiary to share the data and be contacted for marketing or enrollment purposes must be obtained through a clear and conspicuous disclosure that lists each entity receiving the data and allows the beneficiary to consent or reject to the sharing of their data with each individual TPMO.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 44. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 45. Section 423.4 is amended by adding the definitions of ''Authorized generic drug'', ''Biological product'', ''Biosimilar biological product'', ''Brand name biological product'', ''Interchangeable biological product'', ''MTM program'', ''Reference product'', and ''Unbranded biological product'' in alphabetical order to read as follows:

§ 423.4 Definitions.

* * * * *

Authorized generic drug means a drug as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(t)).

Biological product means a product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

Biosimilar biological product means a biological product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that, in accordance with section 351(i)(2) of the Public Health Service Act (42 U.S.C. 262(i)(2)), is highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and has no clinically meaningful differences between the biological product and the reference product, in terms of the safety, purity, and potency of the product.

* * * * *

Brand name biological product means a product licensed under section 351(a) (42 U.S.C. 262(a)) or 351(k) (42 U.S.C. 262(k)) of the Public Health Service Act and marketed under a brand name.

* * * * *

Interchangeable biological product means a product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that FDA has determined meets the standards described in section 351(k)(4) of the Public Health Service Act (42 U.S.C. 262(k)(4)), which in accordance with section 351(i)(3) of the Public Health Service Act (42 U.S.C. 262(i)(3)), may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

* * * * *

MTM program means a medication therapy management program described at § 423.153(d).

* * * * *

Reference product means a product as defined in section 351(i)(4) of the Public Health Service Act (42 U.S.C. 262(i)(4)).

* * * * *

Unbranded biological product means a product licensed under a biologics license application (BLA) under section 351(a) or 351(k) of the Public Health Service Act (42 U.S.C. 262(a) or 262(k)) and marketed without a brand name. It is licensed under the same BLA as the corresponding brand name biological product.

* * * * *

■ 46. Section 423.32 is amended by adding paragraphs (h), (i), and (j) to read as follows:

§ 423.32 Enrollment process.

* * * * *

(h) *Notification of reinstatement based on beneficiary cancellation of new enrollment.* When an individual is disenrolled from a Part D plan due to the election of a new plan, the Part D plan sponsor must reinstate the individual's enrollment in that plan if the individual cancels the election in the new plan within timeframes established by CMS. The Part D plan sponsor offering the plan from which the individual was disenrolled must send the member notification of the reinstatement within 10 calendar days of receiving confirmation of the individual's reinstatement.

(i) *Exception for employer group health plans.* (1) In cases when a PDP sponsor has both a Medicare contract and a contract with an employer, and in which the PDP sponsor arranges for the employer to process election forms for Part D eligible group members who wish to enroll under the Medicare contract, the effective date of the election may be retroactive. Consistent with § 423.343(a), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) In order to obtain the effective date described in paragraph (i)(1) of this section, the beneficiary must certify that, at the time of enrollment in the PDP, he or she received the disclosure statement specified in § 423.128.

(3) Upon receipt of the election from the employer, the PDP sponsor must submit the enrollment to CMS within timeframes specified by CMS.

* * * * *

(j) *Authorized representatives.* As used in this subpart, an authorized representative is an individual who is the legal representative or otherwise legally able to act on behalf of an enrollee, as the law of the State in which the beneficiary resides may allow, in order to execute an enrollment or disenrollment request.

(1) The authorized representative would constitute the ''beneficiary'' or the ''enrollee'' for the purpose of making an election.

(2) Authorized representatives may include court-appointed legal guardians, persons having durable power of attorney for health care decisions, or individuals authorized to make health care decisions under state surrogate consent laws, provided they have the authority to act for the beneficiary in this capacity.

■ 47. Section 423.36 is amended by adding paragraphs (b)(4), (d), (e), and (f) to read as follows:

§ 423.36 Disenrollment process.

* * * * *

(b) * * *

(4) In the case of an incomplete disenrollment request—

(i) Document its efforts to obtain information to complete the disenrollment request;

(ii) Notify the individual (in writing or verbally) within 10 calendar days of receipt of the disenrollment request; and

(iii) The organization must deny the request if any additional information needed to make the disenrollment request ''complete'' is not received within the following timeframes:

(A) For disenrollment requests received during the AEP by December 7, or within 21 calendar days of the request for additional information, whichever is later; and

(B) For disenrollment requests received during all other election periods, by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information, whichever is later.

* * * * *

(d) *Incomplete disenrollment.* A disenrollment request is considered to be incomplete if the required but missing information is not received by the PDP sponsor within the timeframe specified in paragraph (b)(4)(iii) of this section.

(e) *Exception for employer group health plans.* (1) In cases when a PDP sponsor has both a Medicare contract and a contract with an employer, and in which the PDP sponsor arranges for the employer to process election forms for Part D eligible group members who wish to disenroll from the Medicare contract, the effective date of the election may be retroactive. Consistent with § 423.343(a), payment adjustments based on a retroactive effective date may be made for up to a 90-day period.

(2) Upon receipt of the election from the employer, the PDP sponsor must submit the disenrollment to CMS within timeframes specified by CMS.

* * * * *

(f) *Effect of failure to submit disenrollment notice to CMS promptly.* If the PDP sponsor fails to submit the correct and complete notice required in paragraph (b)(1) of this section, the PDP sponsor must reimburse CMS for any capitation payments received after the month in which payment would have ceased if the requirement had been met timely.

* * * * *

■ 48. Section 423.38 is amended by—

■ a. Revising paragraph (c)(4)(i), (c)(7), and (c)(23) introductory text;

■ b. Redesignating paragraphs (c)(23)(i) through (c)(23)(iii) and (c)(35), as paragraphs (c)(23)(ii) through (c)(23)(iv) and (c)(36), respectively; and
■ c. Adding new paragraphs (c)(23)(i) and (c)(35).

The revision and addition read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(4) * * *

(i) Except as provided in paragraph (ii) of this section, the individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in § 423.772, who is making a one-time-per month election into a PDP.

* * * * *

(7)(i) The individual is no longer eligible for the PDP because of a change in his or her place of residence to a location outside of the PDP region(s) in which the PDP is offered; or

(ii) The individual who, as a result of a change in permanent residence, has new Part D plan options available to them.

* * * * *

(23) Individuals affected by an emergency or major disaster declared by a Federal, State or local government entity are eligible for an SEP to make a Part D enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier. The SEP ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, the date the incident automatically ends under applicable state or local law, or, if the incident end date is not otherwise identified, the incident end date specified in paragraph (c)(23)(i) of this section.

(i) If the incident end date of an emergency or major disaster is not otherwise identified, the incident end date is 1 year after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration, whichever is later. Therefore, the maximum length of this SEP, if the incident end date is not otherwise identified, is 14 full calendar months after the SEP start date or, if applicable, the date of a renewal or extension of the emergency or disaster declaration.

* * * * *

(35)(i) The individual is a full-benefit dual eligible individual (as defined in § 423.772) making a one-time-per month election into a fully integrated dual eligible special needs plan as defined in § 422.2 of this chapter, a highly integrated dual eligible special needs plan as defined in § 422.2 of this chapter, or an applicable integrated plan as defined in § 422.561 of this chapter.

(ii) The SEP is available only to facilitate aligned enrollment as defined in § 422.2 of this chapter.

* * * * *

■ 48a. Section 423.40 is amended by adding paragraph (f) to read as follows:

§ 423.40 Effective dates.

* * * * *

(f) *Beneficiary choice of effective date.* If a beneficiary is eligible for more than one election period, resulting in more than one possible effective date, the Part D plan sponsor must allow the beneficiary to choose the election period that results in the individual's desired effective date.

(1) To determine the beneficiary's choice of election period and effective date, the Part D plan sponsor must attempt to contact the beneficiary and must document its attempts.

(2) If the Part D plan sponsor is unable to obtain the beneficiary's desired enrollment effective date, the Part D plan sponsor must assign an election period using the following ranking of election periods:

(i) ICEP/Part D IEP.

(ii) MA–OEP.

(iii) SEP.

(iv) AEP.

(v) OEPI.

(3) If the Part D plan sponsor is unable to obtain the beneficiary's desired disenrollment effective date, the Part D plan sponsor must assign an election period that results in the earliest disenrollment.

■ 49. Section 423.44 is amended by—
■ a. Adding paragraph (b)(1)(iii);
■ b. Revising paragraphs (d)(1) introductory text, (d)(1)(iii)(A), (d)(1)(v), (d)(1)(vi) and (d)(2)(iii);
■ c. Redesignating paragraphs (d)(2)(iv) through (vii) as paragraphs (d)(2)(v) through (viii);
■ e. Adding new paragraph (d)(2)(iv);
■ f. Revising newly redesignated paragraph (d)(2)(v);
■ g. Revising paragraphs (d)(5)(i) and (d)(5)(ii); and
■ h. Adding paragraph (d)(9).

The revisions read as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(b) * * *

(1) * * *

(iii) The individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card as specified in paragraph (d)(9) of this section.

* * * * *

(d) * * *

(1) Except as specified in paragraph (d)(1)(v) of this section, a PDP sponsor may disenroll an individual from the PDP for failure to pay any monthly premium under the following circumstances:

* * * * *

(iii) * * *

(A) Be at least 2 whole calendar months; and

* * * * *

(v) A PDP sponsor may not disenroll either of the following:

(A) An individual who had monthly premiums withheld per § 423.293(a) and (e) of this part or who is in premium withhold status, as defined by CMS.

(B) A member or initiate the disenrollment process if the sponsor has been notified that an SPAP, or other payer, is paying the Part D portion of the premium, and the sponsor has not yet coordinated receipt of the premium payments with the SPAP or other payer.

* * * * *

(vi) *Extension of grace period for good cause and reinstatement.* When an individual is disenrolled for failure to pay the plan premium, CMS (or a third party to which CMS has assigned this responsibility, such as a Part D sponsor) may reinstate enrollment in the PDP, without interruption of coverage, if the individual does all of the following:

(A) Submits a request for reinstatement for good cause within 60 calendar days of the disenrollment effective date.

(B) Has not previously requested reinstatement for good cause during the same 60-day period following the involuntary disenrollment.

(C) Shows good cause for failure to pay within the initial grace period.

(D) Pays all overdue premiums within 3 calendar months after the disenrollment date.

(E) Establishes by a credible statement that failure to pay premiums within the initial grace period was due to circumstances for which the individual had no control, or which the individual could not reasonably have been expected to foresee.

* * * * *

(2) * * *

(iii) *Effort to resolve the problem.* The PDP sponsor must make a serious effort to resolve the problems presented by the individual, including providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions,

including mental illness, Alzheimer's disease, and developmental disabilities. In addition, the PDP sponsor must inform the individual of the right to use the PDP's grievance procedures, through the notices described in paragraph (d)(2)(viii) of this section. The individual has a right to submit any information or explanation that he or she may wish to the PDP.

(iv) *Documentation.* The PDP sponsor—

(A) Must document the enrollee's behavior, its own efforts to resolve any problems, as described in paragraph (d)(2)(iii) of this section, and any extenuating circumstances;

(B) May request from CMS the ability to decline future enrollment by the individual; and

(C) Must submit the following:

(*1*) The information specified in paragraph (d)(2)(iv)(A) of this section.

(*2*) Any documentation received by the individual to CMS.

(*3*) Dated copies of the notices required in paragraph (d)(2)(viii) of this section.

* * * * *

(viii) *Required notices.* The PDP sponsor must provide the individual two notices prior to submitting the request for disenrollment to CMS.

(A) The first notice, the advance notice, informs the member that continued disruptive behavior could lead to involuntary disenrollment and provides the individual an opportunity to cease the behavior in order to avoid the disenrollment action.

(*1*) If the disruptive behavior ceases after the member receives the advance notice and then later resumes, the sponsor must begin the process again.

(*2*) The sponsor must wait at least 30 days after sending the advance notice before sending the second notice, during which 30-day period the individual has the opportunity to cease their behavior.

(B) The second notice, the notice of intent to request CMS permission to disenroll the member, notifies the member that the PDP sponsor requests CMS permission to involuntarily disenroll the member.

(*1*) This notice must be provided prior to submission of the request to CMS.

(*2*) These notices are in addition to the disenrollment submission notice required under § 423.44(c).

* * * * *

(5) * * *

(i) *Basis for disenrollment.* The PDP must disenroll an individual, and must document the basis for such action, if the PDP establishes, on the basis of a written statement from the individual or other evidence acceptable to CMS, that the individual has permanently moved out of the PDP service area and must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section within 10 calendar days of the plan's confirmation of the individual's residence outside of the plan service area.

(ii) *Special rule.* If the individual has not moved from the PDP service area, but has been determined by the PDP sponsor to be absent from the service area for more than 12 consecutive months, the PDP sponsor must disenroll the individual from the plan, and document the basis for such action, effective on the first day of the 13th month after the individual left the service area and must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section within the first 10 calendar days of the 12th month of an individual's temporary absence from the plan service area or, if the sponsor learns of the individual's temporary absence from the plan service area after the expiration of the 12 month period, within 10 calendar days of the sponsor learning of the absence. The individual is considered to be temporarily absent from the plan service area when one or more of the required materials and content referenced in § 423.2267(e), if provided by mail, is returned to the Part D plan sponsor by the U.S. Postal Service as undeliverable and a forwarding address is not provided.

* * * * *

(9) *Individual commits fraud or permits abuse of enrollment card*—(i) *Basis for disenrollment.* A PDP may disenroll the individual from a Part D plan if the individual—

(A) Knowingly provides, on the election form, fraudulent information that materially affects the individual's eligibility to enroll in the PDP; or

(B) Intentionally permits others to use his or her enrollment card to obtain drugs under the PDP.

(ii) *Notice of disenrollment.* The Part D plan must give the individual a written notice of the disenrollment that meets the requirements set forth in paragraph (c) of this section.

(iii) *Report to CMS.* The Part D plan must report to CMS any disenrollment based on fraud or abuse by the individual.

* * * * *

■ 50. Section 423.100 is amended by revising paragraph (3) of the definition of ''Exempted beneficiary'' and adding the definitions of ''Affected enrollee'', ''Corresponding drug'', ''Immediate negative formulary change'', ''Maintenance change'', ''Negative formulary change'', ''Non-maintenance change'', and ''Other specified entities'' in alphabetical order to read as follows:

§ 423.100 Definitions.

* * * * *

Affected enrollee, as used in this subpart, means a Part D enrollee who is currently taking a covered Part D drug that is subject to a negative formulary change that affects the Part D enrollee's access to the drug during the current plan year.

* * * * *

Corresponding drug means, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product.

* * * * *

Exempted beneficiary means with respect to a drug management program, an enrollee who—

* * * * *

(3) Is being treated for cancer-related pain or

* * * * *

Immediate negative formulary change means an immediate substitution or market withdrawal that meets the requirements of § 423.120(e)(2)(i) or (ii) respectively.

* * * * *

Maintenance change means one of the following negative formulary changes with respect to a covered Part D drug:

(1) Making any negative formulary changes to a drug within 90 days of adding a corresponding drug to the same or a lower cost-sharing tier and with the same or less restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements (other than immediate substitutions that meet the requirements of § 423.120(e)(2)(i)).

(2) Making any negative formulary changes to a reference product within 90 days of adding a biosimilar biological product other than an interchangeable biological product of that reference product to the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements.

(3) Removing a non-Part D drug.

(4) Adding or making more restrictive PA, ST, or QL requirements based upon a new FDA-mandated boxed warning.

(5) Removing a drug withdrawn from sale by the manufacturer or that FDA determines to be withdrawn for safety or effectiveness reasons if the Part D

sponsor chooses not to treat it as an immediate negative formulary change.

(6) Removing a drug based on long term shortage and market availability.

(7) Making negative formulary changes based upon new clinical guidelines or information or to promote safe utilization.

(8) Adding PA to help determine Part B versus Part D coverage.

* * * * *

Negative formulary change means one of the following changes with respect to a covered Part D drug:

(1) Removing a drug from a formulary.

(2) Moving a drug to a higher cost-sharing tier.

(3) Adding or making more restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements. Negative formulary changes do not include safety-based claim edits which are not submitted to CMS as part of the formulary.

* * * * *

Non-maintenance change means a negative formulary change that is not a maintenance change or an immediate negative formulary change.

* * * * *

Other specified entities means 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.

§ 423.104 [Amended]

■ 51. Section 423.104 is amended in paragraph (d)(2)(iv)(A)(6) by removing the phrase ''subject to the requirements at § 423.120(b)'' and adding in its place the phrase ''subject to the requirements at §§ 423.120(b), (e), and (f)''.

■ 52. Section 423.120 is amended by-—

■ a. Revising paragraph (b)(3)(i)(B);

■ b. Revising paragraphs (b)(5) and (6); and

■ c. Adding paragraphs (e) and (f).

The revisions and additions read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(3) * * *

(i) * * *

(B) Not apply in cases of immediate changes as permitted under paragraph (e)(2) of this section.

* * * * *

(5) Notice of formulary changes. Part D sponsors must provide notice of changes to CMS-approved formularies as specified in § 423.120(f).

(6) Changes to CMS-approved formularies. Changes to CMS-approved formularies may be made only in accordance with paragraph (e) of this section.

* * * * *

(e) *Approval of changes to CMS-approved formularies.* A Part D sponsor may not make any negative formulary changes to its CMS-approved formulary except as specified in this section.

(1) *Negative change request.* Except as provided in paragraph (e)(2) of this section, prior to implementing a negative formulary change, Part D sponsors must submit to CMS, at a time and in a form and manner specified by CMS, a negative formulary change request.

(2) *Exception for immediate negative formulary changes.* A negative change request is not required in the following circumstances:

(i) *Immediate substitutions.* A Part D sponsor may make negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug to its formulary on the same or lower cost sharing tier and with the same or less restrictive formulary prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements, so long as the Part D sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval consistent with paragraph (b)(2) of this section because such drug was not yet available on the market, and the Part D sponsor has provided advance general notice as specified in paragraph (f)(2) of this section.

(ii) *Market withdrawals.* A Part D sponsor may immediately remove from its formulary any Part D drugs withdrawn from sale by their manufacturer or that the Food and Drug Administration (FDA) determines to be withdrawn for safety or effectiveness reasons.

(3) *Approval process for negative formulary changes*—(i) *Maintenance changes.* Negative change requests for maintenance changes are deemed approved 30 days after submission unless CMS notifies the Part D sponsor otherwise.

(ii) *Non-maintenance changes.* Part D sponsors must not implement non-maintenance changes until they receive notice of approval from CMS. Affected enrollees are exempt from non-maintenance changes for the remainder of the contract year.

(4) *Limitation on formulary changes prior to the beginning of a contract year.* Except as provided in paragraph (e)(2) of this section, a Part D sponsor may not make a negative formulary change that takes effect between the beginning of the annual coordinated election period described in § 423.38(b) and 60 days after the beginning of the contract year associated with that annual coordinated election period.

(f) *Provision of notice regarding changes to CMS-approved formularies*—

(1) *Notice of negative formulary changes.* Except as specified in paragraphs (f)(2) and (3) of this section, prior to making any negative formulary change, a Part D sponsor must provide notice to CMS and other specified entities at least 30 days prior to the date such change becomes effective, and must either: provide written notice to affected enrollees at least 30 days prior to the date the change becomes effective, or when an affected enrollee requests a refill of the Part D drug, provide such enrollee with an approved month's supply of the Part D drug under the same terms as previously allowed and written notice of the formulary change. The requirement to provide notice to CMS is satisfied upon a Part D sponsor's submission of a negative change request described in paragraph (e) of this section. The requirement to provide notice to other specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2).

(2) *Advance general notice of immediate negative formulary changes.* In the case of immediate negative formulary changes described in paragraph (e)(2) of this section, a Part D sponsor must provide advance general notice to all current and prospective enrollees and other specified entities in its formulary and other applicable beneficiary communication materials advising that the Part D sponsor may make immediate negative formulary changes consistent with the requirements of paragraph (e)(2) at any time. Such advance general notice must include information about how to access the plan's online formulary; about how to contact the plan; and that written notice of any change made will describe the specific drugs involved. Advance general notice of immediate substitutions must also specify that the written notice will contain information on the steps that enrollees may take to request coverage determinations and exceptions. Advance general notice of immediate substitutions is provided to CMS during bid submission. Advance general notice of market withdrawals is provided to CMS in the advance notice of immediate negative formulary changes that Part D sponsors provide to enrollees and other specified entities required earlier in this paragraph (f)(2).

(3) *Retrospective notice and update.* In the case of a negative formulary change described in paragraph (e)(2) of this section, the Part D sponsor must provide notice to other specified entities and written notice to affected enrollees as soon as possible, but no later than by the end of the month following any month in which the change takes effect. The requirement to provide notice to other specified entities is satisfied by the Part D sponsor's compliance with § 423.128(d)(2). Part D sponsors also must submit such changes to CMS, in a form and manner specified by CMS, in their next required or scheduled formulary update.

(4) *Content of written notice:* Any written notice required under this paragraph (other than advance general notice) must contain all of the following information:

(i) The name of the affected covered Part D drug.

(ii) Whether the plan is removing the covered Part D drug from the formulary, moving it to a higher cost-sharing tier, or adding or making more restrictive PA, ST, or QL requirements.

(iii) The reason for the negative formulary change.

(iv) Appropriate alternative drugs on the formulary in the same or a lower cost-sharing tier and the expected cost sharing for those drugs.

(v) For formulary changes other than those described in paragraph (e)(2)(ii) of this section, the means by which enrollees may obtain a coverage determination under § 423.566, including an exception to a coverage rule under § 423.578.

(5) *Notice of other formulary changes.* Part D sponsors provide appropriate notice of all formulary changes other than negative formulary changes by providing—

(i) Advance general notice to all current and prospective enrollees, CMS, and other specified entities in formulary and other applicable beneficiary communication materials advising them that the Part D sponsor may make formulary changes other than negative formulary changes at any time and providing information about how to access the plan's online formulary and how to contact the plan; and

(ii) Notice of specific formulary changes to other specified entities by complying with § 423.128(d)(2) and to CMS by submitting such changes to CMS in their next required or scheduled formulary update.

* * * * *

■ 53. Section 423.128 is amended by revising paragraphs (d)(1)(v)(B), (d)(2)(iii), and (e)(6) to read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(d) * * *

(1) * * *

(v) * * *

(B) Establishes contact with a customer service representative within 7 minutes on no fewer than 80 percent of incoming calls requiring TTY services.

* * * * *

(2) * * *

(iii) Provides current and prospective Part D enrollees with notice that is timely under § 423.120(f) regarding any negative formulary changes on its Part D plan's formulary.

* * * * *

(e) * * *

(6) Include any negative formulary changes applicable to an enrollee for which Part D plans are required to provide notice as described in § 423.120(f).

* * * * *

■ 54. Section 423.129 is added to read as follows:

§ 423.129 Resolution of complaints in complaints tracking module.

(a) *Definitions.* For the purposes of this regulation, the following terms have the following meanings:

Assignment date is the date CMS assigns a complaint to a particular Part D sponsor in the Complaints Tracking Module.

Complaints Tracking Module is an electronic system maintained by CMS to record and track complaints submitted to CMS about Medicare health and drug plans from beneficiaries and others.

Immediate need complaint is a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 2 or fewer days.

Urgent complaint is a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they do not have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 3 to 14 days.

(b) *Timelines for complaint resolution*—(1) *Immediate need complaint*s. The Part D sponsor must resolve immediate need complaints within 2 calendar days of the assignment date.

(2) *Urgent complaints.* The Part D sponsor must resolve urgent complaints within 7 calendar days of the assignment date.

(3) *All other complaints.* The Part D sponsor must resolve all other complaints within 30 calendar days of the assignment date.

(4) *Extensions.* Except for immediate need complaints, urgent complaints, and any complaint that requires expedited treatment under § 423.564(f), if a complaint is also a grievance within the scope of § 423.564 and the requirements for an extension of the time to provide a response in § 423.564(e)(2) are met, the Part D sponsor may extend the timeline to provide a response.

(5) *Coordination with timeframes for grievances, PACE service determination requests, and PACE appeals.* When a complaint under this section is also a grievance within the scope of §§ 423.564 or 460.120, a PACE service determination request within the scope of § 460.121, or a PACE appeal within the definition of § 460.122, the Part D sponsor must comply with the shortest applicable timeframe for resolution of the complaint.

(c) *Timeline for contacting individual filing a complaint.* Regardless of the type of complaint received, the Part D sponsor must attempt to contact the individual who filed a complaint within 7 calendar days of the assignment date.

§ 423.150 [Amended]

■ 55. Section 423.150 is amended in paragraph (a) by removing the phrase ''medication therapy management programs (MTMP)'' and adding in its place ''MTM programs''.

■ 56. Section 423.153 is amended by—

■ a. Revising the section heading;

■ b. Removing the paragraph heading from paragraph (d);;

■ c. Removing the phrase ''MTMP'' and adding in its place the phrase ''MTM program'' in paragraph (d)(1) introductory text;

■ d. Revising paragraphs (d)(1)(vii)(B)(*1*)(*i*) and (d)(1)(vii)(B)(*2*);

■ e. Removing the phrase ''MTMP'' and adding in its place the phrase ''MTM program'' in paragraph (d)(2) introductory text;

■ f. Revising paragraph (d)(2)(i)(C);

■ g. Adding paragraphs (d)(2)(iii) and (iv);

■ h. Removing the phrase ''MTMP'' and adding in its place the phrase ''MTM program'' in paragraphs (d)(3) and (4);

■ i. Revising paragraph (d)(5)(i) and (ii); and

■ j. Removing the phrase ''*MTMP*'' and adding in its place the phrase ''*MTM program*'' in paragraph (d)(6).

■ k. In paragraph (f)(8)(i) introductory text, removing the phrase ''paragraph (f)(8)(ii)'' and adding in its place ''paragraphs (f)(8)(ii) and (iii)'';

■ l. Revising paragraph (f)(8)(i)(A);
■ m. Redesignating paragraph (f)(8)(ii) as paragraph (f)(8)(iii); and
■ n. Adding a new paragraph (f)(8)(ii).

The revisions and additions read as follows:

§ 423.153 Drug utilization management, quality assurance, medication therapy management programs (MTMPs), drug management programs, and access to Medicare Parts A and B claims data extracts.

* * * * *

(d) ***

(1) * * *

(vii) * * *

(B) * * *

(*1*) * * *

(*i*) Must include an interactive consultation, performed by a pharmacist or other qualified provider, that is either in person or performed via synchronous telehealth; and

* * * * *

(*2*) If a beneficiary is offered the annual comprehensive medication review and is unable to accept the offer to participate due to cognitive impairment, the pharmacist or other qualified provider may perform the comprehensive medication review with the beneficiary's prescriber, caregiver, or other authorized individual.

* * * * *

(2) * * *

(i) * * *

(C) Are likely to incur annual covered Part D drug costs greater than or equal to the MTM cost threshold determined by CMS, as specified in this paragraph (d)(2)(i)(C) of this section.

(*1*) For 2011, the MTM cost threshold is set at $3,000.

(*2*) For 2012 through 2024, the MTM cost threshold is set at $3,000 increased by the annual percentage specified in § 423.104(d)(5)(iv).

(*3*) For 2025, the MTM cost threshold is set at the average annual cost of eight generic drugs, as defined at § 423.4, as determined using the PDE data specified at § 423.104(d)(2)(iv)(C).

* * * * *

(iii) Beginning January 1, 2025, in identifying beneficiaries who have multiple chronic diseases under paragraph (d)(2)(i)(A) of this section, Part D plan sponsors must include all of the following diseases, and may include additional chronic diseases:

(A) Alzheimer's disease.

(B) Bone disease-arthritis (including osteoporosis, osteoarthritis, and rheumatoid arthritis).

(C) Chronic congestive heart failure (CHF).

(D) Diabetes.

(E) Dyslipidemia.

(F) End-stage renal disease (ESRD).

(G) Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS).

(H) Hypertension.

(I) Mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions).

(J) Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders).

(iv) Beginning January 1, 2025, in identifying the number of Part D drugs under paragraph (d)(2)(i)(B) of this section, Part D plan sponsors must include all Part D maintenance drugs, relying on information in a widely accepted, commercially or publicly available drug database to make such determinations, and may include all Part D drugs.

* * * * *

(5) * * *

(i) Describe in its application how it takes into account the resources used and time required to implement the MTM program it chooses to adopt in establishing fees for pharmacists or others providing MTM services for covered Part D drugs under a Part D plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTM services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

* * * * *

(f) * * *

(8) * * *

(i) * * *

(A) Within 3 days of the date the sponsor makes the relevant determination.

* * * * *

(ii) In the case of a beneficiary who is determined by a Part D sponsor to be exempt, the sponsor must provide the alternate second notice within 3 days of the date the sponsor makes the relevant determination, even if such determination is made less than 30 days from the date of the initial notice described in paragraph (f)(5) of this section.

* * * * *

§ 423.165 [Amended]

■ 57. Section 423.165 is amended in paragraph (b)(2) by removing the phrase ''MTMPs'' and adding the phrase ''MTM programs'' in its place.

■ 58. Section 423.184 is amended by—
■ a. Revising paragraph (d)(1)(v);
■ b. Reserving paragraph (g)(1)(ii); and
■ c. Adding paragraph (h)(3).

The revision and addition read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(d) * * *

(1) * * *

(v) Add alternative data sources or expand modes of data collection.

* * * * *

(g) * * *

(1) * * *

(ii) [Reserved]

* * * * *

(h) * * *

(3) Beginning with the 2025 measurement year (2027 Star Ratings), Part D sponsor may request that CMS review its contract's administrative data for Patient Safety measures provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

* * * * *

■ 59. Section 423.186 is amended by—
■ a. Revising paragraph (e)(2);
■ b. Revising paragraph (f)(2)(i)(B); and
■ c. Adding paragraphs (f)(3)(viii)(A) and (B).

The revisions and addition read as follows:

§ 423.186 Calculation of Star Ratings.

* * * * *

(e) * * *

(2) *Rules for new and substantively updated measures.* New measures to the Star Ratings program will receive a weight of 1 for their first year in the Star Ratings program. Substantively updated measures will receive a weight of 1 in their first year returning to the Star Ratings after being on the display page. In subsequent years, a new or substantively updated measure will be assigned the weight associated with its category.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(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.

(*1*) For the first 2 years following a consolidation, for the surviving contract of a contract consolidation involving two or more contracts for health or drug services of the same plan type under the same parent organization, the enrollment data for the month of December for the measurement period of the Star Ratings year are combined

across the surviving and consumed contracts in the consolidation.

(*2*) 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.

(*3*) 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.

(*4*) 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.

* * * * *

(3) * * *

(viii) * * *

(A) 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 calculates the HEI reward for the surviving contract accounting for both the surviving and consumed contract(s). For the first year following a consolidation, the HEI reward for the surviving contract is calculated as the enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using total contract enrollment from July of the most recent measurement year used in calculating the HEI reward. A reward value of zero is used in calculating the enrollment-weighted mean for contracts that do not meet the minimum percentage of enrollees with the SRF thresholds or the minimum performance threshold specified at paragraph (f)(3)(vii) of this section.

(B) For the second year following a consolidation when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score will be combined from the consumed and surviving contracts and used in calculating the HEI score.

* * * * *

■ 60. Section 423.265 is amended by adding paragraph (b)(5) to read as follows:

§ 423.265 Submission of bids and related information.

(b) * * *

* * * * *

(5) *Limitations on changes.* After a Part D sponsor is permitted to begin marketing prospective plan year offerings for the following contract year (consistent with § 423.2263(a)), the Part D sponsor must not change, and must provide the benefits described in its CMS-approved plan benefit package (PBP) (as defined at § 423.182) for the contract year without modification, except where a modification in benefits is required by law.

* * * * *

§ 423.293 [Amended]

■ 61. Section 423.293 is amended in paragraph (a)(4) by removing the phrase ''Medicare Advantage organization'' and adding in its place ''Part D sponsor''.

* * * * *

■ 62. Section 423.294 is added to subpart F to read as follows:

§ 423.294 Failure to collect and incorrect collections of premiums and cost sharing.

(a) *Requirement to collect premiums and cost sharing.* A Part D sponsor violates the uniform benefit provisions at § 423.104(b) if it fails to collect or incorrectly collects applicable cost sharing, or fails to collect or incorrectly collects premiums as required by § 422.262(e) of this chapter—

(1) In accordance with the timing of premium payments;

(2) At the time a drug is dispensed; or

(3) By billing the enrollee or another appropriate party after the fact.

(b) Refunds of incorrect collections—(1) *Definitions.* As used in this section the following definitions are applicable:

Amounts incorrectly collected. (A) Means amounts that exceed the monthly Part D enrollee premium limits under § 423.286 or exceed permissible cost-sharing or copayment amounts as specified in § 423.104(d) through (f), whether paid by or on behalf of the enrollee;

(B) Includes amounts collected with respect to an enrollee who was believed to be entitled to Medicare benefits but was later found not to be entitled; and

(C) Excludes de minimis amounts, as calculated per PDE transaction or per monthly premium billing.

De minimis amounts means an amount per PDE transaction for claims adjustments and per month for premium adjustments that does not exceed the de minimis amount determined for purposes of § 423.34(c)(2).

Other amounts due means amounts due to affected enrollees or others on their behalf (other than de minimis amounts) for covered Part D drugs that were—

(A) Accessed at an out-of-network pharmacy in accordance with the requirements at § 423.124; or

(B) Initially denied but, upon appeal, found to be covered Part D drugs the enrollee was entitled to have provided by the Part D plan.

(2) *General rule.* A Part D sponsor must make a reasonable effort to identify all amounts incorrectly collected and to pay any other amounts due during the timeframe for coordination of benefits as established at § 423.466(b). A Part D sponsor must issue a refund for an identified enrollee overpayment within the timeframe specified at § 423.466(a).

(3) *Refund methods*—(i) *Lump-sum payment.* The Part D sponsor must use lump-sum payments for the following:

(A) Amounts incorrectly collected as cost-sharing.

(B) Other amounts due.

(C) All amounts due if the Part D plan is going out of business or terminating its Part D contract for a prescription drug plan(s).

(ii) *Premium adjustment, lump-sum payment, or both.* If the amounts incorrectly collected were in the form of premiums, or included premiums as well as other charges, the Part D sponsor may refund by adjustment of future premiums or by a combination of premium adjustment and lump-sum payments.

(iii) *Refund when enrollee has died or cannot be located.* If an enrollee has died or cannot be located after reasonable effort, the Part D sponsor must make the refund in accordance with State law.

(4) *Premium reduction and compliance.* (i) If the Part D sponsor does not issue the refund as required under this section within the timeframe specified at § 423.466(a), CMS reduces the premium the Part D sponsor is allowed to charge a Part D enrollee by the amounts incorrectly collected or otherwise due.

(ii) The Part D plan may receive compliance notices from CMS or, depending on the extent of the non-compliance, be the subject of an intermediate sanction (for example, suspension of marketing and enrollment activities) in accordance with subpart O of this part.

(c) *Collections of cost-sharing and premium amounts*—(1) *General rule.* A Part D sponsor must make a reasonable effort to attempt to collect cost sharing from a beneficiary or to bill cost sharing or premiums to another appropriate party for all amounts other than de minimis amounts.

(2) *Timeframe.* Recovery notices must be processed and issued in accordance with the timeframe specified at § 423.466(a). A Part D sponsor must make a reasonable effort to attempt to collect these amounts during the timeframe for coordination of benefits as established at § 423.466(b).

(3) *Retroactive collection of premiums.* Nothing in this section alters the requirements of § 423.293(a)(4) of

this part with respect to retroactive collection of premiums.

■ 63. Section 423.308 is amended by adding in the definition for ''Reopening'' in alphabetical order to read as follows:

§ 423.308 Definitions and terminology.

* * * * *

Reopening—(1) *Global reopening* means a reopening under § 423.346 in which CMS includes all Part D sponsor contracts that meet the inclusion criteria at § 423.346(g).

(2) *Targeted reopening* means a reopening under § 423.346 in which CMS includes one or more (but not all) Part D sponsor contracts that meet the inclusion criteria at § 423.346(g).

* * * * *

■ 64. Section 423.346 is amended by—

■ a. Revising paragraph (a) introductory text;

■ b. Removing ''within 4 years'' and adding ''within 6 years'' in its place in paragraph (a)(2); and

■ c. Adding paragraphs (e) through (g).

The revision and additions read as follows:

§ 423.346 Reopening.

(a) CMS may conduct a global or targeted reopening to reopen and revise an initial or reconsidered final payment determination (including a determination on the final amount of direct subsidy described in § 423.329(a)(1), final reinsurance payments described in § 423.329(c), the final amount of the low income subsidy described in § 423.329(d), or final risk corridor payments as described in § 423.336) or the Coverage Gap Discount Reconciliation (as described at § 423.2320(b))—

* * * * *

(e) CMS notifies the sponsor(s) that will be included in the reopening of its intention to conduct a global or targeted reopening when it is necessary for the sponsor(s) to submit prescription drug event (PDE) data or direct and indirect remuneration (DIR) for the reopening. The notification to sponsor(s) must include the following:

(1) The date by which PDE or DIR data must be accepted by CMS to be included in the reopening, which is at least 90 calendar days after the date of the notification.

(2) A statement indicating the Part D contracts or types of contracts that is included in the reopening.

(f) CMS announces when it has completed a reopening and provide the sponsor(s) with all of the following information:

(1) A description of the data used in the reopening.

(2) A statement indicating the Part D contracts or types of contracts that were included in the reopening.

(3) The date by which reports describing the reopening results is available to the sponsor.

(4) The date by which a sponsor must submit an appeal, in accordance with § 423.350, if the sponsor disagrees with the reopening results.

(g) Inclusion criteria—

(1) For a global reopening, CMS includes only those Part D sponsor contracts that were in effect for the contract year being reopened and for whom CMS has not sent the ''Notice of final settlement,'' as described at § 423.521(a), as of the date CMS announces the completion of the reopening in accordance with paragraph (f) of this section.

(2) For a target reopening, CMS includes only Part D sponsor contracts that meet the criteria for inclusion in a global reopening as specified in paragraph (1) of this section and that CMS specifies for inclusion in the reopening as provided in paragraph (e)(2) or (f)(2) of this section.

■ 65. Section 423.501 is amended by adding the definitions of ''Final settlement adjustment period'', ''Final settlement amount'', and ''Final settlement process'' in alphabetical order to read as follows:

§ 423.501 Definitions.

* * * * *

Final settlement adjustment period means the period of time between when the contract terminates and the date the Part D sponsor is issued a notice of the final settlement amount.

Final settlement amount means the final payment amount that CMS owes and ultimately pays to a Part D sponsor, or that a Part D sponsor owes and ultimately pays to CMS, with respect to a Part D contract that has consolidated, nonrenewed, or terminated. The final settlement amount is calculated by summing final retroactive payment adjustments for a specific contract that accumulated after that contract ceases operation but before the calculation of the final settlement amount and all of the following applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating these reconciliation amounts:

(1) Risk adjustment reconciliation, as applicable (described in § 422.310 of this chapter).

(2) Part D annual reconciliation (described in § 423.343).

(3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320).

(4) MLR remittances (described in §§ 422.2470 of this chapter and 423.2470).

Final settlement process means for a contract that has been consolidated, nonrenewed, or terminated, the process by which CMS does all of the following:

(1) Calculates the final settlement amount.

(2) Issues the final settlement amount along with supporting documentation in the notice of final settlement to the Part D sponsor.

(3) Receives responses from the Part D sponsor requesting an appeal of the final settlement amount.

(5) Takes final actions to adjudicate an appeal (if requested) and make payments to or receive payments from the Part D sponsor. The final settlement amount is calculated after all applicable reconciliations have occurred after a contract has been consolidated, nonrenewed, or terminated.

* * * * *

■ 66. Section 423.503 is amended by—

■ a. Adding paragraph headings for paragraphs (a)(1) through (3) and adding paragraph (a)(4); and

■ b. Revising paragraphs (b)(1)(i)(A) and (C).

The addition and revisions read as follows:

§ 423.503 Evaluation and determination procedures.

* * * * *

(a) * * *

(1) *Information used to evaluate applications.* * * *

(2) *Issuing application determination.* * * *

(3) *Limitation on PDP contracts under a single parent organization* * * *

(4) *Substantially incomplete applications.* (i) CMS does not evaluate or issue a notice of determination described in § 423.503(c) when an organization submits a substantially incomplete application.

(ii) An application is substantially incomplete when the submission as of the deadline for applications established by CMS is missing content or responsive materials for one or more sections of the application form required by CMS.

(iii) A determination that an application is substantially incomplete is not a contract determination as defined in § 423.641 and a determination that an organization submitted a substantially incomplete application is not subject to the appeals provisions of subpart N of this part.

* * * * *

(b) * * *
(1) * * *
(i) * * *
(A) Was under an intermediate sanction under subpart O of this part, or a determination by CMS to prohibit the enrollment of new enrollees under § 423.2410(c).
* * * * *
(C) Filed for or is currently in federal or state bankruptcy proceedings.
* * * * *

■ 67. Section 423.505 is amended by revising paragraph (b)(22) and adding paragraph (i)(6) to read as follows:

§ 423.505 Contract provisions.

* * * * *
(b) * * *
(22) As described in § 423.129, address and resolve complaints received by CMS against the Part D sponsor in the Complaints Tracking Module.
* * * * *
(i) * * *
(6) If the Part D plan sponsor delegates any of the following functions to a first tier, downstream, or related entity, the Part D sponsor's written arrangements must state that a termination initiated by such entity must provide, at minimum, 60-days' prior notice and have an effective termination date that coincides with the end of a calendar month:
(i) Authorization, adjudication, and processing of prescription drug claims at the point of sale.
(ii) Administration and tracking of enrollees' drug benefits in real time, including automated coordination of benefits with other payers.
(iii) Operation of an enrollee appeals and grievance process.
(iv) Contracting with or selection of prescription drug providers for inclusion in the Part D sponsor's network.

■ 68. Section 423.507 is amended by revising paragraph (a)(3) to read as follows:

§ 423.507 Nonrenewal of contract.

* * * * *
(a) * * *
(3)(i) If a Part D plan sponsor does not renew a contract under this paragraph (a), CMS cannot enter into a contract with the organization for 2 years in the PDP region or regions served by the contract unless there are circumstances that warrant special consideration, as determined by CMS.
(ii) If a PDP sponsor does not renew any of its PBPs in a PDP region, CMS does not approve plan bids submitted by the organization in that PDP region for 2 years unless there are circumstances that warrant special consideration, as determined by CMS.
(iii) The provisions of this paragraph do not apply to employer group waiver plans offered by a Part D plan sponsor.
* * * * *

■ 69. Section 423.508 is amended by revising paragraph (e) to read as follows:

§ 423.508 Modification or termination of contract by mutual consent.

* * * * *
(e) *Agreement to limit new Part D applications.* (1) As a condition of the consent to a mutual termination, CMS requires, as a provision of the termination agreement, language prohibiting the Part D plan sponsor from applying for new contracts or service area expansions in the PDP region or regions served by the contract for a period up to 2 years unless there are circumstances that warrant special consideration, as determined by CMS.
(2) A PDP sponsor that agrees to terminate its offering of PBPs in a PDP region also agrees that it is not eligible to apply to resume offering plans in that region for 2 years.
(3) The provisions of this paragraph do not apply to employer group waiver plans offered by a Part D plan sponsor.
* * * * *

■ 69a. Section 423.509 is amended by adding paragraph (f) to read as follows:

§ 423.509 Termination of contract by CMS.

* * * * *
(f) If CMS makes a determination to terminate a Part D sponsor's contract under § 423.509(a), CMS also imposes the intermediate sanctions at § 423.750(a)(1) and (3) in accordance with the following procedures:
(1) The sanction will go into effect 15 days after the termination notice is sent.
(2) The Part D sponsor will have a right to appeal the intermediate sanction in the same proceeding as the termination appeal specified in paragraph (d) of this section.
(3) A request for a hearing does not delay the date specified by CMS when the sanction becomes effective.
(4) The sanction will remain in effect—
(i) Until the effective date of the termination; or
(ii) If the termination decision is overturned on appeal, when a final decision is made by the hearing officer or Administrator.

■ 69b. Section 423.514 is amended by revising paragraph (a) introductory text and paragraph (a)(2) to read as follows:

§ 423.514 Validation of Part D reporting requirements.

(a) *Required information.* Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, information indicating the following—
* * * * *
(2) The procedures related to and utilization of its services and items.
* * * * *

■ 69c. Section 423.521 is added to read as follows:

§ 423.521 Final settlement process and payment.

(a) *Notice of final settlement.* After the calculation of the final settlement amount, CMS sends the Part D sponsor a notice of final settlement. The notice of final settlement contains at least the following information:
(1) A final settlement amount for the contract that has been consolidated, nonrenewed, or terminated, which may be one of the following:
(i) An amount due to the Part D sponsor.
(ii) An amount due from the Part D sponsor.
(iii) $0 if nothing is due to or from the Part D sponsor.
(2) Relevant banking and financial mailing instructions for Part D sponsors that owe CMS a final settlement amount.
(3) Relevant CMS contact information.
(4) A description of the steps for requesting an appeal of the final settlement amount calculation, in accordance with the requirements specified in § 423.522.
(b) *Request for an appeal.* A Part D sponsor that disagrees with the final settlement amount has 15 calendar days from issuance of the notice of final settlement, as described in paragraph (a) of this section, to request an appeal of the final settlement amount under the process described in § 423.522.
(1) If a Part D sponsor agrees with the final settlement amount, no response is required.
(2) If a Part D sponsor disagrees with the final settlement amount but does not request an appeal within 15 calendar days from the date of the issuance of the notice of final settlement, CMS does not consider subsequent requests for appeal.
(c) *Actions if a Part D sponsor does not request an appeal.* (1) For Part D sponsors that are owed money by CMS, CMS remits payment to the Part D sponsor within 60 calendar days from the date of the issuance of the notice of final settlement.

(2) For Part D sponsors that owe CMS money, the Part D sponsor is required to remit payment to CMS within 120 calendar days from issuance of the notice of final settlement. If the Part D sponsor fails to remit payment within that 120-calendar-day period, CMS refers the debt owed to CMS to the Department of the Treasury for collection.

(d) *Actions following a request for appeal.* If a Part D sponsor responds to the notice of final settlement disagreeing with the final settlement amount and requesting appeal, CMS conducts a review process under the process described at § 423.522.

(e) *No additional payment adjustments.* After the final settlement amount is calculated and the notice of final settlement, as described under § 423.521(a), is issued to the Part D sponsor, CMS—

(1) No longer applies retroactive payment adjustments to the terminated, consolidated or nonrenewed contract; and

(2) There are no adjustments applied to amounts used in the calculation of the final settlement amount.

■ 69d. Section 423.522 is added to read as follows:

§ 423.522 Requesting an appeal of the final settlement amount.

(a) *Appeals process.* If a Part D sponsor does not agree with the final settlement amount described in § 423.521(a) of this section, it may appeal under the following three-level appeal process:

(1) *Reconsideration.* A Part D sponsor may request reconsideration of the final settlement amount described in § 423.521(a) according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 15 days from the date that CMS issued the notice of final settlement to the Part D sponsor.

(ii) *Content of request.* The written request for reconsideration must do all of the following:

(A) Specify the calculation with which the Part D sponsor disagrees and the reasons for its disagreement.

(B) Include evidence supporting the assertion that CMS's calculation of the final settlement amount is incorrect.

(C) Not include new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS does not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the calculations that were used to determine the final settlement amount and any additional evidence timely submitted by the Part D sponsor.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the Part D sponsor of its decision on the reconsideration in writing.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (a)(2) of this section.

(2) *Informal hearing.* A Part D sponsor dissatisfied with CMS's reconsideration decision made under paragraph (a)(1) of this section is entitled to an informal hearing as provided for under paragraphs (a)(2)(i) through (a)(2)(iv) of this section.

(i) *Manner and timing of request.* A request for an informal hearing must be made in writing and filed with CMS within 15 calendar days of the date of CMS's reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the Part D sponsor disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing is conducted in accordance with the following:

(A) The CMS Hearing Officer provides written notice of the time and place of the informal hearing at least 30 calendar days before the scheduled date.

(B) The CMS reconsideration official provides a copy of the record that was before CMS when CMS made its decision to the hearing officer.

(C) The hearing officer review is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made its decision.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the Part D sponsor explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with paragraph (a)(3) of this section.

(3) *Review by the Administrator.* The Administrator's review is conducted in the following manner:

(i) *Manner and timing of request.* A Part D sponsor that has received a hearing officer's decision may request review by the Administrator within 15 calendar days of the date of issuance of the hearing officer's decision under paragraph (a)(2)(iv) of this section. The Part D sponsor may submit written arguments to the Administrator for review.

(ii) *Discretionary review.* (A) After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (a)(3)(iii) of this section or to decline to review the hearing officer's decision within 30 calendar days of receiving the request for review.

(B) If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iii) *Electing to review.* If the Administrator elects to review the hearing officer's decision, the Administrator reviews the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the Part D sponsor, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(iv) *Effect of Administrator's decision.* The Administrator's decision is final and binding.

(b) *Matters subject to appeal and burden of proof.* (1) The Part D sponsor's appeal is limited to CMS's calculation of the final settlement amount. CMS does not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(2) The Part D sponsor bears the burden of proof by providing evidence demonstrating that CMS' calculation of the final settlement amount is incorrect.

(e) *Stay of financial transaction until appeals are exhausted.* If a Part D sponsor requests review of the final settlement amount, the financial transaction associated with the issuance or payment of the final settlement amount is stayed until all appeals are exhausted. Once all levels of appeal are exhausted or the Part D sponsor fails to request further review within the applicable 15-calendar-day timeframe, CMS communicates with the Part D sponsor to complete the financial transaction associated with the issuance or payment of the final settlement amount, as appropriate.

(f) *Continued compliance with other law required.* Nothing in this section limits a Part D sponsor's responsibility to comply with any other statute or regulation.

■ 70. Section 423.530 is added to read as follows:

§ 423.530 Plan crosswalks.

(a) *General rules*—(1) *Definition of plan crosswalk.* A plan crosswalk is the movement of enrollees from one plan benefit package (PBP) in a PDP contract to another PBP under a PDP contract between a Part D Sponsor and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibitions.* (i) Plan crosswalks between PBPs under one PDP contract and PBPs under another PDP contract are prohibited unless both the PDP sponsors with which CMS contracts are the same legal entity or have the same parent organization.

(ii) Plan crosswalks are prohibited that split the enrollment of one PBP into multiple PBPs.

(iii) Plan crosswalks are prohibited from a PBP offering basic prescription drug coverage to a PBP offering enhanced alternative coverage.

(3) *Compliance with renewal/non-renewal rules.* The PDP sponsor must comply with renewal and non-renewal rules in §§ 423.506 and 423.507 in order to complete plan crosswalks.

(4) *Eligibility.* Enrollees must be eligible for enrollment under § 423.30 in order to be moved from one PBP to another PBP.

(5) *Applicability to Employer group health or waiver plans.* Nothing in this section permits the crosswalk of enrollees in an employer group health or waiver plan PBP to another PBP outside the usual process for enrollment in employer group health or waiver plans.

(b) *Mandatory plan crosswalks.* A Part D sponsor of a PDP must perform a plan crosswalk in the following circumstances:

(1) *Renewal of a PBP offering basic prescription drug coverage.* A PDP sponsor that plans to continue operating a PBP offering basic prescription coverage in the same service area for the upcoming contract year must crosswalk enrollment from the PBP offering basic prescription drug coverage in the current contract year into a PBP offering basic prescription drug coverage under the same PDP contract in the upcoming contract year. The PBP for the upcoming contract year must retain the same plan ID as the PBP for the current contract year.

(2) *Renewal of a PBP offering enhanced alternative drug coverage.* A PDP sponsor that plans to continue operating a PBP offering enhanced alternative coverage in the same service area for the upcoming contract year must crosswalk enrollment from the PBP offering enhanced alternative drug coverage in the current contract year into a PBP offering enhanced alternative drug coverage in the upcoming contract year. The PBP for the upcoming contract year PBP must retain the same plan ID as the PBP for the current contract year.

(c) *Plan crosswalk exceptions.* A Part D sponsor of a PDP may perform a plan crosswalk in the following circumstances after receiving approval from CMS under the procedures described in paragraph (d) of this section.

(1) *Consolidated renewals.* If a PDP sponsor wishes to non-renew a PBP offering enhanced alternative prescription drug coverage under a PDP contract that is not non-renewing or reducing its service area so that the contract no longer includes the service area of the non-renewing PBP, it may crosswalk enrollment from the non-renewing PBP into a PBP offered under the contract in the upcoming contract year.

(i) The plan ID for the upcoming contract year PBP must be the same plan ID as one of PBPs for the current contract year.

(ii) The PBPs being consolidated must be under the same PDP contract.

(iii) A PBP offering basic prescription drug coverage may not be discontinued if the PDP contract continues to offer coverage (other than employer group waiver plans) in the service area of the PBP.

(iv) Enrollment from a PBP offering enhanced alternative coverage may be crosswalked into a PBP offering either enhanced alternative or basic prescription drug coverage.

(v) If the PDP contract includes more than one renewing PBP into which enrollment of the non-renewing PBP can be crosswalked, the enrollment of the non-renewing PBP must be crosswalked into the renewing PBP that will result in lowest increase in monthly premiums for the enrollees.

(vi) A plan crosswalk is not approved under this paragraph if it will result in a premium increase for the following benefit year (as reflected in the bid for the receiving PBP submitted on the first Monday in June) that is higher than the greater of the following:

(A) The current year's premium for the non-renewing PBP.

(B) The current year's average base beneficiary premium, as described in § 423.286(c) of this part, for the PDP region in which the PBP operates.

(vii) If an organization that non-renews an enhanced alternative PBP does not request and receive a plan crosswalk exception as provided in paragraph (d) of this section, CMS does not approve a new enhanced alternative PBP in the same service area as the non-renewing PBP in the following contract year.

(2) *Contract consolidations.* If a PDP sponsor non-renews all or part of the service area of its contract with CMS in accordance with §§ 423.507 or 423.508, the enrollees of the non-renewing PBPs may be crosswalked into one or more PBPs in another PDP contract (the surviving contract).

(i) The non-renewing PDP contract and the surviving contract must be held by the same legal entity or by legal entities with the same parent organization.

(ii) The approved service area of the surviving contract must include the service area of the non-renewing PBPs whose enrollment will be crosswalked into the surviving contract.

(iii) Enrollment may be crosswalked between PBPs offering the same type of prescription drug coverage (basic or enhanced alternative).

(iv) Enrollment from a PBP offering enhanced alternative coverage may be crosswalked into a PBP offering basic prescription drug coverage.

(v) Enrollment from a PBP offering enhanced alternative coverage must be crosswalked into the PBP in the surviving contract that will result in the lowest premium increase.

(vi) A plan crosswalk is not approved under this paragraph if it will result in a premium increase for the following benefit year (as reflected in the bid for the receiving PBP submitted on the first Monday in June) that is higher than the greater of:

(A) The current year's premium for the non-renewing PBP, or

(B) The current year's average base beneficiary premium, as described in § 423.286(c), for the region in which the PBP operates.

(d) *Procedures.* (1) A PDP sponsor must submit the following:

(i) All plan crosswalks described in paragraph (b) of this section in writing through the bid submission process in HPMS by the bid submission deadline.

(ii) All plan crosswalk exception requests described in paragraph (c) of this section in writing through the plan crosswalk exceptions process in HPMS by the plan crosswalk exception request deadline announced annually by CMS.

(2) CMS verifies the requests and notifies a requesting PDP sponsor of the approval or denial after the crosswalk exception request deadline.

■ 71. Section 423.551 is amended by revising paragraph (e) to read as follows:

§ 423.551 General provisions.

* * * * *

(e) Effect of change of ownership without novation agreement. Except to

the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The current PDP sponsor, with respect to the affected contract, has substantially failed to comply with the regulatory requirements as described in § 423.509(a)(4)(ix) and the contract may be subject to intermediate enrollment and marketing sanctions as outlined in § 423.750(a)(1) and (a)(3). Intermediate sanctions imposed as part of this section remain in place until CMS approves the change of ownership (including execution of an approved novation agreement), or the contract is terminated.

(i)(A) If the new owner does not participate in the Medicare program in the same service area as the affected contract, it must apply for, and enter into, a contract in accordance with subpart K of this part and part 422 if applicable; and

(B) If the application is conditionally approved, must submit, within 30 days of the conditional approval, the documentation required under § 423.551(d) for review and approval by CMS; or

(ii) If the new owner currently participates in the Medicare program and operates in the same service area as the affected contract, it must, within 30 days of imposition of intermediate sanctions as outlined in paragraph (e)(1) of this section, submit the documentation required under § 423.551(d) for review and approval by CMS.

(2) If the new owner fails to begin the processes required under paragraph (e)(1)(i) or (e)(1)(ii) of this section, within 30 days of imposition of intermediate sanctions as outlined in paragraph (e)(1) of this section, the existing contract is subject to termination in accordance with § 423.509(a)(4)(ix).

* * * * *

■ 72. Section 423.562 is amended by revising paragraph (a)(1)(v) to read as follows:

§ 423.562 General provisions.

(a) * * *

(1) * * *

(v) 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.

* * * * *

■ 73. Section 423.578 is amended by revising paragraph (d) to read as follows:

§ 423.578 Exceptions process.

* * * * *

(d) Notice regarding formulary changes. Whenever a Part D plan sponsor makes any negative formulary change, as defined in § 423.100, to its CMS-approved formulary, the Part D plan sponsor must provide notice in accordance with the requirements at § 423.120(b)(5) and (f).

■ 74. Section 423.582 is amended by revising paragraph (b) to read as follows:

§ 423.582 Request for a standard redetermination.

* * * * *

(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 after receipt of the written coverage determination notice or the at-risk determination under a drug management program in accordance with § 423.153(f).

(1) The date of receipt of the coverage determination or at-risk determination is presumed to be 5 calendar days after the date of the written coverage determination or at-risk determination, unless there is evidence to the contrary.

(2) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the Part D plan sponsor or delegated entity specified in the Part D plan sponsor's written coverage determination or at-risk determination.

* * * * *

■ 75. Section 423.584 is amended by revising paragraph (b) introductory text and adding paragraph (b)(3) and (4) to read as follows:

§ 423.584 Expediting certain redeterminations.

* * * * *

(b) *Procedure and timeframe for filing a request.* A request for redetermination must be filed within 60 calendar days after receipt of the written coverage determination notice or at-risk determination notice.

* * * * *

(3) The date of receipt of the coverage determination or at-risk determination is presumed to be 5 calendar days after the date of the written coverage determination or at-risk determination, unless there is evidence to the contrary.

(4) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the Part D plan sponsor or delegated entity specified the Part D plan sponsor's written coverage determination or at-risk determination.

* * * * *

■ 76. Section 423.600 is amended by revising paragraph (a) to read as follows:

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request an IRE reconsideration. The enrollee, or the enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must file a written request for reconsideration with the IRE within 60 calendar days after receipt of the written redetermination by the Part D plan sponsor.

(1) The date of receipt of the redetermination is presumed to be 5 calendar days after the date of the Part D plan sponsor's written redetermination, unless there is evidence to the contrary.

(2) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the IRE specified in the Part D plan sponsor's written redetermination.

* * * * *

■ 77. Section 423.760 is amended by revising paragraph (b)(3) to read as follows:

§ 423.760 Definitions for calculating penalty amounts.

* * * * *

(b) * * *

(3)(i) Definitions for calculating penalty amounts—

(A) *Per determination.* The penalty amounts calculated under paragraph (b)(1) of this section.

(B) *Per enrollee.* The penalty amounts calculated under paragraph (b)(2) of this section.

(C) *Standard minimum penalty.* The per enrollee or per determination penalty amount that is dependent on the type of adverse impact that occurred.

(D) *Aggravating factor(s).* Specific penalty amounts that may increase the per enrollee or per determination standard minimum penalty and are determined based on criteria under paragraph (a) of this section.

(ii) CMS sets minimum penalty amounts in accordance with paragraphs (b)(1) and (2) of this section.

(iii) CMS announces the standard minimum penalty amounts and

aggravating factor amounts for per determination and per enrollee penalties on an annual basis.

(iv) CMS has the discretion to issue penalties up to the maximum amount under paragraphs (b)(1) and (2) of this section when CMS determines that an organization's non-compliance warrants a penalty that is higher than would be applied under the minimum penalty amounts set by CMS.

* * * * *

■ 78. Section 423.2267 is amended by revising paragraph (e)(33) to read as follows:

§ 423.2267 Required materials and content.

* * * * *

(e) * * *

(33) *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability).*

(i) Prior to contract year 2026 marketing on September 30, 2025, the notice is referred to as the *Multi-language insert (MLI).* This is a standardized communications material which states, ''We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1–xxx–xxx–xxxx]. Someone who speaks [language] can help you. This is a free service.'' in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(A) Additional languages that meet the 5-percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5 percent service area threshold, where it determines that this inclusion would be appropriate.

(B) Except where otherwise provided in paragraph (e)(33)(i)(G) of this section, the MLI must be provided with all required materials under paragraph (e) of this section.

(C) The MLI may be included as a part of the required material or as a standalone material in conjunction with the required material.

(D) When used as a standalone material, the MLI may include organization name and logo.

(E) When mailing multiple required materials together, only one MLI is required.

(F) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

(G) At plan option for CY 2025 marketing and communications beginning September 30, 2024, the plan may use the model notice described in § 423.2267(e)(33)(ii) to satisfy the MLI requirements set forth in paragraph (e)(33)(i) of this section.

(ii) For CY 2026 marketing and communications beginning September 30, 2025, the required notice is referred to as the *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability).* This is a model communications material through which MA organizations must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge.

(A) This notice of availability of language assistance services and auxiliary aids and services must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States associated with the plan's service area and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(B) If there are additional languages in a particular service area that meet the 5 percent service area threshold, described in paragraph (a)(2) of this section, beyond the languages described in paragraph (e)(33)(i) of this section, the notice of availability of language assistance services and auxiliary aids and services must also be translated into those languages. MA organizations may also opt to translate the notice in any additional languages that do not meet the 5-percent service area threshold, where the MA organization determines that this inclusion would be appropriate.

(C) The notice must be provided with all required materials under paragraph (e) of this section.

(D) The notice may be included as a part of the required material or as a standalone material in conjunction with the required material.

(E) When used as a standalone material, the notice may include organization name and logo.

(F) When mailing multiple required materials together, only one notice is required.

(G) The notice may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

■ 79. Section 423.2274 is amended by—

■ a. Revising paragraph (i) of the definition of ''Compensation'' and the definition of ''Fair market value'' in paragraph (a);

■ b. Adding paragraph (c)(13);

■ c. Revising paragraphs (c)(5), (d)(1)(ii), (d)(2) introductory text, (d)(3) introductory text, (e)(1) and (e)(2);

■ d. Adding paragraph (g)(4).

The revisions and addition read as follows:

§ 423.2274 Agent, broker, and other third-party requirements.

* * * * *

(a) * * *

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale, renewal, or services related to a plan or product offered by a Part D sponsor including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(E) Beginning with contract year 2025, payment of fees to comply with state appointment laws, training, certification, and testing costs.

(F) Beginning with contract year 2025, reimbursement for mileage to, and from, appointments with beneficiaries.

(G) Beginning with contract year 2025, reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

(H) Beginning with contract year 2025, any other payments made to an agent or broker that are tied to enrollment, related to an enrollment in a Part D plan or product, or for services conducted as a part of the relationship associated with the enrollment into a Part D plan or product.

* * * * *

Fair market value (FMV) means, for purposes of evaluating agent or broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into a Part D plan. Beginning January 1, 2021, the national FMV is 81. In contract year 2025, there will be a one-time increase of $100 to the FMV to account for administrative payments included under the compensation rate. For subsequent years, FMV is calculated by adding the current year FMV and the produce of the current year FMV and Annual Percentage Increase for Part D, which is published for each year in the rate announcement issued under § 422.312.

* * * * *

(c) * * *

(5) On an annual basis for plan years through 2024, by the last Friday in July, report to CMS whether the MA organization intends to use employed, captive, or independent agents or brokers in the upcoming plan year and the specific rates or range of rates the plan will pay independent agents and brokers. Following the reporting deadline, MA organizations may not change their decisions related to agent or broker type, or their compensation rates and ranges, until the next plan year.

* * * * *

(13) Beginning with contract year 2025, ensure that no provision of a contract with an agent, broker, or other TPMO has a direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best fits the health care needs of a beneficiary.

* * * * *

(d) * * *

(1) * * *

(ii) For contract years through contract year 2024, Part D sponsors may determine, through their contracts, the amount of compensation to be paid, provided it does not exceed limitations outlined in this section. Beginning with contract year 2025, Part D sponsors are limited to the compensation amounts outlined in this section.

(2) Initial enrollment year compensation. For each enrollment in an initial enrollment year for contract years through contract year 2024, Part D sponsors may pay compensation at or below FMV.

* * * * *

(3) *Renewal compensation.* For each enrollment in a renewal year for contract years through contract year 2024, Part D sponsors may pay compensation at a rate of up to 50 percent of FMV. For contract years beginning with contract year 2025, for each enrollment in a renewal year, MA organizations may pay compensation at 50 percent of FMV.

* * * * *

(e) * * *

(1) For contract years through contract year 2024, payments for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Beginning with contract year 2025, administrative payments are included in the calculation of enrollment-based compensation.

(g) * * *

(4) Beginning October 1, 2024, personal beneficiary data collected by a TPMO for marketing or enrolling them into a Part D plan may only be shared with another TPMO when prior express written consent is given by the beneficiary. Prior express written consent from the beneficiary to share the information and be contacted for marketing or enrollment purposes must be obtained through a clear and conspicuous disclosure that lists each entity receiving the data and allows the beneficiary to consent or reject to the sharing of their data with each individual TPMO.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 80. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 80a. Section 460.12 is amended by revising paragraph (a) to read as follows:

§ 460.12 Application requirements.

(a) *Submission of application.* (1) An individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its service area or add a PACE center site must submit to CMS a complete application in the form and manner, including timeframes for submission, specified by CMS, that describes how the entity or PACE organization meets all requirements in this part.

(2) An individual authorized to act for an entity that seeks to become a PACE organization must submit an application to qualify as a Part D sponsor in the form and manner required by CMS in accordance with 42 CFR part 423, subpart K.

■ 81. Section 460.18 is amended by adding paragraphs (c) and (d) to read as follows:

§ 460.18 CMS evaluation of applications.

* * * * *

(c) *Use of information from a current or prior PACE program agreement.* (1) If, during the 12 months preceding the deadline established by CMS for the submission of an application or submission of a response to a CMS request for additional information, a PACE organization fails to comply with the requirements of the PACE program under any current or prior PACE program agreement or fails to complete a corrective action plan during the applicable 12-month period, CMS may deny an application based on the applicant's failure to comply with the requirements of the PACE program under any current or prior PACE program agreement even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with the requirements of the PACE program under a PACE program agreement for purposes of an application denial under paragraph (c)(1) of this section if any of the following conditions apply with respect to the applicant during the applicable 12-month review period:

(A) Was subject to the imposition of an enrollment or payment sanction under § 460.42(a) or (b) for one or more of the violations specified in § 460.40.

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 460.80(a) after the end of the trial period.

(C) Filed for or is currently in State bankruptcy proceedings.

(D) Met or exceeded 13 points for compliance actions for any one PACE program agreement.

(*1*) CMS determines the number of points accumulated during the performance period for compliance actions based on the following point values:

(*i*) Each corrective action plan issued under § 460.19(c)(3) during the performance period counts for 6 points. Corrective action requests issued under § 460.194 are not included in the point calculations.

(*ii*) Each warning letter issued under § 460.19(c)(2) during the performance period counts for 3 points.

(*iii*) Each notice of non-compliance issued under § 460.19(c)(1) during the performance period counts for 1 point.

(*2*) CMS adds all the point values for each PACE organization's program agreement to determine if the 13-point threshold described in paragraph (c)(1)(i)(D) of this section has been reached.

(ii) CMS may deny an application submitted by an organization that does not hold a PACE program agreement at the time of the submission if the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (c)(1)(i) of this section. This paragraph does not apply to a parent organization that completed the acquisition of a subsidiary that meets the criteria for denial within the 24 months preceding the application submission deadline.

(d) If CMS has terminated a PACE program agreement under § 460.50, or

did not renew a PACE program agreement, and that termination or non-renewal took effect within the 38 months preceding the submission of an initial or expansion PACE application from the same organization, CMS may deny the application based on the applicant's substantial failure to comply with the requirements of the PACE program, even if the applicant currently meets all of the requirements of this part.

* * * * *

■ 81. Section 460.19 is added to read as follows:

§ 460.19 Issuance of compliance actions for failure to comply with the terms of the PACE program agreement.

(a) CMS may take compliance actions as described in paragraph (c)(1) of this section if CMS determines that the PACE organization has not complied with the terms of a current or prior PACE program agreement with CMS and a State administering agency.

(1) CMS may determine that a PACE organization is out of compliance with requirements when the organization fails to meet performance standards articulated in sections 1894 and 1934 of the Act and regulations in this chapter.

(2) If CMS has not already articulated a measure for determining non-compliance, CMS may determine that a PACE organization is out of compliance when its performance in fulfilling requirements represents an outlier relative to the performance of other PACE organizations.

(b) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the non-compliance, including all of the following:

(1) The nature of the conduct.

(2) The degree of culpability of the PACE organization.

(3) The actual or potential adverse effect on beneficiaries which resulted or could have resulted from the conduct of the PACE organization.

(4) The history of prior offenses by the PACE organization or its related entities.

(5) Whether the non-compliance was self-reported.

(6) Other factors which relate to the impact of the underlying non-compliance or to the PACE organization's inadequate oversight of the operations that contributed to the non-compliance.

(c) CMS may take one of three types of compliance actions based on the nature of the non-compliance.

(1) *Notice of non-compliance.* A notice of non-compliance may be issued for any failure to comply with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section.

(2) *Warning letter.* A warning letter may be issued for serious and/or continued non-compliance with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section and as assessed in accordance with paragraph (b) of this section.

(3) *Corrective action plan.* (i) Corrective action plans are issued for particularly serious or continued non-compliance with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section and as assessed in accordance with paragraph (b) of this section.

(ii) CMS issues a corrective action plan if CMS determines that the PACE organization has repeated or not corrected non-compliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its non-compliance, or must implement a detailed plan to correct the underlying causes of the non-compliance.

■ 82. Section 460.20 is amended by revising paragraph (c) to read as follows:

§ 460.20 Notice of CMS determination.

(c) *Incomplete application due to the lack of required State assurances documentation.* An application that, upon submission, is determined to be incomplete under § 460.12(b)(3) is withdrawn by CMS and the applicant is notified accordingly. The applicant is not entitled to a fair hearing when CMS withdraws an incomplete application on this basis.

■ 83. Section 460.64 is amended by revising paragraph (a)(5) and adding paragraph (a)(6) to read as follows:

§ 460.64 Personnel qualifications for staff with direct participant contact.

(a) * * *

(5) Be medically cleared for communicable diseases before engaging in direct participant contact.

(i) Staff must be cleared for communicable diseases based on a physical examination performed by a licensed physician, nurse practitioner, or physician assistant acting within the scope of their authority to practice, unless—

(A) The PACE organization conducts an individual risk assessment that meets the conditions specified in paragraph (a)(5)(iii) of this section; and

(B) The results of the risk assessment indicate the individual does not require a physical examination for medical clearance.

(ii) As part of the initial physical examination, staff must be determined to be free of active Tuberculosis disease.

(iii) If the PACE organization conducts a risk assessment on an individual under paragraphs (a)(5)(i)(A) and (B) of this section—

(A) Policies and procedures for conducting a risk assessment on each individual with direct participant contact must be based on accepted professional standards of care;

(B) The PACE organization's risk assessment must identify when a physical examination is required based on the results of the assessment; and

(C) The results of the risk assessment must be reviewed by a registered nurse, physician, nurse practitioner, or physician assistant.

(D) At a minimum, the risk assessment must do both of the following:

(*1*) Assess whether staff have been exposed to or have any symptoms of the following diseases:

(*i*) COVID–19.

(*ii*) Diphtheria.

(*iii*) Influenza.

(*iv*) Measles.

(*v*) Meningitis.

(*vi*) Meningococcal Disease.

(*vii*) Mumps.

(*viii*) Pertussis.

(*ix*) Pneumococcal Disease.

(*x*) Rubella.

(*xi*) Streptococcal Infection.

(*xii*) Varicella Zoster Virus.

(*xiii*) Any other infectious diseases noted as a potential threat to public health by the CDC.

(*2*) Determine if staff are free of active Tuberculosis during the initial risk assessment.

(6) Have all immunizations up to date before engaging in direct participant contact.

* * * * *

■ 84. Section 460.71 is amended by—

■ a. Revising paragraph (b)(4);

■ b. Redesignating paragraph (b)(5) and (6) as paragraphs (b)(6) and (7), respectively; and

■ c. Adding new paragraph (b)(5).

The revision and addition read as follows:

§ 460.71 Oversight of direct participant care.

* * * * *

(b) * * *

(4) Be medically cleared for communicable diseases before engaging

in direct participant contact as required under § 460.64(a)(5).

(5) Have all immunizations up to date before engaging in direct participant contact.

* * * * *

■ 85. Section 460.98 is amended by:
■ a. Removing paragraph (b)(4);
■ b. Redesignating paragraphs (b)(5) and (c) through (e) as paragraphs (b)(4) and (d) through (f), respectively; and
■ c. Adding new paragraph (c).

The addition reads as follows:

§ 460.98 Service delivery.

* * * * *

(c) *Timeframes for arranging and providing services*—(1) *Medications.* The PACE organization must arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after a primary care provider orders the medication.

(2) *All other services.* The PACE organization must arrange or schedule the delivery of interdisciplinary team approved services, other than medications, as identified in paragraph (c)(2)(i) of this section, as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the interdisciplinary team or member of the interdisciplinary team first approves the service, except as identified in paragraph (c)(3) of this section.

(i) Interdisciplinary team approved services include:

(A) Services approved by the full interdisciplinary team.

(B) Services approved by a member of the interdisciplinary team.

(C) Services ordered by a member of the interdisciplinary team.

(D) Care planned services.

(ii) [Reserved]

(3) *Routine or preventative services.* Routine or preventive services are excluded from the requirement in paragraph (c)(2) of this section when all of the following requirements are met:

(i) The PACE organization documents that they were unable to schedule the appointment due to circumstances beyond the control of the PACE organization.

(ii) The participant does not have a change in status that requires the service to be provided more quickly.

(iii) The PACE organization provides the service as expeditiously as the participant's condition requires.

(4) *Providing approved services.* Services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, social, and emotional needs.

■ 87. Section 460.102 is amended by revising paragraph (d)(1) to read as follows:

§ 460.102 Interdisciplinary team.

* * * * *

(d) * * *

(1) The interdisciplinary team is responsible for the following for each participant:

(i) *Assessments and plan of care.* The initial assessment, periodic reassessments, and plan of care.

(ii) *Coordination of care.* Coordination and implementation of 24-hour care delivery that meets participant needs across all care settings, including but not limited to the following:

(A) Ordering, approving, or authorizing all necessary care.

(B) Communicating all necessary care and relevant instructions for care.

(C) Ensuring care is implemented as it was ordered, approved, or authorized by the IDT.

(D) Monitoring and evaluating the participant's condition to ensure that the care provided is effective and meets the participant's needs.

(E) Promptly modifying care when the IDT determines the participant's needs are not met in order to provide safe, appropriate, and effective care to the participant.

(iii) *Documenting recommended services.* Documenting all recommendations for care or services and the reason(s) for not approving or providing recommended care or services, if applicable, in accordance with § 460.210(b).

(iv) *Consideration of recommended services.* The interdisciplinary team must review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists. Specifically, the interdisciplinary team must ensure the following requirements are met:

(A) The appropriate member(s) of the interdisciplinary team must review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 48 hours from the time of the participant's discharge.

(B) The appropriate member(s) of the interdisciplinary team must review all recommendations from other employees and contractors and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 7 calendar days from the date the recommendation was made.

(C) If recommendations are authorized or approved by the interdisciplinary team or a member of the interdisciplinary team, the services must be promptly arranged and furnished under § 460.98(c).

■ 88. Section 460.104 is amended by revising paragraph (e) to read as follows:

§ 460.104 Participant assessments.

* * * * *

(e) *Changes to plan of care.* When the interdisciplinary team conducts semiannual or unscheduled reassessments, the interdisciplinary team must reevaluate and, if necessary, revise the plan of care in accordance with § 460.106(c) following the completion of all required assessments.

■ 87. Section 460.106 is revised to read as follows:

§ 460.106 Plan of care.

(a) *Definition and basic requirements*—(1) *Definition.* For purposes of this section, a ''change in participant's status'' means a major decline or improvement in a participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant's health status and requires interdisciplinary team review or revision of the care plan, or both.

(2) *Basic requirements.* (i) The interdisciplinary team members specified in § 460.102(b) must develop, evaluate, and if necessary, revise a comprehensive person-centered plan of care for each participant.

(ii) Each plan of care must do all of the following:

(A) Take into consideration the most current assessment findings.

(B) Identify the services to be furnished to attain or maintain the participant's highest practicable level of well-being.

(b) *Timeframes for developing, evaluating, and revising plan of care.* (1) *Initial plan of care.* The interdisciplinary team must complete the initial plan of care within 30 calendar days of the participant's date of enrollment.

(2) *Semi-annual plan of care evaluation.* At least once every 180 calendar days from the date the latest plan of care was finalized the interdisciplinary team must complete a reevaluation of, and if necessary,

revisions to each participant's plan of care.

(3) *Change in participant's status.* (i) Except as specified in paragraph (b)(3)(ii) of this section, the interdisciplinary team must complete a re-evaluation of, and if necessary, revisions to a participant's plan of care within 14 calendar days after the PACE organization determines, or should have determined, that there has been a change in the participant's health or psychosocial status, or more expeditiously if the participant's condition requires.

(ii) If a participant is hospitalized within 14 calendar days of the change in participant status, the interdisciplinary team must complete a reevaluation of, and if necessary, revisions to the plan of care as expeditiously as the participant's condition requires but no later than 14 calendar days after the date of discharge from the hospital.

(c) *Content of plan of care.* At a minimum, each plan of care must meet the following requirements:

(1) Identify all of the participant's current medical, physical, emotional, and social needs, including all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring. At a minimum, the care plan must address the following factors:

(i) Vision.

(ii) Hearing.

(iii) Dentition.

(iv) Skin integrity.

(v) Mobility.

(vi) Physical functioning, including activities of daily living.

(vii) Pain management.

(viii) Nutrition, including access to meals that meet the participant's daily nutritional and special dietary needs.

(ix) The participant's ability to live safely in the community, including the safety of their home environment.

(x) Home care.

(xi) Center attendance.

(xii) Transportation.

(xiii) Communication, including any identified language barriers.

(2)(i) Identify each intervention (the care and services) needed to meet each medical, physical, emotional, and social needs.

(ii) It does not have to identify the medications needed to meet the participant's needs if a comprehensive list of medications is already documented elsewhere in the medical record.

(3) Utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome.

(4) Identify how each intervention will be implemented, including a timeframe for implementation.

(5) Identify a measurable goal for each intervention.

(6) Identify how the goal for each intervention will be evaluated to determine whether the intervention should be continued, discontinued, or modified.

(7) The participant's preferences and goals of care.

(d) *Implementation of the plan of care.* The team must continuously do all of the following:

(1) Implement, coordinate, and monitor the plan of care regardless of whether the services are furnished by PACE employees or contractors, across all care settings.

(2) Evaluate and monitor the participant's medical, physical, emotional, and social needs as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the interdisciplinary team and other employees or contractors.

(e) *Participant and caregiver involvement in plan of care.* (1) The interdisciplinary team must develop, evaluate, and revise each plan of care in collaboration with the participant, the participant's caregiver, or both.

(2) The interdisciplinary team must review and discuss each plan of care with the participant or the participant's caregiver or both before the plan of care is completed to ensure that there is agreement with the plan of care and that the participant's concerns are addressed.

(f) *Documentation.* The team must do all of the following:

(1) Establish and implement a process to document and maintain records related to all requirements for plans of care, in the participant's medical record.

(2) Ensure that the most recent care plan is available to all employees and contractors within the organization as needed.

■ 88. Section 460.112 is amended by—

■ a. Removing paragraph (d);

■ b. Redesignating paragraphs (a) through (c) as paragraphs (b) through (d);

■ c. Adding new paragraph (a);

■ d. Adding paragraph (b)(8);

■ e. Revising newly redesignated paragraph (c) introductory text;

■ f. Adding paragraph (c)(5);

■ g. Revising paragraph (e)(1);

■ h. Redesignating paragraphs (e)(2) through (6) as (e)(3) through (7);

■ i. Adding new paragraph (e)(2);

■ j. Revising the paragraph heading for paragraphs (g) introductory text and revise paragraph (g)(2); and

■ k. Adding paragraph (g)(3).

The additions and revisions read as follows:

§ 460.112 Specific rights to which a participant is entitled.

(a) *Right to treatment.* Each participant has the right to appropriate and timely treatment for their health conditions, including the right to all of the following:

(1) Receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being.

(2) Access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team.

(b) * * *

(8) To have all information regarding PACE services and treatment options explained in a culturally competent manner.

(c) *Information disclosure.* Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health decisions. A participant has the right to have all information in this section shared with their designated representative. Specifically, each participant has the following rights:

* * * * *

(5) To be fully informed of the following, in writing, before the PACE organization implements palliative care, comfort care, or end-of-life care services:

(i) A description of the PACE organization's palliative care, comfort care, and end-of-life care services (as applicable) and how they differ from the care the participant is currently receiving.

(ii) Whether palliative care, comfort care, or end-of-life care services (as applicable) is provided in addition to or in lieu of the care the participant is currently receiving.

(iii) Identify all services that are impacted and provide a detailed explanation of how the services will be impacted if the participant or designated representative elects to initiate palliative care, comfort care, or end-of-life care, including but not limited to the following types of services.

(A) Physician services, including specialist services.

(B) Hospital services.

(C) Long-term care services.

(D) Nursing services.

(E) Social services.

(F) Dietary services.

(G) Transportation.
(H) Home care.
(I) Therapy, including physical, occupation, and speech therapy.
(J) Behavioral health.
(K) Diagnostic testing, including imaging and laboratory services.
(L) Medications.
(M) Preventative healthcare services.
(N) PACE center attendance.
(ii) The right to revoke or withdraw their consent to receive palliative, comfort, or end-of-life care at any time and for any reason, either verbally or in writing.

* * * * *

(e) * * *

(1) To make health care decisions, including the right to all of the following:

(i) Have all treatment options fully explained.

(ii) Refuse any and all care and services.

(iii) Be informed of the consequences their decisions may have on their health and/or psychosocial status.

(2) To fully understand the PACE organization's palliative care, comfort care, and end-of-life care services. Specifically, the PACE organization must do all of the following before palliative care, comfort care, or end-of-life care services can be initiated:

(i) Fully explain the applicable treatment options.

(ii) Provide the participant with written information about their treatment options, in accordance with paragraph (c)(5) of this section.

(iii) Obtain written consent from the participant or designated representative prior to initiating palliative care, comfort care, or end-of-life care.

* * * * *

(g) *Complaints, requests, and appeals.*

* * * * *

(2) To request services from the PACE organizations, its employees, or contractors through the process described in § 460.121.

(3) To appeal any treatment decision of the PACE organization, its employees, or contractors through the process described in § 460.122.

■ 89. Section 460.119 is added to read as follows:

§ 460.119 Resolution of complaints in the complaints tracking module.

The PACE organization must comply with requirements of §§ 422.125 and 422.504(a)(15) of this chapter, through the CMS complaints tracking module as defined in § 422.125(a) of this chapter, address and resolve complaints received by CMS against the PACE organization within the required timeframes. References to the MA organization or MA plan in those regulations must be read as references to the PACE organization. Nothing in this section should be construed to affect the PACE organization's obligation to resolve grievances as described in § 460.120, service determinations as described in § 460.121, or appeals as described in § 460.122.

■ 90. Section 460.120 is revised to read as follows:

§ 460.120 Grievance process.

(a) *Written procedures.* A PACE organization must have a formal written process to promptly identify, document, investigate, and resolve all medical and nonmedical grievances in accordance with the requirements in this part.

(b) *Definition of grievance.* For purposes of this part, a grievance is a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested. Grievances may be between participants and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant.

(c) *Grievance process notification to participants.* Upon enrollment, and at least annually thereafter, the PACE organization must give a participant written information on the grievance process in understandable language, including all of the following:

(1) A participant or other individual specified in paragraph (d) of this section has the right to voice grievances without discrimination or reprisal, and without fear of discrimination or reprisal.

(2) A Medicare participant or other individual specified in paragraph (d) of this section acting on behalf of a Medicare participant has the right to file a written complaint with the quality improvement organization (QIO) with regard to Medicare covered services.

(3) The requirements under paragraphs (b) and (d) through (j) of this section.

(d) *Who can submit a grievance.* Any of the following individuals can submit a grievance:

(1) The participant.

(2) The participant's family member.

(3) The participant's designated representative.

(4) The participant's caregiver.

(e) *Methods for submitting a grievance.* (1) Any individual as permitted under paragraph (d) of this section may file a grievance with the PACE organization either orally or in writing.

(2) The PACE organization may not require a written grievance to be submitted on a specific form.

(3) A grievance may be made to any employee or contractor of the PACE organization that provides care to a participant in the participant's residence, the PACE center, or while transporting participants.

(f) *Conducting an investigation.* The PACE organization must conduct a thorough investigation of all distinct issues within the grievance when the cause of the issue is not already known.

(g) *Grievance resolution and notification timeframes.* The PACE organization must do all of the following:

(1) Take action to resolve the grievance based on the results of its investigation as expeditiously as the case requires, but no later than 30 calendar days after the date the PACE organization receives the oral or written grievance.

(2) Notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE organization resolves the grievance in accordance with paragraph (g)(1) of this section.

(h) *Grievance resolution notification.* The PACE organization must inform the individual who submitted the grievance of the resolution as follows:

(1) Either orally or in writing, based on the individual's preference for notification, except for grievances identified in paragraph (h)(3) of this section.

(2) At a minimum, oral or written notification of grievance resolutions must include the following, if applicable:

(i) A summary statement of the participant's grievance including all distinct issues.

(ii) A summary of the pertinent findings or conclusions regarding the concerns for each distinct issue that requires investigation.

(iii) For a grievance that requires corrective action, the corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur.

(3) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing.

(i) The response must describe the right of a Medicare participant or other individual specified in paragraph (d) of this section acting on behalf of a Medicare participant to file a written complaint with the QIO with regard to Medicare covered services.

(ii) For any complaint submitted to a QIO, the PACE organization must cooperate with the QIO in resolving the complaint.

(4) The PACE organization may withhold notification of the grievance resolution if the individual who submitted the grievance specifically requests not to receive the notification, and the PACE organization has documented this request in writing. The PACE organization is still responsible for paragraphs (h)(1) through (3) of this section.

(i) *Continuing care during grievance process.* The PACE organization must continue to furnish all required services to the participant during the grievance process.

(j) *Maintaining confidentiality of grievances.* The PACE organization must develop and implement procedures to maintain the confidentiality of a grievance, including protecting the identity of all individuals involved in the grievance from other employees and contractors when appropriate.

(k) *Recordkeeping.* The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for grievances received both orally and in writing. These records, except for information deemed confidential as a part of paragraph (j) of this section, must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.

(l) *Analyzing grievance information.* The PACE organization must aggregate and analyze the information collected under paragraph (k) of this section for purposes of its internal quality improvement program.

■ 91. Section 460.121 is amended by revising paragraph (b)(2) to read as follows:

§ 460.121 Service determination process.

* * * * *

(b) * * *

(2) *Requests that do not constitute a service determination request.* Requests to initiate, modify, or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care. For all requests identified in this section, the interdisciplinary team must—

(i) Document the request; and

(ii) Discuss the request during the care planning meeting, and either:

(A) Approve the requested service and incorporate it into the participant's initial plan of care, or

(B) Document their rationale for not approving the service in the initial plan of care.

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■ 92. Section 460.194 is amended by revising paragraph (b) to read as follows:

§ 460.194 Corrective action.

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(b) At their discretion, CMS or the State administering agency may monitor the effectiveness of corrective actions.

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■ 93. Section 460.198 is added to read as follows:

§ 460.198 Disclosure of compliance deficiencies.

CMS may require a PACE organization to disclose to its PACE participants or potential PACE participants the PACE organization's performance and contract compliance deficiencies in a manner specified by CMS.

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§ 460.202 [Amended]

■ 94. Section 460.202(b) is amended by removing the last sentence.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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